Table of Contents

1. **The Effect of *Centella Asiatica* (Gotu Kola) Crude Extract on Healing Activity of Septic and diabetic wounds in Wistar Rats (***Frida Richard Mgonja, Edwina Emili Teobard, Rajabu Rajabu Awami, Shabaan Mshamu, Lusekelo Msomba Mwangwengwa) https://dx.doi.org/10.4314/thrb.v27i5.1*
2. **Androgen receptor tissue expression and associated factors in women with triple negative breast cancers at Muhimbili National Hospital in Tanzania (***Amos Rodger Mwakigonja, Henry Stephen Joseph, Edda MtamboVuhahula) https://dx.doi.org/10.4314/thrb.v27i5.2*
3. **Depression and Hypertension among adults with and without HIV: Prevalence and their association at baseline in a cohort study (***Mayebe Tubeti, Fredrick Cyprian Mwita, Roza Ndaro, Enock Ndaki, Daniel Pungu, Gabriel Mabega) https://dx.doi.org/10.4314/thrb.v27i5.3*
4. **Assessment of Knowledge, Attitudes, and Practices (KAP) regarding Cryptosporidiosis among Livestock Keepers in Northern Tanzania (***Husna Kangusi, Beatus Lyimo, Bernard Ngowi, Elingarami Saul) https://dx.doi.org/10.4314/thrb.v27i5.4*
5. **Delivery and Order Fulfilment Practices of Prime Vendors in Tanga Region, Tanzania: A Cross-Sectional Study (***Mathew Mganga, Romuald Mbwasi) https://dx.doi.org/10.4314/thrb.v27i5.5*
6. **Oral impact on daily performance and behaviours of undergraduate students in Tanzania (***Diocles Desdely Bigilwa, Hawa Shariff Mbawalla) https://dx.doi.org/10.4314/thrb.v27i5.6*
7. **Forms and Patterns of Inter-Spousal Communication on Family Planning in Temeke-Tanzania: A Qualitative Study (***Agbert Timotheo Mshubilo, Rose Upor, Bernard Ngowi) https://dx.doi.org/10.4314/thrb.v27i5.7*
8. **Computed tomography patterns of cerebrovascular accidents among patients at Mbeya regional referral hospital, Tanzania: A retrospective cross-sectional study (***Ngwilo Mwakyusa) https://dx.doi.org/10.4314/thrb.v27i5.8*
9. **Epidemiology of bacterial colonization linked to vascular catheters in the surgical emergency resuscitation department of the Ibn Sina university hospital center Rabat Morocco (***Lakhrissi Alaeddine, Amakassou Halima, El-Allam Youssef, Talal Mohamed Abdoul-Latif, Faroudy Mamoun, Jaouhar Samira, Jazouli Abdelhadi, Himmouche Naoufal, Hadrya Fatine, Bouzid Jawad) https://dx.doi.org/10.4314/thrb.v27i5.9*
10. **Need Assessment Report for Development of the National Research Ethics Information Management System (NREIMS) (***Mwanaidi Yahya Kafuye, David Penford Machaku, Rebecca Edward Rabach, Renatha Joseph Sillo) https://dx.doi.org/10.4314/thrb.v27i5.10*
11. **Availability of Temperature-Sensitive Non-Communicable Disease Medicines and Cold-Chain Storage Facilities in Community Pharmacies in Mwanza City, Tanzania: A Cross-Sectional Study (***Boniface Magige, Daud Molell Romuald Mbwasi, Mathew Bundala) https://dx.doi.org/10.4314/thrb.v27i5.11*
12. **Congenital hyperinsulinism presenting as refractory neonatal hypoglycaemia: A case report from a tertiary neonatal unit in Tanzania (***Adili Haule, Elita E. Nywage and Alinanuswe Kasililika) https://dx.doi.org/10.4314/thrb.v27i5.12*
13. **Response and lessons learned from Marburg Virus Disease outbreaks in Africa: A Systematic Review (***Basiliana Emidi, Mercy Chiduo, Elvis Dodo, Amos Joseph, Gerald Mwing'a, Angelina M. Lutambi) https://dx.doi.org/10.4314/thrb.v27i5.13*
14. **Evaluation of Product Quality Management Practices of Regional Prime Vendors: Compliance, Shelf-Life, and Supply Consistency. A Case Study of Tanga Region (***Mathew Mganga, Romuald Mbwasi) https://dx.doi.org/10.4314/thrb.v27i5.14*

15. **Development of a Patient Safety Model for Independent Midwifery Practice Implementation** (*Mozha Desri Puji Astuti, Yudhy Dharmawan, Daru Lestantyo, Nurjazuli*) *https://dx.doi.org/10.4314/thrb.v27i5.15*
16. **Fathers' Involvement in Childcare Practices and Its Determinants: A Case Study of Fathers with Under Five Children in Njombe Region, Tanzania** (*Salvatory Mwanyingili, Hadijah Mbwana Victoria Gowele*) *https://dx.doi.org/10.4314/thrb.v27i5.16*
17. **Physician Volunteering and Health System Gaps in Morocco: A Qualitative Study** (*Said Zerrad, Laila Mrabti, Bahija Ghiati Ibn Ziad, Hakima Elhatri*) *https://dx.doi.org/10.4314/thrb.v27i5.17*
18. **An analysis of the Level and Factors Influencing Adolescent Mothers' Resilience to Gender-Based Violence in Shinyanga Region, Tanzania** (*Sylvester Josephat Nyakoki, Mathew Magripinus Senga Joyce Manahili*) *https://dx.doi.org/10.4314/thrb.v27i5.18*
19. **The Relationship Between Psychosocial Therapy and Drug Abuse Relapse Among Adolescent Students in Public Secondary Schools in Tanzania** (*Bernadetha Gabriel Rushahu*) *https://dx.doi.org/10.4314/thrb.v27i5.19*
20. **Assessment of factors associated with knowledge of antimicrobial resistance among patients attended referral hospitals in Dodoma region, Tanzania** (*Hindu Ibrahim, Shemsa Said Khatibu, Mkhoi Mkhoi, Sanuni Ally Kessy, Emiliana Myovela, Sylvia Jumbe, Abdallah Baja, Joseph R. Nkungugu, Lugoba Bushi, Monica Kessy, Abel Makubi, Samwel Saringe Mollel https://dx.doi.org/10.4314/thrb.v27i5.20*
21. **Culture-Confirmed Meningitis in a Tertiary Hospital in Central Morocco (2017–2019): A Retrospective Single-Center Study** (*Samira Jaquhar, Dounia Benammi, Soufyane Yassara, Nissrine Harrafa, Oussama Rharib, Saadia Radouane, Jawad Bouzid, Soukaina Laaraj, Najia EL Hamzaouia*) *https://dx.doi.org/10.4314/thrb.v27i5.21*
22. **Family Burden and Self-Care Practices of Hypertensive Clients: A Cross-Sectional Study in Indonesia** (*Rita Nofita Sari, Tantut Susanto, Latifa Aini Susumaningrum*) *https://dx.doi.org/10.4314/thrb.v27i5.22*
23. **Perceptions, religious beliefs and the use of herbs in management of Type 2 Diabetes Mellitus in Morogoro, Tanzania** (*Temba, B.B., H. Muhimbula, A.W. Mwanri*) *https://dx.doi.org/10.4314/thrb.v27i5.23*
24. **Exploring the Drivers of Consumer Self-Medication: A Factor Analysis Approach** (*Satinder Singh, Rahul Sharma*) *https://dx.doi.org/10.4314/thrb.v27i5.24*
25. **Developing a Comprehensive Literature Review Chapter for Qualitative Research: An Evidence-Informed Guide for Students and Early-Career Researchers in Low-Income Contexts** (*Kahabi Ganka Isangula*) *https://dx.doi.org/10.4314/thrb.v27i5.25*

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The Effect of *Centella Asiatica* (Gotu Kola) Crude Extract on Healing Activity of Septic and diabetic wounds in Wistar Rats

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Abstract

Background: Chronic wounds cause unbearable suffering to patients and are increasingly being reported in hospitals despite the variety of conventional drugs available for treatment. Thus, effective treatment alternatives are increasingly needed. Medicinal herbs with wound-healing properties could be among the alternatives worth exploring. This research evaluated the effectiveness of *Centella asiatica* leaf extract on the healing of septic and diabetes wounds in rats.

Methods: Forty (40) male rats (6 months) were divided into 2 groups (n=20): Group 1 contained non-diabetic rats with septic wounds and Group 2 contained diabetic rats with non-infectious wounds. Each group was subdivided into 4 sub-groups of 5 rats each. Alloxan 120mg/kg was injected into intraperitoneally to induce diabetes. *C. asiatica* leaves were macerated in ethanol to prepare crude extract. Excision wounds made on non-diabetic rats were inoculated with *Staphylococcus aureus* to produce septic wounds excluding diabetic rats. Each subgroup received different treatment on a wound as follows; G1 and G5 0.5% Gotu kola extract, G2 and G6 1% Gotu kola extract, G3 and G7 Gentamicin, G4 and G8 Normal Saline. Wound sizes were assessed using a meter rule. Contraction percentages and time taken for complete epithelialization and healing of wounds were assessed on days 3, 7 and 14.

Results: The study revealed that both the concentration of 1% and 0.5% of the crude extract promoted higher contraction percentages, and shorter time for complete epithelialization, and wound healing in both the diabetic and non-diabetic groups compared to the negative control ($P<0.05$) and were comparable to the positive control group under Gentamycine ($P>0.05$). Moreover, corroborative results depicted through visual assessments revealed the plant extract-treated wounds to be healing faster, drier, less swollen and appearing to be more contracted with a brownish scar like the positive control group.

Conclusion: At both dosages of 1% and 0.5% the crude extracts of *C. asiatica* promoted wound healing at the same rate in diabetic and septic non-diabetic wounds like efficacy caused by Gentamicin, suggesting its potential use in septic and diabetes wound management.

Keywords: *diabetic wound, septic wound, rats, Alloxan, C. asiatica, crude extracts, Wistar rats*

Introduction

Wounds are injuries referring to skin continuity disruption and are normally classified into incised wounds, lacerated wound, abrasion, contusion, ulcer, and burn wounds (Rieger *et al.*, 2015). Diabetic wounds are wounds that develop as a complication of diabetes often on the feet or legs (Cooper, 1990). The absence of insulin in diabetes mellitus causes impaired metabolism of carbohydrates, fat, and proteins which are necessary for cellular activities and tissue synthesis in

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wound healing (Cooper, 1990; Burgess *et al*., 2021). Septic wounds are infected wounds often caused by pathogenic bacteria. The body parts with septic wounds are normally swollen, reddish, and sometimes hot also have other complications like purulent discharge, pain, impaired function and systemic disease (Healy and Freedman, 2006).

The normal healing processes of cutaneous wounds involve several controlled steps such as fibroplasia, angiogenesis, re-epithelization, the migration and proliferation of cells such as fibroblasts, endothelial cells and epithelial cells, deposition of connective tissue and contraction of the wound (Abatangelo *et al.,* 1995). The control mechanisms of wound healing processes include a variety of bioactive molecules like the growth factors, cytokines, their receptors and matrix molecules (Nguyen *et al*., 2009; Burgess *et al*., 2021). However, such controlled processes can be disrupted in diseases like diabetes, immunocompromised persons and ischemia, leading to complications in healing wounds (Nguyen *et al*., 2009; Burgess *et al*., 2021).

Delayed healing of both septic and diabetic wounds can cause unbearable suffering to patients (Ingold, 1993) diminishing the value of life. While complications in septic wounds are normally attributable to improper wound management (Mas-Celis *et al.,* 2021); diabetic wounds, are a common complication of diabetes and are often slow to heal, sometimes painless, and have a higher risk of becoming infected due to nerve damage and poor blood flow (Frykberg and Banks, 2015; Burgess *et al*., 2021). There are increasing incidences of chronic wounds despite the abundance of conventional drugs available for treatment. The increase in chronic wound cases could be attributable either to the lowered efficacy or high cost of conventional drugs making them less effective or unaffordable.

Hence, the need is increasing to search for cheap and effective alternative products to supplement the available treatment measures. Natural products of plant origin could be among the potential alternatives requiring investigations. *Centella. asiatica* also known in some places by local name as Gotu Kola are among the medicinal plants with wound healing properties. The plant has been reported elsewhere to hasten wound healing after the plant extracts were treated in animals (Liu and Li, 2008; Jamil *et al.,* 2007; Gray *et al*., 2018; Sun *et al*., 2020). Traditionally, *C. asiatica*, has been used for centuries in ancient medicine to treat various ailments, including skin diseases, gastrointestinal disorders, respiratory problems, and anxiety, owing to its bioactive compounds such as triterpenoids, flavonoids, and phenolic acids (Rahmawati *et al*., 2021). The distribution of *C. aciatica* has been reported in many places worldwide where it can be identified by different local names (Gray *et al*., 2018). The plant is shown to be plentiful in India, Sri Lanka, Madagascar, South Africa, Australia, China, Indonesia, and Japan and it is largely abundant in shady, moist, or marshy areas (Gray *et al*., 2018).

The wound-healing mechanism of *C. aciatica* extracts is shown to involve the promotion of fibroblast proliferation and increased synthesis of collagen and intracellular fibronectin content (Liu and Li, 2008). Also, plant extracts have been reported to strengthen the newly formed skin as well as inhibit the inflammatory phase of hypertrophic scars and keloids (Liu and Li 2008). While triterpene is the frequently reported *C. sciatica* phytocompunds with great wound healing effects (Jamil *et al.,* 2007; Gray *et al*., 2018; Sun *et al*., 2020), there are other phytochemicals including saponins, glycosides, alkaloids and flavonoids (Jamil *et al.,* 2007; Gray *et al*., 2018). Therefore, triterpene, saponins and sapogenins are shown to be the key wound-healing agents in *C. aciatica* extracts (Gohil, 2010; Sun *et al*., 2020).

Other secondary metabolites from *C. sciatica* include amino acids, flavonols, fatty acids, alkaloids, sterols, saccharides, and inorganic salts (Kunjumon, 2020). However, *C. aciatica* found in different regions or places may differ significantly in the concentrations of the active phytocompounds leading to differing efficacy due to the variations in the properties of the soils holding the plants. Thus, it is vital to assess whether the *C. aciatic* available in Tanzania could be as effective enough as those reported in other parts of the world to hasten the healing process of septic and diabetic wounds.

Methodology

Study Area

The research was conducted in Morogoro (6°49'20'' S, 37°39'55'' E), under relative humidity 80% and 80.5% and temperatures of 22C° to 37C°. The laboratory experiments were done at Sokoine University of Agriculture (SUA), in the College of Veterinary Medicine and Biomedical Sciences (CVMBS) in the Pharmacology Laboratory, Department of Physiology, Pharmacology and Biochemistry.

Materials

The materials gathered for experiments were the Wistar rats, leaves of *C. asiatica*, ethanol solution for extraction, gauze and cotton wool for filtration, motor and pestle (local mill) for grinding of *C. asiatica* leaves, diabetogenic agent (Alloxan 120mg/kg), surgical blade, Gloves, Pippete, weighing balance of maximum 5 to 10 kg for weighing plant materials after grinding.

Preparation of ethanolic extract of *C. asiatica*

The *C. asiatica* leaves were harvested and dried under the shade for two weeks. Then the leaves were ground to powder using an electrical grinder to give 500g. The powder was macerated in 98% ethanol at a ratio of 1:4 for 3 days. The macerate was filtered two times using gauze and cotton wool and the extract was concentrated using a rotor vapour to obtain a viscous solid (1g). Two different solutions of varying concentrations 0.5% (5mg/ml) and 1% (10mg/ml) were prepared by dissolving extract paste in distilled water as per Kandasamy *et al*. (2023) with some modification.

Research animal and experimental setup

A total of 40 male Wistar rats 6 months old purchased at the small animal research units of the CVMBS were used in the study. The rats were divided into 2 major groups based on their wound types. The first group contained the diabetes-induced rats with artificial wounds made on the skin. The second group consisting of non-diabetic rats had artificial wounds infected with *staphylococcus aureus.* The two groups were each subdivided into 4 subgroups of 5 rats each based on treatment types as detailed in Tables 1 and 2 below. Before treatment, rats from all groups were allowed to acclimatize for 7 in the experimental room under standard environmental temperature (25 ± 5°C), relative humidity (35-60% mmHg) and 12/12 day-night cycles while given a commercial pellet diet, and ad lib water.

The induction of diabetes in rats was achieved by an intra-peritoneal injection with a single dose of alloxan monohydrate (120mg/kg) body weight in normal saline. Fasting glucose levels were measured after 3 days to confirm diabetes at a blood glucose level >200mg/dl. Guidelines for the care and use of laboratory animals were followed adequately during the rat's handling and restraints. All surgical procedures were carried out under chloroform anaesthesia. The septic wounds were achieved by inoculating *Staphylococcus aureus* in the excision wound of non-diabetic rats.

Table 1: Group allocations in diabetic Wistar rats (n=20) with artificial skin wounds subjected to treatments until complete healing with *C. asiatica* (Gotukola) crude extracts

GROUP (DIABETIC)	NUMBER OF RATS	TREATMENT
G5	5	Gotukola extract 0.5%
G6	5	Gotukola extract 1%
G7	5	Gentamicin
G8	5	Normal saline

Table 2: Group allocations in non-diabetic Wistar rats (n=20) with staphylococcal infected artificial skin wounds subjected for treatments until complete healing with *C. asiatica* (Gotukola) crude extracts

GROUP(INFECTED)	NUMBER OF RATS	TREATMENT
G1	5	Gotukola extract 0.5%

G2	5	Gotukola extract 1%
G3	5	Gentamicin
G4	5	Normal saline

Full-thickness, completely transdermal circular wounds were made on the pre-shaved, 70% alcohol-sterilized dorsal surface of the animal with the help of forceps, a scissor, and a skin marker. Non-diabetic wounds were infected with a confirmed strain of *Staphylococcus aureus* obtained from the Department of Microbiology at the CVMBS. Wounds made on diabetic rats were not infected. The *C. aciatica* extract solution of 0.1% and 0.5%, concentrations were applied topically on wounds once daily until complete wound healing was attained. While the negative control received nothing; the positive control rats received topical Gentamicin. The size of wounds was measured by a meter rule on days 0, 3, 7 and 14.

Determination of wound contraction percentages

Wound contraction percentages (wound size reduction rate) were obtained by dividing the extent to which wound contract (area) on a specific day by that of day zero and multiplying by 100 (Somboonwong *et al*., 2012).

$$\text{Wound contraction (\%)} = \frac{A0 - A1}{A0} \times 100$$

Whereby: A1 = area of the wound on a specific day, & A0 = area of the wound at day zero.

Determination of epithelialization and complete wound healing duration

Epithelialization simply refers to the process of covering denuded epithelial surfaces that are necessary for the successful closure of the wound (Pastar *et al.,* 2014). And it is a defining parameter of successful wound healing. In the current study, the falling off of the old scar signifying its replacements by the newly formed epithelial tissues marked the completion of epithelialization time (Pastar *et al.,* 2014). Complete wound healing time signified the duration taken for complete restoration of the epidermis on the excision wound (Pastar *et al.,* 2014).

Visual or gross assessment of excision wounds

Visual assessments of the wounds followed the criteria of Somboonwong *et al*. (2012) whereby the excision wound was evaluated for size, wound bed, colour, exudates, swelling of the wound surface, and the consistency of tissues surrounding the wounds.

Data Analysis

Data storage and cleaning were performed using Microsoft Excel. Data analysis involved the SPSS software version 20. Means and standard error of means were calculated for wound sizes and epithelialization times. Statistically significant differences between groups were tested by the Analysis of variance (ANOVA) and the Bonferroni test for pairwise comparisons between individual groups. Statistically significant differences between groups were considered at $p < 0.05$.

Results

Wound contraction percentage

Figure 1 shows the diabetic wound reduction rate (percentage) among different groups of rats. The contraction rate of diabetic wound increased proportionally with the treatment duration as assessed at 3, 7 and 14 days and both dosages of 1% and 0.5% of *C. aciatica* extracts were shown to be equally effective compared to healing rate displayed by the negative control (Table 3).

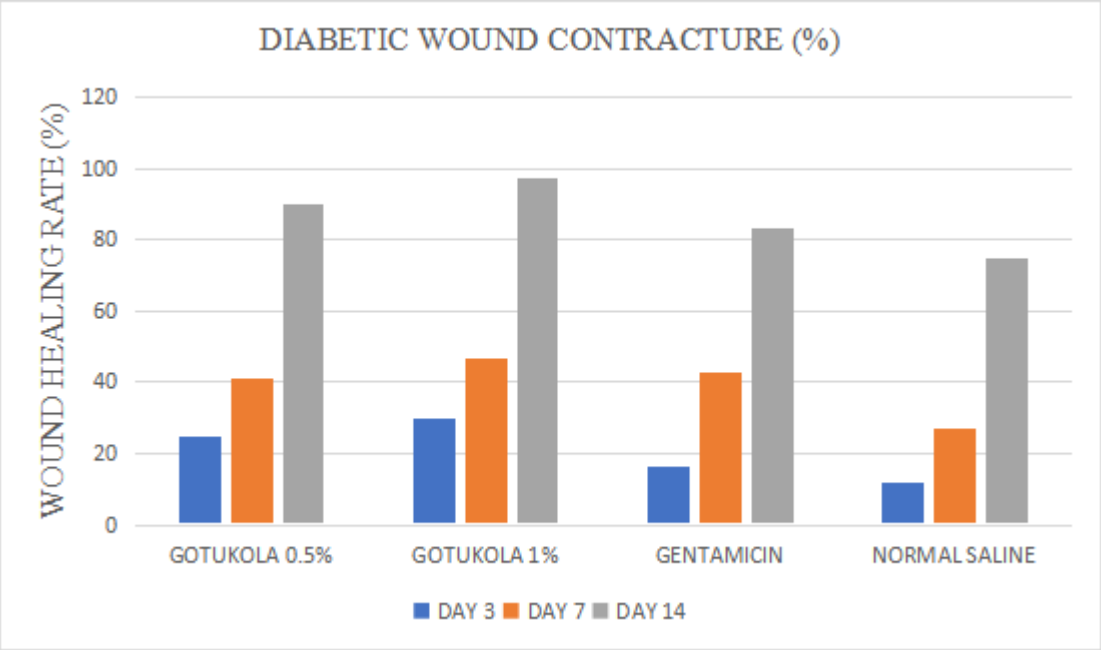


Figure 1**:** The contraction rate (percentages) of diabetic wounds assessed at different durations (3, 7, and 14 days) after a topical treatment with 0.5% or 1% of Gotukola (*C. asiatica*) leaf extract on wistar rats. Gentamicin represents Positive control, and Normal saline represent negative control.

Figure 2 shows the reduction rate of staphylococcal infected wound among the studied groups of rats. The contraction percentages of septic wounds increased proportionately with treatment duration as assessed at 3, 7 and 14 days of treatment and both dosages of the *C. aciatica* crude extracts of 0.5% and 1% showed equal higher efficacy compared to the negative control (figure 2).

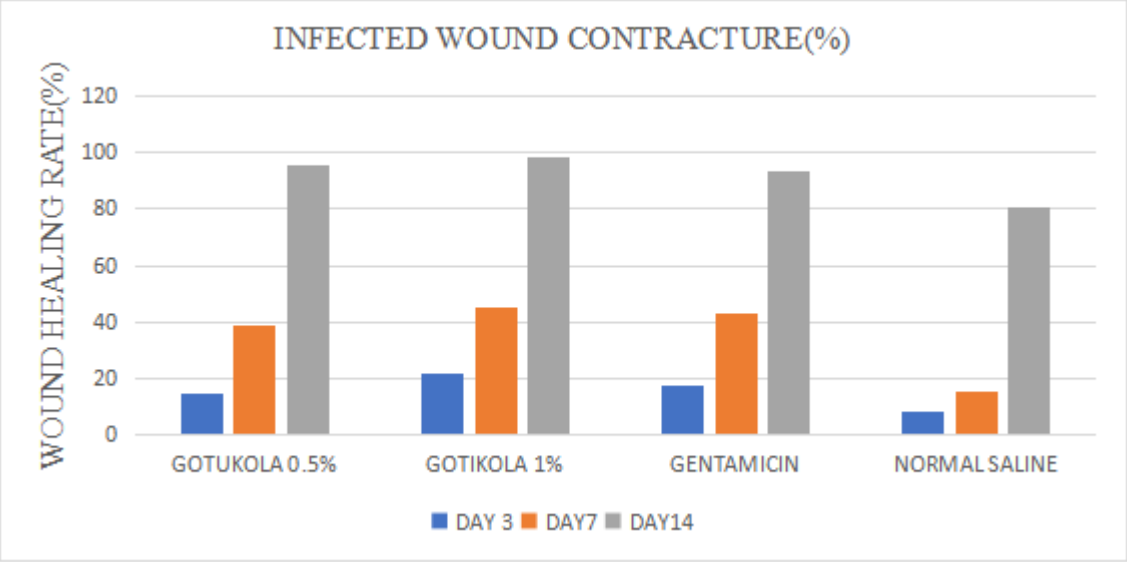


Figure 2**:** The contraction rate (percentages) of staphylococcal infected septic wound assessed at different durations (3, 7, and 14 days) after a topical treatment with 0.5% or 1% of *C. asiatica* leaf extract on wistar rats. Gentamicin represents Positive control, and Normal saline represent negative control.

Table 1: Pair-wise comparisons (Bonferonni test) of wound contraction percentages in both the infected and diabetic wounds treated with 1% or 0.5% of *C. aciatica* extract, positive control under Gentamicin, and Negative control under normal saline.

Treatment group	Compared Group	Mean Difference (I-J)	Std. Error	p-value
Septic Wound				
0.5% Gotukola Extract	1% Gotukola Extract	0.04	0.06	1
	Gentamicin	-0.2	0.06	0.05
	Normal Saline	-.28	0.06	0.00
1% Gotukola Extract	0.5% Gotukola Extract	-0.04	0.06	1
	Gentamicin	-.24	0.06	0.01
	Normal Saline	-.32	0.06	0.001
Gentamicin	0.5% Gotukola Extract	0.2	0.06	0.05
	1% Gotukola Extract	.24	0.06	0.01
	Normal Saline	-0.08	0.06	1
Normal Saline	0.5% Gotukola Extract	.28	0.06	0.004
	1% Gotukola Extract	.320000*	0.067	0.001
	Gentamicin	0.08	0.067	1
Diabetic Wound				
1% Gotukola Extract	0.5% Gotukola Extract	0.26	0.1166	0.2427
	Gentamicin	.400000*	0.1166	0.0206
	Normal Saline	0.2	0.1166	0.6338
Gentamicin	0.5% Gotukola Extract	-0.14	0.1166	1
	1% Gotukola Extract	-.400000*	0.1166	0.0206
0.5% Gotukola Extract	1% Gotukola Extract	1.11022E-16	0.0927	1
	Gentamicin	0.12	0.0927	1
	Normal Saline	-.360000*	0.0927	0.0079
1% Gotukola Extract	0.5% Gotukola Extract	-1.11022E-16	0.092	1
	Gentamicin	0.12	0.092	1
	Normal Saline	-.360000*	0.092	0.0079
Gentamicin	0.5% Gotukola Extract	-0.12	0.092	1
	1% Gotukola Extract	-0.12	0.092	1
	Normal Saline	-.480000*	0.092	0.0005
Normal Saline	0.5% Gotukola Extract	.360000*	0.092	0.0079
	1% Gotukola Extract	.360000*	0.092	0.0079
	Gentamicin	.480000*	0.0927	0.0005
1% Gotukola Extract	0.5% Gotukola Extract	-0.1	0.04	0.1420
	Gentamicin	-0.04	0.04	1
	Normal Saline	-.220000*	0.04	0.0002
Gentamicin	0.5% Gotukola Extract	-0.06	0.04	0.9185

	1% Gotukola Extract	0.04	0.04	1
	Normal Saline	-.180000*	0.04	0.0021
Normal Saline	0.5% Gotukola Extract	0.12	0.04	0.0508
	1% Gotukola Extract	.220000*	0.04	0.0002
	Gentamicin	.180000*	0.04	0.0021

Visual or gross assessment of excision wounds

On day 3 of treatments, wounds from all groups of rats were viewed to be less contracted; relatively wet, swollen, and reddish brown (Figure 3). However, continued treatment (day 7 and 14) with 0.5% or 1% of *C. aciatica* extract showed both wounds the diabetic and septic that were less swollen, relatively drier, and appeared contracted with a brownish scar and were comparable to wounds under gentamycin treatment (Figure 3).

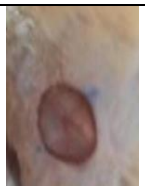
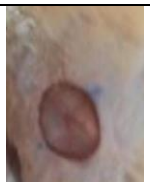
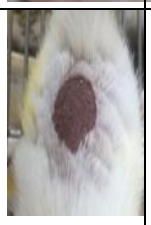
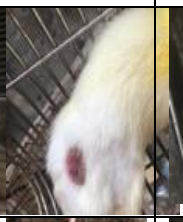
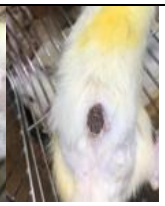
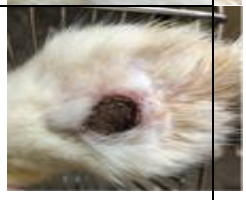
	SEPTIC WOUNDS				DIABETIC WOUNDS			
Days	**0.5% gotukola extract**	**1% gotukola extract**	**Gentamicin**	**Normal saline**	**0.5% gotukola extract**	**1% gotukola extract**	**Gentamicin**	**Nor mal saline**
0								
3								
7								
14								

Figure 2: Physical appearance of both septic and diabetic wounds assessed at an interval of 0,3,7and 14 days of treatment with 0.5% and 1% of *C. aciatica* extract. Gentamicin represents Positive control, and Normal saline represents negative control.

Discussion

The research demonstrated significant wound healing properties of *C. aciatica* (Gotukola) crude extract on both the septic wounds in non-diabetic rats and chronic wounds model made on diabetic rats. Both the concentrations of 0.5% and 1% of the plant crude extracts exhibited a significant healing effect of septic and chronic wounds. Wounds treated with 1% and 0.5% of *C.*

aciatica leaf extract exhibited higher contraction percentages, shorter epithelialization time, and quicker complete healing compared to wounds of untreated counterpart rats, and were comparable to those under gentamicin treatment.

Results from this research aligned well with a study by Mgonja *et al*. (2022) which revealed a significant healing effect caused by concentrations of 1% and 0.5% of crude extracts of Gotukola leaf on excision wounds in rats. Other related results were those obtained by Shukra *et al*. (1999 and 2007) on both diabetic and normal wounds treated with *C. aciatica* leaf extracted asiaticoside under the mechanism involving the promotion of angiogenic activity by enhancing collagen synthesis and tensile strength in wound tissue.

Furthermore, such active compounds like saponins and triterpenes, specifically Asiatic acid, madecassic acid, asiaticoside, and madecassoside, contained in *C. aciatica* leaves could be the key candidates working synergistically to enhance wound healing through their antioxidant properties (Shukla *et al*., 1999 &2007; Liu and Li., 2008), antimicrobial effects (Gohil *et al*., 2010), and support for angiogenesis and wound epithelialization (Shukla *et al*., 1999). Additionally, the high content of vitamin C in the plants could be playing a crucial role in collagen synthesis to enhance wound healing (Dewi, 2023).

Conclusion and recommendation

The *C. aciatica* plant locally available in Tanzania showed positive wound healing effects when their crude extracts were applied on the artificially made septic and diabetic wounds models on the Wistar rats. The dosages of 1% and 0.5% of *C. asiatica* crude extracts promoted wound healing at the same rate in diabetic and septic non-diabetic wounds similar to effect caused by Gentamicin, suggesting its potential use in diabetes wound management.

Declarations

Ethical clearance

Ethical clearance was obtained from the Research Ethical Committee of the SUA before the study's commencement with approval reference number DPRTC/R/186/64. All experimental procedures were conducted in accordance with established animal welfare guidelines, more particularly during the animal's confinement, handling, and restraints. Every effort was made to minimize animal discomfort throughout the study.

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Androgen receptor tissue expression and associated factors in women with triple negative breast cancers at Muhimbili National Hospital in Tanzania

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Abstract

Background: The androgen receptor (AR) is a steroid nuclear receptor involved in complex signaling pathway that is thought to play a role in breast cancer (BC) development. Its tissue overexpression, characterizes a distinct subset in triple negative breast cancer (TNBC) including increasing evidence of possible therapeutic implications.

Broad objective: To determine the AR immunohistochemical (IHC) overexpression in formalin-fixed paraffin-embedded (FFPE) tissue biopsies of women with TNBC with associated clinicopathological factors.

Material and methods: A retrospective hospital-based cross-sectional study of FFPE mastectomy tissue blocks diagnosed with invasive TNBC were retrieved, reviewed, subtyped and graded, based on the Scarff-Bloom-Richardson system, and then immunostained with the anti-AR antibody at Muhimbili National Hospital (MNH) from January - December 2018. A cut-off points of 1% was used to define the threshold of AR immunoreactivity. Patients' demographic data were retrieved from the request forms and associated with the AR expression.

Results: A total of 89 mastectomy cases initially diagnosed with invasive TNBC were retrieved, reviewed and AR-immunostained. Among the studied cases 33% (n=29) were AR positive. Age ranged from 28-86 years (mean = 52, median 53 and mode 57 years). AR immunoreactivity was significantly correlated with axillary lymph node metastasis (P-value<0.001) and larger tumour size (P-value<0.05) including to a lesser extentwith the histopathological subtype (P-value=0.0575) some of which included ductal, lobular and medullary carcinomas.

Conclusion: Breast cancer is relatively common at MNH, a good number are TNBC of which one third showing AR expression with subsequent therapeutic and prognostic implications. The fact that there are AR-positive and AR-negative TNBC seems to support the heterogeneity of breast cancers including the presence of "quadruple" negative cases (QNBC; ER-, PR-, HER2- & AR-) although further studies are indicated.

Recommendation: Further longitudinal studies on AR and TBNC in correlation with other hormonal receptors/biomarkers, clinical pathological and sociodemographic factors, are strongly recommended so as to establish it as a routine biomarker and subsequently formulate a targeted therapy. Further exploration of the QNBC also needs to be done.

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Keywords: Androgen Receptor, Immunohistochemistry, Triple Negative, Breast Cancer

Introduction

Breast cancer (BC) is a prevalent malignant tumour among women presenting about 25% to 35% of all female malignancies globally (Parkin *et al.,* 2001). It is the second most common female malignancy in Sub-Saharan African countries including Tanzania, after cervical cancer (Mwakigonja *et al.,* 2017). Breast cancer presents about 14.4% of all new cancers in females in Tanzania (Ministry of Health, 2017). Breast cancer is known to be a heterogeneous disease, and studies have demonstrated that its biological behaviour varies according to regions as well as race in terms of its progression and survival rate (Burson *et al.,* 2010). Its heterogeneity is demonstrated by varied morphologies, molecular and immunophenotypic profiles, clinical behaviour, response to therapy, as well as patient outcomes (Ricciardi *et al.,* 2015).

Currently, breast cancer is classified into five groups based on their molecular profiles. The classification includes distinct molecular subtypes including normal breast-like, luminal A/B, HER2-related, basal-like and claudin-low (Vogkou & Koutsilieris, 2017, Rweyemamu *et al.,* 2021). Breast cancers are then further sub-classified with respect to the presence or absence of hormonal receptors, with cancers lacking all three (ER, PR and HER2) designated as triple negative breast cancers (TNBC) [Adamo *et al.,* 2017, Anders *et al.,* 2016, Hon *et al.,* 2016, Mina et al., 2017, Rampurwala & Wisinski, 2016, Shabana *et al.,* 2018, Sutton *et al.,* 2012]. Triple negative breast cancer patients attending at the Ocean Road Cancer Institute (ORCI) receive only chemotherapy and radiotherapy prior to or following surgery while hormonal therapy for ER/PR and/or Herceptin (Trastuzumab) for HER2 positive breast cancers is well established in different parts of the world including Tanzania (Mwakigonja *et al.,* 2017, Rambau *et al.,* 2014).

Previous studies from Tanzania reporting on the frequency of triple negative (TNBC) breast cancers from tissue biopsies are scanty and all of them found that the majority of their evaluated cohorts presented with this subtype which also poses a great challenge to treatment options including a high recurrence rate as well as poor disease outcome due to lack of targeted therapy (Gnanamuttupulle *et al.,* 2021, Kivuyo *et al.,* 2025, Rambau *et al.,* 2014, Rweyemamu *et al.,* 2021). The TBNC proportions reported in these studies included 22.1% at ORCI in Dar es Salaam (Rweyemamu *et al.,* 2021), 28.4% at the Kilimanjaro Christian Medical Center (KCMC) in Moshi (Gnanamuttupulle *et al.,* 2021), 36.5% at Muhimbili National Hospital (MNH) in Dar es Salaam (Kivuyo *et al.,* 2025) which study focused only on the response to neo-adjuvant therapy (NAT) and for all breast cancers; and lastly 38.4% at Bugando Medical Center (BMC) in Mwanza (Rambau *et al.,* 2014). These four, are the only studies reporting on the immunohistological profile of TBNC in Tanzania and our current study further evaluates and consolidates knowledge from them. Moreover, our index study is the first to focus only on a TBNC cohort in Tanzania. Thus, our current study also besides further evaluating the magnitude and histological subtypes of TBNC at MNH in order to contribute to the characterization of the trend and pattern of the disease in Tanzania, as also investigates the association between TBNC and various clinical, pathological and demographic factors which may help the formulation of intervention strategies and targeted therapies for this tumour which lacks the common biomarkers hence not amenable to either hormonal- or immuno-therapy.

The androgen receptor (AR) is a nuclear transcription factor in the steroid hormone receptor super family including ER and PR (Fujii *et al.,* 2017, Rampurwala & Wisinski, 2016). The AR is uniformly expressed in metaplastic apocrine cells which is the major component of fibrocystic changes and lack expression of PR and ER. About 5% to 30% of luminal epithelial cells express AR commonly with ER or PR and previous studies suggest that breast cancer arising from these cells are morphologically

distinct and may share AR expression (Rampurwala & Wisinski, 2016, Shabana *et al.,* 2018). Significant variability exists in the reported literature regarding the frequency of AR expression in TNBC, however, with a wide range of 6.6% to 75%. This heterogeneity primarily results from variability among reported studies in terms of the number of patients included, geographical location and the cut-off used for AR positivity (≥1% or >10%) [Rampurwala & Wisinski, 2016]. Furthermore, TNBC exhibit wide range of heterogeneity in molecular classification including six intrinsic subtypes are reported, two Basal-Like subtypes (BL1 & BL2), two Mesenchymal subtypes, Immunomodulatory subtype and Luminal Androgen Receptor subtype with distinct biological behaviour and molecular alterations in terms of RNA expression, somatic mutations and copy number variations (Ahn *et al.,* 2016, Garrido-Castro *et al.,* 2019).

Furthermore, TNBC harbours basal like tumors which are often associated with BRCA mutations. At current BRCA mutated tumours show response to PARP inhibitors (Jain *et al.,* 2025, Turk & Wisinski, 2018). Also PDL-1 expression has been found to be more common in cancers with lymphocytic infiltrates and AR receptor expression, thus AR positivity can be a predictor for immune checkpoint for TNBC (Chen *et al.,* 2023, Lin *et al.,* 2024). If AR proves to be a target for TNBC then this could be a second specific treatment for TNBC (Aysola *et al.,* 2013, McGhan *et al.,* 2014).

Furthermore, only one previous study in Tanzania compares AR expression between the Tanzanian and European (Italian) populations. This previous study from northern Tanzania (Lake Zone) reports that Tanzanian patients harboured tumors with lower AR expression than Italian patients according to the median percentage of immunopositive tumor cells (30% versus 80%, $p < 0.0001$) and staining intensity ($p = 0.0003$) and the proportion of AR negative patients was likewise higher among Tanzanian patients compared to their Italian counterparts (Bravaccini *et al.,* 2018). Whether this pattern of AR expression is similarly found in other Tanzanian cohorts is not yet known; however, this study from Bugando Medical Center (Mwanza, Tanzania) was done on all BC tissues and not TNBC specifically. Thus, this current study aimed at evaluating the immunohistochemical expression of the androgen receptor (AR) in TNBC only for the first time in Tanzania including the association with age, axillary lymphnode metastasis, tumour grade, tumour size, histopathological pattern as well as the menopausal status.

Material and methods

Study design and settings

This was a hospital-based retrospective cross-sectional study done at Muhimbili National Hospital (MNH) Department of Anatomical Pathology. MNH is a teaching hospital with 1,500 bed facility and attending about 1000-1200 outpatient and inpatients per week (www.mnh.or.tz). The histopathology unit can handle about 13000 biopsies per year and capacity of performing immunohistochemistry and special stains for different tissues. Data collected included from archived investigation request forms, histopathology reports as well as clinical notes besides the slides/sections and tissue blocks.

Study population

All archived mastectomy formalin-fixed paraffin-embedded (FFPE) breast biopsies of women registered at MNH-Histopathology unit from Jan 2018 to Dec 2018 and confirmed to have TBNC by haematoxylin and eosin (H & E) stain and immunohistochemistry (IHC).

Inclusion criteria

- All FFPE tissue blocks of female patients who underwent mastectomy at MNH from January 2018 to December 2018 and
- Whose tissue blocks and clinical/pathological information was retrievable and
- Whose sections were negative to all three ER, PR and HER2 by IHC.

Exclusion criteria

- Tissues with poor morphology (poorly fixed and/or autolyzed).
- Specimens exhibiting extensive tumour necrosis, haemorrhage or severe artefact on preliminary H&E evaluation.
- Breast cancer cases with equivocal stain for any hormonal receptor
- Male breast cancer patients.

Sampling procedure

Purposive sampling according to the procedure elaborated in the results Figure 1.

Laboratory Methods and Microtomy

Biopsies:

FFPE tissue blocks and histopathological sections were retrieved from the archives after scanning through the register cases initially confirmed to have TNBC. New sections were made and H & E staining was done for those cases with sub-optimal quality. Well preserved and representative tissue blocks were re-sectioned at 4-micrometres thickness and used for AR immunostaining.

Routine H & E staining

This was done as previously described. (Mwakigonja *et al.,* 2016, Mwakigonja *et al.,* 2017). Briefly, the sections were de-waxed by placing the slides on hot plate at 60°C for 50 minutes, before being placed in xylene. Thereafter, a H&E staining procedure was done as previously described (Mwakigonja *et al.,* 2016, Mwakigonja *et al.,* 2017), followed by clearing in xylene and mounting. Microscopy was done by the principal investigator, and slides were reviewed by the Senior Anatomical Pathologists (ARM and EMV) using LEICA DM 750 microscope. Pictures were taken by a LEICA DM750 camera and visualized by using LEICA soft imaging solutions GMBH software in OSIS USB camera input mode.

AR immunohistochemistry

Immunohistochemistry (IHC) was generally done as previously described (Mwakigonja *et al.,* 2017). Briefly, four micrometres (thin) sections were made from the same tissue blocks used for H & E stain and then used for AR IHC. Sections were dewaxed by subjecting them to a hot plate at 60 degrees Celsius for 50 minutes. Sections were ringed using a PAP pen to avoid spread of the antibody solution and 3 drops of hydrogen peroxide was added for blocking of endogenous peroxidase activity and left for 15 minutes in darkness. Sections were then placed in distilled water. Heat induced antigen retrieval method was applied using a modified pressure cooker and citrate buffer solution at pH of 6 and removed after 2 minutes of two full pressure hits.

Thereafter, sections were removed and placed in humidity chamber and the Tris-buffered saline (TBS) was added for 3 minutes to wash the slides. TBS was then drained and **Rabbit Anti-Androgen Receptor [EP120]:RM0004, RM0004RTU7** was added at optimal dilution and incubated for 60 minutes thereafter, washed using buffer for 5 minutes. At room temperature, TBS was drained off and 2 to 3

drops of **Horseraddish peroxidase** was added and incubated for 30 minutes. Then washing of the section gently with TBS followed by addition of one drop of diaminobenzidine (DAB) chromogen to 1 mil of substrate buffer and then incubated for 5 minutes, washed well in water, after which Harris haematoxylin counterstain was done for 30 seconds and then differentiation in 1% acid-alcohol in 2 dips followed by blueing in alkaline water for 2 minutes. Lastly, sections were dehydrated, cleared in xylene then mounted with DPX and cover-slipped for microscopic evaluation (Mwakigonja *et al.,* 2017).

Microscopic evaluation of AR immunohistochemical expression

As there is no specific scoring system for androgen receptor expression in breast cancer, a system adopted by previous studies reported AR positive if more than 10% of nuclei of the tumour cells stained for AR protein expression (Moinfar *et al.,* 2003, Abouelfadl *et al.,* 2018). Scores were considered as 0% = none, 10% = weak, 20% =moderate and 30% equal to strong (Moinfar *et al.,* 2003, Abouelfadl *et al.,* 2018).

Microscopic evaluation of ER, PR and HER 2 immunohistochemical expression

This was done as previously described (Mwakigonja *et al.,* 2017). Briefly, after appropriate immunostaining was done results for receptor expression were scored semi-quantitatively by an experienced Anatomical Pathologist (ARM) using Reiner's four-point scale based on intensity and percentage of positive IHC reaction [Reiner *et al.,* 1990]. Thus, for each antibody microscopic evaluation of sections was done by performing cell counting and recording the number as well as intensity of positive staining cells.

Hormonal receptors status

A section was ER or PR positive when more than 1% of tumour cells showed positive nuclear staining for each hormonal marker and negative if there was no nuclear staining in tumour cells in the presence positive controls including internal.

HER2 receptor status

Human epidermal growth factor receptor 2 HER2 staining was evaluated according to manufacturer's instructions (DAKO) as previously described (Mwakigonja *et al.,* 2017). Grading for HER2 positivity was based on completeness of cytoplasmic membrane reactivity and the proportion of staining tumor cells. Score of 0–1+ was considered negative for HER2 and score of 2+ was considered equivocal and 3+ or complete membrane staining was considered positive for HER2. (Astvatsaturyan *et al.,* 2018, Gasparini *et al.,* 2014) In this study all equivocal cases were excluded. Study definition of TNBC was those tumours which didn't stain any cell for HER2, ER and PR.

Breast cancer grading

Breast cancer tumour grades were assessed based on the score given. Grading was done using Scarff-Bloom-Richardson system in which tubular formation, nuclear pleomorphic and mitotic count per high power field were assessed. Each category was scored from 1 to 3 and make a total of 9 points. Grade 1 breast cancer was from score 3-5, grade 2 from 6-7 and grade 3 from 8-9. All sample cases were scored by the investigator and reviewed by supervising pathologists. This was applied in all breast carcinoma.

Variables

The broad objective of this study was to evaluate proportion of AR expression in TBNC in FFPE tissue blocks of women with breast cancer at MNH in relation to age of the patient, tumour grade, size, axillary node status and histopathological pattern.

Dependent variable: Androgen receptor expression in triple negative breast cancer.

Independent variable: Tumour grade, size, axillary lymph node involvement, age and histological pattern of diagnosis.

Data collection and analysis

A check list to obtain demographic data of patients was designed and included age and sex, final histopathological report, type of biopsy and ER, PR, HER2 reported in the Jeeva system. Diagnosis was reviewed by the principal investigator followed by supervising pathologists. Data was captured and recorded in a special sheet and later imported into computer software SPSS 24.0 for clearing and analysis. Association between the categories was assessed by *Chi*-square tables. A two-tailed P-value < 0.05 was considered statistically significant.

Results

General findings

A total of 11,783 biopsies were registered in the Histopathology Unit at CPL from January 2018 to December 2018 and of these 469 (3.98%) were breast biopsies (**Figure 1**) and furthermore, the patients' general characteristics are listed in **table 1** below:

Table 1: Patients' general characteristics

Characteristic item	Result/Findings
Minimum age for breast biopsies	18 years
Maximum age for breast biopsies	86 years
Mean age for breast biopsies	(50.1±12) years
Peak age for breast biopsies	41-50 years
Mean age at breast cancer diagnosis	(53.1 ±14) years
Peak age at breast cancer diagnosis	47-57 years
Total malignant lesions (breast cancer)	334 (71.2%)
Non-malignant lesions of the breast	135 (27.8%)
Total Breast Biopsies	**469 (100.0%)**

Histopathological findings/subtypes:

Out of the 334 cases which were malignant, a great majority 284 (85%) were infiltrating ductal carcinomas, 14 (4.2%) medullary carcinomas, 9 (2.7%) infiltrative lobular carcinoma, 4 (1.2%) lobular carcinoma *in situ (LCIS)*, 3 (0.9%) ductal carcinoma *in situ* (DCIS) and the rest were mucinous carcinomas, secretory carcinomas, invasive papillary carcinomas, invasive squamous cell carcinomas as well as rhabdomyosarcomas **(Figures 2-4).** Furthermore, figures 2 and 3 indicate that more histological subtypes of TBNC were reported after reviewing the initial diagnosis which could partly be due to more careful assessment as well as the application of newer classification criteria.

Immunohistochemical findings

ER, PR and HER2 immunohistochemistry

Of all the 334 breast cancer cases, 229 (68.6%) were evaluated for estrogen receptors (ER), progesterone receptors (PR) and human epidermal growth factor receptor type 2 (HER2) and 101 (44.1%), 53 (23.1%) and 66 (28.8%) were positive for ER, PR and HER2 respectively. Furthermore, 128 (55.9%), 176 (76.9%) and 163 (71.2%) were ER, PR and HER2 negative respectively and 13 (5.7%) cases were triple positive breast cancer. Furthermore, 94 (41%) cases were tipple negative breast cancers (TNBC) and out of these, 89 (94.7) cases met the inclusion criteria for AR IHC studies.

Androgen receptor immunohistochemistry

Proportion of AR expression

When 1% was used as a cut-off point to define AR positivity, 29 (33%) were AR positive TNBC and 60 (67%) were AR negative TNBC. Among AR positive tumors 5 (18%) were strongly positive, 10 (33%) were intermediate and 14 (49%) were weakly stained (Figure 5).

Association between age of the patient with AR expression

AR negative patients had a mean age of 52 years which was higher than 49 years of AR positive patients. However, 50 (56.2%) of female patients were above the age of 50 years and 39 (43.8%) were below the age of 50 years. There was no statistical significance as P-value >0.05 (Table 2).

Association between tumour size with AR expression

Tumour size ranged from 2 cm to 14 cm with the mean tumour size of 4.89 ± 2.04 cm. AR positive TNBC had a mean tumour size of 5.2 cm which was significantly higher compared to AR negative TNBC 4.1 cm. This was statistically significant with a P-value=0.005. Also 5 (6%) presented with ≥ 5 cm and 60% of these were AR+ (Table 2).

Association between axillary lymph node metastasis with AR expression

All study cases were assessed for nodal metastasis and 25 (86.2%) of AR positive TNBC had axillary lymph node metastasis compared to 4 (13.8%) of AR positive TNBC without nodal metastasis. These showed statistical significance with a P-value <0.001. (Table 2)

Association between histopathological grade with AR expression

Majority of AR positive TNBC 21 (72.4%) presented with high grade tumors compared to 8 (27.6%) AR positive TNBC who had low grades. There was borderline statistical significance with the P-value=0.0575 (Table 2).

Association between histopathological subtypes with AR Expression

The association between AR expression and histopathological subtype of TBNC was not statistically significant (P-value=0.141) [Table 2, Figure 5].

Tanzania Journal of Health Research
Volume 27: Issue 5 (2026) https://dx.doi.org/10.4314/thrb.v27i5.2

Table 2: Association of AR immunoexpression with age, menopausal status, tumour size and histological grade

Variable	AR + (No of patients (%)	AR- (No of patients (%)	Total (%)	P-Value
Age (Years)				
25-35	6 (21%)	10 (17%)	16 (18%)	
36-46	4 (14%)	16 (27%)	20 (23%)	
47-57	8 (28%)	11 (18%)	19 (21%)	0.059
58-68	7 (24%)	12 (20%)	19 (21%)	
≥69	4 (14%)	11 (18%)	15 (17%)	
Mean Age	**49 years**	**52 years**	**53.3±14 years**	
Menopausal Status				
≤ 50years	10 (34.5%)	29 (48.3%)	39 (43.8%)	
≥ 50years	19 (65.5%)	31 (51.7%)	50 (56.2%)	0.001
Tumor Size (cm)				
2-5	16 (23.5%)	52 (76.5%)	68 (77%)	
6-9	10 (62.5%)	6 (37.5%)	16 (18%)	0.005
≥ 10	3 (60%)	2 (40%)	5 (6%))	
Mean Tumor Size	**5.2 cm**	**4.1 cm**	**4.79 cm**	
Number of Lymph Node				
0-3	7 (24%)	42 (70%)	49 (55%)	
4-7	15 (52%)	11 (18%)	26 (29%)	
8-11	5 (17%)	7 (12%)	12 (14%)	0.009
≥12	2 (7%)	0 (0%)	2 (3%)	
Histological Grade				
Low Grade (I)	8 (28%)	27 (45%)	35 (39%))	
High Grade (II&III)	21 (72%)	33 (55%)	54 (61%)	0.057
Total Number of Patients (%)	**29 (33%)**	**60 (67%)**	**89 (100%)**	

Discussion

In our current study, thin findings of an age range of 18-86 years, the mean age at diagnosis of breast cancer of (52.1 ±14) years and peak age between 41-50 years appears to agree well with our previous reports from Muhimbili National Hospital (MNH) including the one which showed that the age ranged from 28–79 years; mean age at diagnosis of 52.08 years and peak age-group of 36–55 years (Mwakigonja *et al.*, 2016) as well as another report showing the age ranged at diagnosis from 18 to 75 years, mean of 48.36 ± 0.6 years and again peak age of 36-55 years (Mwakigonja *et al.*, 2017).

Thus, the current age findings confirm our previous reports and generally imply that the association of breast cancer and age at diagnosis at this center has not changed with time with an implication as well, in the stability of the clinical behavior of BC presenting at MNH over time. Furthermore, although these age-related findings seem to agree well also with a previous report from Bugando Medical Center (BMC), Mwanza (Rambau *et al.*, 2011) in the Lake Zone where the mean age at diagnosis was 47.8 (+/- 13), however, the peak age-group was 30 - 40 years, followed by 41-50 years (25.9%) implying the peak age at presentation in the Lake Zone for BC patients is younger than at MNH thus a slight zonal variation within Tanzania which may partly be due to geographical, ethnic as well as life style differences between the two centers (Rambau *et al.*, 2011).

Furthermore, for women with TNBC age ranged from 28-86 years and the mean age of 52.28±14.86 years appeared to be similar with age characteristics of BC generally both in our current and previous reports. However, a previous report on TNBC from the Lake Zone (Bugando) showed that the mean age at diagnosis of breast cancer was 49 years which generally corresponds to our index results although slightly younger (Rambau *et al.,* 2014). Similarly in our current study, the mean age for Androgen Receptor (AR) positive TBNC was 49 years which is well in agreement with the previous report findings above from the Lake Zone (Rambau *et al.,* 2014) but for those AR negative it was 52 years although the difference in mean age between AR+ and AR- TBNC was bordering statistical significance (p-value=0.059). The apparent similarity in age characteristics for TBNC between MNH and BMC in the Lake Zone appear to suggest a comparable clinical behavior of this disease group between different geographical zones in Tanzania (Rambau *et al.,* 2014).

The major histological subtypes of TBNC diagnosed at MNH in our index study included infiltrating ductal carcinoma (IDC), infiltrating lobular carcinoma (ILC) and medullary carcinoma (MC) with less than 5% representing other subtypes of breast carcinoma. These current findings appear to be like previous studies in the Lake Zone and Dar es Salaam respectively (Rambau *et al.,* 2011, Rambau *et al.,* 2014, Mwakigonja *et al.,* 2016) as well as to findings by Sutton *et al.,* 2012 suggesting common pathogenetic pathways.

Our current findings of 33% of TBNC cases at MNH were found to express AR while 66% AR negative, is well in agreement with a report from a study done in USA where 31.4% were AR positive TNBC and 68.4% were AR negative TNBC (Sutton *et al.,* 2012). This finding also appears to concur with proportions ranging from 36.5-38.4% from two previous Tanzania reports (Kivuyo *et al.,* 2025, Rambau *et al.,* 2014) suggesting similar populations. However, the findings differs from other Tanzania reports form ORCI and KCMC (Gnanamuttupulle *et al.,* 2021, Rweyemamu *et al.,* 2021) and also from studies from Egypt and South Korea where 23.4% and 17% were AR positive TNBC and 76.6% and 82.3% were AR negative, respectively (Mcghan *et al.,* 2014, Choi *et al.,* 2015) suggesting possibly different populations and/or risk factors.

However, AR expression has been reported to vary between different studies with a wide range of 6.6% to 80% (Rampurwala & Wisinski, 2016, Chottanapund *et al.,* 2016) which could be attributed to the use of ancillary tests like tissue microarrays in sorting TNBC cases, use of different cut off points for AR immunoreactivity, use of core biopsies which would have optimal fixation with minimal tissue autolysis and necrosis and the use automated IHC machines as well as differences in ethnic groups on which the studies were conducted (Mcghan *et al.,* 2014, Choi *et al.,* 2015).

Another interesting finding in our current study was that majority of AR positive TBNC at MNH were significantly associated with axillary lymph node metastasis (p-value 0.009) and this is also in agreement with previous reports from Egypt and United States of America (Mcghan *et al.,* 2014, Astvatsaturyan *et al.,* 2018).

Interestingly, majority of AR positive TNBC patients presented with high histological grades (grade II and III) although this was not statistically significant however, this finding concurs with studies done in United States, Turkey and Egypt which reported as well, that the association between AR positivity and histological grades was not statistically significant (Mcghan *et al.,* 2014, Sutton *et al.,* 2012, Cinkaya *et al.,* 2016). Conversely, a previous report from South Korea found a strong association between AR positivity and high histological grades which was statistically significant (p-value<0.05). The discrepancy between our findings and the Korean study could partly be attributed to a larger sample size (492 TNBC cases), the use of tissue microarrays including a longer (14 years) study duration (Choi *et al.,* 2015).

Furthermore, in our current findings, there seems to be an association between AR positivity and the histological subtype of TBNC showing borderline (p-value=0.0575) statistical significance. This finding corresponds to a previous report from Egypt showing significant association between AR receptor status and tumor histological types but this was only for ductal carcinoma in situ [DCIS] (Shabana *et al.,* 2018) while a previous United States study found a significant association between AR tissue expression and Apocrine breast carcinoma (Astvatsaturyan *et al.,* 2018). These differential histological associations with AR positivity could partly be explained by the existence of intrinsic molecular subtypes of triple negative breast cancer (Garrido-castro *et al.,* 2019, Ahn *et al.,* 2016).

Interestingly still, AR positivity appeared to be significantly (p-value=0.005) associated with larger tumor size which concurs with previous studies done in the United States (Astvatsaturyan *et al.,* 2018, Sutton *et al.,* 2012) but differs from studies done in Egypt and South Korea who reported the opposite (Mcghan *et al.,* 2014, Choi *et al.,* 2015).

Furthermore, our current study appears to show a strong association between AR positivity and the age above 50 years used here as a proxy to post-menopausal status (p-value=0.001). Previous studies including from Tanzania report menopausal status to be a prognostic factor in breast cancer and influence treatment choices (Akoko et al., 2022, Bosompem *et al.,* 2024, Burson *et al.,* 2010, Mwakigonja *et al.,* 2016, Rambau *et al.,* 2014). Thus in areas where ER, PR and HER2 are not routinely used, hormonal therapy is given only to premenopausal women whereas postmenopausal women are treated with radio-chemotherapy (Bosompem *et al.,* 2024, Rweyemamu et al., 2021).

However, it is noteworthy that although the cut-off point of 50 years was used as a proxy to define menopausal status, not all patients who are above 50 years are necessarily postmenopausal and the same applies to those below 50 years to be premenopausal. Besides age, menopause can be induced by premature ovarian failure, surgical (bilateral salpingoophorectomy-BSO), radiation as well as chemical (chemotherapy) ovarian ablation, (Rocca *et al.,* 2023). Thus, about the finding of about one third of TNBC in our settings express AR will have therapeutic as well as prognostic implications and expected to inform clinical practice.

Conclusions

This study appears to show that breast cancer is still relatively a common problem at MNH and about one third of TNBC appeared to express androgen receptors (AR) seemingly associated with older age-groups, post-menopausal status, larger tumour sizes, increased lymph nodes metastasis as well as higher histopathological grades all of which have therapeutic/prognostic implications. The fact that there are AR positive, and AR negative TNBC seems to support that it is a group of diseases rather than a single entity including the presence of "quadruple" negative cases (QNBC; ER, PR, HER2 & AR negative) suggesting different pathogenetic mechanisms with consequent therapeutic and prognostic implications.

Recommendations

Larger and longer duration studies on androgen receptor (AR) expression together with other hormonal receptors and clinicopathological and sociodemographic parameters will help to establish it as a routine biomarker and formulate targeted therapies for TBNC. Further exploration of the QNBC also needs to be done.

Study limitations

Financial constraints did not allow the application of ancillary studies such as FISH to confirm the negative and equivocal immunohistochemical results of HER 2. TNBC is not a single disease entity, but has different molecular subgroups with peculiar biological behaviour, these could not be studied due to lack of ancillary tests to categorize them. False negative IHC stain for AR were anticipated due to pre-analytical errors of tissues such as being poorly fixed or prolonged fixation which could not be controlled in archived (retrospective) tissue blocks and slides used in this study.

Declarations

Ethical considerations and approval

Ethical clearance was obtained from the MUHAS Institutional Review Board (IRB) through letter Ref. No. DA 287/298/01A/ dated 19th June 2018. Administrative permission to conduct the study was obtained from Muhimbili National Hospital (MNH) Management. All patients' data was de-identified and treated confidentially.

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Authorship contributions statement

Amos Mwakigonja: Conceptualization, Data collection, analysis and curation, methodology and writing original draft. Also correcting, formatting and polishing the manuscript. Corresponding author. Henry Stephen: Conceptualization, Data collection, analysis and curation, methodology and writing original draft. Edda Vuhahula: Conceptualization, Data collection and curation, methodology and writing original draft.

Conflict of Interest: The authors declare no any competing interests.

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Assessment of Knowledge, Attitudes, and Practices (KAP) regarding Cryptosporidiosis among Livestock Keepers in Northern Tanzania

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Abstract
Introduction: Cryptosporidiosis is an important but neglected zoonotic enteric disease that is endemic in many developing countries, where it poses significant public health and economic challenges to both livestock and human populations. This quantitative cross-sectional study was conducted in northern Tanzania between September 2024 and February 2025 across five districts to assess livestock keepers' knowledge, attitudes, and practices (KAP) regarding cryptosporidiosis, with particular emphasis on its causes, symptoms, transmission, and prevention.
Methods: A pre-tested structured questionnaire was used to collect data from 216 livestock keepers. Descriptive statistics were used to summarize the data, while bivariable and multivariable logistic regression were performed to identify the factors associated with KAP. Statistical significance was set at p <0.05.
Results: Among the 216 livestock keepers interviewed, 181(83.8%) had poor knowledge, 163 (75.5%) exhibited a negative attitude, and 159(73.6%) demonstrated unsatisfactory practices regarding cryptosporidiosis. Most participants, 142 (65.7%), had heard about cryptosporidiosis; however, only 61 (28.2) reported receiving information about disease from veterinary officers, and just 24(11.1%) correctly identified protozoan parasites as causative agents. In contrast, 130 (60.2%) respondents correctly recognized the fecal-oral route as the primary mode of disease transmission. Furthermore, 75(34.7%) respondents strongly agreed that cryptosporidiosis is a serious disease, while 95(44%) believed that it is preventable. Although most respondents, 190 (88%), reported having regular contact with livestock and their faces, only 59(27.3%) reported consistently wearing protective tools during livestock handling. Multivariable logistic regression analysis identified 6-10 years of farming experience (p=0.042), male sex (p=0.042), and the use of a semi-intensive farming system (p=0.041) as factors significantly associated with the knowledge, attitude, and practice domains, respectively.
Conclusion: These findings highlight the need for targeted community-based health education interventions to improve awareness and promote effective prevention and control practices for cryptosporidiosis among livestock keepers.
Keywords: Cryptosporidiosis, *Cryptosporidium,* Livestock-keepers, KAP, northern Tanzania, zoonoses

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Introduction

Cryptosporidiosis is a zoonotic disease caused by a protozoan parasite that belongs to the genus *Cryptosporidium* (CDC 2025). This parasite infects a wide range of vertebrate hosts, including humans and livestock (Hatam-Nahavandi *et al.,* 2019). To date, more than 40 valid species and 50 genotypes have been identified, with *Cryptosporidium parvum* and *Cryptosporidium hominis* accounting for the majority of human cryptosporidiosis cases (Feng *et al.,* 2018, CDC 2025). Transmission occurs predominantly through the fecal-oral route, either directly via contact with infected animals or humans, or indirectly through ingestion of food or water contaminated with infectious oocysts (WHO 2022, WHO 2024).

Cryptosporidiosis is one of the leading causes of diarrheal disease worldwide (WHO 2022). In immunocompetent individuals, the infection is typically self-limiting; however, in immunocompromised individuals, it can become life-threatening and may result in chronic diarrhea (Kotloff 2017, Hatam-Nahavandi *et al.,* 2019, CDC 2025). In livestock, disease can cause severe diarrhea, dehydration, and mortality, leading to substantial economic losses and adversely affecting livestock production.

Cryptosporidiosis poses substantial occupational health risks to livestock keepers, largely due to routine husbandry practices that increase the likelihood of exposure and infection. These practices include frequent close contact with livestock, particularly during cleaning of livestock housing without the use of protective tools, as well as milking and consumption of raw or inadequately processed milk (Hasan *et al.,* 2018, Amenu *et al.,* 2019). *Cryptosporidium* has a low infectious dose, and infected livestock, particularly calves, kids, and lambs, can shed large numbers of the oocysts into the surroundings, facilitating transmission to livestock keepers, especially where hand hygiene practices are inadequate (Amenu *et al.,* 2019, CDC 2025).

The occurrence and persistence of cryptosporidiosis are further influenced by poor sanitation, ingestion of contaminated food and water, and limited community awareness regarding parasite transmission route, may contribute to the continued endemicity of the disease (Korpe *et al.,* 2018, Krumkamp *et al.,* 2021, Narkkul *et al.,* 2022, Hugho *et al.,* 2023). In endemic settings, several strategies have been implemented to control cryptosporidiosis, including treatment of infected individuals and livestock, improvement of sanitation infrastructure, and health education initiatives (Aboelsoued and Abdel Megeed 2022). Despite global efforts to prevent and control the disease, cryptosporidiosis remains a significant public health concern among livestock-keeping communities worldwide, particularly in sub-Saharan Africa, Southeast Asia, and Latin America (Krumkamp *et al.,* 2021, CDC 2025).

In Tanzania, the burden of cryptosporidiosis has been extensively investigated, with reported infection rates ranging from 6% to 63% among humans and livestock (Pedersen *et al.,* 2014, Lyimo *et al.,* 2017, Korpe *et al.,* 2018, Krumkamp *et al.,* 2021, Hugho *et al.,* 2023, Issae and Katakweba 2024). Cryptosporidiosis is associated with significant socioeconomic impacts on both human and livestock populations, including financial costs associated with prevention, diagnosis, treatment, and control measures, as well as economic losses resulting from decreased livestock productivity and restrictions on the trade of livestock and livestock-derived products (Halliday *et al.,* 2015).

Limited knowledge of disease risk factors, transmission pathways, prevention and control measures is considered a major factor contributing to the persistence of cryptosporidiosis in many livestock -keeping communities (Nachaiwieng *et al.,* 2024). In addition, poor knowledge may promote the adoption of husbandry and hygiene practices that facilitate the maintenance and transmission of the parasite within communities (Narkkul *et al.,* 2022). Consequently, improving community

knowledge, attitude, and practices (KAP) is essential for implementing effective prevention, control, and long-term elimination strategies for cryptosporidiosis (Sazmand *et al.,* 2020, Ola-Fadunsin *et al.,* 2026). Communities with adequate knowledge are likely to adopt appropriate management practices such as improving hygienic and sanitary conditions, which can contribute to reducing the prevalence of cryptosporidiosis (Shapu *et al.,* 2021, Narkkul *et al.,* 2022). KAP surveys provide important information on existing gaps in knowledge, attitudes, and practices regarding cryptosporidiosis transmission and prevention, thereby supporting the development of targeted intervention strategies (Narkkul *et al.,* 2022, Yigrem *et al.,* 2025). However, information on KAP regarding cryptosporidiosis in several African countries, including Tanzania, is limited (Abunna *et al.,* 2024, Esonu *et al.,* 2024, Munyaneza *et al.,* 2025). Therefore, this study was conducted to assess knowledge, attitude, and practice regarding cryptosporidiosis among livestock keepers in northern Tanzania. The findings may provide the baseline information for designing and evaluating future health education interventions aimed at improving parasite management in the study area.

Materials and methods

Study area

This study was conducted in three regions, Kilimanjaro, Manyara, and Tanga, specifically in five districts, Hai, Moshi, Simanjiro, Mbulu, and Korogwe. The area experiences a relatively cool and moderate climate, with average annual temperatures ranging between 15°C and 25°C. These areas have a distinctive climate pattern, characterized by a dry season (June to October) and two rainy seasons, occurring between March and May (long rains) and November to December (short rains). Administratively, the northern zone comprises four regions; however, these regions are predominantly inhabited by communities engaged in pastoral and agro-pastoral livelihoods as primary sources of household income, as shown in **Fig 1.**

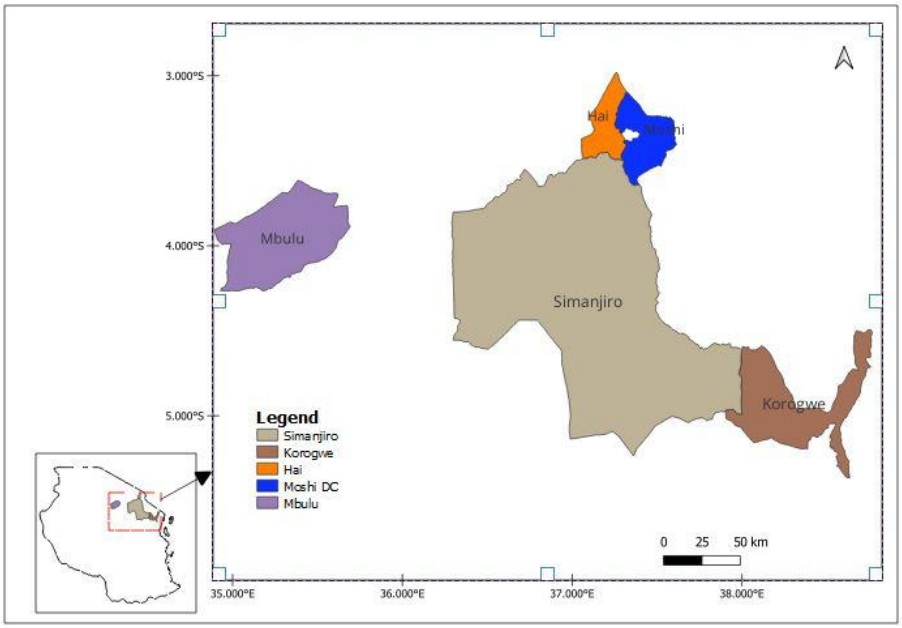

Figure 1: Map of the study area, Hai, Moshi, Simanjiro, Korogwe, and Mbulu districts, Northern zone, Tanzania

Study design, Sample size determination, and recruitment

A quantitative cross-sectional study was conducted between September 2024 and February 2025 in seven selected health facilities across five administrative districts of northern Tanzania. The sample size was calculated based on an estimated prevalence of 15% as reported by Krumkamp et al.(2021), using a 95% confidence interval and a 5% margin of error. The sample size calculation was performed using Cochran's formula, as described by Ali and Al Hatef (2024). After adjusting for a 10% non-response rate, the minimum required sample size was 216 livestock keepers. The study districts and health facilities were selected purposively based on their relevance to livestock production activities. Livestock keepers were selected using a simple random approach from eligible participants available at the selected study sites. Participants aged 18-80 years who provided written informed consent were included in the study, whereas individuals younger than 18 years and those who did not provide written informed consent were excluded.

Data collection

The structured questionnaire was adapted from previously published knowledge, attitude, and practice (KAP) studies on cryptosporidiosis and zoonotic diseases, with modifications to reflect the local context of livestock keepers in northern Tanzania. The questionnaire items were further modified to capture key domains of knowledge, attitude, and practice relevant to livestock keepers. The tool consisted of four sections: (1) socio-demographic characteristics, including age, gender, education, occupation, and marital status; (2) knowledge regarding the causes, transmission, and prevention of cryptosporidiosis. (3) The attitude towards cryptosporidiosis and (4) prevention practices against cryptosporidiosis, including the use of personal protective tools such as gloves, safety boots, as well as handwashing practices.

The questionnaire was initially developed in English, then translated into Swahili, and then back translated by a different person who was blinded to the original version to ensure the meaning of the questions remained unchanged. Prior to data collection, the questionnaire was pre-tested among ten livestock keepers in communities surrounding the Nelson Mandela African Institution of Science and Technology before administration to evaluate its clarity, validity, and applicability. After pretesting, the tools were improved accordingly.

Thus, unclear questions were rephrased, and the time to administer the entire tool was determined. The structured questionnaire was administered to 216 livestock keepers through face-to-face interviews conducted in Swahili, with assistance from an interpreter when required, to facilitate accurate understanding and responses from participants. The reliability of the questionnaire was evaluated using Cronbach's Alpha coefficient as a measure of internal consistency among items within each domain.

The attitude domain demonstrated acceptable internal consistency ($\alpha = 0.72$), whereas the knowledge ($\alpha = 0.043$) and practice ($\alpha = 0.28$) domains showed low internal consistency. Data were collected by researchers and trained health personnel who received standardized training on the study procedures and administration of the questionnaires. To minimize interviewer bias, research assistants (trained health personnel) were blinded to the study hypotheses or correct answers to the survey questions during data collection.

Scoring system

KAP assessment was performed using a structured scoring system adapted from previously described approaches by Balasubramanian (2012) and Mohd Yusof et al.(2018). Knowledge regarding cryptosporidiosis was scored as 1 for each correct response and 0 for incorrect responses or "do not know". The same scoring system was applied to practice-related items. Attitudes were assessed using

a five-point Likert scale. For the positively worded statements, responses were scored as follows: 5 to strongly agree, 4 to agree, 3 to neutral, 2 to disagree, and 1 to strongly disagree. However, for negatively worded statements, scoring was reversed, with strongly disagree assigned a score of 5 and strongly agree assigned a score of 1.

These scores for individual items within each domain were added to obtain composite scores for knowledge, attitude, and practice. The maximum possible scores were 12 for knowledge, 15 for attitude, and 9 for practice. No weighting system was applied; all items within each domain contributed equally to the overall domain score. Respondents were classified as having "good" or "poor" knowledge and practice, and "positive" or "negative" attitudes based on a modified Bloom's cut-off point with little modification, as described by Mohd Yusof et al.(2018). There were two categories of knowledge level: poor (less than 60%; 0-7points) and good (more than 61%; 8-12 points). On the other hand, the attitude scores were also broken into two categories: negative (less than 60%; 0-9 points) and positive (more than 61%; 10-15 points). The level of practice was then categorized as poor (less than 60%; 0-5points) and good (more than 61%; 6-9 points).

Data management

All completed questionnaires were reviewed, verified, and cross-checked on the same day of data collection to ensure completeness, accuracy, and internal consistency. The collected data were subsequently entered into Microsoft Excel, and all datasets were thoroughly checked and cleaned prior to statistical analysis. Data analysis was performed using IBM SPSS version 20. Descriptive statistics were used to summarize participants' demographic characteristics and overall knowledge, attitude, and practice (KAP) scores. Bivariable logistic regression analysis (BLRA) was initially performed to assess the association between explanatory and outcome variables. Explanatory variables included in the model were farming system, duration of farming experience, education level, marital status, age, and sex of the respondent. The outcome variables were created for each KAP domain, categorized as either "good" or "poor" knowledge/practice and "positive" or "negative" attitude. Variables with a *p*-value ≤ 0.25 in bivariable logistic regression analysis were considered for inclusion in the multivariable logistic regression model. A backward stepwise likelihood ratio (Backward LR) method was used to identify variables significantly associated with outcome variables. Variables with $p < 0.05$ were considered statistically significant and retained in the final model.

Results

Socio-demographic characteristics of the study participants

A total of 216 livestock keepers participated in the study, comprising participants from Hai 58(26.9%), Moshi 29(13.4%), Korogwe 56(25.9%), Simanjiro 36(16.7%), and Mbulu 37(17.1%) districts. Female respondents outnumbered male respondents. The participants' ages ranged from 18 to 80 years, with the largest proportion falling within the 30-39-year age category. Nearly half 101(46.8%) of the respondents had primary education. Furthermore, the majority of respondents 210 (97.2%) were married. About 110(50.9%) of respondents were practicing an intensive farming system. In addition, 96(44.4%) of the respondents had more than 10 years of farming experience, as shown in **Table 1**.

Table 1: Demographic characteristics of the livestock keepers (n = 216)

Characteristic	No. of participants	Percentage (%)
Age(years)		
18-29	47	21.8

30-39	57	26.4
40-49	42	19.4
50-59	38	17.6
60-69	16	7.4
70-80	16	7.4
Sex		
Male	100	46.3
Female	116	53.7
Education		
No education	44	20.4
Primary	101	46.8
Secondary	60	27.8
Postsecondary	11	5.1
Farming system		
Intensive	110	50.9
Semi-intensive	79	36.6
Extensive	27	12.5
Farming experience		
<5years	39	18.1
5-10years	81	37.5
>10	96	44.4
Marital status		
Single	4	1.9
Married	210	97.2
Divorced	2	0.9
District		
Hai	58	26.9
Moshi	29	13.4
Mbulu	37	17.1
Korogwe	56	25.9
Simanjiro	36	16.7

Respondent's knowledge on the cause, transmission, symptoms, and prevention measures regarding cryptosporidiosis.

Among the 216 respondents interviewed, 181(83.8%) had poor knowledge, as illustrated in **Figure 2.** Despite the overall low level of knowledge, the majority of the respondents 142 (65.7%) had heard about cryptosporidiosis. Veterinary officers were the most frequently mentioned source, accounting for 61(28.2%). Only 24(11.1%) of the respondents identified parasitic protozoa as potential causative agents of cryptosporidiosis. Furthermore, 94 (43.5%) of the respondents recognized the major clinical symptoms associated with cryptosporidiosis. Young children 67(31%) and neonatal livestock 25(11.6%) were the most frequently identified risk groups for cryptosporidiosis. Moreover, 130 (60.2%) of the respondents correctly recognized the fecal-oral as the major route of transmission of disease. However, awareness of preventive measures was limited, with only 30(13.9%) respondents identifying protective tools, as summarized in **Table 2**

Attitude of the study participants towards cryptosporidiosis

The findings indicate that the majority of respondents 163 (75.5%) had a negative attitude, as summarized in **Figure 2**. Among the respondents 75 (34.7%) strongly agreed that cryptosporidiosis is a serious disease, while 95(44%) strongly agreed that the disease is preventable. Moreover, only 54 (25%) and 94 (43.5%) respondents agreed that handwashing after using the toilet and before meals, respectively, is essential. In addition, 64(29.6%) respondents strongly agreed on the importance of wearing protective tools during cleaning and handling livestock, as shown in **Table 2**

Practices of the study participants related to control and prevention of cryptosporidiosis

Of the respondents interviewed, 159(73.6%) demonstrated poor practices related to cryptosporidiosis control and prevention, as summarized in **Figure 2**. Furthermore, the majority of livestock keepers 190(88%) reported frequent contact with livestock and their feces. However, the adoption of personal protective measures during cleaning and handling of sick livestock was limited, with only 59 (27.3%) respondents reported regularly use of the protective tools. Additionally, 149 (69%) respondents reported consistent use of the toilet, while 111 (51.4%) and 97(44.9%) reported washing their hands after using the toilet and before meals. Moreover, 147(68.1%) respondents reported seeking medical or veterinary care when they or their livestock experienced gastrointestinal illness, as shown in **Table 2.**

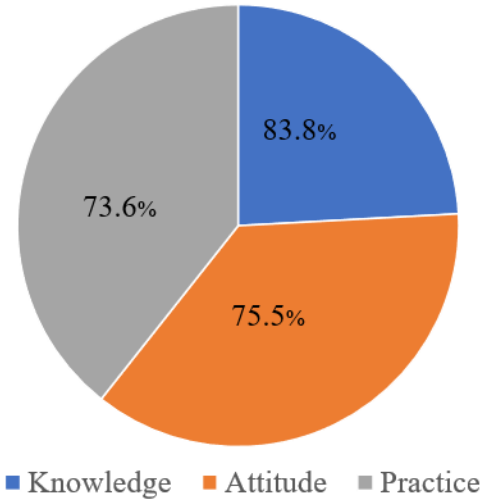

Figure 2: Overall scores for the knowledge, attitudes, and practices towards cryptosporidiosis amongst livestock keepers in northern Tanzania (n = 216)

Table 2: The knowledge, attitude, and practice about cryptosporidiosis among livestock keepers

Item	No. of respondents	Percentage (%)
Knowledge		
Have you ever heard about cryptosporidiosis cases in your community?		
Yes	142	65.7
No	74	34.3
From which of the following sources do you usually get information about diseases such as cryptosporidiosis?		
Veterinary workers	61	28.2

Health workers	28	13
Media	19	8.8
Neighbors	19	8.8
I don't know	89	42.2
What is the causative agent of cryptosporidiosis?		
Bacteria	17	7.9
Virus	10	4.6
Parasite	24	11.1
Fungi	15	6.9
Microorganism	137	63.4
I don't know	13	6
What are the symptoms of cryptosporidiosis?		
Diarrhea	50	23.1
Fever	11	5.1
Nause	6	2.8
Abdominal pain	17	7.9
Vomiting	10	4.6
I don't know	122	56.5
Which group is at risk of getting cryptosporidiosis?		
Underfive children	67	31
Elders	17	7.9
Immunocompromised people	19	8.8
Young animals	25	11.6
I don't know	88	40.8
Which of the following is a major route of cryptosporidiosis transmission?		
Fecal-oral route	130	60.2
Mosquito bite	22	10.2
Airborne droplets	3	1.4
I don't know	61	28.2
Which materials do you use for hand washing after visiting the toilet and before meals?		
Soap and water	75	34.7
Water only	138	63.9
Soil	3	1.4
What method do you always use to prepare drinking water for household consumption?		
Boiling and filtering	45	20.8
Filtering only	37	17.1
Boiling only	99	45.8
I don't know	35	16.2
What method do you usually use to prepare milk for household consumption?		
Filtering and boiling	44	20.4
Filtering	37	17.1
Boiling only	107	49.5
Fermentation	2	0.9
Boiling and fermentation	10	4.6
Filtering and fermentation	1	0.5
I don't know	15	6.9
What method do you always use to prepare vegetables/fruits for household consumption?		
Wash and cook/eat	71	32.9
Cook/eat	125	57.9

I don't know	20	9.3
What measures do you take to prevent the spread of cryptosporidiosis within your household?		
Boiling and filtering drinking water	66	30.6
Filtering and boiling milk	5	2.3
Observe hand hygiene	30	13.9
Seeking medical/ veterinary help	108	50
I don't know	7	3.2
Which of the following personal protective tools do you always use when handling livestock and performing cleanliness in their houses?		
Gloves	29	13.4
Gumboots	59	27.3
Gloves and gumboots	46	21.3
Gloves, gumboots, apron	30	13.9
I don't know	52	24.1
Attitude		
Is cryptosporidiosis a serious health issue?		
Strongly disagree	14	6.5
Disagree	56	25.9
Neutral	39	18.1
Agree	32	14.8
Strongly agree	75	34.7
Do you agree that medical and veterinary are sources of information?		
Strongly disagree	2	0.9
Disagree	44	20.4
Neutral	25	11.6
Agree	76	35.2
Strongly agree	69	31.9
Do you agree that the parasitic protozoan is the causative agent of cryptosporidiosis?		
Strongly disagree	19	8.8
Disagree	85	39.4
Neutral	26	12
Agree	41	19
Strongly agree	45	20.8
Do you agree that diarrhea and abdominal pain are symptoms of cryptosporidiosis?		
Strongly disagree	4	1.9
Disagree	44	20.4
Neutral	25	11.6
Agree	74	34.3
Strongly agree	69	31.9
Do you agree that cryptosporidiosis can be transmitted through the fecal-oral route?		
Strongly disagree	4	1.9
Disagree	67	31
Neutral	33	15.3
Agree	48	22.2
Strongly agree	64	29.6

Do you agree that contact with livestock and their feces can enhance transmission of cryptosporidiosis?		
Strongly disagree	2	0.9
Disagree	59	27.3
Neutral	28	13
Agree	62	28.7
Strongly agree	65	30.1
Do you agree that young children, immunocompromised individuals, and neonatal livestock are risk groups for cryptosporidiosis?		
Strongly disagree	3	1.4
Disagree	40	18.5
Neutral	24	11.1
Agree	83	38.4
Strongly agree	66	30.6
Do you agree that cryptosporidiosis is preventable?		
Strongly disagree	8	3.7
Disagree	36	16.7
Neutral	7	3.2
Agree	70	32.4
Strongly agree	95	44
Do you agree that it is important to drink boiled water to prevent getting cryptosporidiosis?		
Strongly disagree	18	8.3
Disagree	60	27.8
Neutral	26	12
Agree	23	10.6
Strongly agree	89	41.2
Do you agree that it is important to drink boiled milk to prevent getting cryptosporidiosis?		
Strongly disagree	20	9.3
Disagree	60	27.8
Neutral	21	9.7
Agree	42	19.4
Strongly agree	73	33.8
Do you agree that it is important to eat washed and/or cooked vegetables and/or fruits to prevent getting cryptosporidiosis?		
Strongly disagree	4	1.9
Disagree	29	13.4
Neutral	22	10.2
Agree	98	45.4
Strongly agree	63	29.2
Do you agree that it is important to use a toilet in preventing cryptosporidiosis?		
Strongly disagree	22	10.2
Disagree	63	29.2
Neutral	26	12
Agree	43	19.9
Strongly agree	62	28.7
Do you agree that it is important to wash hands with water and soap after using the toilet?		

Strongly disagree	28	13
Disagree	48	22.2
Neutral	38	17.6
Agree	54	25
Strongly agree	48	22.2
Do you agree that it is important to wash hands with water and soap before a meal?		
Strongly disagree	20	9.3
Disagree	77	35.6
Neutral	22	10.2
Agree	94	43.5
Strongly agree	3	1.4
Do you agree that it is important to wear protective tools (gloves, gumboots) when handling livestock or performing cleanliness tasks?		
Strongly disagree	4	1.9
Disagree	67	31
Neutral	33	15.3
Agree	48	22.2
Strongly agree	64	29.6
Practice		
How consistently do you drink boiled water?		
Every time	45	20.8
Rarely	83	38.4
I never do	88	40.7
How consistently do you drink boiled milk?		
Every time	42	19.5
Rarely	155	71.8
I never do	19	8.8
How consistently do you eat washed and/or cooked vegetables and/or fruits?		
Every time	20	9.3
Rarely	196	90.7
How consistently do you use the toilet for defecation?		
Every time	149	69
Rarely	36	16.7
I never do	31	14.4
How consistently have you had contact with animals and their feces?		
Every time	190	88
Rarely	26	12
How consistently do you wash your hands after using the toilet?		
Every time	111	51.4
Rarely	60	27.8
I never do	45	20.8
How consistently do you wash your hands with soap and water before meals?		
Every time	97	44.9
Rarely	116	53.7
I never do	3	1.4
How consistently do you wear protective tools (gloves, gumboots, aprons) when handling animals or cleaning animal houses/toilets?		

Every time	59	27.3
Rarely	85	39.4
I never do	72	33.3
How consistently do you seek medical/veterinary attention when experiencing symptoms of cryptosporidiosis?		
Every time	69	31.9
Rarely	147	68.1

Multivariable association with KAP scores of livestock keepers (n=216)

The variables that met the inclusion criterion in the bivariable logistic regression ($p < 0.25$) were entered into the multivariable logistic regression model. Following backward elimination, only three factors remained independently associated with the knowledge, attitude and practice: 6-10 years of farming experience (AOR 0.383; 95%CI 0.152-0.965; $p = 0.042$), male sex (AOR 1.92; 95%CI 1.024-3.599; $p= 0.042$), and semi-intensive farming system (AOR 0.266; 95%CI0.075-0.948; $p = 0.041$), respectively, as presented in **Table 3**.

Table 3: Factors associated with knowledge, attitude, and practice (KAP) regarding cryptosporidiosis

The association between sociodemographic factors and knowledge, attitude, and practice. The associations between variables and cryptosporidiosis are presented as an adjusted odds ratio (AOR) with a 95% confidence interval (CI) and corresponding p-values, whereby (*) represents statistically significant at p<0.05.

Characteristic	Level		COR	95%CI	*p*-value	AOR	95%CI	*p*-value
	Poor	Good						
	Knowledge							
Sex								
Male	84(46.4)	16(45.7)	1.568	0.758-3.245	0.225	—	—	—
Female	97(53.6)	19(54.3)						
Age(years)								
18-29	39(21.5)	8(22.9)	1.436	0.272-7.593	0.67	—	—	—
30-39	48(26.5)	9(25.7)	1.312	0.254-6.792	0.746	—	—	—
40-49	37(20.4)	5(14.3)	0.946	0.164-5.451	0.95	—	—	—
50-59	32(17.7)	6(17.1)	1.312	0.235-7.232	0.757	—	—	—
60-69	11(6.1)	5(14.3)	3.182	0.516-19.639	0.213	—	—	—
70-80	14(7.7)	2(5.7)						
Education								
No education	38(21)	6(17.1)	1.000	0.105-9.505	1.000			
Primary Education	81(44.8)	20(57.1)	0.897	0.097-8.272	0.924			
Secondary Education	51(28.2)	9(25.9)	1.042	0.11-9.908	0.972			
Postsecondary Education	11(6.1)	0(0)						
Farming system								
Intensive	71(39.2)	8(22.9)	0.478	0.2-1.142	0.097	—	—	—
Semi-intensive	89(49.2)	21(60)	1.211	0.435-3.373	0.714	—	—	—
Extensive	21(11.6)	6(17.1)						
Farming experience								
<5 years	30(16.6)	9(25.7)	1.216	0.495-2.985	0.67	1.216	0.495-2.985	0.67

6-10 years	74(40.9)	7(20)	0.383	0.152-0.965	0.042	0.383	0.152-0.965	0.042*
>10 years	77(42.5)	19(54.3)						
Marital status								
Single	4(2.2)	0(0)	0.999	0.000	0.999			
Married	175(96.7)	35(34)	0.999	0.000	0.999			
Divorce	2(1.1)	0(0)						
Attitude level								
Negative	135(74.6)	28(80)	0.734	0.3-1793	0.497			
Positive	46(25.4)	7(20)						
Practice level								
Poor	137(75.7)	22(62.9)	1.84	0.856-3.954	0.118			
Good	44(24.3)	13(37.1)						
	Negative	**Positive**						
	Attitude							
Sex								
Male	69(42.3)	31(58.5)	1.92	1.024-3.599	0.042	1.92	1.024-3.599	0.042*
Female	94(57.7)	22(41.5)						
Age(years)								
18-29	36(22.1)	11(20.8)	0.393	0.119-1.3	0.126	—	—	—
30-39	42(25.8)	15(28.3)	0.459	0.145-1.451	0.185	—	—	—
40-49	33(20.2)	9(17)	0.351	0.102-1.203	0.096	—	—	—
50-59	29(17.8)	9(17)	0.399	0.116-1.377	0.146	—	—	—
60-69	14(8.6)	2(3.8)	0.184	0.031-1.09	0.062	—	—	—
70-80	9(5.5)	7(13.2)						
Education								
No education	34(20.9)	10(18.9)	0.515	0.125-2.122	0.358			
Primary	77(47.2)	24(45.3)	0.545	0.147-2.024	0.365			
Secondary	45(27.6)	15(28.3)	0.583	0.15-2.274	0.437			
Postsecondary	7(4.3)	4(7.5)						
Farming system								

Intensive	60(36.8)	19(35.8)	0.884	0.454-1.725	0.719
Semi-intensive	81(49.7)	29(54.7)	0.635	0.22-1.832	0.401
Extensive	22(13.5)	5(9.4)			
Farming experience					
<5 years	28(17.2)	11(20.8)	1.179	0.511-2.721	0.7
6-10 years	63(38.7)	18(34)	0.857	0.426-1.723	0.665
>10 years	72(44.2)	24(45.3)			
Marital status					
Single	4(2.5)	0(0)	0.00	0.000	0.999
Married	158(96.9)	52(98.1)	0.329	0.2-5.355	0.435
Divorce	1(0.6)	1(1.9)			
Knowledge level					
Poor	135(82.8)	46(86.8)	1.363	0.558-3.33	0.497
Good	28(17.2)	7(13.2)			
Practice level					
Poor	120(73.6)	29(73.6)	1.002	0.496-2.023	0.996
Good	43(26.4)	14(26.4)			
	Poor	**Good**			
	Practice				
Sex					
Male	73(45.9)	27(47.4)	1.386	0.755-2.543	0.292
Female	86(54.1)	30(52.6)			
Age(years)					
18-29	29(18.2)	18(31.6)	1.366	0.41-4.578	0.614
30-39	46(28.9)	11(19.3)	0.526	0.151-1.827	0.312
40-49	33(20.8)	9(15.8)	0.6	0.165-2.177	0.437
50-59	28(17.6)	10(17.5)	0.786	0.218-2.826	0.712
60-69	12(7.5)	4(7)	0.733	0.156-3.45	0.695
70-80	11(6.9)	5(8.8)			
Education					
No education	29(18.2)	15(26.3)	0.609	0.101-3.681	0.589
Primary	71(44.7)	30(52.6)	0.556	0.095-3.256	0.515

Secondary	48(30.2)	12(21.1)	1.135	0.191-6.73	0.889			
Postsecondary	11(6.9)	0(0)						
Farming system								
Intensive	52(32.7)	27(47.4)	1.047	0.555-1.973	0.887	1.047	0.555-1.973	0.887
Semi-intensive	86(54.1)	24(42.1)	0.266	0.075-0.948	0.041	0.266	0.075-0.948	0.041*
Extensive	21(13.2)	6(10.5)						
Farming experience								
< 5 years	30(18.9)	9(15.8)	1.643	0.686-3.934	0.255	—	—	—
6-10 years	55(34.6)	26(45.6)	1.091	0.559-2.127	0.789	—	—	—
>10 years	74(46.5)	22(38.6)						
Marital status								
Single	4(2.5)	0(0)	1.333	0.057-31.121	0.858			
Married	153(96.2)	57(100)	0.335	0.021-5.46	0.443			
Divorce	2(1.3)	0(0)						
Knowledge level								
Poor	137(86.2)	44(77.2)	0.544	0.253-1.168	0.118			
Good	22(13.8)	13(22.8)						
Attitude level								
Negative	120(75.5)	43(75.4)	1.002	0.496-2.023	0.996			
Positive	39(24.5)	14(24.6)						

Discussion

Understanding livestock keepers' knowledge, attitude, and practice regarding cryptosporidiosis, particularly its causes, transmission pathways and prevention measures, is essential for designing effective and sustainable control interventions. Successful management of zoonotic diseases depends not only on the availability of preventive measures but also on community knowledge and awareness. In the present study, most respondents demonstrated poor knowledge regarding cryptosporidiosis, suggesting a significant challenge in disease prevention and control, as limited knowledge may hinder the adoption of appropriate preventive practices.

This knowledge gap may be attributed to inadequate access to veterinary extension services, limited community health education on zoonotic diseases, and insufficient dissemination of information on cryptosporidiosis among livestock-keeping communities. Consequently, livestock keepers may have fewer opportunities to acquire accurate knowledge about disease transmission and prevention. Similar findings were reported in Ethiopia (Alemayehu *et al.,* 2022). However, the present findings differ from studies conducted in Rwanda, Finland, and Uganda, where most livestock keepers demonstrated adequate knowledge related to cryptosporidiosis (Suolaniemi *et al.,* 2023, Masiku *et al.,* 2024, Munyaneza *et al.,* 2025). These findings highlight the need for coordinated efforts among

veterinarians, public health professionals, community health workers, and other relevant stakeholders to promote integrated surveillance, early detection, and appropriate response strategies.

The current result revealed that the majority of the respondents had heard about cryptosporidiosis, suggesting that disease is recognized to some extent within the study area. This finding is comparable with a study conducted in Finland(Suolaniemi *et al.,* 2023) but contrasts from findings reported in Rwanda, where only a small proportion of respondents had heard about the disease(Munyaneza *et al.,* 2025). This difference may be attributed to variations in access to veterinary extension services and exposure to health education programs. Furthermore, our findings are consistent with a study conducted in Rwanda, which reported that veterinarians are the primary sources of information on cryptosporidiosis among livestock keepers (Munyaneza *et al.,* 2025), highlighting their important role in disseminating accurate information on causes, transmission, and prevention measures of cryptosporidiosis and other zoonotic diseases.

The present finding revealed that only a small portion of respondents correctly identified the causative agent of cryptosporidiosis, indicating a significant knowledge gap that may hinder the adoption of appropriate preventive measures, thereby increasing risk of disease transmission between humans and livestock. Similar knowledge gaps have been reported among livestock keepers in India (Singh *et al.,* 2019). In contrast, more than half of the respondents correctly mentioned the fecal-oral route as primary mode of transmission, suggesting a moderate level of knowledge of an important transmission pathway. This finding aligns with a study conducted in Rwanda (Munyaneza *et al.,* 2025). Despite awareness of transmission route, the limited knowledge of the disease etiology highlights the need for targeted educational interventions that emphasize the causative agent, transmission dynamics, and evidence-based prevention strategies for cryptosporidiosis.

Furthermore, the current findings align with a study conducted in Uganda, which reported that more than half of the respondents recognized young children, livestock, and immunocompromised individuals as the most vulnerable groups for cryptosporidiosis (Mugasa *et al.,* 2023), indicating relatively good knowledge of high-risk populations. Additionally, the current findings also correspond with a study conducted in Uganda (Mugasa et al., 2023), which reported that only a small proportion of the respondents correctly identified the major clinical symptoms of cryptosporidiosis. This limited knowledge regarding disease symptoms may be attributed to inadequate exposure to cryptosporidiosis cases within households or communities, which results in misinterpretation of clinical signs and delays in seeking appropriate healthcare, as cryptosporidiosis may present symptoms like other gastrointestinal diseases, including cholera, amebiasis, and typhoid.

Livestock keepers with six to ten years of farming experience in livestock keeping demonstrated significantly higher knowledge scores, possibly indicating greater exposure to livestock management practices, veterinary extension services, or recent training initiatives related to animal health. In contrast, formal education level was not significantly associated with knowledge scores, highlighting the need for inclusive educational interventions that target livestock keepers regardless of educational background. However, the present finding differs from studies conducted in Nigeria, Iran, and Vietnam, which reported that higher educational attainment was significantly associated with knowledge among dairy and wildlife farmers (Sazmand *et al.,* 2020, Ghali-Mohammed *et al.,* 2025).

The present finding found that most respondents had a negative attitude toward cryptosporidiosis, suggesting that livestock keepers may have an unfavorable perception, which could limit the adoption of recommended preventive measures and reduce community engagement in disease control efforts, potentially increasing the risk of transmission at the human- animal interface. This finding is consistent with reports from Ethiopia and Nigeria (Abunna *et al.,* 2024, Esonu *et al.,* 2024). The current results may be attributed to limited access to veterinary extension services and

community-based health education, which are essential for improving awareness and encouraging positive behavioral change. These findings highlight the need to strengthen multidisciplinary collaboration to enhance health education, promote timely reporting of suspected cases, and improve integrated zoonotic disease surveillance, thereby supporting effective prevention and control of cryptosporidiosis among livestock-keeping communities.

A relatively small proportion of respondents perceived cryptosporidiosis as a serious health issue, indicating persistent gaps in risk perception and awareness of its zoonotic importance. The present result, however, differs from a study conducted in Finland, which reported a higher proportion of livestock keepers considered the disease as an important health concern (Suolaniemi *et al.,* 2023), highlighting the need for targeted community-based health education to improve understanding of the public health and economic consequences of cryptosporidiosis. In contrast, nearly half of the respondents perceived that cryptosporidiosis is preventable, suggesting a favorable perception that could facilitate the adoption of recommended preventive measures if supported by appropriate health education and veterinary extension services. This finding is consistent with the study conducted in Finland (Suolaniemi *et al.,* 2023). The present findings demonstrated a significant association between respondents' sex and attitude, with male respondents exhibiting more positive attitude towards cryptosporidiosis than female respondents. This finding suggests perceptions may vary by sex. However, it contrasts with a study conducted in Ghana, which reported that male individuals had lower odds of having a positive perception of zoonotic disease prevention (Squire *et al.,* 2025). This difference highlights the importance of designing gender-based health education strategies that ensure equitable access to information and training opportunities. Although no significant association was observed between attitude and duration of farming experience, respondents with more than ten years of farming experience tended to demonstrate positive attitudes towards cryptosporidiosis. This pattern may reflect the cumulative influence of practical experience and previous exposure to animal health information.

The present findings found that the majority of respondents demonstrated poor preventive practices regarding cryptosporidiosis, suggesting inadequate adoption of recommended measures for disease prevention and control. This finding is consistent with studies conducted in Nigeria and Ethiopia (Abunna *et al.,* 2024, Esonu *et al.,* 2024). The present findings highlight the need to strengthen adherence to appropriate livestock management, biosecurity measures, and personal hygiene practices to reduce exposure to *Cryptosporidium* and other zoonotic pathogens. Addressing these gaps requires targeted interventions, including veterinary extension services and community-based education programs, which can play a critical role in enhancing awareness, promoting behavioral change, and supporting the adoption of evidence-based prevention strategies to reduce the risk of zoonotic disease transmission. Furthermore, most respondents reported frequent contact with livestock, indicating substantial occupational exposure to livestock and a potentially increased risk of zoonotic disease transmission. Similar findings have been reported in Bangladesh (Ahmed *et al.,* 2025). These findings underscore the importance of integrated one health interventions to improve livestock handling, sanitation and waste management, and hygiene practices.

Despite frequent contact with livestock, only one-quarter of respondents regularly used protective tools when handling sick livestock, highlighting poor adoption of preventive measures, which may increase the risk of zoonotic disease transmission, including cryptosporidiosis. This finding is consistent with studies conducted in Ethiopia and Greece (Moutos *et al.,* 2022, Abunna *et al.,* 2024), but contrasts with reports from India, where the majority of the respondents used personal protective tools (Yaseen *et al.,* 2024). Preventive practice was significantly associated with a semi-intensive farming system, suggesting that respondents using this production system may have better access to

training or veterinary extension services on zoonotic disease prevention. In addition, respondents with six to ten years of farming experience demonstrated better preventive practices, possibly because practical experience improved the adoption of recommended livestock management and preventive measures. A similar finding was reported in Nigeria(Ola-Fadunsin *et al.,* 2025). Furthermore, no significant association was observed between preventive practice and respondents' knowledge and attitude. This suggests that having adequate knowledge and a positive attitude alone may not be sufficient to promote appropriate preventive practices. This finding differs from a study conducted in Finland, which reported that a significant association was observed between respondent attitude, practice, and knowledge (Suolaniemi *et al.,* 2023).

The results of our study must be interpreted with caution because the study was a quantitative cross-sectional study that assessed relationships based on one point in time and did not account for the dynamics of relationships between the factors analysed. More importantly, the study includes the use of binary (Yes/No) response formats for some items within the knowledge domain, which may have limited the ability to capture the depth and variability of respondents' understanding. Thirdly, the study did not collect information on training history, information-seeking behavior, or access to extension services that could clarify why livestock keepers with 6-10 years of experience performed better in these domains.

Conclusion

The findings highlight the need for integrated and sustained interventions to improve awareness and promote effective prevention and control practices for cryptosporidiosis among livestock keepers. Collaborative efforts involving veterinarians, community health workers, and public health professionals are essential for implementing a One Health approach to disease control. Furthermore, continued community-based health education, complemented by further research to identify factors influencing the adoption of recommended practices, is necessary to enhance the effectiveness and sustainability of cryptosporidiosis control strategies.

Declarations

Ethics statement

The Kibong'oto Nelson Mandela CEDHA Health Research Ethics Committee (approval# KNCHREC00029/01/2024) provided ethical approval for this study. The study received further approval from the District Executive Directors and District Medical Officers of Korogwe, Moshi, Mbulu, Simanjiro, and Hai District Councils. Prior to the study, the research team conducted meetings with healthcare personnel, medical and clinical officers, laboratory personnel, and livestock keepers, respectively. During these meetings, the objectives and purpose of the study, the study procedures, sampling, study benefits, potential risks, and discomforts were clearly explained to all prospective participants. Informed consent for all livestock keepers who participated in the study was sought through an informed consent form. Participation was entirely voluntary, and participants were assured that all information provided would be treated as private, confidential, and used solely for research and academic purposes. Participants were also informed of their right to refuse to participate in the study and to withdraw at any time.

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Author Contributions

Husna Kangusi conceptualized and developed the research. Elingarami Sauli, Bernard Ngowi, and Beatus Lyimo supervised the research. All the authors have read and approved the final version to be published and agree to be accountable for all aspects of the work.

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Conflict of interest

The authors declare no conflicts of interest.

Data availability statement

Data will be available upon reasonable request to the corresponding author

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Delivery and Order Fulfilment Practices of Prime Vendors in Tanga Region, Tanzania: A Cross-Sectional Study

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Abstract

Introduction: Persistent stock-outs and inefficiencies in Tanzania's pharmaceutical supply chain prompted the introduction of the Prime Vendor System (PVS) in 2018 to complement the Medical Stores Department (MSD). While national evaluations highlight improvements in procurement efficiency, evidence on delivery and order-fulfilment practices at the regional level remains limited. This study addressed that gap by assessing the performance of Regional Prime Vendors in Tanga Region, focusing on timeliness, accuracy, lead times, and distribution reliability.

Objective: To evaluate delivery performance and order fulfillment practices of Regional Prime Vendors, focusing on accuracy, timeliness, lead times, and distribution reliability.

Materials and Methods: A cross-sectional design was employed, involving 277 healthcare workers across 11 councils and 56 facilities. Data were collected through structured questionnaires and procurement record reviews and analyzed using descriptive statistics and binary logistic regression. Results are reported as Adjusted Odds Ratios (AORs) with 95% confidence intervals (CIs) and p-values.

Results: Findings showed strong adherence to procurement protocols, with 99.3% of facilities accessing PVS only after MSD stock-out notifications. Delivery timeliness was the strongest factor associated with improved medicine availability, with delivery lead time (AOR = 6.537, 95% CI: 2.201–19.42, p = 0.0007) emerging as statistically significant. Order accuracy was consistently high: 62.1% agreed, and 16.3% strongly agreed that delivered commodities matched orders, while shortages or oversupplies were rare. Vendors responded quickly to correct errors (AOR = 2.390, 95% CI: 1.051–5.437, p = 0.0377), reinforcing confidence in the system. Shelf-life management remained problematic, with some commodities delivered close to expiry. Cold-chain logistics were a persistent weakness, with only 42.2% of respondents confirming evidence of temperature control during delivery.

Conclusion: 88% of respondents perceived PVS as associated with improved commodity availability, citing fewer stock-outs, reduced emergency procurement costs, and enhanced patient satisfaction. These findings underscore PVS's complementary role in strengthening Tanzania's pharmaceutical supply chain. However, sustained improvements will require targeted investments in infrastructure, standardized monitoring frameworks, and stronger cold-chain systems to ensure equitable and reliable access to essential medicines across diverse facility contexts.

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Introduction

Reliable access to essential medicines is a cornerstone of effective healthcare delivery. In Tanzania, persistent stock-outs at the Medical Stores Department (MSD) and high transaction costs from private procurement have long undermined medicine availability (MoHCDGEC, 2017). To address these challenges, the Government introduced the Prime Vendor System (PVS), locally known as Mshitiri. Piloted in Dodoma in 2011 and later expanded to Morogoro and Shinyanga, the system was scaled nationwide in 2018 to complement MSD by improving procurement efficiency, reducing costs, and enhancing transparency (Kuwawenaruwa, Wyss, Wiedenmayer, & Mcharo, 2020). In 2021, the President's Office for Regional Administration and Local Government (PORALG, 2022) directed regions to establish four procurement lots to strengthen resilience against MSD stock-outs.

While national evaluations have reported improvements in procurement reliability and order fulfilment rates exceeding 90% (Campbell, 2023), evidence on delivery performance and order-fulfilment practices at the regional level remains limited. Studies in sub-Saharan Africa highlight that weak transport infrastructure, fragmented procurement systems, and poor cold-chain management often compromise distribution timeliness and product quality (Schöpperle, 2013; Yadav, 2015). In Tanzania, regional disparities persist, with rural councils facing longer lead times due to poor road networks, while urban facilities benefit from more reliable distribution (Mganga, 2024). Moreover, cold-chain logistics remain a persistent weakness, raising concerns about the safety of temperature-sensitive commodities such as vaccines and antibiotics (Thelen, Meier, & Wiedenmayer, 2023).

This study therefore addresses a critical knowledge gap by evaluating delivery and order fulfilment practices of Regional Prime Vendors in Tanga Region. Specifically, it examines delivery timeliness, order accuracy, lead times, error correction, and cold-chain compliance, and analyzes their association with medicine availability.

Material and Methodology

Study Design

A cross-sectional study design was employed to assess delivery performance and order Fulfilment practices of Regional Prime Vendors (RPVs) in Tanga Region. This design was appropriate for capturing quantitative data at a single point in time, enabling systematic evaluation of timeliness, accuracy, lead times, and distribution reliability (Creswell & Plano Clark, 2018).

Study Setting

The research was carried out in Tanga Region, which comprises 11 councils (urban and rural) and 56 primary health facilities, including one Regional Referral Hospital, health centers, and dispensaries. The region's geography ranges from coastal urban centers to remote rural councils, with poor road infrastructure and limited cold-chain capacity influencing delivery practices.

Study Population

The study population consisted of healthcare workers directly involved in procurement, storage, and distribution of commodities. Facility types included 1 Regional Referral Hospital, 12 health centers, and 43 dispensaries, ensuring representation across healthcare levels.

Inclusion and Exclusion Criteria

Inclusion: Registered health facilities operating during the study period; healthcare workers responsible for procurement and storage; facilities participating in the Prime Vendor System.
Exclusion: Facilities closed during data collection; facilities without a responsible staff member available; facilities outside the defined geographical area.

Sample Size and Sampling
A total of 277 respondents were recruited using stratified random sampling to ensure representation from both urban and rural councils. The sample size was calculated using Cochran's formula (1977) for cross-sectional studies, with a 95% confidence level and 5% margin of error. The calculation used an estimated proportion of 50% to maximize sample size, yielding 277 respondents.

Data Collection and Data Processing
The study was conducted between May 2026 and June 2026, covering procurement and delivery cycles from January to December 2025 to capture seasonal variations in supply chain performance. Data were collected through structured questionnaires (quantitative indicators such as timeliness, accuracy, shortages, and cold-chain compliance). Key-informant interviews (qualitative insights from council health management teams and facility in-charges). Procurement records and delivery notes (validation of reported practices). We coded, cleaned, and analyzed quantitative data in SPSS/SAS. Qualitative interview data were transcribed, thematically coded, and triangulated with quantitative findings.

Data Analysis
We analyzed quantitative data using descriptive statistics to summarize frequencies and percentages. For example, 62.1% of respondents agreed, and 16.3% strongly agreed that delivered commodities matched orders. We used binary logistic regression to identify predictors of improved medicine availability and reported results as Adjusted Odds Ratios (AORs). Delivery lead time (AOR = 6.537) was identified as a statistically significant predictor of improved availability.

Regression Analysis
Binary logistic regression was applied to identify predictors of perceived improvement in medicine availability. Composite variables (e.g., order fulfilment practices, communication practices) were constructed from multiple questionnaire items using Likert-scale responses. Reference categories were defined (e.g., dispensary for facility type, male for sex, 18–30 years for age). Results are reported as Adjusted Odds Ratios (AORs) with 95% confidence intervals (CIs) and p-values.
The suspicious age result noted by reviewers (non-significant variation across age groups) has been verified: the wide confidence intervals and p-values >0.05 indicate no statistically significant association, and the regression output has been retained with clarification in the text.
Dependent variable: Perceived improvement in medicine availability (binary outcome: improved vs. not improved). Independent variables: Delivery lead time, order fulfilment practices, communication practices, product quality at delivery, handling accuracy, and cold-chain compliance.

Results
This section presents empirical findings on delivery and order-fulfilment practices among Regional Prime Vendors in Tanga Region, based on responses from 277 healthcare workers across 11 councils.

The results are organized to describe vendor performance in relation to procurement protocols, delivery timeliness, order accuracy, error correction, and distribution reliability. Data are summarized using percentages and averages, and logistic regression identifies predictors of improved medicine availability. This section highlights how delivery practices affect the Prime Vendor System's effectiveness in ensuring timely, reliable access to essential medicines.

Respondent and facility characteristics

A total of 277 healthcare workers from 56 facilities participated. Facilities included 1 Regional Referral Hospital (1.8%), 6 District Hospitals (10.7%), 12 Health Centers (21.4%), and 37 Dispensaries (66.1%). Respondents were nearly evenly split by sex (51.3% male, 48.7% female), with the largest age group being 31–40 years (40.4%).

Table 1: Characteristics of Respondents and Facilities (N = 277; Facilities = 56)

Variable	Frequency	Percent (%)
Age		
18-30	98	35.4
31-40	112	40.4
>40	67	24.2
Sex		
Male	142	51.3
Female	135	48.7
Facility Type		
Regional Referral Hospital	1	1.8%
District Council Hospital	6	10.7%
Health Centre	12	21.4%
Dispensary	37	66.1%

Of the 277 respondents, 245 (88.4%) agreed or strongly agreed that the Prime Vendor System was associated with improved commodity availability. This perception was based on reduced stock-outs, fewer emergency procurements, and improved patient satisfaction.

Order Fulfilment Practices

The findings indicate that order Fulfilment under the Prime Vendor System was generally reliable. 62.1% of respondents agreed, and 16.3% strongly agreed that delivered commodities matched the quantities ordered, while 65.3% agreed and 19.1% strongly agreed that shortages or oversupplies were rare. Respondents also noted that vendors promptly corrected delivery errors, with 67.9% agreeing and 15.9% strongly agreeing that mistakes were addressed quickly. However, shelf-life management was highlighted as a challenge, as some facilities received commodities close to expiry, raising concerns about wastage and patient safety.

Table 2: Order Fulfilment Practices (n = 277)

Variable	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
	n (%)	n (%)	n (%)	n (%)	n (%)
Orders placed with the Prime Vendor are supplied in	18(6.50)	36(13.00)	43(15.52)	149(53.79)	31(11.19)

full					
Ordered items are supplied in a single delivery	7(2.53)	25(9.03)	30(10.83)	177(63.90)	38(13.72)
Quantities delivered match quantities ordered	9(3.25)	26(9.39)	25(9.03)	172(62.09)	45(16.25)
Partial deliveries are clearly communicated and documented	4(1.44)	5(1.81)	44(15.88)	179(64.62)	45(16.25)
Back-ordered items are delivered within the agreed time	6(2.17)	21(7.58)	88(31.77)	133(48.01)	29(10.47)

Delivery Lead Time

Delivery timeliness emerged as a critical determinant of system success. Logistic regression analysis identified delivery lead time (AOR = 6.537) as a statistically significant predictor of improved medicine availability. Most respondents reported that deliveries were completed within contractual timelines, though delays were more frequent in rural councils due to poor road infrastructure and limited vendor capacity. Timely deliveries were associated with lower emergency procurement costs and fewer patient complaints about medicine shortages.

Table 3: Delivery Lead Time (n = 277)

Variable	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
	n (%)	n (%)	n (%)	n (%)	n (%)
The Prime Vendor delivers commodities within the contractual lead time (within 21 working days)	11(3.97)	67(24.19)	52(18.77)	127(45.85)	20(7.22)
Delivery timeliness are consistent across different orders	14(5.05)	50(18.05)	78(28.16)	117(42.24)	18(6.50)
Delays in delivery are rare	15(5.42)	48(17.33)	57(20.58)	135(48.74)	22(7.94)
When delays occur, reasons are clearly communicated	12(4.33)	29(10.47)	47(16.97)	159(57.40)	30(10.83)
Delivery lead time does not negatively affect medicine availability at this facility	26(9.39)	61(22.02)	46(16.61)	127(45.85)	17(6.14)

Delivery Point and Completeness

Most respondents confirmed that deliveries were made to the designated delivery points as per contractual agreements. Respondents also reported positive delivery completeness, with most facilities receiving full consignments as ordered. Only a small proportion of respondents indicated partial deliveries, suggesting that vendors generally adhered to agreed distribution protocols.

Table 4: Delivery Point and Completeness (n = 277)

Variable	No n (%)	Yes n (%)
Deliveries from the Prime Vendor are made to the agreed delivery point as per the contract	19(6.86)	258(93.14)

All consignments are delivered directly to the health facility without diversion	38(13.72)	239(86.28)
Any discrepancies in the delivery point are documented and reported	13(4.69)	264(95.31)
Delivery documentation accompanies all consignments	6(2.17)	271(97.83)

Handling of Deliveries and Accuracy

Delivery accuracy improved since implementing the PVS, with 62.5% agreeing and 15.5% strongly agreeing. Respondents noted that vendors demonstrated professionalism in handling deliveries and ensured commodities were transported safely. However, cold-chain logistics remained a persistent weakness, with only 42.24% of respondents confirming evidence of temperature control during delivery. Respondents reported direct observation of cold-chain measures, such as thermometers or digital devices inside cold boxes, and ice packs or insulated carriers used during delivery, Temperature logs or records accompanying consignments. Verbal confirmation from vendors about monitoring. This gap particularly affects temperature-sensitive commodities such as vaccines and certain antibiotics.

Impact on Availability

245 out of 277 respondents (88.4%) agreed or strongly agreed that PVS was associated with improved commodity availability, citing consistent order fulfilment and timely deliveries. Facilities reported fewer stockouts, lower emergency procurement costs, and improved patient satisfaction. These findings underscore PVS's complementary role in strengthening medicine availability alongside MSD.

Factors Associated with a Positive Impact on Availability

Delivery lead time (AOR = 6.537) emerged as the strongest predictor, highlighting that timely distribution is essential for reducing stock-outs and ensuring continuity of care

Table 5:Binary logistic regression for factors associated with the impact of availability

Variable	**Unadjusted regression**		**Adjusted regression**	
	OR [95%CI]	p-value	AOR [95%CI]	p-value
Age				
18-30	ref		ref	
31-40	1.944[1.944, 4.529]	0.1233	1.901[0.781, 4.629]	0.1569
>40	0.787[0.298, 2.078]	0.6290	1.057[0.371, 3.013]	0.9169
Sex				
Male	ref			
Female	1.060[0.500, 2.244]	0.8799		
Facility Type				
Hospitals	1.168[0.384, 3.548]	0.7847		
Health Centre	1.692[0.566, 5.064]	0.3468		
Dispensary	ref			
Experience category	0.977[0.924, 1.0]33	0.4191		
Physical product quality at delivery point	5.237[2.484, 11.04]	<.0001	3.714[1.577, 8.745]	**0.0027**
Practice assessment	2.839[1.520, 5.304]	0.0011	1.899[0.941, 3.832]	0.0733

Quality assurance & handling practices	2.000[1.182, 3.386]	0.0098	2.367[1.950, 5.894]	**0.0135**
Order Fulfilment practices	2.821[1.702, 4.676]	<.0001	2.390[1.051, 5.437]	**0.0377**
Delivery lead time	1.860[1.251, 2.764]	0.0021	6.537[2.201, 19.42]	**0.0007**
Handling of deliveries & accuracy	10.13[4.29, 23.856]	<.0001	1.430[0.883, 2.315]	0.1460
Communication practices	5.58[2.668, 11.683]	<.0001	3.668[1.609, 8.364]	**0.0020**

Discussion

Order Fulfilment Practices

The study found that order Fulfilment under the Prime Vendor System (PVS) was generally reliable, with most respondents reporting that delivered commodities matched the quantities ordered and that shortages or oversupplies were rare. This finding aligns with evaluations of the Jazia PVS pilot in Dodoma and Morogoro, where Fulfilment rates exceeded 90% and bolstered confidence in procurement reliability (Kuwawenaruwa, Wyss, Wiedenmayer, & Mcharo, 2020). However, shelf-life management remained problematic, as some facilities received commodities nearing expiration, echoing concerns raised in Singida Region, where expiry risks persisted (Mganga, 2024). These results suggest that while order accuracy is a strength of the PVS, monitoring frameworks for shelf-life compliance require reinforcement.

Delivery Lead Time

Delivery timeliness emerged as the strongest predictor of improved medicine availability, with logistic regression showing delivery lead time (AOR = 6.537) as statistically significant. Respondents reported that most deliveries were completed within contractual timelines, though rural councils experienced delays due to poor infrastructure. Nationally, lead times under PVS ranged from 17 to 27 days, longer than the recommended 14 working days (PORALG, 2022). In contrast, the Dodoma pilot achieved an average lead time of 10 working days, showing that supportive supervision and vendor accountability can substantially improve timeliness (MoHCDGEC, 2017). These findings highlight the need for infrastructural investment and stricter monitoring of vendor performance.

Delivery Point and Completeness

Respondents confirmed that deliveries were made to designated points and consignments were generally complete. Only a minority reported partial deliveries, suggesting strong compliance with distribution protocols. National evaluations also show fulfilment rates between 74.9% and 91.5%, though multiple installment deliveries remain common and can disrupt facility planning (Campbell, 2023). Delivery completeness is therefore a strength of the system, but installment practices highlight areas for improvement in vendor logistics.

Handling of Deliveries and Accuracy

Delivery accuracy improved under PVS, with respondents noting that vendors were responsive in correcting errors. This responsiveness reinforced trust in vendor accountability and strengthened confidence in the system. However, cold-chain logistics remained a persistent weakness, with only 42.24% of respondents confirming evidence of temperature control during delivery despite strong delivery timeliness and order accuracy; cold-chain reliability is the weakest link undermining the safety of vaccines and antibiotics. Similar weaknesses have been reported in other regions, where

cold-chain management was inconsistent, undermining reliability for vaccines and antibiotics (Schöpperle, 2013; Yadav, 2015). This gap underscores the need for targeted investment in cold-chain infrastructure and monitoring. Cold-chain logistics remain a persistent weakness and require targeted investment in monitoring devices, documentation, and vendor accountability.

Impact on Availability

Generally, 88% of respondents perceived the PVS as improving commodity availability, citing fewer stock-outs, reduced emergency procurement costs, and improved patient satisfaction. These findings align with national data showing that tracer medicine availability rose from 69% in 2014 to 94% in 2018 during the Dodoma pilot, then stabilized above 90% after national scale-up (MoHCDGEC, 2017; PORALG, 2022). This confirms that PVS has had a transformative impact on medicine availability, though regional disparities persist.

Factors Associated with Positive Impact on Availability

Regression analysis identified three key factors associated with improved availability: delivery lead time (AOR = 6.537). These findings align with broader supply chain literature emphasizing timeliness, product quality, and communication as critical drivers of performance (Thelen et al., 2023; Meier et al., 2024). These factors show that PVS effectiveness depends not only on timely distribution but also on maintaining product integrity and transparent communication between vendors and facilities.

Conclusion

The evaluation of delivery and order Fulfillment practices under the Prime Vendor System in Tanga Region shows that the system has significantly improved medicine availability by enhancing timeliness, accuracy, and responsiveness in distribution. Order Fulfilment was generally reliable, with most facilities reporting that delivered commodities matched orders and that shortages or oversupplies were rare. Delivery lead time emerged as the most critical determinant of success, and logistic regression confirmed it as a statistically significant predictor of improved availability. Vendors were responsive in correcting errors, and overall, 88% of respondents perceived PVS as enhancing commodity access. However, challenges remain, particularly in rural councils, where infrastructure limitations contribute to delays, and in cold-chain logistics, where only 42.24% of respondents reported evidence of temperature control. These findings show that while delivery and order Fulfilment are a strong pillar of the PVS, sustained improvements will require targeted investments in infrastructure, standardized monitoring frameworks, and stronger cold-chain systems to ensure equitable and reliable access to essential medicines across diverse health facility contexts.

List of Abbreviations

CHMTs – Council Health Management Teams
RHMTs – Regional Health Management Teams
MSD – Medical Stores Department
PVS – Prime Vendor System
PVPI – Prime Vendor Performance Index
UHC – Universal Health Coverage
HFGC – Health Facility Governing Committee
PORALG – President's Office – Regional Administration and Local Government

MoH – Ministry of Health
WHO – World Health Organization
IV – Intravenous
ODK – Open Data Kit
SPSS – Statistical Package for the Social Sciences
SAS – Statistical Analysis System
MSD – National Medical Stores

Declarations

Ethical Considerations

We obtained ethical clearance from St. John's University of Tanzania. All participants provided informed consent, confidentiality was maintained, and participation was voluntary. Respondents were assured of anonymity and their right to withdraw at any stage without consequence, in line with WHO (2011) standards for health research ethics. The Prime Minister's Office, Regional Administration and Local Government granted administrative permission.

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Oral impact on daily performance and behaviours of undergraduate students in Tanzania

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Abstract

Background: Behaviours are modifiable determinants of oral health, and in young adults, they play a critical role in overall health and well-being, influencing physical, psychological, and social dimensions of life.

Aim: This study aimed to assess the oral health-related quality of life of university students in Tanzania and identify the predicting behaviours.

Methods: This was a cross-sectional study among the undergraduate university students attending public and private universities in Dar es Salaam, Tanzania. Data were collected using a self-administered semi-structured questionnaire in English, inquiring about: basic socio-demographic characteristics, oral health related behaviours, and oral health-related quality of life using the adult version of the oral impacts in daily performance questionnaire (OIDP). The data were entered and analysed using computer software (SPSS version 25.0), where adjusted binary logistic regression identified the behavioural determinants of OIDP. The P-value was set at $p < 0.05$.

Results: The study involved 358 undergraduate students aged 18-35 years, and 67.0% were males. The proportion of having at least one OIDP was 64.5%, with experiencing difficulties in eating (44.7%) being the most reported oral impact. Tooth brushing at least twice daily, using toothpaste with fluoride, sugary foods intake of more than five times a day, and smoking were reported in 62.0%, 79.9%, 47.3 %, and 8.9%, respectively. The odds of reporting having an impact were lower (OR 0.45, 95% CI 0.27, 0.77) for those who had no dental visit and those who reported not smoking (OR 0.29, 95% CI 0.11, 0.80).

Conclusion: The proportion of reporting oral impact on daily performance among the studied undergraduate students was high; likewise, poor oral health behaviours such as smoking and frequent sugary food intake were observed. It was the behaviours that predicted the oral impacts, specifically dental visits and smoking.

Key words: Oral Impact on Daily Performance; behaviours; University Students; Tanzania

Introduction

Oral health is a fundamental component of general health and well-being, influencing not only physical functioning but also psychological and social aspects of life (Glick et al., 2016). Among young adults, particularly undergraduate students, oral health plays a critical role in shaping daily activities, self-esteem, and interpersonal interactions (Balgiu et al., 2025) Despite being in a transitional stage of life characterized by increased independence, this population often adopts behaviours that may negatively affect oral health, such as irregular dental visits, poor dietary habits, and inadequate oral hygiene practices (Azam et al., 2025; Lawrence et al., 2017; Peltzer & Pengpid, 2014).

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The concept of Oral Impact on Daily Performance (OIDP) has been widely used as a socio-dental indicator to assess how oral conditions affect an individual's ability to carry out essential daily activities, including eating, speaking, studying, and socializing (Alvarez-Azaustre et al., 2022; Anthony et al., 2023; Peres et al., 2019; Simangwa et al., 2020). Oral problems such as dental caries, periodontal diseases, and malocclusion can lead to pain, discomfort, and functional limitations, thereby impairing academic performance and overall quality of life (Chimbinha et al., 2023; Haag et al., 2017; Peres et al., 2019). Furthermore, these impacts may influence behavioural patterns, including avoidance of social interactions, reduced participation in academic activities, and changes in dietary habits. The proportion of poor oral health quality of life for the college and university students is reported at 1.6% to 53.6% (Chantre et al., 2021; Drachev et al., 2018; Uzarevic & Bulj, 2021; Yamane-Takeuchi et al., 2016). Displaying a wide range of information from developing countries.

Undergraduate students represent a unique and important group for studying oral health impacts due to their vulnerability to lifestyle-related risk factors and their potential to establish long-term health behaviours. However, there remains a gap in understanding the extent to which oral health conditions affect their daily performances and associated behaviours, particularly in developing country contexts.

Therefore, this study aims to assess the oral impact on daily performance and examine related behavioural patterns among undergraduate students. Understanding these relationships is essential for informing targeted interventions, promoting positive oral health behaviours, and improving the overall well-being and academic success of this population.

Materials and Methods

This was a cross-sectional study among the undergraduate university students attending public and private universities in Dar es Salaam, Tanzania. Dar es Salaam is the most influential city in Tanzania and harbours the highest number of universities, and hence, a diverse community of university students from all over the country attends these institutions, providing an ideal site for the study. Ethical clearance for the study was obtained from the Muhimbili University of Health and Allied Sciences Institutional Review Board, participating universities provided permission through their respective office of the Dean of Students, and all participants signed informed consent for their voluntary participation.

Data were collected using a self-administered semi-structured questionnaire, which was in English. The questionnaire inquired about basic socio-demographic characteristics, oral health-related behaviours, and oral health-related quality of life using the adult version of the oral impacts in daily performance questionnaire (OIDP) (Masalu & Åstrøm, 2003). OIDP was assessed by inquiring about participants' experiences that cause difficulties in their daily life due to their dental and oral health status in the past six months. The difficulties were in eating, speaking, cleaning teeth, sleeping and relaxing, smiling and showing teeth, emotional status, work and social role, and enjoying social contact. The responses were scored as 0 for those reporting no difficulties experienced to 3= having experienced difficulties daily.

This was then summed and later re-coded into those having at least one impact (total score 1-8) and having no impact 9 (sum score =0). Oral health-related behaviours constituted the independent variable, where behaviours related to the common oral diseases, namely dental caries and periodontal diseases, were assessed. These were tooth brushing frequency twice in a day, consumption of sugary food/drinks more than five times per day, use of fluoridated toothpaste, having had a dental visit within the past year, and smoking. Each of these behaviours was scored as 0 if not practiced, 1 for those who reported as "sometimes", and 2=most of the time, which was then dichotomized into those

who practice the behaviours (score 1 and 2) and those who did not (score 0). The assessed socio-demographic characteristics were; age of the participants (required to mention their ages in years), sex (selected either male or female), year of study (training level as either first, second, third, fourth or fifth), degree program (categories of their bachelor degree programs either health, education, arts, business), source of finance (either private or received pubic loan funds) and residence (university hostels or off-campus).

The data obtained from this study were entered and analysed using computer software (SPSS version 25.0). The data are presented using frequencies and percentages in the form of tables and charts. Chi-square test was used to determine the associations between two variables, whereas adjusted binary logistic regression reported as odds ratio and 95% confidence interval, identifies the socio-behavioural determinants of OIDP among the studied Tanzania university students. P-value was set at $p < 0.05$.

Results

The study involved 358 university students aged between 18 and 35 years, who were composed of; 67.0% males, 54.7% being aged 18-22 years, 58.9%, were residing in university hostels, 38.3% were undertaking health sciences, and more than half were being beneficiary of government education loans (Table 1). The proportion of having at least one OIDP was 64.5%, specifically, experiencing difficulties in eating (44.7%) and cleaning teeth (41.6%) were the most commonly reported oral impacts. Proportion of having difficulties in school (26.7% and difficulties in sleeping (27.1%) were the least reported impacts on oral performance (Figure 1).

Distribution of participants according to their oral health-related behaviors is presented in Table 2, whereby the majority reported brushing at least twice daily (62.0%), using toothpaste with fluoride (79.9%), and not visiting a dentist for more than a year. In terms of behaviours that negatively affect oral health, 47.3 % reported using sugary foods more than five times a day, and that 8.9% were smoking.

The distribution of having at least one OIDP according to their socio-demographics is presented in Table 3. Socio-demographic factors that showed statistical significance between those with OIDP and those without were: age of the participants, field of study, and source of education funding. Specifically, a higher proportion of the participants who were aged 18-22 years old (70.4%) reported having OIDP compared to their counterparts (56.8%). A lower proportion of participants who were in the health sciences field (55.5%) reported OIDP compared to those in education, arts, humanities, and business. Additionally, a lower proportion of participants supported by the education loan board reported having OIDP (59.9%) compared to those who were supported privately (69.9%).

Regarding the distribution of reporting at least one OIDP by oral health-related behaviours, it was observed that statistically significant differences were in tooth brushing frequency, dental visits, and smoking. The proportion of reporting having OIDP was higher among those brushed twice or more (68.5%), higher among those who had a dental visit within a year (75.0%), and those who reported being currently smoking (84.4%) compared to their counterparts (Table 4).

Table 5 presents results on predictors of reporting at least one OIDP among university students, whereby, following adjusted binary logistic regression of socio-demographics and behavioral factors, the statistically significant relation was retained for age of the participants, dental visit, and smoking. Specifically, lower odds (OR 0.6, 95% CI 0.4, 0.9) for reporting OIDP were among participants aged 23-35 years as compared to those aged 18-22 years. The odds of reporting having an impact were also lower (OR 0.45, 95% CI 0.27, 0.77) for those who had no dental visit and those who reported not smoking (OR 0.29, 95% CI 0.11, 0.80).

Discussion

This study assessed oral health–related quality of life (OHRQoL) and associated behaviours among undergraduate students in Tanzania, representing young adults within the higher education system. The main finding was that a substantial proportion of participants reported experiencing at least one Oral Impact on Daily Performance (OIDP). Furthermore, dental attendance and smoking emerged as independent predictors of these reported impacts.

These findings should, however, be interpreted with caution, as the study was conducted in Dar es Salaam, the most affluent city in Tanzania, where access to oral health care services is relatively better than in other regions. Nevertheless, the inclusion of students from diverse academic disciplines, socioeconomic backgrounds, and multiple higher learning institutions enhances the representativeness of the sample. Therefore, the findings may be cautiously generalized to similar urban university settings within the region.

Demographically, the study population reflects a typical profile of university students in many African contexts, predominantly young adults, male, enrolled in humanities and arts programs, and largely supported through government education loans. This profile suggests a relatively socioeconomically advantaged group within a developing country context. Despite this, the high proportion of students reporting at least one OIDP is concerning. It is generally expected that individuals with such advantages would demonstrate healthier behaviours; however, the present study revealed suboptimal oral health practices, including frequent consumption of sugary foods, smoking, and inadequate tooth brushing habits. Similar patterns of inadequate oral health behaviours among university students have been reported in other settings (Peltzer & Pengpid, 2014). Comparatively lower proportions of university students with poor oral health-related quality of life are reported in a number of developed countries (Chantre et al., 2021; Drachev et al., 2018; Uzarevic & Bulj, 2021; Yamane-Takeuchi et al., 2016).

The findings further indicate that poor OHRQoL, as measured by the presence of at least one OIDP, was more strongly associated with behavioural factors, specifically dental attendance and smoking, than with sociodemographic characteristics. This underscores the significant role of modifiable health behaviours in influencing oral health outcomes, potentially overriding sociodemographic differences. This observation aligns with previous studies demonstrating that behavioural factors such as oral hygiene practices and health service utilization are key determinants of OHRQoL (Almoznino et al., 2015; Lawal et al., 2022). However, studies in other populations have reported that sociodemographic factors also significantly influence OHRQoL, indicating that contextual differences may play an important role (Drachev et al., 2018; Lawal et al., 2022)

The observed lower likelihood of reporting oral impacts among participants who had not visited a dentist may indicate that dental visits in this population are largely problem-driven rather than preventive. In other words, individuals tend to seek dental care primarily when experiencing symptoms. This suggests limited utilization of preventive dental services, such as routine check-ups, early diagnosis, and interventions including fissure sealants, professional fluoride application, and tailored oral health education. This interpretation is consistent with studies conducted in Tanzania, which have reported low dental attendance rates largely driven by treatment needs rather than preventive care (Kikwilu et al., 2008). Similar findings have also been reported among university students in other countries (Peltzer & Pengpid, 2014).

In addition, the study found that non-smokers were less likely to report oral impacts compared to smokers. This is an expected finding given the well-established adverse effects of smoking on oral health, including oral malodour, tooth discoloration, periodontal disease, and increased risk of oral mucosal lesions and oral cancer (Al Ankily et al., 2024; Gajendra & McIntosh, 2025; Ibrahim & Hassan,

2021). Smoking has also been shown to negatively affect multiple domains of daily performance, particularly social interaction, oral hygiene practices, and smiling, due to both functional and aesthetic concerns (Ahsan et al., 2020; Ciantelli et al., 2023). Comparable associations between smoking and poor OHRQoL have been documented in various populations (Soares et al., 2022).

Conclusion

The proportion of undergraduate students reporting oral impacts on daily performance was high, alongside the presence of unfavourable oral health behaviours such as smoking and frequent consumption of sugary foods. Importantly, behavioural factors, particularly dental attendance patterns and smoking, were the key predictors of these impacts. These findings highlight the need for targeted oral health promotion interventions focusing on behaviour modification, increased awareness, and improved utilization of preventive dental services among university students.

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Tables and figures

Table 1: Distribution of participants' characteristics (n=358)

Characteristics	Categories	%(n)
Age groups	18-22 years	54.7 (196)
	23-35 years	45.3 (162)
Sex	Male	67.0 (240)
	Female	33.0 (118)
Residence	Hostels	58.9 (211)
	Off campus	41.1 (147)
Field of study	Health sciences	38.3 (137)
	Education	14.0 (50)
	Arts and humanities	22.3(80)
	Business	25.4(91)
Year of study	Juniors	50.3 (180)
	Seniors	49.7 (178)
Source of education funding	Loan board	56.4 (202)
	Private	43.6 (156)

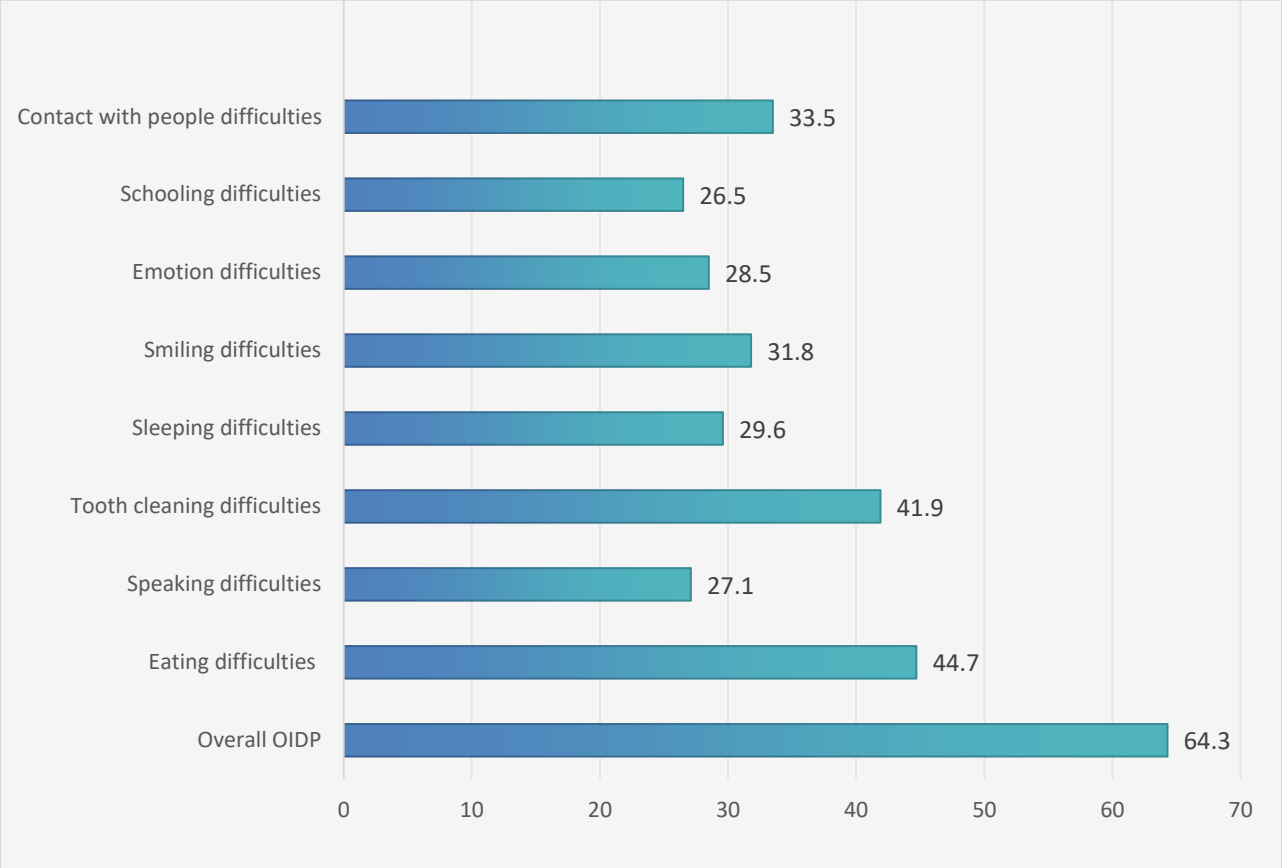

Figure 1: Distribution of reporting at least one OIDP in past six months

Table 2: Distribution of participants by their oral health related behaviours (n=358)

Oral health related behaviours	Categories	%(n)
Frequency of tooth brushing	Brush at least twice daily	62.0 (222)
	Brush less than twice daily	38.0 (136)
Use of toothpaste with fluoride	Yes	79.9 (285)
	No or not aware	20.4 (73)
Dental visits	Visited within past one year	33.5 (120)
	Never been to dentist for more than a year	66.5 (238)
Sugar consumption	Less than five sugar intake in a day	52.5 (188)
	Five times or more sugar intake in a day	47.3 (170)
Current smoking	Smoking	8.9 (32)
	Not smoking	91.1 (326)

Table 3: Distribution of having at least one OIDP by socio-demographic characteristics

Variables	Categories	Reported at least once %(n)	P-value
Sex	Male	61.7 (148)	0.160
	Female	69.5 (82)	
Age groups	18-22 years	70.4 (138)	0.005
	23-35 years	56.8 (92)	
Residence	Hostels	63.5 (134)	0.407
	Outside hostels	65.3 (96)	
Year of study	Junior	66.7 (120)	0.197
	Senior	61.8 (110)	
Field of study	Health	55.5 (76)	0.039
	Education	68.0 (34)	
	Arts and humanities	73.8 (59)	
	Business	67.3 (61)	
Source of education funding	Education loan board	59.9 (121)	0.032
	Private	69.9 (109)	

Table 4: Distribution of having at least one OIDP by oral health related behaviours

Variables	Categories	Having at least one OIDP %(n)	P-value
Brushing frequency in a day	Twice or more	68.5 (152)	0.022
	Less than twice	57.4 (78)	
Use of toothpaste during brushing	Use	62.8 (179)	0.162
	Don't use	69.9 (51)	
Dental visits	Visited within a year ago	75.0 (90)	0.002
	Have not visited for more than a year ago	58.8 (140)	
Sugar consumption in a day	Less than five sugar intake in a day	61.7 (116)	0.321
	Five times or more sugar intake in a day	67.1 (114)	
Smoking	Currently smoking	84.4 (27)	0.008
	Not smoking	62.3 (203)	

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Table 5: Socio-demographic and behavioural predictors for having at least one OIDP

Variable	Categories	OR (95% CI)	P-value
Sex	Male	1	
	Female	1.1 (0.7, 1.9)	0.675
Age groups	18-22 years	1	
	23-35 years	0.6 (0.4, 0.9)	0.045
Field of study	Health Sciences	1	
	Education	0.7 (0.4, 1.3)	0.246
	Arts and humanities	1.2 (0.5, 2.6)	0.663
	Business	1.5 (0.8, 3.1)	0.237
Source of education funding	Loan board	1	
	Private	1.3 (0.8, 2.1)	0.362
Brushing frequency in a day	At least twice	1	
	Less than twice	0.80 (0.5, 1.3)	0.391
Dental visits	Visited within a year ago	1	
	Have not visited for more than a year ago	0.45 (0.27, 0.77)	0.004
Smoking	Currently smoking	1	
	Not smoking	0.29 (0.11, 0.80)	0.017

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Forms and Patterns of Inter-Spousal Communication on Family Planning in Temeke-Tanzania: A Qualitative Study

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Abstract

Introduction: Inter-spousal communication is essential for effective family planning decision-making; however, there is limited knowledge regarding how couples in Tanzania discuss fertility and contraceptive use. This study examined the forms and patterns of communication between spouses about family planning among couples in Temeke Municipality, Dar es Salaam.

Methods: A qualitative cross-sectional study was conducted in August 2025 involving 20 cohabiting couples aged 18 to 49 years. Couples were purposively selected using maximum variation sampling. Data were collected through semi-structured, in-depth interviews conducted in Kiswahili, which were audio-recorded with the participants' consent. The transcripts were then translated into English and analyzed thematically using NVivo software.

Results: Couples primarily relied on verbal communication, especially face-to-face discussions, to address family planning issues. Text messaging served as a supplementary tool for reminders and coordination, particularly regarding the timing of methods. Non-verbal cues, such as mood, timing, and emotional readiness, also influenced when discussions took place. Five communication patterns emerged: collaborative, supportive, persuasive, authoritative, and avoidance. Collaborative and supportive patterns promoted joint decision-making and mutual understanding, while persuasive communication facilitated negotiation through reasoning. In contrast, authoritative and avoidance patterns limited dialogue, reinforced gender power imbalances, and constrained women's reproductive autonomy.

Conclusion and Recommendations: Constructive spousal communication enhances shared family planning decisions. Family planning programs should promote couple-centered counseling, male engagement, and mobile-based reminders to support equitable and sustained contraceptive use.

Keywords: Communication, Family Planning, Contraceptives

Introduction

Communication between spouses is a crucial mechanism for forming, negotiating, and translating reproductive intentions into concrete reproductive health decisions. It is widely recognized as essential for effective fertility planning and joint decision-making within intimate partnerships (S. Islam et al., 2014). Empirical evidence indicates that couple communication significantly influences desired family size, sexual and reproductive needs, birth spacing, and the adoption and sustained use of modern contraceptive methods (Islam et al., 2014; Shrestha & Niaraula, 2009). Through dialogue, partners develop a shared understanding of contraceptive options and their implications, allowing for informed and negotiated choices (Islam et al., 2010). Consequently, reproductive decisions emerge as relational processes shaped by discussion, negotiation, and mutual agreement (Mosha, 2017). This positions family planning as a couple-centered social practice rather than an individual act.

Couple communication is not a straightforward or linear process; rather, it is a complex phenomenon influenced by emotional states, relationship histories, and contextual pressures. This communication manifests through various forms, including verbal exchanges, non-verbal cues, silence, attentive listening, and symbolic expressions of understanding and support (Sandu et al., 2019; Terec-Vlad, 2015). Research indicates that relational closeness is demonstrated through verbal, nonverbal, and physical intimacy, all of which are strongly linked to marital satisfaction. In contrast, distressed relationships often exhibit emotions such as fear, anger, contempt, and disgust, which negatively impact the emotional climate of interactions (Estlein, 2016). Despite this evidence, there is still limited empirical clarity on how these communicative expressions directly affect reproductive negotiations and family planning decision-making processes.

Previous research identifies positive and negative communication styles as critical factors influencing how couples manage conflict and disagreements. Positive behaviors such as open dialogue, active listening, collaboration, support, and persuasion are essential for fostering mutual understanding (Bukhari & Hai, 2023; Ruffieux, 2014). In contrast, negative patterns, such as aggression, hostility, withdrawal, and avoidance, are consistently linked to relational strain and ineffective conflict resolution (Bukhari & Hai, 2023). While this literature offers valuable insights into marital interactions, it remains uncertain whether these communication strategies operate similarly in the contexts of reproductive health and family planning, where decisions are shaped by gender norms, power dynamics, and cultural expectations.

Beyond individual interactions, communication between spouses regarding family planning is influenced by broader social, cultural, and gendered frameworks that dictate reproductive roles, authority, and responsibilities within marriage. Norms related to masculinity, femininity, fertility expectations, and reproductive authority significantly affect who initiates conversations, whose preferences take precedence in negotiations, and how disagreements are addressed (Kapadia-Kundu et al., 2022; Sarfraz et al., 2023). Thus, discussions about reproduction operate on both interpersonal and socio-cultural levels, where power dynamics and normative expectations intersect with everyday spousal interactions, ultimately shaping how shared decision-making around reproduction is constructed and understood.

In the context of Tanzania, studies by Keefe (2006), Mosha (2017), and Msoffe and Kiondo (2009) have largely focused on the factors influencing contraceptive use. However, there has been limited empirical research on how couples communicate about family planning. While national initiatives emphasize the importance of involving both partners, there is still a lack of understanding regarding how spouses in Temeke initiate, negotiate, or avoid conversations about fertility and contraceptive use. To address this gap, the present study aims to explore the forms and patterns of inter-spousal communication about family planning among couples in Temeke. The objective is to generate contextually relevant evidence on how these communicative practices influence shared reproductive decision-making.

Methods

Design and setting

The study employed a qualitative cross-sectional design and was carried out in Temeke Municipality of Dar es Salaam, Tanzania, in August 2025. This design facilitated the exploration of the forms and patterns of inter-spousal family planning communication. The choice of Temeke Municipality as a research area is based on the diversity of its residents in terms of culture, religion, education, ethnicity, and socioeconomic status. This diversity creates an environment conducive to selecting study participants who reflect the wide range of perspectives and experiences of the study population.

Additionally, the area has a significant prevalence of family planning (FP) users, with reports indicating that 44% of married women utilize family planning (National Bureau of Statistics (NBS), 2023). This active engagement in family planning in the study area facilitated the exploration of how couples communicate about contraceptives with their partners. Furthermore, the availability of information and services related to FP facilitated by numerous healthcare facilities, community organizations, and social networks enhances the ease of studying couple communication in this context.

Study population

The study included cohabiting couples aged 18-49 years. While the World Health Organization (WHO) defines the reproductive age as spanning from 15 to 49 years, this study limited participation to those aged 18 and older to align with Tanzania's legal framework, which recognizes 18 years as the minimum age for independent consent in research participation. The upper age limit of 49 years was selected to align with the recognized conclusion of the reproductive age for women, ensuring that the study remained pertinent to active reproductive individuals. Cohabitation offers frequent interaction, shared responsibilities that necessitate frequent communication, collective decision-making, and direct observation of family planning behaviors, making these couples an ideal population for investigating their communication dynamics related to family planning.

Sample size

A total of 20 couples were included in this study to share their insights and experiences regarding family planning communication. The sample size was determined based on data saturation, where no new themes emerged from additional interviews.

Sampling procedures

A maximum variation sampling, a purposive sampling technique was used to capture a wide range of perspectives and experiences that reflect the diversity of the study population, was employed to select 20 couples. The participants were deliberately chosen to ensure diversity across key characteristics, including levels of engagement in family planning discussions, socio-economic status, educational attainment, cultural and religious affiliations, age, number of children, and duration of marriage. This heterogeneity was essential for exploring how different demographic, social, cultural, and economic contexts influence nature and quality of inter-spousal communication about family planning.

Data collection procedures

Data were collected using an interview guide, which allowed in-depth exploration of the participants' experiences regarding family planning discussions among couples. Each interview lasted approximately 30 to 45 minutes and took place in a private and comfortable setting to encourage open dialogue and minimize social desirability bias. Open-ended questions, which were used as an interview guide and follow-up prompts, facilitated a conversational atmosphere, enabling participants to share their insights freely. Interviews were conducted in Kiswahili to maximize respondent participation. They were audio-recorded with the participant's consent and later transcribed for analysis. The female research assistants were trained and helped to interview female participants (wives), while the male researchers interviewed male participants (husbands) to maintain a gender-sensitive approach.

Data analysis

We began by thoroughly examining the data to gain a deep understanding of the participants' narratives. All interview recordings were transcribed verbatim to maintain the authenticity of the participants' voices. Next, we translated the transcripts into English to ensure clarity and consistency during the analysis. The translated transcripts were then imported into NVivo software to help in systematic coding. NVivo allowed us to identify and label meaningful segments of text that highlighted important aspects of inter-spousal communication regarding family planning. After coding all the transcripts, we used NVivo to group related codes into potential themes by identifying patterns and relationships among them. We reviewed the themes to ensure they were coherent, internally consistent, and distinct. This involved examining both the coded data and the entire dataset to confirm that each theme accurately reflected the participants' perspectives. We named and defined the themes in a way that captured the patterns and forms of communication regarding family planning between spouses. Finally, we presented the data in a clear and meaningful narrative, using direct quotations from the participants to accurately represent their lived experiences.

Results

Forms of Inter-Spousal Family Planning Communication

This section outlines the various methods of communication that couples employ during discussions about family planning. The presentation of data is enriched by direct quotes from participants, which bolster the analysis and provide evidence for the identified themes. The different forms of communication used by couples in these discussions are organized primarily according to the communication channels, as follows:

Verbal Communication

Verbal communication involves using spoken or written words to convey messages, share ideas, and express emotions. The participants indicated that communication about family planning between spouses is primarily verbal. The data show that couples often rely on conversations to express their preferences, concerns, and decisions regarding family size, birth spacing, and contraceptive use. This verbal exchange not only helps clarify mutual expectations but also strengthens understanding and trust between partners. Spoken dialogue provides a platform for negotiation, emotional support, and joint decision-making, which are crucial for successful and sustained family planning practices. Through verbal interaction, couples address sensitive issues in two ways: face-to-face conversations and written forms such as text messages, as noted by the participants. However, when couples were asked whether they use phone calls or written letters to discuss family planning matters, they responded that these methods are not suitable for such contexts.

Face-to-face Communication

The findings suggest that couples prefer face-to-face conversations when discussing family planning matters. For many couples, living together (cohabitation) eliminates the need for mediated communication methods, such as texting or phone calls. This preference results from the physical and emotional closeness that couples share, which makes direct verbal communication more natural. Couples often select specific moments for important discussions, prioritizing times when distractions are minimal and privacy is ensured. Evening hours, particularly after dinner when the day's activities have settled down, or late at night when children are asleep, were frequently identified as ideal opportunities, as it was revealed by the following paticipants.

> *"In the evening, when the children are asleep, we sit down in our bedroom or sometimes in the living room.... when things settle down, we talk openly."* (**Wife from couple 10**)

This reflects a strategic choice of time that enhances emotional readiness and reduces external distractions. Such timing is essential, considering the delicate nature of family planning, and illustrates a thoughtful, context-sensitive approach to communication within intimate relationships. In addition, the participants explained that couples prefer face-to-face communication since it accommodates emotional cues and timing strategies that shape the progression of these discussions, as it was revealed through the participants' narration below;

> *"I used to get angry, and when she noticed that I was very upset, she would drop the subject... whenever she found me in a happy mood, she would bring it up again."* (**Husband in couple 18)**

This emphasizes that real-time interactions facilitate emotional understanding and adaptive dialogue, which is particularly important in conversations that may provoke resistance or discomfort. The data show that couples significantly depend on verbal timing and emotional tone to negotiate and eventually achieve agreement. As such, face-to-face conversations are not just a practical choice but a conscious communicative strategy that is deeply woven into the rhythms and routines of daily life at home.

Text Messages

The participants revealed that text messages are occasionally used by couples to communicate about family planning issues. Partners particularly rely on text messages as reminders and a supportive tool to reinforce important topics, especially when using traditional family planning methods like the calendar method and withdrawal to prevent mistakes related to timing. This is revealed by one of the participants who stated.

> *"She sends me a text message when her menstrual cycle starts so that I can track her fertile days to avoid any potential mistakes."* (**husband from couple 08)**

For couples, this simple and timely communication helped reinforce shared responsibility and reduce the risk of unintentional pregnancies, especially in situations where precise timing was crucial. Thus, text messaging emerged as a complementary strategy that supported their broader communication practices around FP.

Many participants acknowledged several challenges in discussing and managing modern family planning methods, emphasizing the need for careful coordination and memory. Methods such as the three-month injectable contraceptives and the implant require precise tracking, as missing scheduled follow-ups can reduce their effectiveness. Couples reported that they sometimes forget the exact dates of these injections, which poses a risk to the continuity of protection. To address this, some partners developed a practical system of accountability by sending a text message to their spouses on the day of the injection or implant placement. This is evident from the narrative of the participant as follows.

> *"My wife uses an injection, and when she goes to the hospital to get it, she always texts me. She relies on that message to know when she needs to be injected again, as she usually receives the injection every three months."* **(Husband from couple 02)**

This was affirmed by his wife as follows.

> *"It's fine to use injections, but sometimes we have so much on our minds that we might forget when the next one is due. That's why I text my husband; he keeps all the messages, and later I can check to find the exact date of my previous injection."* (**Wife from couple 02)**

This helped both partners keep track of the timing and ensured timely follow-ups, reflecting a collaborative approach to overcoming the logistical demands of modern contraceptive use.

Non-verbal Communication

The data indicated that although couples normally discuss family planning issues verbally, they also rely on non-verbal cues, such as timing, mood reading, gestures, and the emotional atmosphere, as it was revealed below.

> *"I wait for a good moment when he is calm, then I bring up the discussion again. Then try to persuade him until we both agree. Sometimes, I wait until he is in a good mood before talking to him."* (**Wife in couple 01**)

The narration was also validated by the husband, who remarked on the following

> *"Sometimes, I come home feeling exhausted from everything that happened during the day. When my wife brings up the topic of family planning, I tend to respond with a raised voice to indicate that I don't have time to discuss it. When she notices that I'm feeling overwhelmed, she quickly shifts the conversation to something else. She knows to wait for a better moment when I'm in a good mood to bring up the topic again."* (**Husband from couple 01**)

These instances suggest that spouses often rely on non-verbal emotional cues, such as their partner's facial expressions, tone of voice, and body language, to determine the right moment to discuss sensitive subjects such as family planning. Such cues act as gatekeepers to successful dialogue, enabling smoother communication and reducing the likelihood of conflicts.

The participants further explained that non-verbal environmental cues, such as proximity, the time of day, and shared physical spaces, play a crucial role in facilitating effective dialogues. In this context, non-verbal communication goes beyond just gestures and facial expressions; it also involves the arrangement of physical and temporal aspects of communication settings. The comfort of being physically close and the atmosphere of relaxed environments serve as non-verbal facilitators that promote deeper interpersonal engagement, as one of the participants remarked.

> *"Since we live together, we prefer to discuss family planning topics in the evening after work, when there are no disturbances, and the children are asleep. We take time to talk about our fertility preferences and share our reproductive goals, whether we are in the sitting room or the bedroom."* (**Husband from couple 10**)

Patterns of Inter-Spousal Communication Regarding Family Planning

Communication patterns refer to the consistent ways in which individuals or groups exchange information, express thoughts, share emotions, and respond to each other in specific contexts. The participants indicated that couples communicate about family planning in distinct patterns, and each of these patterns influences how they discuss reproductive issues and make decisions together. The communication patterns outlined below were derived from in-depth interviews and offer insights into how couples handle sensitive reproductive topics within their relationships.

Collaborative pattern

The data indicate that the collaborative approach is one of the most common communication patterns that couples use to address family planning issues. This pattern involves mutual agreement, open discussion, and shared decision-making. As several participants illustrated, couples engage in ongoing conversations where both partners contribute their perspectives, concerns, and preferences, ultimately leading to joint decisions. For example, when one couple was asked how they typically discussed and reached agreements about family planning, the participant responded.

"We sit down, discuss, and agree together that the children are still young, so we need to use family planning to raise them well." **(Wife from couple 01)**

The excerpt above highlights the nature of a collaborative communication pattern that involves equal involvement of both partners in the discussion and reach the decision jointly.

Collaborative communication is particularly evident when couples discuss family planning methods and agree on what works best for them. This often involves assessing different options, considering personal circumstances, and respecting each other's opinions and preferences, as it was reflected below.

This shows how couples engage in a two-way conversation, weigh the pros and cons of each method, and reach an informed, consensual decision.

The data revealed that the collaborative pattern of communication extends beyond just the method of family planning but encompasses the entire decision-making process. Many participants emphasized that cooperation and mutual understanding were key to their discussions. This was revealed below.

"We are educated, so we do everything collaboratively because, at least, we have a little education that Allah has blessed us with. Therefore, we cooperate in everything before making reproductive decisions." (**Husband from couple 11**)

Collaboration in family planning allows couples to discuss, support each other, and make decisions that take into account the perspectives and concerns of both partners. This communicative approach encourages each partner to share their ideas, promoting mutual decision-making in reproductive health. As a result, this collaborative effort leads to positive outcomes in reproductive health for couples.

Authoritative Communication

An authoritative communication pattern refers to a communication style in which one part, typically a person in a position of power, directs or controls the conversation with a clear expectation of compliance. In analysing the participants' interviews, it became evident that some couples communicate family planning issues through an authoritative communication pattern, where the man typically assumes the dominant role in the interaction, as it was revealed in the conversation below.

"The woman is there to bear children at all times, and that's why we marry her, to bring a family, but the man is the one who makes all the decisions, whether the family is enough or if more is needed." (**Husband in couple 16**)

Here, the man expressed a clear belief in his role as the decision-maker, outlining that while the woman's perspective can be taken into consideration, it is ultimately his responsibility to decide on family planning matters. This authoritative communication is not necessarily about domination but rather a role-based exchange where the man positions himself as the one who directs the conversation based on his perceptions and authority over family matters. This communication style reinforces the idea that authority is central to family planning discussions, where the person in power directs the conversation with an expectation of compliance from the less authoritative party. The husband underscores this when he explained,

"She is my wife, and I have authority over her. When I ask her to use contraceptives, she should comply; when I want another child, she must stop using them." (**Husband in couple 18**)

This comment reinforces the view that in the context of family planning, the man is perceived as the one who holds ultimate decision-making power. The interaction is usually hierarchical, where the

woman is expected to listen to her husband and accept the idea. The wife expressed the same sentiment by saying,

> *"I married my husband to build a family, and children are the most important part of that family. So, when my husband tells me he is ready for another child, I can't say no to him."* (**Wife in couple 18**)

Even though the conversation may allow some room for the wife to express her opinions, the underlying assumption is one where the man controls the flow of the discussion. This pattern of communication reveals an expectation of obedience from the woman, reinforcing the authoritative communication style that prevails in family planning conversations among couples in Tanzania.

The authoritative nature of the communication is further exemplified by the husband, who described that while there may be room for the wife to contribute, the husband's role in directing the conversation remains intact, as further elaborated below.

> *"I give instructions to my wife on whether to use a contraceptive or not, and she accepts them, but sometimes she also contributes,"* (**Husband in couple 05**)

This reflects the wife's acceptance of his directive. The use of instructions in communication suggests that the discussion is shaped by the husband's authority, with the wife's role typically more passive, agreeing to her partner's decisions. This reinforces the idea that the communication pattern within family planning is not always a case of democratic exchange, but in some cases, they are driven by the husband's authoritative position.

Persuasive Communication

The participants highlight a distinct persuasive pattern of communication in couples' discussions about family planning, where the goal is not only to share information but also to influence one another's views and decisions through reasoning, explanations, and sometimes gentle persuasion. Persuasive pattern of the communication process, as observed in this study, is characterized by one partner providing explanations, offering rational arguments, or sharing personal experiences to convince the other partner. This pattern is evident in the responses of both wives and husbands, where the couple engages in a dialogue about family planning options, with one partner explaining the rationale behind their standpoint. This was revealed when the participant said

> *"Yes, I want to have a child, but she says we should wait because the situation is a bit difficult now, and she wants to see if things improve. If they do, then we can try, but if not, we will look for other options."* (**Husband from couple 06**)

Similarly, the wife in "couple 08" persuaded her partner by explaining why a certain family planning method is better, leveraging her knowledge to influence his decision. This was evidenced when she said

> *"From my understanding, sometimes those medications, injections, and other modern methods aren't good to use. They might cause some harm because… some people complain when they use family planning methods, like someone may bleed a lot when they use injections, or another might be troubled by implants. That's why I decided to use the calendar method. I consulted my husband and explained everything to him that the calendar is the best method we can use, and since he doesn't like using those injections and stuff, he agreed to the option I proposed."* (**Wife in couple 08**)

In several cases, persuasion is directly tied to explaining the benefits or potential consequences of different family planning methods. For instance, the participant shared how she initially faced resistance from her partner regarding family planning but managed to persuade him by highlighting the possible side effects of methods and offering alternatives. This persuasion process is not about

direct decision-making but rather about providing information and fostering understanding. In her case, she woke her partner from sleep to discuss family planning, presenting the issue with facts and potential risks, which led her partner to agree with her suggested method. This is evident when she said

> *"I just arrived and found him sleeping. First, I woke him up and told him, "Hey, what do you think about us using an injection?" His first reaction was, "Aah, what for?" So, I told him, "Well, it will help us to space our children well, and I've read that there can be side effects, things like this can happen." His first response was, "If it harms you, what will you do?" I told him, "It's not harmful, really. But some people say that certain side effects can occur, like excessive bleeding or the period stopping completely. I explained that if that happened, they usually say you can just go back and change the method. Then he said, "Alright, if you think it's the right method for you, and it will work for you, go ahead and use it."* (**Wife in couple 15**)

This assertion indicates how the persuasive communication pattern focuses on gently influencing the other person's perspective through clear communication, often taking the time to educate and explain. The persuasive communication pattern extends beyond simple agreement or disagreement and often involves a back-and-forth exchange where both partners influence one another. For instance, the wife provided an example of how they engaged in persuasive communication to reach a mutual understanding. She said,

> *"It was a conversation. I told him that after giving birth, we were given education, so we had to start using family planning methods. At first, he was afraid of the side effects of using contraceptives, and he told me what he knew and had heard from the people around. After I cleared his doubt by explaining what I learned from the hospital, he agreed, and that's when I started using it."* (**Wife in couple 16**)

This back-and-forth persuasion process is a key feature of the persuasive communication pattern, emphasizing collaboration and mutual influence. In essence, the data highlights that persuasive communication within couples is not about forcefully convincing the other but rather about creating a space for both partners to share their views, weigh different perspectives, and influence each other respectfully and reasonably.

Avoidance communication pattern

The avoidance communication pattern refers to a style of interaction in which one or both partners deliberately avoid or withdraw from discussing certain topics. In the context of family planning discussions, couples may choose not to initiate conversations about contraception, fertility goals, or reproductive intentions, or they may actively change the subject when these topics come up. Avoidance in this study was marked by a reluctance to engage in direct, open discussions, where one partner deliberately avoids addressing the topic straightforwardly. This instance was evidenced when one of the participants stated.

> "*The first time I asked her when we expect to have another child, she avoided the question. She didn't want to give me a clear answer, and she still hasn't told me to this day*." (**Husband in couple 06**)

Further supporting this notion, other participants provided additional insights into how avoidance manifests in their relationships. A couple shared that when the wife brought up family planning, especially when her husband was distressed, she would drop the topic and discuss something else. This indicates an intentional withdrawal from serious conversation to avoid potential conflict or discomfort. Instead of addressing the issue directly, the wife would wait for a more opportune moment when her husband was in a better mood and then reintroduce the conversation. This

demonstrates a pattern of communication that avoided direct engagement during moments of tension. The avoidance strategy manifested in the couple's responses when they started.

> *"Yes! That happens when I initiate the discussion. My husband listens but doesn't really engage; he wants to talk about other important topics."* (**Wife from couple 18**)

> *"Sometimes, there are challenges because when a man is told such things, he might get angry and upset, leading to conflicts in the house, making it an uncomfortable place to sleep. If she notices that I'm panicking, she drops the topic and talks about something else, … She would bring it up, but I would resist. If she saw I was angry, she would change the subject to avoid a serious argument."* **(Husband from couple 18)**

The avoidance of serious discussions in this context suggests a deeper pattern where conflict avoidance becomes a strategy, limiting the couple's ability to address the matter at hand in a constructive way.

Supportive Communication Pattern

This communication pattern is characterized by mutual understanding, encouragement, willingness to listen, and offering constructive support. Across multiple interviews, participants described instances where the husband or the wife-initiated conversations about family planning, and the other responded with affirmation and constructive dialogue. This was evident through the husband, who recalled the moment he introduced the topic and received a constructive response from his wife. He shared the response below.

> *"I asked her, 'As of now, we have two children, don't you think it is time to start family planning?' and she said, 'I was also thinking just the same."* (**Husband in couple 01**)

This instance reflects how both parties were united in thought, suggesting a shared decision-making process built on open dialogue.

The narrative shared by the participants illustrates a communication pattern characterized by attentive listening and validation of each other's reproductive autonomy. This is evident through one couple, when one partner initiated a conversation about discontinuing the injectable contraceptive, another partner responded with openness and inquiry rather than resistance. This was evident in the response below.

> *"When I wanted to stop using injections, I explained, and he asked why I wanted to stop. I told him, "I want to rest because I've been using the injections for a long time, and I haven't had my period for a long time, so I feel it may cause problems." At last, he didn't make it difficult; he agreed."* (**Wife in couple 03**)

This exchange reflects a form of supportive engagement where the partner seeks to understand rather than control the decision. Furthermore, the ability of a wife to sit and explain the rationale for stopping using the method to her husband indicates a communicative environment where she feels safe and empowered to express personal health concerns.

The participants revealed that supportive communication about family planning was not only two-directional but also informed by external influences such as media exposure and guidance from trusted individuals like family members. Couples indicated that these external sources shaped their perspectives and eased the decision-making process within their relationships, as highlighted below.

> *"Most of the time, it's my wife who initiates the discussion and advises me on what to do. But since I watch a lot of media, I also get influenced and see the need for it. So, when she brings it up,*

I immediately support it because I already have an idea of the pros and cons of family planning methods. When she suggests it, I easily engage in the discussion, and we reach a decision together. (**Husband in couple 07**)

"I chose to use the calendar method because my biological mother is a doctor. She has worked in hospitals and understands family planning well. She explained to me the side effects of modern contraceptives. So, she advised me that when I get married, I should avoid using those medications because they have side effects. I explained it to my wife. She received it well and supported my choice." (**Husband in couple 08**)

In both cases, supportive communication is complemented by informational depth and mutual respect, demonstrating how couples often align their choices through a well-informed and participatory approach.

Supportive family planning communication among couples is fundamentally rooted in active listening, as it fosters mutual understanding and respect for each partner's experiences and concerns. As illustrated by the participant, active listening involves more than merely hearing; it means attentively engaging with the partner's perspective, especially when sensitive issues like health risks are involved. This is evident when he shared.

"Yes! The main issue is that it was her body. She made the decision. I was just listening to her thoughts. I would have supported her, whether it took ten or more years, because my role was to provide for the family. But when she said it was causing her discomfort, I had to listen carefully. As a father, I knew that even if something went wrong, it would still affect me, like any health problem. So, I was listening to her very closely, and she was the one going through the experience. Yes, so that's what happened." (**Husband from couple 16**)

This careful listening allowed him to empathize and support her decision, highlighting that active listening enables couples to align their support based on genuine understanding rather than assumptions.

Discussion

This study explores how couples communicate during family planning discussions. While much of the existing research has focused on the relationship between couple communication and contraceptive use, there has been comparatively less attention given to the actual dynamics of communication among couples. The findings from this study enhance our understanding of communication patterns that foster couples' autonomy, enabling them to navigate various options and make decisions on the contraceptive methods that best meet their needs, as well as implement the chosen plan together.

The findings of this study highlight that face-to-face communication is the preferred form of inter-spousal dialogue on family planning matters. This preference reflects couples' need for immediacy, trust, and emotional reassurance when discussing sensitive reproductive decisions. Couples consistently emphasized that in-person discussions provided a natural and emotionally safe context for decision-making, as partners could rely on both verbal and non-verbal cues to gauge each other's emotions and levels of readiness. These findings resonate with previous research that identified face-to-face communication as the most effective channel for fostering intimacy, responsiveness, and mutual understanding (Battiston et al., 2021; Pollmann et al., 2021). Taken together, this highlights the crucial role of direct interpersonal interaction in facilitating open, supportive, and meaningful family planning discussions between spouses.

Text messaging has emerged as a valuable supplementary tool for reinforcing family planning practices, particularly in situations where memory support is essential, such as tracking injection schedules or fertile periods. Through text messages, couples can coordinate responsibilities and prevent unintended lapses in contraceptive use. This illustrates how mediated communication can serve as an effective strategy for upholding family planning routines. These findings concur with the argument posed by Pollmann et al. (2021) that texting can enhance feelings of understanding and support in face-to-face interactions, as well as provide an alternative when direct communication is not feasible. The use of text messages when discussing family planning issues reflects cognitive convergence, wherein couples adjust to each other's busy schedules and cognitive demands by implementing efficient reminders that bolster shared accountability.

Nonverbal communication has emerged as a crucial yet often overlooked aspect of family planning discussions between spouses. It influences not only how couples communicate but also when these conversations take place. Partners often rely on emotional cues, timing, and subtle behaviors to gauge each other's readiness for dialogue, sometimes choosing to start or avoid discussions based on their perceptions of each other's moods and receptiveness. This reflects the view of Mmamel (2025), who assert that effective communication extends beyond spoken words to include careful observation of a partner's moods, attitudes, movements, and actions. Notably, the tendency to postpone discussions until a partner is calm highlights how silence, avoidance, and emotional sensitivity serve as implicit negotiation strategies. These approaches help maintain harmony while navigating sensitive family planning decisions.

The findings emphasize that collaborative communication serves as the most constructive approach in shaping couples' discussions about family planning. This method promotes open dialogue, mutual respect, and shared responsibility, allowing partners to collectively assess contraceptive options and align their decisions with their reproductive goals. Couples reported discussions where both partners contributed equally, considered one another's viewpoints, and strived for a common understanding, often leading to consensus-based decisions. Notably, this joint decision-making process was seen as fostering positive reproductive responsibilities, including a shared commitment to contraceptive use and coordinated family planning. These results align with the work of Dumlao & Shearma (2023), who assert that collaborative communication enhances partnership by balancing individual concerns with a genuine appreciation for each other's perspectives, facilitating mutual agreement. By valuing one another's viewpoints, couples can minimize interpersonal distance, build trust, and exhibit communicative convergence.

An authoritative pattern of communication between spouses, where men primarily make decisions regarding family planning, reinforces established gender norms and power imbalances in relationships. The findings indicate that some husbands exert control by instructing their wives, deciding on contraceptive use, and setting expectations about family size, often operating under the assumption that their wives will comply. This practice aligns with evidence suggesting that such authoritative communication in family planning restricts women's agency and upholds patriarchal structures, leading to unequal reproductive health outcomes (Kapadia-Kundu et al., 2022; Sarfraz et al., 2023). In Tanzania, where patriarchal social structures are prevalent, women often feel socially obligated to follow their husbands' directives, even when these decisions may not align with the overall well-being of the family. As a result, societal norms not only legitimize male authority but also limit women's ability to question or negotiate decisions that significantly impact their reproductive health and household welfare.

The persuasive communication patterns identified in this study demonstrate that couples engage in discussions about family planning by sharing reasons, explanations, and personal

experiences to influence each other's decisions. This finding aligns with Close (2016), who argues that persuasion goes beyond merely sharing information; it is an essential skill for shaping decision-making. Similarly, Shortreed (2021) and Ardèvol-Abreu et al. (2017) describe persuasion as a dialogic engagement between partners with differing perspectives. Couples preferred this approach because it allowed them to discuss the benefits and consequences, utilize facts, and negotiate toward mutual agreement. These exchanges foster mutual respect, balanced influence, and marital satisfaction, ultimately supporting informed and collective decisions that are crucial for effective family planning implementation.

The findings indicate a significant pattern of avoidance in couples' communication regarding family planning, characterized by withdrawal, topic shifting, and a reluctance to engage. This behavior ultimately hampers meaningful dialogue and joint decision-making. Previous research demonstrates that such demand/withdraw patterns correlate with decreased marital satisfaction, lower compatibility, and even an increased risk of divorce (Hasani-Moghadam et al., 2022; Maserat Mashhadi & Dolatshahi, 2017; Rosen et al., 2025). In this study, avoidance manifested both passively, through vague or absent responses regarding future fertility, and actively, as a conscious strategy to prevent conflict in emotionally charged discussions. This aligns with Hafeez et al. (2025), who describes avoidance as one partner withdrawing while the other presses for engagement. While avoidance may temporarily maintain harmony by diffusing conflict, it gradually undermines mutual understanding, weakens emotional bonds, and restricts couples' ability to make informed, shared reproductive decisions.

A supportive communication pattern has proven to be both effective and appropriate for family planning discussions among couples in Temeke. During these discussions, couples engaged in open dialogue characterized by mutual understanding, encouragement, active listening, and constructive affirmation of each other's ideas. Such interactions foster respect, minimize conflict, and promote collaborative decision-making. These findings are consistent with the work of Adesokan et al. (2019), who highlight supportive communication as a key to enhancing openness, empathy, adaptability, and cooperation between spouses. Notably, this form of communication reduces power imbalances by affirming each partner's autonomy, allowing for a balanced exchange where neither partner dominates the conversation. In line with previous research, this approach strengthens emotional bonds, builds trust and empowerment, and enhances marital quality and cooperative family planning outcomes (Khan & Aftab, 2013; Marmola et al., 2021). Ultimately, supportive communication fosters a relational environment that promotes shared responsibility and sustainable family planning decisions among couples.

Strengths and Limitations

The main strength of this study lies in its use of maximum variation sampling, which allowed for the inclusion of couples from diverse backgrounds, encompassing a wide range of socio-economic, educational, cultural, religious, and reproductive experiences in family planning communication. However, the small, purposively selected sample and cross-sectional design limit the generalizability of the findings and prevent making causal inferences. Additionally, social bias may have influenced the participants' responses, although we minimized this risk by interviewing each spouse separately.

Conclusion

We conclude that the dynamics of spousal communication have a significant impact on discussions surrounding family planning, reproductive autonomy, and shared responsibilities. Collaborative, supportive, and persuasive communication promotes openness, trust, and mutual respect, enabling

couples to make joint and satisfactory decisions regarding family planning. Conversely, authoritative and avoidant communication styles perpetuate power imbalances, limit women's agency, hinder critical discussions about fertility, and often lead to conflict and dissatisfaction within the marriage. The presence of verbal, indirect, and situational communication illustrates how relational norms and socio-cultural contexts shape reproductive dialogue. These findings underscore the importance of family planning interventions that promote equitable, culturally sensitive, and constructive communication to facilitate sustainable and mutually agreed-upon reproductive outcomes.

Recommendation

We recommend that family planning programs in Tanzania prioritize couple-centered interventions that enhance collaborative, supportive, and persuasive communication skills between spouses. Additionally, community- and facility-based counseling should actively involve men to challenge traditional authoritative norms and promote shared decision-making. Moreover, integrating simple mobile phone reminders into reproductive health services can help maintain continuity and improve adherence to modern contraceptive use, as well as in managing traditional family planning methods.

Declarations

Ethical Considerations

The ethical clearance approval with Ref. No. 2023-07-00395 was obtained from the University of Dar es Salaam research ethics committee. Permission to conduct the study was sought from the President's Office, Regional Administration, and the Local Government. Written consent was secured from participants after informing them of the study's purpose and benefits.

Author Contributions

ATM conceptualized the research idea, developed the study protocol, collected, transcribed, and analyzed the data, interpreted the findings, and drafted the manuscript. RU and BN conceptualized the study, designed the study, and revised the manuscript. All authors read and approved the final version of the manuscript.

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Computed tomography patterns of cerebrovascular accidents among patients at Mbeya regional referral hospital, Tanzania: A retrospective cross-sectional study

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Abstract

Introduction: Stroke is a leading cause of death and disability worldwide, with an estimated 11.9 million new cases and 7.3 million deaths in 2021. Low- and middle-income countries carry the majority of this burden, yet imaging data describing the computed tomography (CT) patterns of cerebrovascular accidents (CVA) from regional referral settings in Tanzania remain scarce. This study aimed to determine the CT patterns of CVA among patients attending Mbeya Regional Referral Hospital, Tanzania.

Methods: This was a retrospective cross-sectional study of 227 patients diagnosed with CVA who underwent CT brain scanning at Mbeya Regional Referral Hospital between 2023 and 2024. Data on age, sex, risk factors, clinical presentation, CT stroke type (ischemic, hemorrhagic, lacunar, or mixed/multiple lesion), and anatomical lesion location were abstracted from CT reports and case notes. Descriptive statistics, chi-square tests, and Fisher's exact tests were used, with statistical significance set at $p<0.05$.

Results: Of the 227 patients, 98 (43.2%) had ischemic stroke, 76 (33.5%) had hemorrhagic stroke, 32 (14.1%) had mixed/multiple lesions, and 21 (9.3%) had isolated lacunar infarcts. The mean age was 62.2 ± 16.4 years, and females predominated (64.8%). Hypertension was the most prevalent risk factor (97.4%). The basal ganglia (37.0%) and frontal lobe (36.1%) were the most affected anatomical sites, followed by the thalamus (24.2%). Right-sided (38.3%) and left-sided (36.1%) weakness were the commonest presenting complaints. Age ≥60 years was significantly associated with ischemic rather than hemorrhagic stroke ($p=0.021$, OR=2.09); sex, hypertension, diabetes mellitus, and chronic kidney disease showed no statistically significant association with stroke type.

Conclusions: Ischemic stroke was the predominant CT pattern among CVA patients at Mbeya Regional Referral Hospital, with the basal ganglia and frontal lobe as the leading anatomical sites. These findings provide baseline regional-referral-level imaging data to guide clinical decision-making and stroke-care resource allocation in Tanzania.

Keywords: Cerebrovascular accident; stroke; computed tomography; ischemic; hemorrhagic; Tanzania

Introduction

The World Health Organization has long described stroke as a sudden onset of focal, or sometimes global, impairment of cerebral function, persisting for more than 24 hours or resulting in death, and attributable solely to a vascular cause (Sacco et al., 2013). Stroke remains a leading cause of death and

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disability worldwide. In 2021, there were an estimated 11.9 million new stroke cases, 93.8 million people living with stroke, and 7.3 million deaths, making it the third leading cause of death globally (Feigin et al., 2024). Stroke was also responsible for over 160 million disability-adjusted life-years (DALYs), the fourth leading cause of overall disease burden (Feigin et al., 2024).

The burden of stroke falls disproportionately on low- and middle-income countries (LMICs), which account for approximately 87% of stroke deaths and 89% of stroke-related DALYs (Feigin et al., 2025). While age-standardized incidence and mortality rates have shown modest declines since 1990, the absolute number of strokes has risen substantially owing to population growth and ageing, with incident strokes increasing by 70%, deaths by 44%, prevalence by 86%, and DALYs by 32% over that period (Feigin et al., 2025). Without stronger prevention and health-system measures, annual global stroke deaths are projected to rise to nearly 9.7 million by 2050, with the largest impact concentrated in LMICs (Feigin & Owolabi, 2023).

Stroke constitutes a major and growing public health burden in Tanzania. A prospective, community-based incidence study conducted in rural and urban demographic surveillance sites reported an annual stroke incidence of approximately 316 cases per 100,000 population in the urban setting (Walker et al., 2010). More recent hospital-based data from a multi-centre national stroke surveillance initiative spanning eight tertiary hospitals found hypertension to be the most prevalent risk factor, present in over 90% of registered patients, underscoring the central role of inadequately controlled hypertension in the country's stroke burden (Matuja et al., 2026).

Ischemic stroke is the most common subtype globally, accounting for approximately two-thirds of incident cases, while intracerebral hemorrhage and subarachnoid hemorrhage together represent a smaller, though clinically significant, proportion of the disease burden (Feigin et al., 2024). Computed tomography (CT) remains the first-line imaging modality for the evaluation of cerebrovascular accidents because of its rapid acquisition, wide availability, and high diagnostic utility in differentiating ischemic from hemorrhagic stroke (Shafaat & Sotoudeh, 2026). Non-contrast CT appearances of ischemic stroke vary with the temporal stage of infarction: in the hyperacute phase (<12 hours), CT may appear normal, its main role being the exclusion of hemorrhage, though an early hyperdense vessel sign may reflect acute thrombus; in the acute phase (12–24 hours), subtle loss of grey–white matter differentiation and developing hypoattenuation from cytotoxic edema become apparent; in the subacute phase (1–5 days), progressive edema produces more conspicuous hypoattenuation and mass effect; and in the chronic phase, volume loss and encephalomalacia reflect irreversible tissue loss (Shafaat & Sotoudeh, 2026).

Hemorrhagic stroke, by contrast, is readily detected as a hyperdense intraparenchymal collection with associated mass effect and surrounding edema (Shafaat & Sotoudeh, 2026). Even so, the sensitivity of CT in the hyperacute phase remains limited, and early scans may appear normal despite clinically significant ischemia (Zerna et al., 2018), while the middle cerebral artery territory is the most frequently affected vascular distribution in ischemic stroke (Powers, 2020).

CT-based studies from across sub-Saharan Africa illustrate substantial regional variation in stroke subtype and anatomical distribution. A Nigerian neurosurgical case series found that spontaneous intracerebral hemorrhage predominantly affected patients in their sixth decade, with a male-to-female ratio of approximately 1.5:1, and uncontrolled hypertension present in the great majority of cases; most patients presented late, in a severe clinical state, with hemorrhages frequently involving the basal ganglia and thalamus and a substantial rate of intraventricular extension (Adeleye et al., 2015). A CT-based study from a tertiary facility in Ghana, reviewing 1,750 stroke events, found ischemic stroke in 70.7% of cases, a higher prevalence among males, and a mean patient age of 62.5

years, with the basal ganglia the most affected region, followed by the parietal and frontal lobes (Edzie et al., 2021).

In contrast, a Nigerian study reported the parietal lobe as the predominant site of stroke involvement, followed by the frontal lobe (Kolade-Yunusa et al., 2020) a discrepancy the Ghanaian authors attributed to differences in study population and imaging protocol. Comparable regional CT-based surveillance from other parts of Asia and Latin America similarly documents a higher relative proportion of hemorrhagic stroke than is typically seen in high-income settings, a pattern closely linked to the burden of uncontrolled hypertension and delayed hospital presentation (Feigin et al., 2024; Edzie et al., 2021).

Within Tanzania specifically, a prospective study conducted in Dar es Salaam found that among 17 stroke patients who underwent CT scanning within 15 days of symptom onset, 82.4% had ischemic stroke while 17.6% had cerebral hemorrhage (Walker et al., 2011). By contrast, the more recent multi-centre national stroke surveillance initiative, drawing on 1,000 patients registered across eight tertiary hospitals, reported a predominance of hemorrhagic over ischemic stroke (57.9% vs. 38.3%), with premorbid hypertension present in over 90% of patients (Matuja et al., 2026). These divergent findings one from a small, early community-based cohort and the other from a larger, more recent, tertiary-hospital-based registry highlight how strongly stroke subtype distribution in Tanzania can vary by setting, referral pattern, and study period, and underscore the need for additional imaging data from intermediate, regional referral-level facilities such as Mbeya Regional Referral Hospital.

National data on CVA imaging patterns in Tanzania remain limited, owing largely to reliance on a small number of stroke registries and the concentration of existing studies within a few tertiary institutions; consequently, there is a paucity of evidence from lower-tier and regional healthcare settings. Restricted access to advanced neuroimaging modalities and limited radiologist availability at regional facilities further hamper accurate diagnosis and characterization of stroke subtype. This study therefore aimed to determine the patterns of CT findings among CVA patients attending Mbeya Regional Referral Hospital a key referral centre for CT imaging services serving peripheral health facilities where such imaging is not otherwise available with the following specific objectives: (1) to assess the frequency of ischemic versus hemorrhagic stroke on CT; (2) to identify the common anatomical locations of stroke lesions; (3) to correlate CT findings with clinical presentation and patient characteristics; and (4) to compare these findings with regional and global data.

Methods

Study design, duration, and area

This was a retrospective cross-sectional study reviewing computed tomography (CT) scans and reports of patients diagnosed with cerebrovascular accident (CVA) at Mbeya Regional Referral Hospital (MRRH) over a two-year period, 2023–2024. MRRH is located in Mbeya Region, in the Southern Highlands zone of Tanzania, and is a key referral centre for CT imaging services for peripheral health facilities in the surrounding region where such imaging is not otherwise available.

Study population

The study population comprised all patients clinically diagnosed with CVA who underwent a CT brain scan at MRRH during the study period.

Inclusion criteria

All patients with a clinical diagnosis of CVA who underwent a CT brain scan at MRRH between 2023 and 2024, and whose CT reports and case records contained sufficient information on age, sex, risk factors, clinical presentation, and CT stroke findings, were included.

Exclusion criteria

Patients with incomplete CT reports or case records, scans performed outside the study period, non-CVA diagnoses on CT, and studies of insufficient technical quality to permit interpretation of stroke type or anatomical location were excluded.

Sample size

A total of 227 patients who met the inclusion criteria during the study period were identified and included in the study, representing a total enumeration (census) of eligible CT-confirmed CVA cases at MRRH over 2023–2024, rather than a sample derived from a pre-specified power calculation.

Sampling technique

A total enumeration (consecutive) sampling technique was used: all patients meeting the inclusion criteria within the study period were included. Because inclusion depended on a patient having undergone CT scanning, findings are subject to referral and access bias and may not be representative of all CVA cases presenting to the hospital, including those who died or were not scanned before referral or discharge.

Data collection tools

A structured data abstraction sheet was used to record patient identification code, age, sex, documented risk factors and comorbidities (e.g., hypertension, diabetes mellitus, chronic kidney disease, dyslipidemia, HIV/immunosuppression-related conditions), reason for hospital admission (clinical presentation), CT stroke type (ischemic — acute, subacute, or chronic; hemorrhagic; or lacunar infarct), anatomical location of the lesion(s), and any associated complications (e.g., herniation).

Data collection methods

CT reports and corresponding case notes for patients diagnosed with CVA during the study period were retrieved from the radiology and medical records archive at MRRH. Relevant variables were abstracted onto the structured data sheet by the researcher for each eligible patient.

Measurement of variables

The dependent variable was the CT stroke pattern, characterized according to type (ischemic, hemorrhagic, lacunar, or mixed/multiple lesion) and anatomical location. Mixed/multiple lesion was defined as the presence of two or more distinct, anatomically separate ischemic and/or hemorrhagic lesions identified on the same CT study; hemorrhagic transformation of a primary ischemic infarct was classified under the ischemic category rather than as mixed/multiple lesions. Independent variables included age, sex, documented risk factors/comorbidities, and clinical presentation (reason for admission).

Data processing and analysis

Data were entered into Microsoft Excel and analyzed using Python (pandas and SciPy libraries). Continuous variables (e.g., age) are presented as means with standard deviations; categorical variables are presented as frequencies and percentages. Associations between CT stroke type and

categorical variables (sex, age ≥60 years, hypertension, diabetes mellitus, and chronic kidney disease) were assessed using the chi-square test where expected cell counts permitted, and Fisher's exact test for two-by-two comparisons with small, expected cell counts. Statistical significance was set at $p<0.05$.

Results

Demographic and risk factor characteristics of patients (n=227)

A total of 227 patients diagnosed with CVA who underwent CT brain scanning at Mbeya Regional Referral Hospital between 2023 and 2024 were included. The mean age was 62.2 ± 16.4 years (range 8–99 years). Females predominated, comprising 147 (64.8%) of patients, compared with 80 (35.2%) males. Hypertension was by far the most frequently documented risk factor, present in 221 (97.4%) of patients, followed by diabetes mellitus (6.2%) and chronic kidney disease (5.3%) (Table 1).

Table 1: Demographic and risk factor characteristics of patients diagnosed with CVA (n=227)

Variable	Characteristic	Frequency, n (%)
Age (years)	<45	40 (17.6)
	45–59	54 (23.8)
	60–74	74 (32.6)
	75+	59 (26.0)
	Total	**227 (100.0)**
Sex	Female	147 (64.8)
	Male	80 (35.2)
	Total	**227 (100.0)**
Risk factor/ comorbidity[a]	Hypertension	221 (97.4)
	Diabetes mellitus	14 (6.2)
	Chronic kidney disease	12 (5.3)
	Dyslipidemia	3 (1.3)
	HIV/immunosuppression-related	3 (1.3)
	Alcohol use	1 (0.4)
	Sickle cell disease	1 (0.4)
	None recorded	3 (1.3)

[a]Risk factors/comorbidities are not mutually exclusive; some patients had more than one documented condition, so percentages do not sum to 100%.

Frequency of ischemic versus hemorrhagic stroke on CT

Of the 227 patients, 98 (43.2%) had a pure ischemic stroke pattern, 76 (33.5%) had a pure hemorrhagic pattern, 32 (14.1%) had more than one lesion type recorded (mixed/multiple lesion), and 21 (9.3%) had an isolated lacunar infarct (Figure 1). Among the mixed/multiple lesion cases, the commonest combination was a co-existing ischemic and lacunar lesion (25 patients), followed by hemorrhagic and lacunar lesions (5 patients); one patient each had a combined hemorrhagic-ischemic pattern and all three lesion types together.

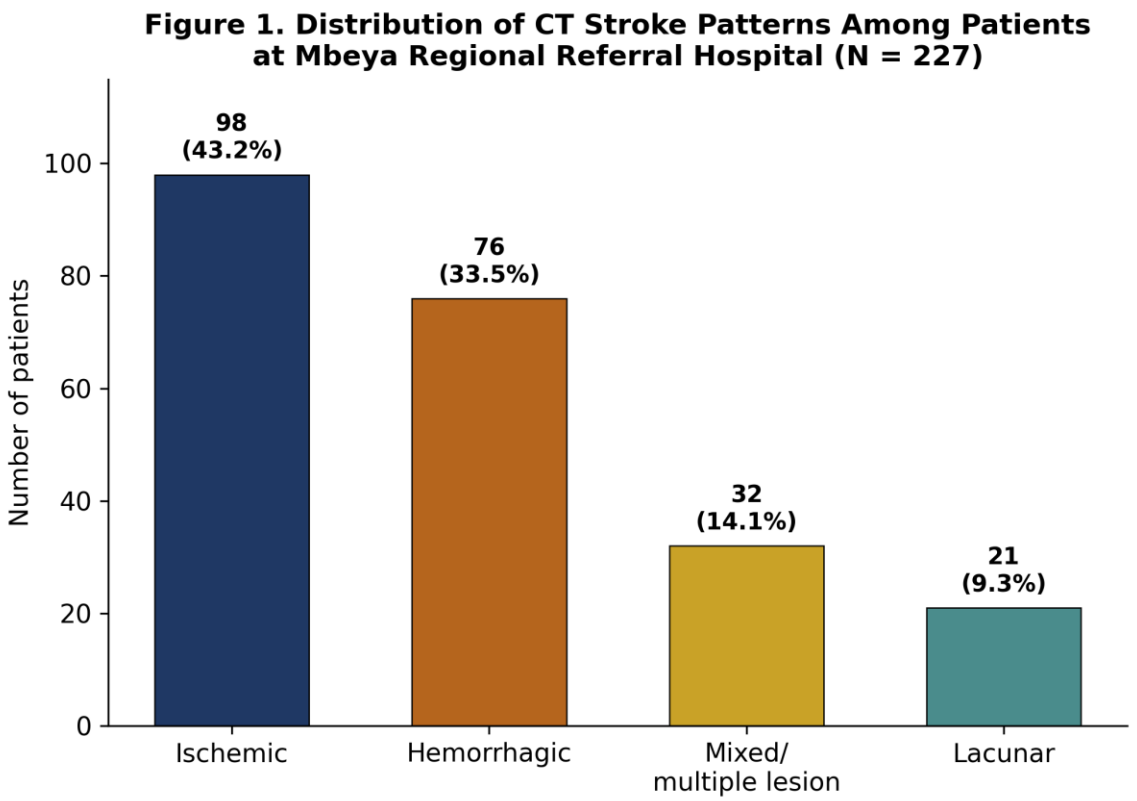

Figure 1: Distribution of CT stroke patterns among patients at Mbeya Regional Referral Hospital (N = 227)

Stratifying by age and sex, hemorrhagic stroke was proportionally more common among patients under 45 years and 45–59 years, while ischemic stroke predominated in the 60–74-year age group; females predominated across every stroke category (Table 2, Figure 3, Figure 4).

Table 2: Distribution of CT stroke pattern by age group and sex (n=227)

Variable	Ischemic n (%)[a]	Hemorrhagic n (%)[a]	Lacunar n (%)[a]	Mixed/ multiple n (%)[a]	Total
Age (years)					
<45	20 (20.4)	12 (15.8)	4 (19.0)	4 (12.5)	40
45–59	14 (14.3)	28 (36.8)	4 (19.0)	8 (25.0)	54
60–74	36 (36.7)	22 (28.9)	5 (23.8)	11 (34.4)	74
75+	28 (28.6)	14 (18.4)	8 (38.1)	9 (28.1)	59
Sex					
Female	63 (64.3)	49 (64.5)	13 (61.9)	22 (68.8)	147
Male	35 (35.7)	27 (35.5)	8 (38.1)	10 (31.2)	80
Total, n	**98**	**76**	**21**	**32**	**227**

[a]Percentages refer to column totals (i.e., percentage of each stroke-type category's own total N).

Common anatomical locations of stroke lesions

The basal ganglia (37.0%) and frontal lobe (36.1%) were the most frequently involved anatomical sites on CT, followed by the thalamus (24.2%), temporal lobe (21.6%), and parietal lobe (15.0%). The occipital lobe, cerebellum, pons/brainstem, and vermis were less commonly affected (Table 3, Figure 2). Because some patients had lesions in more than one anatomical region, percentages do not sum to 100%.

Table 3: Anatomical distribution of stroke lesions on CT (n=227)[a]

Anatomical region	n	%
Basal ganglia	84	37.0
Frontal lobe	82	36.1
Thalamus	55	24.2
Temporal lobe	49	21.6
Parietal lobe	34	15.0
Occipital lobe	18	7.9
Cerebellum	15	6.6
Pons/brainstem	8	3.5
Vermis	1	0.4

[a]Percentages are of the total study population (N=227) with a lesion recorded in that region; patients with lesions in more than one region are counted in each applicable row, so column totals exceed 227/100%.

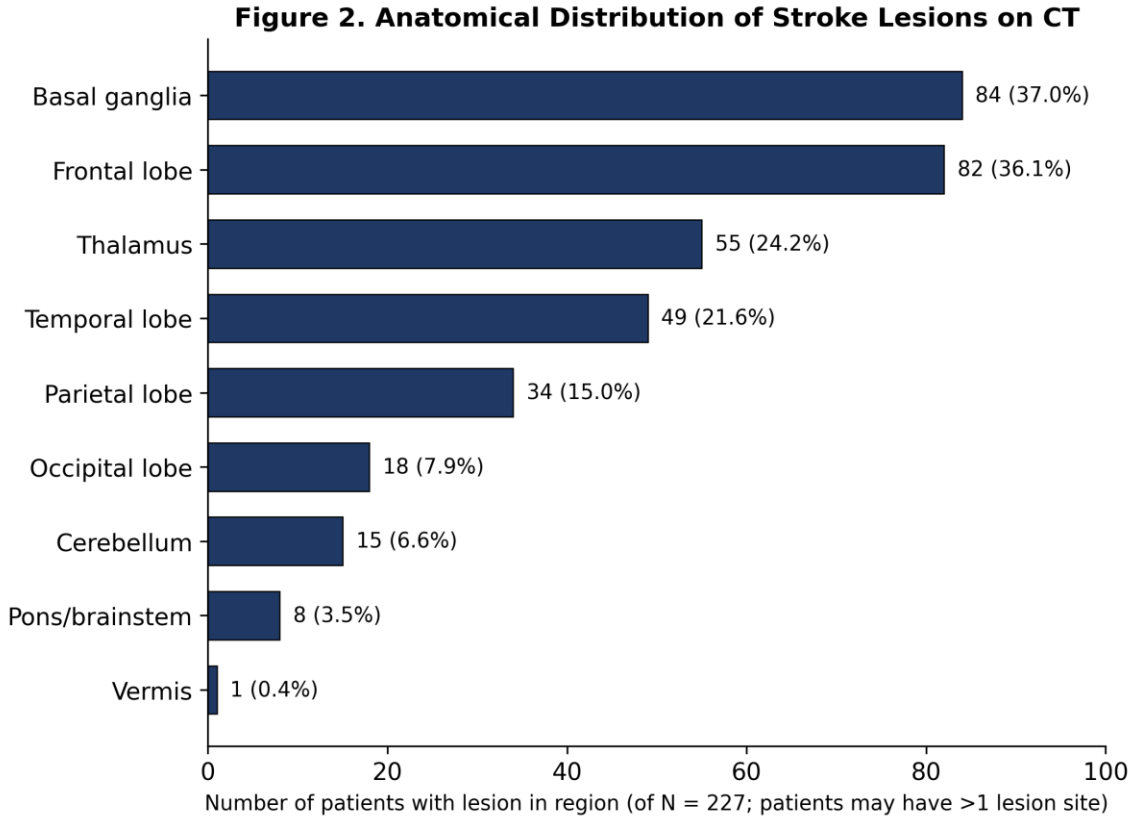

Figure 2: Anatomical distribution of stroke lesions on CT

Correlation of CT findings with clinical presentation and patient characteristics

Right-sided weakness (38.3% overall) and left-sided weakness (36.1% overall) were the commonest presenting complaints across all stroke categories. Loss of consciousness was more frequent among patients with hemorrhagic stroke (13.2%) than ischemic stroke (8.2%), while headache was notably more common among patients with isolated lacunar infarcts (23.8%) than other categories (Table 4).

Table 4: Clinical presentation (reason for admission) by CT stroke type (n=227)[a]

Presenting complaint	Ischemic (n=98) n (%)	Hemorrhagic (n=76) n (%)	Lacunar (n=21) n (%)	Mixed/multiple (n=32) n (%)
Right-sided weakness	39 (39.8)	31 (40.8)	3 (14.3)	14 (43.8)
Left-sided weakness	37 (37.8)	27 (35.5)	6 (28.6)	12 (37.5)
Loss of consciousness	8 (8.2)	10 (13.2)	2 (9.5)	3 (9.4)
Headache	2 (2.0)	4 (5.3)	5 (23.8)	1 (3.1)
Confusion	3 (3.1)	5 (6.6)	1 (4.8)	2 (6.2)
Generalized weakness	7 (7.1)	1 (1.3)	2 (9.5)	0 (0.0)
Convulsions	1 (1.0)	1 (1.3)	2 (9.5)	0 (0.0)

[a]Categories are not mutually exclusive (some patients presented with more than one complaint), so column percentages do not sum to 100%. One patient in the ischemic-stroke group had no presenting complaint documented in the case notes and is therefore not represented in this table, accounting for the ischemic column total of 97 rather than 98.

Figure 3. Age Group Distribution by Stroke Type

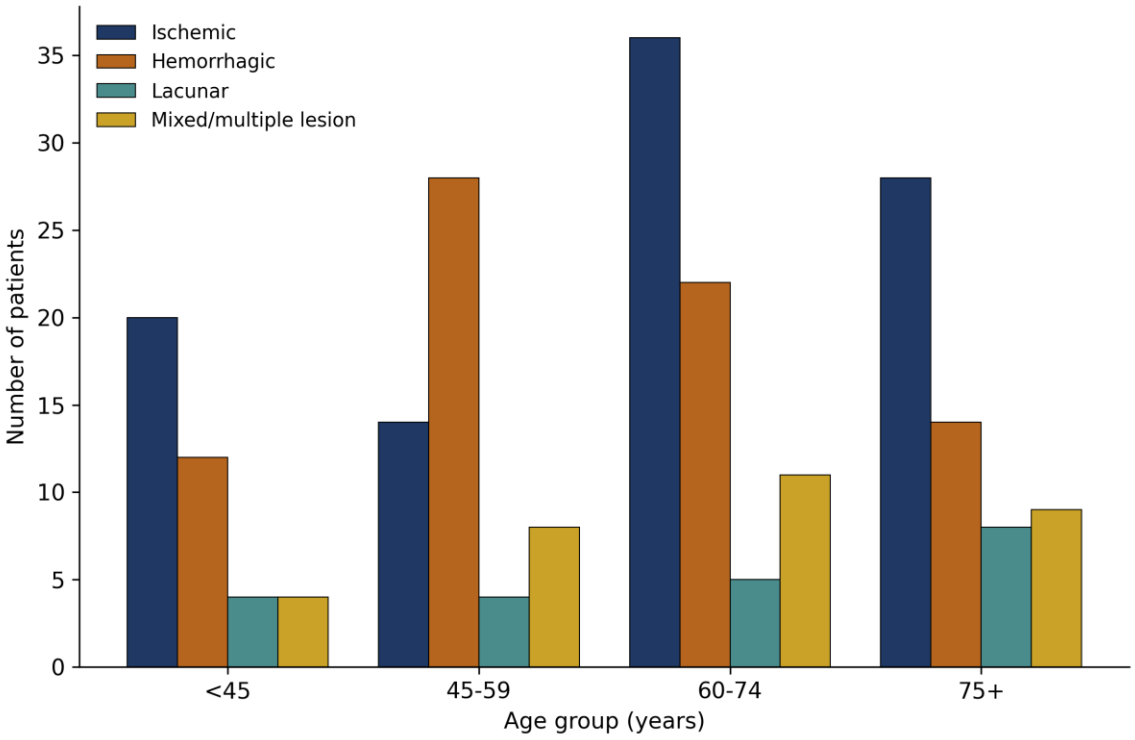

Figure 3: Age group distribution by stroke type

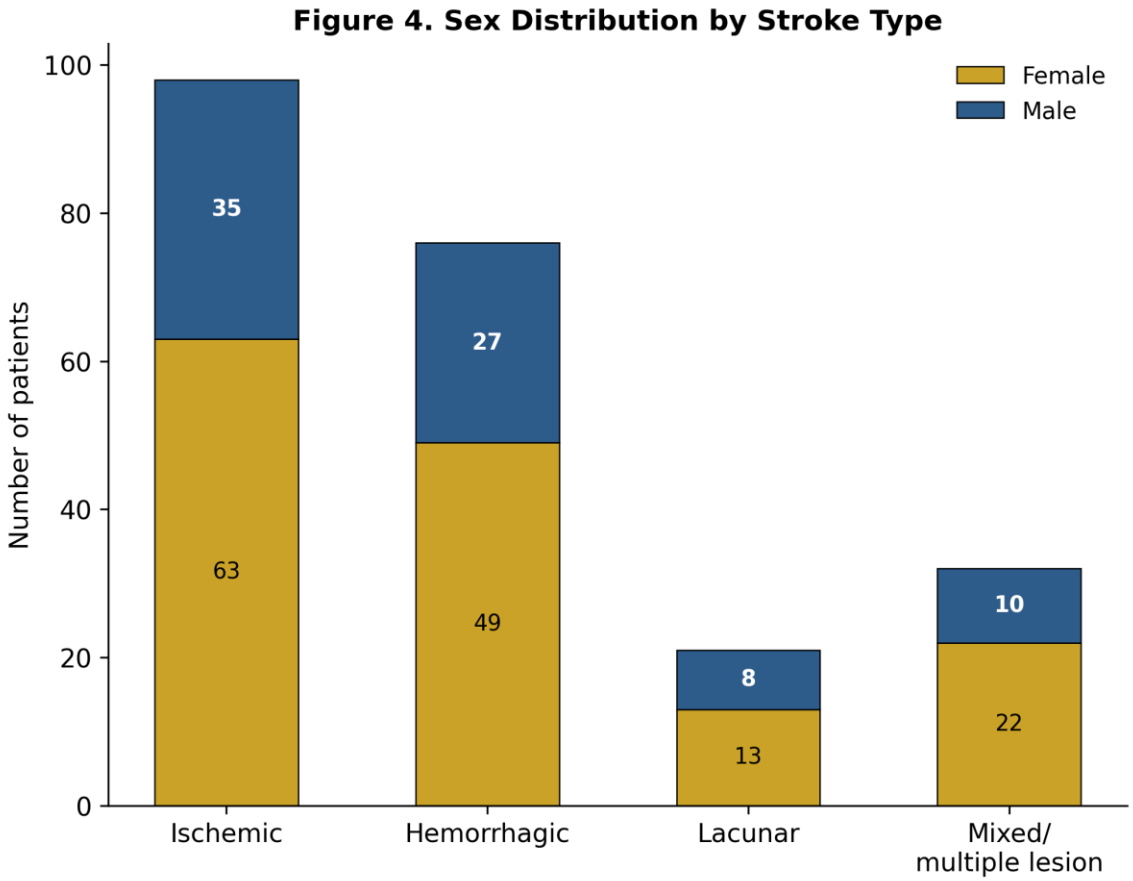

Figure 4: Sex distribution by stroke type

On inferential analysis restricted to patients with a pure ischemic (n=98) or pure hemorrhagic (n=76) stroke pattern, age ≥60 years was significantly associated with ischemic rather than hemorrhagic stroke (65.3% vs. 47.4%; p=0.021; OR=2.09). Sex distribution did not differ significantly between the two stroke types (p=1.000). None of the assessed comorbidities hypertension, diabetes mellitus, or chronic kidney disease showed a statistically significant association with stroke type, although hypertension was too near-universal (present in ≥96% of both groups) to be meaningfully tested, and diabetes mellitus and chronic kidney disease were both under-represented (Table 5).

Table 5: Association between age, sex, and comorbidities with stroke type (pure ischemic vs. pure hemorrhagic stroke)[a]

Variable	Ischemic (n=98) n (%)	Hemorrhagic (n=76) n (%)	p-value[b]
Female sex	63 (64.3)	49 (64.5)	1.000
Age ≥60 years	64 (65.3)	36 (47.4)	**0.021***
Hypertension	94 (95.9)	76 (100.0)	0.133
Diabetes mellitus	6 (6.1)	1 (1.3)	0.139
Chronic kidney disease	8 (8.2)	3 (3.9)	0.352

*[a]Analysis restricted to patients with a pure ischemic or pure hemorrhagic stroke pattern (n=174), excluding lacunar and mixed/multiple lesion categories, to allow valid 2×2 comparison. [b]Fisher's exact test. *Statistically significant at p<0.05.*

Discussion

This retrospective study characterized the CT patterns of CVA among 227 patients attending Mbeya Regional Referral Hospital over a two-year period, providing early imaging-based data from a regional referral setting in Tanzania an evidence gap identified as a national priority given the country's continued reliance on a small number of tertiary-hospital-based stroke registries (Matuja et al., 2026).

Frequency of ischemic versus hemorrhagic stroke

In this study, ischemic stroke was the predominant pattern (43.2%) (Figure 5), followed by hemorrhagic stroke (33.5%), mixed/multiple lesions (14.1%), and isolated lacunar infarcts (9.3%). This finding is broadly consistent with the global pattern, in which ischemic stroke accounts for the majority of cases (Feigin et al.,, 2024), and aligns more closely with the early Dar es Salaam community-based cohort, which found ischemic stroke in 82.4% of scanned patients (Walker et al., 2011), than with the more recent multi-centre national stroke surveillance initiative, which reported a predominance of hemorrhagic stroke (57.9%) over ischemic stroke (38.3%) across eight tertiary hospitals (Matuja et al., 2026).

Several factors may explain this divergence: differences in referral patterns between a regional hospital and tertiary national referral centres, the smaller and community-derived sample in the earlier Dar es Salaam cohort, and possible differences in the threshold for CT referral for milder presumed-ischemic presentations versus more dramatic hemorrhagic presentations. The relatively high proportion of isolated lacunar and mixed/multiple-lesion cases identified in this study (23.4% combined) also suggests that a purely binary ischemic-versus-hemorrhagic framework may understate the true diversity of CT stroke patterns seen in routine regional practice, and that lacunar disease itself a subtype of ischemic stroke warrants explicit reporting alongside the traditional dichotomy.

From a health-systems perspective, the substantial hemorrhagic and mixed-lesion burden observed here reinforces the case for maintaining routine (Figure 7), timely CT access at regional referral hospitals, since clinical differentiation of stroke subtype alone is unreliable and has direct implications for acute management, particularly around blood pressure targets and the appropriateness of antiplatelet therapy (Shafaat & Sotoudeh, 2026).

Anatomical locations of stroke lesions

The basal ganglia (37.0%) (Figure 6) and frontal lobe (36.1%) were the most commonly affected anatomical sites in this study, followed by the thalamus (24.2%) (Figure 8). This finding is consistent with a CT-based Ghanaian study, which similarly identified the basal ganglia as the most affected region, followed by the parietal and frontal lobes, in a series in which ischemic stroke also predominated (70.7%) (Edzie et al., 2021). It also aligns with the pattern reported in a Nigerian neurosurgical series of spontaneous intracerebral hemorrhage, in which the basal ganglia and thalamus were the leading sites of hemorrhage, frequently with intraventricular extension (Adeleye et al., 2015) (Figure 9, Figure 10).

By contrast, a separate Nigerian study identified the parietal lobe, rather than the basal ganglia, as the predominant site of stroke involvement, followed by the frontal lobe (Kolade-Yunusa et al., 2020) a discrepancy that likely reflects differences in study population, stroke-type mix, and imaging protocol between centres, and underscores that anatomical distribution of stroke lesions can vary meaningfully even within the same region. The predominance of basal ganglia and deep grey

matter involvement in the present study is consistent with the vascular territory most vulnerable to small-vessel hypertensive disease, given that hypertension was documented in 97.4% of the study population among the highest prevalence rates reported in any regional African stroke imaging series to date.

These anatomical findings have direct clinical relevance: lesions in the basal ganglia, thalamus, and internal capsule region carry a well-recognized risk of significant motor, sensory, and consciousness-level impairment, and their predominance in this cohort underscores the need for early rehabilitation planning and realistic prognostic counselling for patients and families at the point of CT diagnosis.

Figure 5: Axial non-contrast CT brain showing acute right MCA territory ischemic stroke with parenchymal hypoattenuation, loss of gray–white matter differentiation, and mild sulcal effacement

Figure 6: Axial non-contrast CT brain showing an acute left basal ganglia (gangliocapsular) hemorrhagic stroke, characterized by a hyperdense intraparenchymal hematoma with surrounding edema and mild local mass effect

Figure 7: Axial non-contrast CT brain showing an acute left thalamic/basal ganglia hemorrhagic stroke with intraventricular extension, associated with perihematomal edema, compression of the left lateral ventricle, and mild mass effect

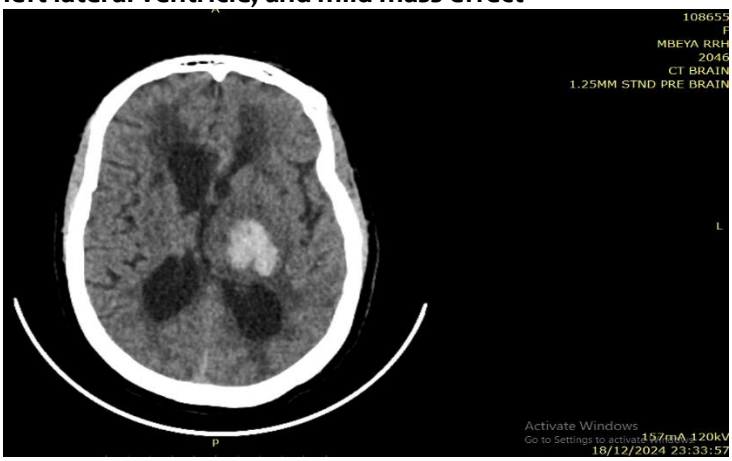

Figure 8: Axial non-contrast CT brain demonstrating an acute left thalamic intracerebral hemorrhage, appearing as a hyperdense hematoma centered within the left thalamus. The hemorrhage is associated with surrounding perihematomal edema, compression of the third ventricle, dilatation of the lateral ventricles and mild local mass effect.

Figure 9: Axial non-contrast CT brain demonstrating an acute left thalamic intracerebral hemorrhage with extension into the third ventricle and both lateral ventricles (intraventricular hemorrhage). The hematoma appears hyperdense with surrounding hypodense perihematomal edema, producing local mass effect

Figure 10: Axial non-contrast CT brain demonstrating an acute left cerebellar hemorrhagic stroke, characterized by a hyperdense intraparenchymal hematoma with surrounding edema and mild local mass effect on the adjacent cerebellar folia.

Correlation of CT findings with clinical presentation and patient characteristics

Right- and left-sided weakness were, as expected, the commonest presenting complaints across all stroke categories, consistent with the typical hemiparetic presentation of both ischemic and hemorrhagic stroke involving the motor pathways. Loss of consciousness was more frequent among patients with hemorrhagic stroke (13.2%) than ischemic stroke (8.2%) in this study, in keeping with the more acute mass-effect and intracranial pressure changes associated with intracerebral hemorrhage (Shafaat & Sotoudeh, 2026). Notably, headache was reported disproportionately among patients with isolated lacunar infarcts (23.8%) in this cohort; while headache is not a classical lacunar-syndrome

feature, this may reflect co-existing, undocumented small-vessel or hypertensive pathology, or simply the small absolute numbers (five of 21 patients) in this sub-group and should be interpreted cautiously. On inferential analysis, age ≥60 years was significantly associated with ischemic rather than hemorrhagic stroke (OR=2.09; p=0.021), a pattern consistent with the well-established shift toward large- and small-vessel atherosclerotic ischemic disease with advancing age, whereas hemorrhagic stroke in this cohort skewed slightly younger (mean age 59.3 vs. 63.8 years for ischemic stroke). Sex was not significantly associated with stroke type, nor were diabetes mellitus or chronic kidney disease, though the latter two comparisons were likely underpowered given their low prevalence in this cohort (6.2% and 5.3%, respectively). Hypertension, present in over 95% of both the ischemic and hemorrhagic groups, could not be meaningfully tested for association with stroke type given its near-universal prevalence itself a striking finding that reinforces hypertension as the dominant, and potentially single most actionable, modifiable risk factor for CVA in this setting, mirroring its documented prevalence of over 90% in Tanzania's national multi-centre stroke surveillance data (Matuja et al., 2026).

Comparison with regional and global data

Taken together, the findings of this study sit at an intermediate point between the ischemic-predominant pattern reported in the earlier, smaller Dar es Salaam cohort (Walker et al., 2011) and the hemorrhagic-predominant pattern reported in the more recent, larger, tertiary-hospital-based national surveillance initiative (Matuja et al., 2026), while broadly resembling the anatomical distribution and hypertension-driven risk profile described in comparable CT-based studies from Ghana and Nigeria (Edzie et al., 2021; Kolade-Yunusa et al., 2020; Adeleye et al., 2015). This intermediate position may reflect Mbeya Regional Referral Hospital's role as a regional rather than purely tertiary or purely community referral centre, serving a population with less selective referral bias than a national tertiary hospital but broader catchment and imaging access than a community-based incidence study. These findings add to the small but growing body of Tanzanian and sub-Saharan African CT-based stroke imaging data (Feigin et al., 2024; Feigin et al., 2025) and support the continued call for routine, standardized CT-based stroke registries at regional referral level to complement existing tertiary-hospital and community-based surveillance efforts.

Limitations

This study has several limitations. First, its retrospective, hospital-based design, dependent on patients having undergone CT scanning, introduces potential selection and referral bias; patients who died or were not scanned before referral, discharge, or death are not represented, and true population-level stroke-type proportions may therefore differ from those reported here. Second, because this study employed total enumeration (census) of all eligible cases rather than a sample derived from an a priori power calculation, it may have been underpowered to detect statistically significant associations for less prevalent comorbidities, such as diabetes mellitus and chronic kidney disease. Third, some CT reports and case records had missing or incompletely documented risk-factor and clinical-presentation data, which may have led to underestimation of the true prevalence of certain comorbidities and presenting complaints. Fourth, the study relied on non-contrast CT findings alone, without access to CT angiography, CT perfusion, or MRI, which may have limited detection of early ischemic changes in the hyperacute phase (Zerna et al., 2018) and precluded vascular-territory-level characterization of ischemic lesions. Finally, as a single-centre study, findings may not be generalizable to other regional referral hospitals in Tanzania with differing catchment populations, referral patterns, or CT protocols.

Conclusion

Ischemic stroke was the predominant CT pattern among CVA patients at Mbeya Regional Referral Hospital, followed closely by hemorrhagic stroke and a substantial proportion of mixed/multiple-lesion and isolated lacunar presentations. The basal ganglia and frontal lobe were the leading anatomical sites of involvement, and hypertension was the near-universal modifiable risk factor in this population. Age ≥60 years was significantly associated with ischemic rather than hemorrhagic stroke. These findings provide baseline regional-referral-level imaging data to guide clinical decision-making, inform stroke-care resource allocation, and support the case for routine CT-based stroke surveillance at regional referral hospitals across Tanzania.

Declarations

Authors' Contributions

NM conceptualized the study, collected and analyzed the data, and prepared the manuscript.

Ethical considerations

This study involved a retrospective review of routinely collected, de-identified hospital records and posed no more than minimal risk to participants, with no direct patient contact, intervention, or change to clinical care. Institutional permission to access and use the relevant CT reports and case records for research purposes was granted by the administration of Mbeya Regional Referral Hospital. Given the retrospective, de-identified, and minimal-risk nature of the study, individual written informed consent was not sought, consistent with institutional practice for this category of records-based research. Only de-identified data (patient ID codes) were abstracted and used for analysis, and patient confidentiality was maintained throughout.

Competing Interests

The author declares no conflicts of interest.

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Epidemiology of bacterial colonization linked to vascular catheters in the surgical emergency resuscitation department of the Ibn Sina university hospital center Rabat Morocco

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Abstract
Introduction: The vascular catheter is one of the most widely used invasive devices in the resuscitation department, and it presents a problem of bacterial colonisation. The objective of this study was to establish the epidemiological and bacteriological profile of these colonisations, then examine the antibiotic resistance of the most frequent pathogens, and identify the main factors associated. The study was conducted from 1 February to 30 April 2022 in the Surgical Emergency Resuscitation Department of Ibn Sina University Hospital Centre, Rabat.
Methods: This was a prospective, descriptive, exhaustive, and analytical study. Data collection was carried out for each patient by completing an operating form and retrieving the various results and available information (reports, medical files, and biological check-ups).
Results: Of the 47 samples taken from catheter tips in 79 admitted patients, 13 were positive for a pathogen, 5 showed two pathogens, with a total of 11 bacterial species identified. We noted the predominance of *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, and *Staphylococcus aureus*, with 21.70%, 17.4%, and 13.04% respectively. The incidence of bacterial colonisation was 17.57 per 1,000 hospitalisation days, while the site-specific incidence was 22.78%. Resistance of the aforementioned strains to multiple antibiotics was also observed.
Conclusion: The analysis of risk factors revealed that colonisation was associated with several variables such as length of stay, medical history, diagnosis, and age. Mortality was found to depend on multiple factors, including bacterial colonisation of vascular catheters.
Key words: Epidemiology, colonisation, vascular catheter, antibiotics, samples

Introduction

Patients admitted to intensive care units are at increased risk of developing secondary infections, primarily due to the use of invasive devices and the critical severity of their underlying conditions (National Network of Intensive Care Units, 2018). Invasive devices are essential in patient management, but their presence is most often accompanied by infectious complications (Ministry of Health, 2007). Microbiological evidence, often quantitative, plays a crucial role in the epidemiological surveillance of these infections (Ministry of Health, 2007).

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Biofilms are the origin of hospital-acquired infections, most frequently associated with invasive devices (Burin Des Roziers, 2002; De Chalvet De Rochemonteix, 2009). Biofilms can form on the surface or inside invasive devices implanted in the body. The microorganisms responsible for biofilm formation may originate from the patient's commensal flora, the environment, or transient exogenous microflora transmitted by hospital staff (De Chalvet De Rochemonteix, 2009). The World Health Organization (WHO) states that between 5% and 12% of hospitalised patients worldwide develop a healthcare-associated infection (HAI), more than 60% of which are linked to the implantation of a medical or surgical device (Ebrey et al., 2004).

Healthcare-associated infections (HAI) currently affect nearly 5% of hospitalised patients in France and are mainly due to the use of invasive devices (INVS Santé Publique France, 2018). In 2006, among the 180,000 patients hospitalised for short stays in French health facilities included in the national nosocomial infection prevalence survey, 43.5% were carrying at least one invasive device; this percentage reached 90% in intensive care units (GRAPES, 2009).

Most hospitalised patients are exposed during their care to a vascular catheter, and its implantation is associated with a significant risk of colonisation, since 60% of care-related infections are thought to originate from invasive devices linked to biofilm formation, among which vascular catheters are prominent (Espinasse et al., 2010). The implantation of a vascular catheter in intensive care enables volume expansion, drug administration, parenteral nutrition or blood products, invasive blood pressure monitoring, and maintenance of venous access in emergency situations. In France, approximately 1 million central venous catheters (CVCs) and arterial catheters are inserted each year (Tacconelli et al., 2009), along with 25 to 30 million peripheral venous catheters (SFHH, 2005).

The indication for vascular catheter placement requires the availability of appropriate aseptic conditions. The lifespan of the catheter depends on the insertion technique, the care provided after placement to preserve the patient's vascular capital, and above all, the prevention of infectious complications (Prevention of Infections, 2019). Colonisation of vascular catheters (VCs) refers to the presence of microorganisms on the internal and/or external surface of the catheter, which may or may not be associated with local or systemic infection. The presence of microorganisms on the catheter requires microbiological analysis by culturing the distal end of the catheter, which necessitates its removal (Timsit, 2005). The presence of a thrombus is associated with a significant increase in colonisation rates and catheter-related infections (Jaouhar et al., 2021).

In this study, we will focus on bacterial colonisation related to vascular catheters. The objective is to establish the epidemiological and bacteriological profile of these colonisations, then examine the antibiotic resistance of the most frequent pathogens, and identify the main factors associated in the surgical emergency resuscitation department of the Ibn Sina University Hospital Centre, Rabat, Morocco.

Materials and methods

***Type of study*:** It was a prospective, descriptive, exhaustive, and analytical study of patients hospitalised in the surgical emergency resuscitation unit.

Place of study: The surgical emergency resuscitation unit at Avicenne Hospital, part of the IBN SINA University Hospital Centre in Rabat, Morocco. The unit has a bed capacity of 16 cubicles, 3 of which are connected to a haemodialysis technical room. It also includes a department manager's office, head nurse's office, four doctors' offices, a nurses' rest room, a doctors' rest room, a classroom, a nurse monitoring station, one cloakroom with shower and toilet for women and another for men, a terrace for waste and linen, a pharmacy, two storage rooms, and a family reception room.

***Target population*:** All hospitalised patients with vascular catheter insertion lasting more than 48 hours

Study period: The study was conducted over a period of three months (February–April 2022).
Inclusion /Exclusion criteria: Excluded patients were those admitted for less than 48 hours, those with vascular catheter colonisation documented at admission, and those whose medical device insertion was less than 48 hours old.
Data collection: For each patient admitted to the unit, a data form was completed containing demographic information (age, sex), reason for admission, medical history, germ resistance profile, prognosis, and duration of hospitalisation.

Sampling technique in the unit*:* This procedure describes the protocol followed to collect samples from the vascular catheter tip in the surgical emergency resuscitation unit. Samples from the medical equipment were taken using the swabbing technique recommended by NF EN ISO 14698-1 (2004). This technique has been used in several studies aimed at detecting pathogens of nosocomial interest (Oumokhtar et al., 2017; Berrada et al., 2017). Samples were taken under aseptic conditions: the insertion site was brushed widely from the inside out, stitches were removed, the catheter was withdrawn without contact with the skin or other surfaces, the distal segment was cut with a sterile scalpel blade, placed directly into a bacteriology jar, and sent to the laboratory.

laboratory analysis Technique
For isolation, samples were seeded on semi-selective media: Chapman, MacConkey, Cetrimide, and Sabouraud. Petri dishes containing bacterial samples were incubated for 24 hours. Purification was carried out on the same medium, enabling isolation of the germ. Bacteria were identified through standard procedures based on cultural characteristics, bacterial morphology after Gram staining, and tests for cytochrome oxidase, catalase (peroxidase), and others. Sensitivity of the germs to antibiotics was assessed using indirect methods, specifically agar diffusion (Thabaut & Durosoir, 1979).

Statistical analysis
The statistical study was conducted using IBM SPSS Statistics 20 software, with $p < 0.05$ considered significant. The incidence rate of bacterial colonisation on vascular catheters per 1000 hospitalisation days (HD) was determined by:
$$\text{Incidence rate} = \frac{\sum \text{number of colonisations linked to vascular catheters} \times 1000}{\text{number of HD}}$$

The specific incidence rate was estimated by the ratio of colonised patients to exposed patients. Quantitative variables were expressed as mean ± standard deviation, with correlation studied using the Pearson Bravais test. Qualitative variables were expressed as percentages and compared using bivariate analysis with the chi-square independence test, odds ratio estimation, and contingency coefficient. Comparison of qualitative and quantitative variables used the one-factor ANOVA test. For risk factor analysis, the population was divided into two groups: colonised and non-colonised. For prognostic factors, the sample was subdivided into two groups: transferred and deceased.

Results

Description of the study population
Of the 149 patients admitted to the surgical emergency department, 79 met the inclusion criteria, with an average length of stay of 13 days and a total of 1,024 hospitalisation days. The male-to-female sex ratio was 3.64. The median age of the patients was 47 years.

Diagnosis
Traumatic conditions represented the most frequent reason for admission, with 30% of patients being polytraumatised, 18% admitted for traumatic brain injuries, and 3% for chest injuries. Together,

these accounted for 51% of the study population. The remaining 49% were admitted for non-traumatic pathologies

Patient history

Table 1: Distribution of patients according to their medical history

Patient History	Frequency	Percentage
Other	10	12,7%
Cardiovascular	5	6,3%
Cardiovascular+ Renal insufficiency	1	1,3%
Cardiovascular + Surgical	1	1,3%
Surgical	5	6,3%
Diabetes	4	5,1%
Diabetes + Cardiovascular	4	5,1%
Diabetes + Cardiovascular + Renal insufficiency	1	1,3%
Renal insufficiency	1	1,3%
None	43	54,4%
Psychiatry	4	5,1%
Total	**79**	**100,0%**

Of all the patients included in the study, 54.4% had no known medical history, while the remainder were divided among those with cardiovascular disease, diabetes, renal failure, surgical conditions, psychiatric disorders, and other antecedents (Table 1).

Prognosis of patients

Slightly more than half of the patients (54.50%) had a favourable prognosis, reflected by their transfer to the corresponding services, while almost 45% had an unfavourable prognosis, resulting in death.

Epidemiology of colonisation

Of the 47 samples taken from the tip of the vascular catheter, 13 were positive for a pathogen, 5 showed two pathogens, while the remainder were negative. The specific incidence was 22.78%, corresponding to 17.57 per 1,000 hospitalisation days (HD).

Bacteriological profile

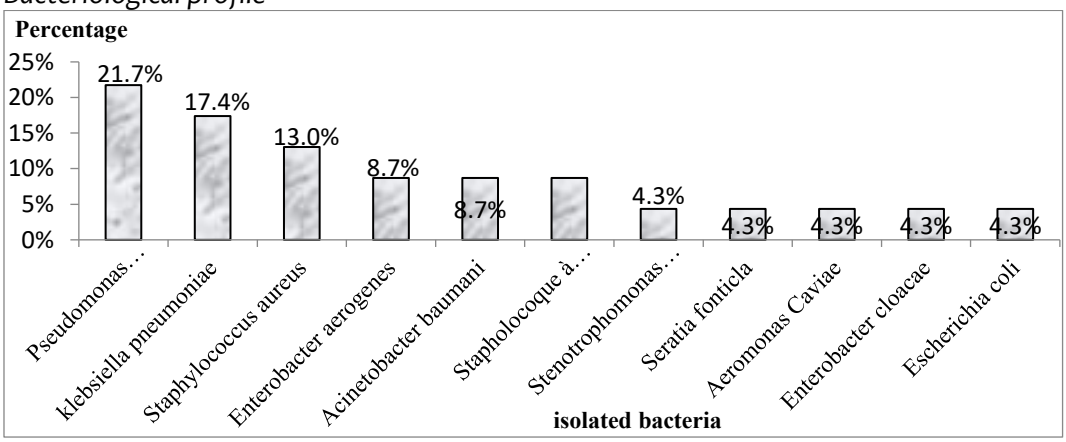

Figure 1: Distribution of isolated bacteria

The positive samples enabled the isolation of 11 bacterial species, dominated by *Pseudomonas aeruginosa* (21.70%), *Klebsiella pneumoniae* (17.4%), *Staphylococcus aureus* (13.04%), *Acinetobacter baumannii*, coagulase-negative staphylococci, and *Enterobacter aerogenes* (8.7% each), as well as *Escherichia coli*, *Enterobacter cloacae*, *Aeromonas caviae*, *Serratia fonticola*, and *Stenotrophomonas maltophilia* (4.3% each) (Figure 1).

The five strains of *Pseudomonas aeruginosa* were resistant to sulfamethoxazole/trimethoprim, with high sensitivity to the other antibiotics tested, except for meropenem and piperacillin/tazobactam, which were tested on four strains and showed 50% sensitivity and 50% resistance. The four strains of *Klebsiella pneumoniae* exhibited high resistance to ampicillin, ticarcillin, amoxicillin, clavulanic acid, and ticarcillin/clavulanic acid. Fifty per cent of the strains were sensitive to sulfamethoxazole/trimethoprim, nalidixic acid, ceftazidime, and ceftriaxone, with high sensitivity to the other antibiotics tested. The three strains of *Staphylococcus aureus* were strictly resistant to penicillin, while remaining sensitive to several other agents tested.

The two strains of *Enterobacter aerogenes* were resistant to ticarcillin/clavulanic acid, amoxicillin/clavulanic acid, ampicillin, cefoxitin, and cefalotin, while sensitivity to the other antibiotics tested was recorded. The two strains of *Acinetobacter baumannii* were strictly sensitive to colistin, with resistance noted against several other antibiotics tested. *Escherichia coli* was sensitive to only three agents (amikacin, imipenem, and colistin), while showing resistance to most antibiotics used in the antibiogram.

Analysis of the results

Table 2: Relationship between patients' diagnoses and sample results

		Value	Approximate meaning
Nominal	Contingency coefficient	0,163	0,142
Number of observations		79	

Juxtaposed with the bivariate analysis carried out using the chi-square test of independence, with estimation of the odds ratio and the contingency coefficient. A contingency coefficient of 0.142 indicates a weak relationship between the patients' diagnoses and the sample results (Table 2), demonstrating that the sample results depend not only on the patients' diagnoses but also on other factors.

Table 3: Prognostic factors of bacterial colonisation

Parameter	Prognosis of bacterial colonisations on vascular catheter
Colonisation of patients on a device	OR 0.81 IC (0,46-1.44)

Juxtaposed with the bivariate analysis carried out using the chi-square test of independence, with calculation of the odds ratio. Uncolonised patients with a vascular catheter have a mortality risk of 81%. The values indicate a weak relationship of dependence between the sample results and the patients' prognosis, showing that prognosis depends not only on the sample results but also on other factors (Table 3).

Table 4: Risk factors for bacterial colonisation on invasive devices

Parameter	OR bacterial colonisation on vascular catheter
medical history	0.89 IC (0.73-1.07)

Juxtaposed with the bivariate analysis carried out using the chi-square test of independence, with calculation of the odds ratio. Patients with no prior history have an 89% probability of not being colonised on a vascular catheter (Table 4).

Discussion

To improve the quality of care in the intensive care setting, the prevention of bacterial colonisation of vascular catheters is of great importance. The prospective monitoring of colonisation, the results of which are presented in this article, had the merit of being conducted in the Department of Surgical Emergency Resuscitation at Ibn Sina University Hospital, Rabat.

In our study, the incidence of bacterial colonisation was higher than that reported in a sample taken from 165 French intensive care units including 22,927 patients, which was 2.31 per 1,000 device-days (Réseau Réa RAISIN, 2009), and higher than the 11.3 per 1,000 device-days observed in Colombia (Moreno et al., 2006). The present study showed a site-specific incidence lower than that found in a study conducted in 2021 at F. Hached University Hospital in Sousse, Tunisia, which reported a predominance with a proportion of 47.1% (Réseau Réa RAISIN, 2009).This incidence is explained by the systematic use of vascular catheters in the management of all patients admitted to the ward, with the placement of two or three vascular access points to facilitate the administration of treatment in accordance with international recommendations and to avoid incompatibilities.

Regarding bacteriological results, our study showed almost equal proportions for enterobacteria, a higher proportion for *Pseudomonas aeruginosa*, and a lower proportion for Gram-positive cocci compared with the figures reported by Réa-RAISIN France in 2007, which noted Gram-positive cocci (49%), enterobacteria (28%), and *Pseudomonas aeruginosa* (13%) (Réseau Réa RAISIN, 2009).

The analysis of the resistance profile of *Klebsiella pneumoniae* strains to different antibiotics is similar to that observed in the Department of Resuscitation and Infectious Diseases, University of Lille in 1991, which reported 32.6% resistance in *Klebsiella* strains producing extended-spectrum β-lactamases (Beaucaire, 1999).Regarding resistance to amoxicillin and clavulanic acid, a study conducted at Biskra University on the resistance of enterobacteria to β-lactams, isolated from various pathological samples at El-Hakim Saâdan Hospital, Biskra, showed that the *Klebsiella pneumoniae* antibiogram revealed a high level of resistance to amoxicillin and clavulanic acid (100%) (Fatnassi, 2020).

The study of *Staphylococcus aureus* strain resistance showed higher levels than those reported in the 1996 national nosocomial infections prevalence survey in France, which noted 64.3% resistance to penicillin (InVS, 1997).The study of *Pseudomonas aeruginosa* resistance is broadly consistent with findings from a study on antibiotic resistance in *Pseudomonas aeruginosa* at Nîmes University Hospital between 2002–2006, which demonstrated that the most active β-lactams were ceftazidime and imipenem, with 17% and 15% resistance respectively. Piperacillin and piperacillin–tazobactam showed 25% and 19% resistance, lower than ticarcillin (54%) but higher than ticarcillin–clavulanic acid (45%). Resistance was lower for amikacin, tobramycin, and gentamicin (20%, 22%, and 41% respectively), and ciprofloxacin (29%) (Minchella et al., 2008).

These results are lower compared with another study conducted in 2009 at the Resuscitation Department of Avicenna Military Hospital, Marrakech, Morocco, on *Pseudomonas* in intensive care, which reported an average resistance rate of 43.2% to ticarcillin, similar resistance to ceftazidime (20.5%), higher resistance to gentamicin (66%), and lower resistance to tobramycin (16%), amikacin (11.4%), and ciprofloxacin (13.7%) (El Ouadnassi & Boughalem, 2009).These

Gram-negative bacteria predominate because they are better adapted to the humid hospital environment and can survive for long periods on surfaces, thereby engaging in an easy process of colonisation and biofilm formation on vascular catheters. This enables them to protect themselves against the action of antibiotics and the host's immune defences.

In addition, they exhibit natural resistance thanks to their double membrane and efflux pumps, which limit the penetration of antibiotics.The frequent use of antibiotics in the ward to treat infections related to the condition of hospitalised patients, particularly those admitted for trauma, favours the selection of multidrug-resistant strains. The workload experienced by healthcare staff and the emergency nature of the ward, together with occasional shortages of hygiene products (paper towels, antiseptic soap), hinder strict adherence to hand hygiene protocols, despite efforts made through service renovation and architectural reorganisation. On the other hand, the average length of hospital stay encourages the use of vascular catheters for prolonged periods, sometimes exceeding recommended durations, thereby increasing the risk of colonisation.

We therefore believe that the incidence and resistance patterns observed in the results can be explained by all these factors, which should prompt the ward to establish, following prospective studies, a clear protocol for the surveillance of these devices. This could also be proposed as a research perspective at the conclusion of this article.

Conclusion

Our study showed that the colonised catheters in the ward under investigation were most often associated with Gram-negative bacteria. Statistical analysis did not reveal significant results in the bi-variate analysis, although multivariate analyses could be performed to deepen the investigation. Nevertheless, given the health status and weakened defences of patients in intensive care, we emphasise the necessity of strict adherence to hospital hygiene protocols and hand hygiene by healthcare staff, careful monitoring of vascular catheter insertion and surveillance procedures, effective control of the care environment, and rigorous application of disinfection protocols for hospital premises, together with continuous epidemiological surveillance

Declarations

Ethical considerations

The ethical approaches adopted in this study can be summarised as follows maintain strict confidentiality and preserve patient anonymity, no manipulation or intervention was performed on patients and vascular catheters were inserted based on therapeutic indication and medical prescription.

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Conflicts of interest: The authors declare that they have no conflicts of interest

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Need Assessment Report for Development of the National Research Ethics Information Management System (NREIMS)

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Abstract

***Background*:** Research Ethics Committees (RECs) are mandated to protect human participants in research. Digitalization has improved RECs' efficiency in fulfilling their role. Through the Consortium for Clinical Research Regulation and Ethics capacity in Eastern Africa Region (CCRREEA) project we conducted a needs assessment for the development of a national centralized digital platform to enhance research governance in Tanzania.

***Objectives*:** The study aimed to understand the status and digitalization of RECs in Tanzania and provide recommendations for an integrated system.

***Methodology*:** This was a cross-sectional study using a mixed-methods approach conducted in 2021. Quantitative data were collected via a self-administered survey form completed by 15 institutions. Qualitative interviews were conducted with purposively selected clinical trial researchers. Descriptive statistics were analyzed from the quantitative data by using SPSS version 20. While thematic analysis was used to analyze the qualitative data through NVivo 12.

***Results*:** The quantitative study comprised 15 institutions, consisting of 12 RECs and three National Regulatory Authorities (NRAs). In terms of jurisdiction, four operated at the national level, three at the zonal level, and eight at the institutional level. Regarding digitalization, five institutions used no digital systems, six utilized a combination of email and web platforms, and four relied exclusively on web platforms. The qualitative study recruited eight participants. Three qualitative themes emerged: Lengthy turnaround time of review, System Usability and Digital Infrastructure, and The Need for System Integration.

***Conclusion*:** The findings indicate an urgent need for a harmonized digital platform for the ethics review process. The NREIMS will serve as a centralized, one-stop platform for all RECs to work with. Integrating the NREIMS with other digital systems from NRAs will be a tremendous leap forward for all stakeholders in health research governance.

Keywords: Research Ethics Committee, Institutional Review Board, National Research Information Management System, Research Oversight, clinical trials

Introduction

Globally, research ethics review committees (RECs) were established to oversee health research and protect the rights and welfare of research participants. In Africa, formal research ethics committees began with the first REC at the University of the Witwatersrand in 1966. Other national and institutional RECs were established from the late 1970s and especially the 1980s onward in countries such as The Gambia (1980) and Uganda (1986), and later across the continent (Moodley and Myer,

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2007; Ochieng *et al.*, 2020; Batchilly, Sowe and Jobe, 2023). This growth in formal oversight capacity reflected a broader global recognition that robust ethical infrastructure is essential to high-quality, participant-protective research.

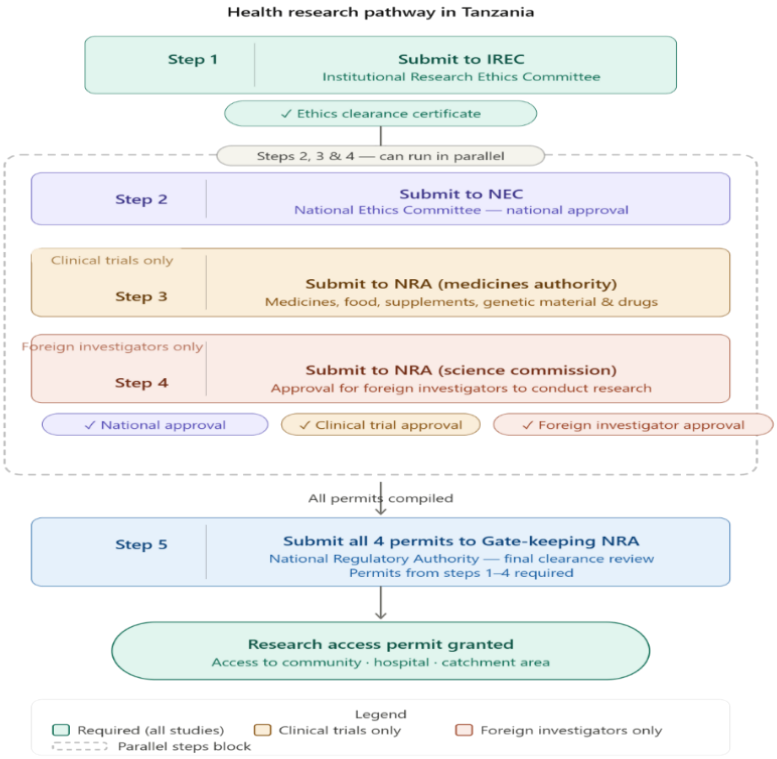
Studies in Africa have assessed the quality of RECs using key performance indicators such as efficiency and effectiveness, revealing significant operational gaps. Some of these challenges include administrative and financial constraints, limited capacity building, inadequate training, and inconsistent review processes (Silaigwana and Wassenaar, 2015; Mokgatla, Bahati and Jsselmuiden, 2017; Thurtle *et al.*, 2021).

In Tanzania, health research governance involves close collaboration between institutional RECs (IRECs), the National REC (NEC), and national regulatory authorities (NRAs), including the Tanzania Medicines and Medical Devices Authority (TMDA) and the Tanzania Commission for Science and Technology (COSTECH). The President's Office – Regional Administration and Local Government (PORALG) is a key government body responsible for overseeing regional administration and local government authorities (LGAs) to ensure effective service delivery at the local level. COSTECH works collaboratively with PO-RALG to ensure research participants are well protected. In other words, PO-RALG serves the role of gatekeeper in the protection of research participants in Tanzania (Figure 1).

In 2018, the National Institute for Medical Research (NIMR), which also hosts the NEC, pioneered the digitalization of the Research Information Management System (REIMS). However, some RECs had not yet digitalized their ethics review process at the time of this study (Mrisho and Essack, 2021). NIMR then undertook the Consortium for Clinical Research Regulation and Ethics Capacity in the Eastern Africa Region (CCRREEA) project funded by the Developing Countries Clinical Trials Partnership (EDCTP) as part of a consortium in Sub-Saharan Africa. A comprehensive needs assessment was conducted by the CCRREEA team to evaluate the institutional status and digital capacity of RECs and NRAs. The results would then provide the grounds for the development of a centralized digital platform called the National Research Ethics Information Management System (NREIMS) for all RECs within the country.

The figure depicts the pathway for health research governance in Tanzania. Researchers submit their protocols to IREC(s) before the NEC. For NRA approvals, a permit from the NEC is required. The gatekeeping NRA provides the final permit to conduct a study. It must be noted that this is not the typical pathway for all studies. Also, submissions to NRAs can be done simultaneously.

Figure 1: The health research pathway in Tanzania.



Methodology

Study Design and Settings

This was a cross-sectional study that employed a mixed-methods approach conducted in July to September of 2021. Qualitative and quantitative methods were used concurrently to understand the status of RECs, their digitalization, and the perspectives of researchers. The study was conducted in Dar es Salaam, Mwanza, Mbeya, Arusha, Kilimanjaro, and Dodoma regions in Tanzania. Within each of these regions, there was one or more RECs. The diversity of these institutions was an important factor in the study as it would highlight generalizable areas for improvement.

Study Population

For the quantitative phase, RECs and NRAs were recruited. RECs were selected because they are at the forefront of the protection of human participants in health research. NRAs were selected because they are part of the health research governance ecosystem. Clinical trial researchers were recruited as participants for the qualitative study, sourced through the NIMR researcher database. All active RECs at the time of this study were selected. All NRAs dealing with health research were eligible. Researchers were eligible if they had submitted a considerable number of clinical trials as well as non-clinical trial proposals through more than one REC and had experience with the NRAs.

Sample Size and Sampling Method

The quantitative study employed convenience sampling, where all functioning IRECs were recruited, as well as the NRAs. This non-probability approach was appropriate given the small and finite number of active RECs in Tanzania, ensuring complete national coverage without the need for a calculated sample. In these institutions, only one administrator was appointed by the institution to fill out the survey. For the qualitative phase, purposive sampling was used to select participants with extensive multi-REC ethical clearance application experience, ensuring data richness and theoretical sufficiency within the scope of these exploratory needs assessment.

Data Collection Methods

Quantitative data were collected by using a structured questionnaire designed to capture the status and digitalization of the RECs. Qualitative data were collected by using semi-structured interviews conducted in Swahili and English. The interviews lasted for 40 to 60 minutes, were conducted with participant consent, and audio-recorded.

Data analysis

Quantitative data were analyzed descriptively using SPSS version 20. The descriptive statistics included demographics and profiles of all participating institutions, showing their organizational jurisdiction, ICT capacities, accreditation statuses, and other parameters. Qualitative data were analyzed by using thematic analysis through coding, development of themes and subthemes, and a final report draft. This analysis was conducted using NVivo 12 software by all four investigators of this study.

Results

The results are presented in two parts: quantitative findings from the institutional survey of 15 RECs and NRAs, followed by qualitative themes derived from interviews with 8 clinical trial researchers.

Quantitative findings

This part presents the quantitative findings obtained from the survey completed by REC administrators.

Demographics

During the study period, 15 institutions were active and were assessed, showing their diverse jurisdictions and mandates. Of these institutions, 12 were RECs, and 3 were NRAs. The RECs were categorized as national, zonal, and institutional. All NRAs were government institutions with nationwide jurisdiction, while five of the RECs were private (Table 1).

Table 1: Demographics of institutions

Institution	Category	Frequency	Total
REC Jurisdiction	National REC	1	12
	Institutional REC	8	
	Zonal REC	3	
REC type	Private Institution	5	12
	Government Institution	7	

NRA	Private Institution	0	3
	Government Institution	3	
Institutional Mandates	Research, Education & Consultancy	7	15
	Research, Treatment & Consultancy	2	
	Research and oversight	3	
	Advisory / Regulatory	1	
	Gatekeeping	1	
	Regulatory	1	

The Status of RECs

RECs have guidelines and Standard Operating procedures that are usually revised periodically. Most RECs had revised their official documents within the last 3 years. However, 3 of them could not verify their accreditation status. The number of REC members ranges from 11 to 20 for almost all RECs. RECs reviewed up to 20 clinical trials per year, but only 8 of them conducted active research oversight (Table 2).

Table 2: The status of RECs

Item	Category	Frequency (*n*=12)
Latest update of policies/ guidelines	Within the last 3 years	7
	within the last 6 years	2
	Within the last 10 years	3
Accreditation status	Not clear	3
	Accredited	9
Number of REC members	11 - 20	11
	More than 20	1
Number of clinical trials reviewed/ year	None	4
	1 – 10	3
	11 - 20	3
	More than 20	3
Research Oversight	Active and/ or passive	8
	None	4

The ICT status of Institutions

The governance and coordination of health research oversight were only partially digitized for most institutions, with only four having fully functional web portals for research governance. Research information was mostly hosted electronically in local servers and backed up in several ways, such as external drives, local computers, and servers (Table 3).

Table 3: ICT status of Institutions

Status of the institutions	Category	Frequency	Total
	No digitalization (Paper)	5	

Digitalization of the business process	Email and web platforms	6	15
	Web platforms only	4	
System host	Personal computer	2	12
	Local server	6	
	Remote server	4	
Means of Research Information backup	External drive	2	15
	Local computer	3	
	Local server	3	
	Multiple means	7	

The qualitative study

This part presents the thematic findings from eight (8) researchers. Their demographics and perspectives regarding their experiences with digital platforms, the IRECs, the NEC, and the NRAs have been presented.

Participant Demographics

The ratio of male to female was 1:1. Most (75%) of the participants had a postgraduate degree. Participants were adept in both clinical and non-clinical trials, as 88% had more than 5 years of experience dealing with RECs and NRAs (Table 4).

Table 4: Demographics of respondents of the qualitative study

Participant Demographic	**Category**	**Frequency** (*n=8*)
Sex	Male	4
	Female	4
Academic qualification	PhD.	3
	Masters	3
	Bachelors	2
Expertise in clinical research	All clinical research	3
	Only clinical trials	3
	Only non-clinical trials	2
Year of research experience	0 – 5	1
	>5	7
Recent research ethics training	In the previous year	2
	In the previous 3 years	6

Qualitative themes developed

Three overarching themes emerged, each containing sub-themes supported by direct participant quotes: the timeliness & process inefficiency, system usability & digital infrastructure, and the need for system integration and training of users.

Table 5: Themes and Sub-themes

Theme	Sub-themes
Theme 1: Timeliness & Process Inefficiency	Lengthy Ethics Clearance Timelines
	IREC Delays and Back-and-Forth Processes
	The Gatekeepers' Administrative Burden
Theme 2: System Usability & Digital Infrastructure	The Advantages of the Prototype Digital Systems
	The Challenges of the Prototype Digital Systems

Theme 3: The Need for System Integration and Training of Users.	Need for System Integration Across Bodies
	Demand for Training and Stakeholder Awareness

Theme 1: Timeliness and Process Inefficiency

Respondents consistently highlighted delays and slow turnaround times as a major challenge across multiple regulatory bodies. This theme captures frustrations with health research processing timelines at RECs and NRAs.

Sub-theme: Lengthy Ethics Clearance Timelines

Most respondents (five of eight) reported experiencing delays in ethics clearance, ranging from six weeks to six months. One participant stated: "*Timeline is a challenge from 6 weeks to 6 months with an average of 2-3 months*." [Researcher 1]. This was described as a significant barrier to research progress, especially in multi-center and time-sensitive studies, as one participant noted: "*The review process is too long. For multicenter studies, we get clearance in other countries faster than here in Tanzania*." [Researcher 3]

Sub-theme: IREC Delays and Back-and-Forth Processes

Respondents raised specific concerns about the IRECs, noting unclear processes and excessive back-and-forth between reviewers and researchers.

"*There was a lot of back and forth. Our collaborators were impatient with us. We're not sure if we should use the expedited review options.* [Researcher 5]. The researchers also claimed that reviewers were sometimes too rigid and took too long to come to a consensus. As participants noted: "*One query remained; that one query we have been corresponding with the reviewer back and forth. The reviewer does not accept our response… until we decided to complain at a higher level.*" [Researcher 4]. Another added: "*Takes time for the reviewers to respond to comments.*" [Researcher 8].

Sub-theme: The Gatekeepers' Administrative Burden

Respondents noted that accessing the community members required physical travel across regions to request permission from the gate-keeping NRA, as one participant noted: "*Our catchment area cuts across three districts and regions, so sometimes I need to notify the authorities in several districts. So, I travel a lot, which takes a lot of cost and time.*" [Researcher 1]. Researchers also noted that even though information from the NEC is supposed to be shared with the NRAs, sometimes the NRAs claim not to have received any notice: one participant revealed: "*Sometimes the gate-keeping NRA says that they do not have information about research.*" [Researcher 3].

Theme 2: System Usability and Digital Infrastructure

This theme captures participants' experiences with the digital systems used across the research approval landscape. Contrasting experiences of ease and frustration were documented.

Sub-theme: The Advantages of the Prototype Digital Systems

A majority of respondents felt that the NEC's digital platform was a positive improvement over the previous manual process, praising its navigability and timely email notifications. One participant noted: "*For sure, the NEC's system is very good. You can easily navigate and follow up on your approval; you get emails. For sure, it is good and easy for us.*" [Researcher 2]. Another researcher added: "*I think it has improved the timeliness. What is most impressive is the timely feedback.*" [Researcher 7].

Sub-theme: The Challenges of the Prototype Digital Systems

On the other hand, participants identified specific gaps, including payment method limitations and a lack of offline functionality. A participant revealed that: "*Only difficulty is in obtaining the control number, it needs follow-up. If we could pay by using Visa cards the way we pay for air tickets, it would've been much better and easier*." [Researcher 3]. Another participant highlighted that: "*If I can download the digital platform, I want to work offline, and when I am ready, I can go online and send my documents.*" [Researcher 6]. In addition, four of the eight respondents experienced problems with the NRA's digital system. One researcher revealed that: "*Their system has a lot of issues. Starting from the initial submission, responding to comments, uploading responses, at every stage, you find there is a problem.*" [Researcher 4].

Theme 3: The Need for System Integration and Training of Users.

This theme encompasses respondents' views on inter-institutional coordination, the need for system integration, reviewer quality, and suggestions for systemic improvements.

Sub-theme: Need for System Integration Across Bodies

Five of the eight respondents expressed a desire for the prototype digital platforms from the NEC and NRAs to be integrated, citing redundancy and inefficiency in the current multi-submission model. A researcher noted: "*Yes. There are several back and forth, but if they are combined [integrated], that can be improved. I really support the linking of digital platforms.*" [Researcher 1]. Another participant gave an example of how systems work in other countries: "*Other countries, for example, South Africa, they do not go through this multiple review. If there's a possibility to streamline the process to do only one submission through the NEC.*" [Researcher 4]. Researchers also highlighted that integration of systems would hasten the review process: "*Yes! For example, if the NRAs could have access to the NEC, they can just see it and continue with the approval process.*" [Researcher 2].

Sub-theme: Demand for Training and Stakeholder Awareness

Researchers stated they are often neglected when it comes to digital systems training; they either teach themselves how to operate the platform or have to seek help from others: "*I learned on my own. It's user-friendly, and someone can learn on their own*." [Researcher 6]. "*I had to look for someone who knows it and ask them to show me*." [Researcher 4]. All respondents agreed that training and awareness campaigns are needed for investigators and stakeholders. Suggestions included online forums, recorded videos, and updated websites. One researcher revealed: "*We need knowledge and information for us to know what institution does what. If we have a forum for investigators to get all information regarding research.*" [Researcher 5]. Another added: "*Keep your website updated in case of any changes. Record training videos and put on the website.*" [Researcher 8].

Discussion

This needs assessment provided a comprehensive baseline evaluation of the research ethics governance landscape in Tanzania, with a particular focus on the digital infrastructure supporting ethics review and regulatory oversight. The study aimed to assess the need for a harmonized one-stop digital platform that will enable the IRECs, the NEC, and the NRAs to work together. A dominant finding of this study is the persistent fragmentation and delay in the ethics clearance process. Researchers reported clearance timelines ranging from six weeks to six months, with an average of

two to three months. These figures are broadly consistent with previous studies conducted in Tanzania and across sub-Saharan Africa.

In Tanzania, studies found a median review turnaround time of 32 days across seven Tanzanian IRBs, with a maximum of 396 days (Mrisho and Essack, 2021). Clinical trials specifically had well over an average of 70 days of review time at the NEC (Machaku *et al.*, 2023). The governance and accreditation status of Tanzania's RECs warrant further attention. Studies have explicitly stated the importance of accreditation and its association with the RECs' performance (Caligiuri *et al.*, 2017; Van De Mheen and Vincent, 2023).

Furthermore, the inadequacy of RECs in conducting research oversight is concerning. Studies consistently show that African RECs face major structural and resource limitations that hinder their ability to conduct active oversight, including inadequate funding, lack of trained personnel, weak legal frameworks, and dependence on external partners (Thurtle *et al.*, 2021). The NREIMS, if designed to include oversight modules for tracking study progress and adverse event reporting from the level of Institutional REC, could contribute significantly to closing this gap, moving the ethics infrastructure from a gatekeeping function toward a sustained monitoring role.

The multi-step approval pathway identified in this study, requiring sequential submissions to IRECs, the NEC, and up to two NRAs before a gatekeeping authority grants community access, compounds these delays significantly. This pathway, while designed to ensure thorough oversight, creates redundancy and administrative burden that disproportionately affects time-sensitive and multi-center studies. An Intuition Labs report revealed that a single clinical trial in the US and Europe may require approval from up to six different agencies, delaying the official launch by up to seven months (IntuitionLabs, 2026).

One way to improve efficiency would be to conduct joint reviews of clinical trials among the RECs and NRAs. This initiative has been proposed by the Advancing Clinical Trials Excellence in Africa, originally established as the African Vaccine Regulatory Forum (AVAREF) (Akanmori, Bellah and Rago, 2015). However, it is unknown if this practice has been normalized in Tanzania. Another way to improve efficiency would be to harmonize the health research governance process in all RECs and NRAs. A study in the United States pointed out that centralized Institutional Review Boards (IRBs) significantly shorten approval timelines (Das, 2024).

In Tanzania, NIMR retains the mandate of governing all other IRECs, and the NREIMS has the potential to harmonize the review process in IRECs as well as the NRAs. The NEC's digital platform received positive assessments from study participants. In contrast, the NRAs' digital systems were noted to have systemic gaps that hindered smooth user experiences. This asymmetry between NEC and NRA digital readiness highlights the importance of harmonized platform development. The integration of NRAs' systems within the broader NREIMS architecture would address the inefficiency most directly felt by researchers navigating multiple separate portals.

The development and implementation of a national digital platform is therefore not merely a technological convenience but a structural necessity for sustaining a competitive and ethically robust research environment in Tanzania. The NREIMS has the potential to effectively capture all clinical trial protocols from the IRECs that may otherwise be missed in manual recording systems.

The proposed system ensures real-time ethics and regulatory oversight across all IRECs, NEC, and NRAs. Evidence from Sub-Saharan Africa also supports the establishment of centralized digital platforms for efficiency (Mokgatla, Bahati and Jsselmuiden, 2017; Mkumbwa, Pancras and Sirili, 2025). Comparable regional models offer instructive precedent: South Africa's more streamlined multi-center review process, cited by one participant, illustrates that a unified submission model is operationally achievable and valued by the research community (iAfrica, 2025).

Consequently, the implementation of digital platforms has to go together with the training of their users. Similar to what researchers in this study have revealed, studies have reported the uneven pace at which digital platforms are being rolled out, compared to the training of users (Dodoo, Al-Samarraie and Alsswey, 2022; Bokolo, Bhattarai and Getachew, 2023). Comparable regional models offer instructive precedent: South Africa's more streamlined multi-center review process, cited by one participant, illustrates that a unified submission model is operationally achievable and valued by the research community (iAfrica, 2025). Consequently, the implementation of digital platforms has to go hand in hand with the training of their users.

Researchers in this study revealed that they are often neglected in user acceptance training. This is corroborated by studies in Africa that reported the uneven pace at which digital platforms are being rolled out, compared to the training of their users (Dodoo, Al-Samarraie and Alsswey, 2022; Bokolo, Bhattarai and Getachew, 2023). All participants recommended the development of the NREIMS, aspiring that it will improve the efficiency of research governance in all institutions, improve monitoring of the approved studies, and most importantly, ensure that all RECs are accredited.

Limitations of the Assessment

The qualitative sample, while purposively selected for depth of experience, comprised only eight participants, limiting the breadth of researcher perspectives captured. Secondly, as a cross-sectional study conducted in 2021, the findings reflect a snapshot in time; given the pace of change in digital infrastructure across the region, some institutional capacities may have evolved since data collection. Finally, the study did not include perspectives from REC members or chairs, whose views on workload, review quality, and digital readiness would complement the researcher and administrator perspectives gathered here. Future research should address these gaps through longitudinal evaluation following NREIMS implementation and through studies capturing the experiences of reviewers themselves.

Conclusion

The increasing volume and complexity of clinical research in Tanzania have exposed longstanding structural gaps in the ethics review system, gaps that this needs assessment was designed to characterize and address. The findings are consistent with evidence from comparable sub-Saharan African settings, pointing unambiguously toward the development of the NREIMS as the central policy response: a centralized, integrated digital platform connecting the NEC, all IRECs, and the relevant NRAs into a single workflow would eliminate redundant multi-body submissions, improve process transparency, and enable electronic post-approval oversight.

Nevertheless, by providing the first comprehensive, nationally inclusive baseline of Tanzania's research ethics digital infrastructure and governance capacity, this work establishes a critical evidence foundation upon which the NREIMS can be purposefully designed, and upon which Tanzania, and the broader CCRREEA regional consortium, can build a harmonized, equitable, and resilient research ethics ecosystem fit for the demands of twenty-first century health research.

Abbreviations

CCRREEA: Consortium for Clinical Research Regulation and Ethics Capacity in the Eastern Africa Region.
NRAs: National Regulatory Authorities
IRECs: Institutional Research Ethics Committees
NEC: National Ethics Committee
TMDA: Tanzania Medicines and Medical Devices Authority
COSTECH: Commission for Science and Technology

NIMR: National Institute for Medical Research
PO-RALG: President's Office – Regional Administration and Local Government
EDCTP: European & Developing Countries Clinical Trials Partnership

Declaration

Ethical Consideration

The project was ethically approved for implementation by the National Institute for Medical Research (NIMR) with certificate number NIMR/HQ/C.54/Vol.I/10. Informed consent was sought and obtained from all study participants during the surveys and interviews. Data was anonymized and de-identified to preserve the confidentiality of the participants. Raw data were only available to the researchers and were stored in encrypted files.

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Conflict of interest

The authors declare that they have no conflict of interest.

Authors contributions

MK, DP, RR, and RJ conceptualized the study, collected data, analyzed data, and wrote the manuscript.

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Availability of Temperature-Sensitive Non-Communicable Disease Medicines and Cold-Chain Storage Facilities in Community Pharmacies in Mwanza City, Tanzania: A Cross-Sectional Study

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Abstract

Background: Non-communicable diseases (NCDs) like diabetes and heart disease need reliable access to medicines, especially temperature-sensitive ones like insulin, which requires strict cold-chain storage. Cold-chain compliance is inconsistent, with nearly half of facilities failing WHO standards (Ringo et al., 2017). In Mwanza, only 55.2% of pharmacies had refrigerators, and less than 40% had backup power (Mwita & Mutta, 2024). Although insulin access is improving, data on the broader availability and storage of temperature-sensitive NCD medicines is limited and fragmented. Community pharmacies are crucial as they are often the first and most accessible care point for chronic patients, providing extended hours and treatment outside public facilities (Ashok et al., 2017). Mwanza, a major urban center with rising NCDs and dependence on private pharmacies, lacks evidence on whether these pharmacies maintain a cold-chain system, including refrigerators, monitoring devices, documentation, and backup power, to ensure medicine quality.

Objective: To assess the availability of temperature-sensitive non-communicable disease (NCD) medicines and cold-chain storage facilities in community pharmacies in Mwanza City, Tanzania.

Methods: A cross-sectional study was conducted in 200 registered community pharmacies in Mwanza City, Tanzania, with one responsible staff member interviewed per pharmacy. Data were collected through structured questionnaires and direct observation of medicine stocks and storage facilities. Descriptive statistics were generated in STATA version 17.

Results: 168/200 (84.0%) pharmacies stocked at least one temperature-sensitive NCD medicine, with insulin most common (142/200; 71.0% of all pharmacies). Cold-chain infrastructure was present in 180/200 (90.0%) pharmacies, but only 145/200 (72.5%) used refrigerators exclusively for medicines. Temperature-monitoring devices were absent in 88/200 (44.0%), and 90/200 (45.0%) did not maintain temperature records.

Conclusion: Availability of temperature-sensitive NCD medicines in Mwanza City pharmacies is relatively high, but cold-chain storage infrastructure is inconsistently applied. Gaps in exclusive refrigerator use, monitoring devices, and documentation highlight vulnerabilities in medicine quality assurance. Strengthening infrastructure, regulatory oversight, and monitoring systems is essential to safeguard patient outcomes.

Keywords: Cold-chain storage, NCD medicines, community pharmacies, insulin, Tanzania

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Introduction

Non-communicable diseases (NCDs) are a growing public health challenge in Tanzania, accounting for an estimated 34% of all deaths nationally (Ministry of Health, 2024; WHO, 2023). Diabetes prevalence has risen to 3–5% in urban populations, while cardiovascular diseases (CVDs) and chronic respiratory conditions are increasingly reported in hospital admissions (Kazibwe et al., 2021). Effective management of these conditions requires continuous access to safe medicines, especially since some NCD treatments are temperature-sensitive. Insulin, certain injectable cardiovascular drugs, and selected biologics require strict cold-chain storage between +2°C and +8°C to maintain potency (Braune et al., 2019; Heinemann et al., 2021). Other NCD medicines, such as oral antihypertensives or statins, do not require refrigeration. This distinction is critical, as gaps in cold-chain infrastructure directly affect the therapeutic quality of medicines that depend on controlled temperatures, particularly insulin for diabetes care.

Community pharmacies are increasingly central to medicine access in Tanzania, particularly for patients with chronic NCDs who require continuous treatment. Community pharmacies offer extended operating hours, proximity to residential areas, and more reliable stock availability, making them the first point of care for many urban patients (Ashok et al., 2017). However, studies show that Tanzanian pharmacies face significant infrastructure gaps: in Mwanza's Nyamagana District, only 55.2% had refrigerators and fewer than 40% had backup power systems (Mwita & Mutta, 2024).

Broader assessments also highlight persistent shortages of tracer commodities, including insulin (Mathias et al., 2024). Mwanza City is particularly relevant as one of Tanzania's largest urban centers with a growing NCD burden and heavy reliance on private pharmacies. Tanzanian studies may have examined medicine availability or pharmacy storage generally, but few have examined the complete cold-chain system for temperature-sensitive NCD medicines in community pharmacies, including refrigerator use, monitoring devices, documentation, and backup power needed to safeguard medicine quality and ensure continuity of treatment. Previous

Recent assessments highlight persistent challenges in pharmaceutical cold-chain infrastructure, including unreliable electricity, inadequate refrigeration equipment, and limited access to temperature-monitoring devices (Govindaraj & Gopalan, 2024; WHO Africa Region, 2023). These constraints raise concerns about whether patients can consistently access medicines stored under recommended conditions. In Mwanza City, where NCD prevalence is rising and community pharmacies are central to medicine distribution, assessing the availability of temperature-sensitive medicines and cold-chain facilities is critical to safeguarding patient outcomes and informing regulatory oversight.

Materials and Methodology

Study Design

This study employed a cross-sectional analytical design to assess the availability of temperature-sensitive non-communicable disease (NCD) medicines and cold-chain storage facilities in community pharmacies. Descriptive statistics were the primary focus; inferential analysis was considered but not reported beyond descriptive summaries.

Study Setting

The study was conducted in Mwanza City, which comprises Mwanza City Council and Ilemela Municipal Council. Together, these councils host most registered community pharmacies in the region. Mwanza is Tanzania's second-largest urban center, with a rapidly growing population and

increasing burden of NCDs. According to the Tanzania Pharmacy Council (PC), approximately 291 pharmacies were registered in the city at the time of the study. The urban context, characterized by high reliance on private pharmacies, makes Mwanza a relevant setting for evaluating cold-chain infrastructure.

Study Population and Unit of Analysis

The target population was all registered community pharmacies in Mwanza City. The unit of analysis was the pharmacy, as outcomes concerned medicine availability and storage infrastructure. One pharmaceutical personnel member was interviewed at each pharmacy to provide information and confirm direct observations.

Sample Size and Sampling

A total of 200 pharmacies were selected using simple random sampling from the Pharmacy Council registry. Sample size was determined using Cochran's formula for proportions, adjusted for finite population correction. The sample size calculation is presented below.

Inclusion Criteria

- Registered community pharmacies within Mwanza City Council and Ilemela Municipal Council.
- Availability of a responsible staff member during the study period.
- Pharmacies operating during the study period.

Exclusion Criteria

- Pharmacies closed during data collection.
- Pharmacies outside the defined geographical area.
- Pharmacies without an available staff member responsible for medicine storage.

Sample Size Determination

The sample size was calculated using **Cochran's formula for proportions**:

$$n_o = \frac{Z^2 \times p \times (1-p)}{e^2}$$

Where:

Z = standard normal deviate corresponding to the desired confidence level (1.96 for 95% CI)

p = estimated proportion of the attribute present in the population (0.5, assuming maximum variability)

e = desired margin of error (0.05)

Substituting values:

$$n_o = \frac{(1.96)^2 \times 0.5 \times (1-0.5)}{(0.05)^2} = 384$$

Finite Population Correction (FPC):

$$n = \frac{n_o}{1 + \frac{n_o - 1}{N}}$$

Since the total number of registered pharmacies in Mwanza City is N=XXX, then:

$$n = \frac{384}{1 + \frac{383}{N}}$$

After applying the finite population correction and adding a 10% non-response allowance, the final sample size was 200 pharmacies (Cochran, 1977; Israel, 1992).

Data Collection and Processing

Data were collected between 05/05/2026 and 20/06/2026. Of the eligible pharmacies, 200/291 (response rate %) participated, with one respondent representing each pharmacy. Data were collected using a structured, pretested questionnaire administered to pharmaceutical personnel, complemented by a direct observation checklist to verify the presence and functionality of cold-chain storage facilities. The questionnaire captured information on medicine availability, refrigerator use, temperature-monitoring devices, and documentation practices. Observations minimized self-report bias and provided objective evidence of infrastructure status. Data were cleaned and coded prior to analysis to ensure accuracy and consistency.

Data Analysis

Data were entered, cleaned, and analyzed using statistical software. Descriptive statistics (frequencies, proportions, and percentages) summarized pharmacy-level availability of temperature-sensitive medicines and cold-chain infrastructure. Results are presented as numerators/denominators with percentages. No regression analysis was performed.

Data Quality Assurance

To ensure validity and reliability, the questionnaire was pretested in pharmacies outside the study area, data collectors were trained on study objectives and procedures, and field supervisors monitored daily activities. Completed questionnaires were checked each day for completeness, double-entered, and cleaned to minimize errors, while variables were systematically coded according to operational definitions. Missing data were documented, and analyses were restricted to complete pharmacy-level cases to maintain consistency and accuracy.

Results

Respondents' Demographic Information

A total of 200 pharmaceutical personnel participated in the study. Most respondents were aged 30–34 years (33.7%), followed by those aged 35–40 years (24.1%). Gender distribution was nearly balanced, with 50.8% male and 49.2% female participants. By professional cadre, pharmacy in-charges (41.9%) formed the largest group, followed by store in-charges (32.6%) and laboratory personnel (25.6%). Regarding professional experience, most respondents had 6–10 years of practice (38.5%), while a smaller proportion had less than five years of experience (21.0%). These demographics reflect a workforce with moderate experience and a balanced gender profile, providing a representative sample of community pharmacy personnel in Mwanza City.

Table 1: Characteristics of Respondents and Pharmacies (N = 200)

Characteristic	Category	n/N (%)

Age of respondent	21-30 years	48/200 (24.0%)
	31- 40 years	116/200 (58.0%)
	41-50 years	28/200 (14.0%)
	≥51 years	8/200 (4.0%)
Gender	Male	127/200 (63.5%)
	Female	73/200 (36.5%)
Professional Cadre	Pharmacist	43/200 (21.5%)
	Pharmaceutical technician	82/200 (41.0%)
	Dispenser/assistant	75/200 (37.5%)
Pharmacy ownership	Private (independent)	162/200 (81.0%)
	Branch	38/200 (19.0%)
Location	Mwanza City Council	112/200 (56.0%)
	Ilemela Municipal Council	88/200 (44.0%)

Availability of Temperature-Sensitive Medicines

Based on direct observation, 168/200 (84.0%) pharmacies had at least one temperature-sensitive NCD medicine available at the time of the visit, with insulin the most frequently available product (142/200; 71.0%). Other temperature-sensitive NCD medicines, such as certain cardiovascular injectables, were stocked less often. This indicates that while insulin is widely accessible, the range of refrigerated NCD medicines remains limited.

Table 2: Availability of Temperature-Sensitive NCD Medicines in Community Pharmacies (N = 200)

Medicine	**Availability Definition**	**n/N (%)**
Any refrigerated medicine	At least one temperature-sensitive NCD medicine physically observed in stock	168/200 (84.0%)
Insulin	Insulin vials or pens physically observed in stock	142/200 (71.0%)
Other injectable cardiovascular medicine	e.g. digoxin, certain biologics requiring refrigeration	38/200 (19.0%)
Multiple refrigerated medicines	Pharmacies stocking ≥2 different temperature-sensitive NCD medicines	64/200 (32.0%)

Cold-Chain Storage Facilities

90.0% had a refrigerator designated for medicine storage, while 72.5% reported/observed exclusive use of the refrigerator for medicines, while the remainder also stored non-pharmaceutical items, potentially compromising medicine quality.

Table 3: Cold-Chain Infrastructure in Community Pharmacies (N = 200)

Infrastructure Component	Definition/Criteria	n/N (%)
Refrigerator present	At least one refrigerator observed on site	180/200 (90.0%)
Exclusive pharmaceutical use	Refrigerator used only for medicines	92/200 (46.0%)
Backup power supply	Generator or alternative power source available	78/200 (39.0%)
Temperature monitoring device	Thermometer or digital monitoring device present	104/200 (52.0%)
Temperature documentation	Written/electronic records of refrigerator temperatures	86/200 (43.0%)

	available	
Adequate cold-chain system	Refrigerator + monitoring device + documentation + backup power	64/200 (32.0%)

Temperature Monitoring and Documentation

Direct observation revealed that only 56% of pharmacies had a functional temperature-monitoring device, and just 55% maintained temperature records. Conversely, 44% lacked monitoring devices, and 45% did not retain records, highlighting a major gap in cold-chain management despite widespread refrigerator availability. Among those with monitoring devices, documentation practices were inconsistent, and many failed to record temperatures at recommended intervals. These highlight significant gaps in infrastructure and in compliance with good storage practices.

Table 4: Temperature Monitoring and Documentation in Community Pharmacies (N =200)

Indicator	**Criteria**	**n/N (%)**
Monitoring devices present	Thermometer or digital device observed in refrigerator	112/200 (56.0%)
Monitoring device absent	No thermometer or digital device observed	88/200 (44.0%)
Temperature records available	Written/ electronic records observed	110/200 (55.0%)
No temperature records	Records absent	90/200 (45.0%)

Discussion

The study revealed that 84% of pharmacies stocked refrigerated medicines, with insulin being the most common (71%). This is consistent with the 2023 Tanzania Service Availability and Readiness Assessment (SARA), which reported that insulin was generally available in urban facilities but often faced stockouts due to supply chain delays (Ministry of Health, 2024). Similarly, a 2024 study in Nyamagana District, Mwanza found that only 55.2% of pharmacies had refrigerators and just 35.2% had backup power systems, underscoring infrastructure weaknesses that compromise medicine quality (Mwita & Mutta, 2024).

Availability of Temperature-Sensitive Medicines

The study revealed that 84% of pharmacies stocked refrigerated medicines, with insulin available in 71%. This aligns with the 2023 Tanzania Service Availability and Readiness Assessment (SARA), which reported insulin as generally available in urban facilities, though subject to stockouts due to supply chain delays (Ministry of Health, 2024). Similarly, Mwita & Mutta (2024) found insulin present in most pharmacies in Nyamagana District, but other refrigerated medicines were inconsistently stocked. Regionally, studies in Kenya and Uganda report comparable patterns: insulin is prioritized, while other refrigerated NCD medicines are inconsistently supplied (Springer Nature, 2024). Globally, the WHO (2023) highlights persistent inequities in access to non-insulin refrigerated NCD medicines in resource-constrained settings.

Insulin's relatively high availability reflects its central role in diabetes management and established procurement systems, whereas cardiovascular injectables and biologics face weaker

demand and supply chain challenges. These findings suggest that while insulin availability in Mwanza City pharmacies is encouraging, the narrow cold-chain medicine portfolio may undermine comprehensive NCD management. Availability was assessed at a single time point and may not capture seasonal or supply-chain fluctuations.

Cold-Chain Infrastructure

Although 90% of pharmacies reported having refrigerators, only 46% used them exclusively for medicines, and 56% had monitoring devices. Just 55% maintained temperature records, and fewer than half had backup power systems. These findings echo Mwita & Mutta (2024), who reported that only 55.2% of pharmacies had refrigerators and 35.2% had backup power. Mathias et al. (2024) similarly noted poor monitoring and documentation practices in Tanzanian private pharmacies. In other low-resource settings, a human-centered design study in Kenya and Niger identified unreliable electricity and inadequate monitoring devices as major barriers (Springer Nature, 2024). Pharmacies often use refrigerators for mixed purposes, and monitoring devices are not consistently supplied or enforced. Documentation gaps reflect weak regulatory oversight and limited awareness among pharmacy personnel.

Without reliable monitoring, exclusive refrigeration, and backup power, the therapeutic quality of insulin and other refrigerated medicines is at risk. The study assessed the presence of devices and records but did not measure actual temperature ranges or record accuracy.

General Summary

This study aligns with other recent evidence suggesting that insulin availability is improving, but cold-chain infrastructure remains fragile. Addressing these gaps requires regulatory oversight, infrastructure investment, and training for pharmacy personnel to ensure compliance with good storage practices.

Conclusion

This study assessed the availability of temperature-sensitive NCD medicines and cold-chain storage facilities in community pharmacies in Mwanza City. Insulin was widely available, but other refrigerated NCD medicines were limited. While most pharmacies had refrigerators, many did not use them exclusively for medicines, and nearly half lacked monitoring devices or documentation. These findings highlight that availability alone is insufficient; reliable infrastructure and monitoring are essential to safeguard medicine quality. Strengthening procurement systems, regulatory oversight, and investment in cold-chain infrastructure are critical to ensure safe and equitable access to temperature-sensitive medicines.

List of Abbreviations

CVDs – Cardiovascular Diseases
FPC – Finite Population Correction
NCDs – Non-Communicable Diseases
PC – Pharmacy Council
STATA – Statistical Software for Data Analysis
TMDA – Tanzania Medicines and Medical Devices Authority
WHO – World Health Organization

Operational Definitions

Temperature-Sensitive Medicine: Medicines that require storage between +2°C and +8°C to maintain potency. In this study, this included insulin and selected injectable NCD medicines (e.g., certain cardiovascular injectables and biologics). Oral NCD medicines such as antihypertensives or statins were not classified as temperature-sensitive.
Cold-Chain Storage: The presence of a dedicated refrigerator for medicine storage, used exclusively or partially for pharmaceuticals. Cold-chain storage was considered adequate if refrigerators were observed on site and used for medicines, regardless of whether non-pharmaceutical items were also stored.
Availability: A medicine was considered "available" if it was physically observed in stock during the survey visit. Availability was not based solely on respondent report; direct observation was required to confirm presence.
Temperature Monitoring: The presence of functional thermometers or digital monitoring devices within refrigerators. Adequacy was defined as both the presence of a device and retention of temperature records.
Documentation: Availability of written or electronic records of refrigerator temperatures. Documentation was considered adequate if records were available and updated at recommended intervals.

Declarations

Ethical Considerations

Ethical approval for this study was obtained from the St. John's University of Tanzania Research Ethics Committee, and Administrative permission to conduct the study and access community pharmacies was separately obtained from the Tanzania Medicines and Medical Devices Authority (TMDA) and the respective local councils (Mwanza City Council and Ilemela Municipal Council). Written informed consent was obtained from all pharmacy personnel who participated in the interviews. Confidentiality was maintained by anonymizing responses and restricting data access to the research team.

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Congenital hyperinsulinism presenting as refractory neonatal hypoglycaemia: A case report from a tertiary neonatal unit in Tanzania

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Abstract

Introduction: Congenital hyperinsulinism (CHI) is the most common cause of persistent hyperinsulinaemic hypoglycaemia in neonates. It results from dysregulated pancreatic beta-cell insulin secretion independent of blood glucose, predisposing affected newborns to severe and recurrent hypoglycaemia with significant risk of irreversible neurological injury. Early recognition and targeted medical management are critical, yet CHI remains underdiagnosed in resource-limited settings across sub-Saharan Africa.

Case Presentation: We report a term female neonate with a birth weight of 4.5 kg delivered by Caesarean section for macrosomia, who presented on day two of life with neonatal convulsions and severe hypoglycaemia (blood glucose 2.1 mmol/L). Despite escalating glucose infusion rates (GIR) to 12.5 mg/kg/minute, empirical hydrocortisone therapy, and a single dose of glucagon, hypoglycaemia remained refractory. Hormonal investigations on day 15 of life confirmed congenital hyperinsulinism: serum insulin 4.3 µU/mL (non-suppressed during hypoglycaemia), serum C-peptide 1,043 pmol/L (markedly elevated), and serum cortisol <27 nmol/L. Oral diazoxide was initiated at 5 mg/kg/day and titrated with a prompt reduction in hypoglycaemic episodes. The infant was discharged after 32 days of hospitalisation on oral diazoxide with scheduled outpatient follow-up.

Conclusion: This case highlights the diagnostic and therapeutic challenges of CHI in resource-constrained settings and underscores the importance of early hormonal profiling in neonates with refractory hypoglycaemia. Diazoxide remains an effective first-line treatment for diazoxide-responsive CHI accessible in district and regional hospitals.

Keywords: Congenital hyperinsulinism, neonatal hypoglycaemia, diazoxide, macrosomia, Tanzania, resource-limited settings, C-peptide; glucose infusion rate

Introduction

Neonatal hypoglycaemia is one of the most commonly encountered metabolic emergencies in the newborn period, with a reported incidence of 1–5 per 1,000 live births globally (Adamkin, 2011). While transient hypoglycaemia is common and often self-limiting, particularly in infants of diabetic mothers, large-for-gestational-age (LGA) neonates, and those with perinatal asphyxia; persistent and recurrent hypoglycaemia demands a systematic aetiological evaluation to exclude pathological conditions (Thornton et al., 2015).

Congenital hyperinsulinism (CHI) is the most common cause of persistent hyperinsulinaemic hypoglycaemia in neonates and infants, with an estimated incidence of 1 in 25,000–50,000 live births in the general population and up to 1 in 2,500 in consanguineous populations (De Leon & Stanley, 2017). CHI results from dysregulated insulin secretion by pancreatic beta cells, independent of prevailing blood glucose levels. The most common genetic causes involve mutations in genes encoding the ATP-sensitive potassium channel subunits (KCNJ11 and ABCC8), with additional mutations identified in GLUD1, GCK, HADH, SLC16A1, and HNF1A, among others (Demirbilek & Hussain, 2017).

In sub-Saharan Africa, CHI is likely underdiagnosed due to limited availability of hormonal assays, genetic testing, and subspecialty paediatric endocrinology expertise (Yarhere & Jaja, 2023).

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Delayed diagnosis increases the risk of hypoglycaemic brain injury, neurodevelopmental delay, and death. Recognition of the clinical hallmarks of CHI, including macrosomia, early-onset convulsions, high GIR requirement exceeding 8 mg/kg/minute, absence of ketonaemia, and non-suppressed insulin during hypoglycaemia — is therefore critical for frontline clinicians in resource-limited settings (De Leon & Stanley, 2017; Stanley, 2016).

We report a case of CHI in a term macrosomic female neonate admitted to a tertiary neonatal intensive care unit (NICU) in Tanzania, who responded well to oral diazoxide following a prolonged diagnostic course. This case highlights key clinical lessons relevant to the paediatric and neonatal community in Africa. The objective of this case report was to describe the clinical presentation, diagnostic course, and successful management of congenital hyperinsulinism in a term macrosomic neonate at a tertiary neonatal unit in Tanzania, and to highlight practical diagnostic and therapeutic lessons for frontline clinicians managing refractory neonatal hypoglycaemia in resource-limited settings.

Case presentation

Patient information and history

A 2-day-old term female neonate (Baby B/O A.N.) was referred from the postnatal ward to the NICU following a convulsive episode associated with documented hypoglycaemia (date of admission: 24 April 2026; date of birth: 22 April 2026). The infant had been delivered by elective Caesarean section at 38 weeks gestation for macrosomia, with a birth weight of 4.5 kg (>97th centile for gestational age, classifying her as large-for-gestational-age). APGAR scores were 9 and 10 at one and five minutes, respectively, and the infant cried immediately after birth (Figure 1).

The convulsive episode occurred approximately six hours post-delivery. The seizure was characterised by sudden onset, lasted less than three minutes, and was associated with eye rolling, lip smacking, and focal jerking of the left upper limb. Concurrent random blood glucose (RBG) was 2.1 mmol/L, consistent with neonatal hypoglycaemia (defined as blood glucose <2.6 mmol/L in a symptomatic neonate). High-pitched crying and poor breastfeeding were noted from birth. There was no fever, jaundice, or cyanosis at presentation (Figure 2).

The mother was a 23-year-old primigravida university student (Para 1, Living 1) who attended six antenatal care contacts from 13 weeks gestation. She was PMTCT category 2, normotensive throughout pregnancy, with a haemoglobin of 13.4 g/dL and non-reactive VDRL. Blood group was O+. She received four doses of intermittent preventive treatment with sulfadoxine-pyrimethamine, anthelmintics, haematinics, folic acid, and two doses of tetanus toxoid. A history of recurrent urinary tract infections in the third trimester was noted. Critically, there was no history of diabetes mellitus (gestational or pre-existing) in the mother, no family history of neonatal hypoglycaemia, no history of CHI in siblings, and no known consanguinity.

The infant received BCG and OPV vaccines at birth.

Figure 1: Clinical photograph of the patient at admission to the NICU on day two of life. The neonate demonstrates macrosomic body habitus with birth weight 4.5 kg at 38 weeks gestation. The umbilical stump is dry and clamped. A peripheral intravenous cannula is visible on the left foot.

Figure 2: Clinical photograph showing the infant during the NICU admission, demonstrating the macrosomic physique and preserved level of alertness. Desquamation of the skin consistent with post-dates physiology in a term macrosomic neonate is visible.

Physical examination

On examination, the neonate was alert, afebrile (axillary temperature 36.8°C), not pale, not jaundiced, and not cyanosed. Vital signs: pulse rate 138 beats per minute, respiratory rate 56 breaths per minute, and oxygen saturation 94% on room air. Weight 4.5 kg. Neurological assessment demonstrated normal tone and posture, normal anterior fontanelle, diminished sucking reflex, and intact grasp reflex. Cardiovascular examination revealed warm extremities, capillary refill time less than two seconds, bounding peripheral pulses, and normal heart sounds (S1 and S2) with no murmur. Respiratory examination showed no signs of distress, with equal air entry bilaterally and vesicular breath sounds. Abdominal examination was unremarkable with a dry, clamped umbilicus and no hepatosplenomegaly.

Investigations

Initial RBG on admission was 2.1 mmol/L. Following an intravenous bolus of 10% dextrose, repeat RBG was 2.6 mmol/L. Despite nasogastric tube (NGT) feeding with expressed breast milk at 34 mL every three hours, two further hypoglycaemic episodes occurred within 24 hours of admission.

Serial haematological and biochemical parameters are summarised in Table 1. On day one, leucocytosis (WBC 23.47 × 10^9/L with neutrophilia 16.95 × 10^9/L) and a mildly elevated C-reactive protein (CRP 9 mg/L) raised concern for early-onset neonatal sepsis (EONS). Haemoglobin was consistently elevated (>18 g/dL), consistent with polycythaemia in a macrosomic neonate. A clinically significant hyponatraemia (serum sodium 115 mmol/L at 13:00 hours on day one) was identified and corrected over 12 hours with 0.3% sodium chloride infusion.

Table 1: Serial haematological and biochemical parameters during admission

Date	WBC (x10^9/L)	Neutrophils (x10^9/L)	Lymphocytes (x10^9/L)	Hb (g/dL)	Platelets (x10^9/L)	CRP (mg/L)	Na^+ (mmol/L)	K^+ (mmol/L)
24/04/2026	23.47	16.95	5.2	19.4	250	9	115 → 130*	7.9
27/04/2026	17.1	8.4	6.9	18.4	340	4	132	4.4
30/04/2026	20.5	6.3	13.8	18.3	314	4	131	4.6
04/05/2026	10.18	6.0	6.2	19.5	304	5	131	4.7

**Na^+ corrected from 115 to 130 mmol/L within 12 hours using 0.3% sodium chloride infusion. WBC = white blood cells; Hb = haemoglobin; CRP = C-reactive protein; K^+ = potassium.*

Hormonal profiling was performed on day 15 of life (06/05/2026) and yielded the following results: serum insulin 4.3 µU/mL (non-suppressed during hypoglycaemia; expected value during hypoglycaemia <2 µU/mL), serum C-peptide 1,043 pmol/L (markedly elevated, confirming autonomous endogenous insulin secretion), and serum cortisol <27 nmol/L (severely low). The co-existence of non-suppressed insulin and disproportionately elevated C-peptide during a documented hypoglycaemic episode was biochemically diagnostic of congenital hyperinsulinism.

Differential diagnoses

The differential diagnoses systematically considered during the admission are summarised in Table 2.

Table 2: Differential diagnoses considered during the clinical evaluation

Diagnosis	Clinical Reasoning and Status
Congenital Hyperinsulinism (CHI) — CONFIRMED	Elevated C-peptide (1,043 pmol/L), non-suppressed insulin during hypoglycaemia, macrosomia without maternal diabetes, GIR >12.5 mg/kg/min, refractory course. Diazoxide-responsive.
Adrenocortical Insufficiency	Serum cortisol <27 nmol/L supports this diagnosis; hydrocortisone trial produced minimal glycaemic response; may co-exist with CHI or reflect pituitary axis immaturity.
Congenital Hypopituitarism	Combined cortisol deficiency with persistent hypoglycaemia raises suspicion. Full anterior pituitary hormonal panel (TSH, GH, ACTH) was not feasible due to resource constraints.
Infant of Diabetic Mother (IDM)	Macrosomia and early hypoglycaemia consistent; however, maternal diabetes was excluded by antenatal screening. IDM hypoglycaemia is typically transient, resolving within 48 hours.
Early-Onset Neonatal Sepsis (EONS)	Initial leucocytosis (WBC 23.47 x10^9/L) and CRP 9 mg/L prompted empirical antibiotics. CRP normalised by day 3; sepsis cannot account for 32-day persistent hypoglycaemia.

Clinical course and management

On admission, an intravenous glucose infusion was commenced at a GIR of 4 mg/kg/minute via peripheral venous access. Over the subsequent 12 hours, three further hypoglycaemic episodes occurred, prompting escalation of GIR to 8 mg/kg/minute. Blood glucose values partially stabilised between 2.5–3.6 mmol/L over the following 24 hours. Attempts to wean the GIR below 4 mg/kg/minute resulted in recurrent hypoglycaemia (RBG 1.7–2.6 mmol/L). A central venous catheter was subsequently inserted, and the GIR was escalated to 12.5 mg/kg/minute alongside continuous NGT breast milk feeding, reducing hypoglycaemic episodes to two per 24 hours.

Recurrent seizures were managed with intravenous phenobarbitone. On day four of life, empirical intravenous hydrocortisone was administered over three days in view of the severely low serum cortisol; however, hypoglycaemia persisted. On day five, a single dose of intramuscular glucagon was administered as a bridging measure, resulting in a transient improvement in RBG (2.1–3.0 mmol/L) sustained for approximately 24 hours, after which hypoglycaemia recurred. Further glucagon doses were not administered due to financial constraints (Figure 3).

The infant was treated empirically for EONS with intravenous ampiclox (450 mg twice daily) and cefotaxime (225 mg twice daily) for seven days, with normalisation of inflammatory markers by day three.

Following receipt of hormonal profile results confirming CHI on day 15, oral diazoxide was commenced at 7.5 mg eight-hourly (22.5 mg/day total, approximately 5 mg/kg/day) administered in three divided doses. Clinical review the following day demonstrated a reduction in hypoglycaemic frequency. The dose was titrated to 14.5 mg eight-hourly over subsequent days, with maintenance of blood glucose ≥3.5 mmol/L. The GIR was progressively weaned and ultimately discontinued. The clinical management timeline is summarised in Table 3.

Table 3: Clinical course and management timeline

Day of life	GIR (mg/kg/min)	Key interventions / clinical events
Day 2 (admission)	4	IV 10% dextrose bolus; NGT breast milk 34 mL/3 hourly; IV ampiclox + cefotaxime commenced
Day 2–3	8	GIR escalated; RBG 2.5–3.6 mmol/L; 3 further hypoglycaemic episodes
Day 3–4	12.5	Central venous catheter inserted; GIR escalated; phenobarbitone for recurrent seizures
Day 4	12.5	IV hydrocortisone commenced (3-day empirical course); minimal glycaemic response
Day 5	12.5	Single-dose glucagon injection; transient RBG improvement 2.1–3.0 mmol/L for ~24 hours; further doses limited by financial constraints
Day 15	12.5	Hormonal profile: insulin 4.3 µU/mL, C-peptide 1,043 pmol/L, cortisol <27 nmol/L. CHI confirmed. Oral diazoxide 7.5 mg/kg/day 8-hourly (33.75 mg/day total, ≈11mg/dose) commenced.
Day 16—18	Weaning	Reduced hypoglycaemic episodes. Diazoxide titrated to 14.5 mg 8-hourly; GIR progressively weaned
Day 32 (discharge)	Nil	Discharged on oral diazoxide 14.5 mg 8-hourly; follow-up in 7 days; neurodevelopmental referral planned

Outcome and follow-up

The infant was discharged on day 32 of life (23 May 2026) in stable condition. At discharge she was alert, tolerating breast and formula milk feeding, and free of convulsions. She was discharged on oral diazoxide 14.5 mg eight hours with written instructions for home blood glucose monitoring. A follow-

up appointment was scheduled for seven days post-discharge. Plans were made for referral to a paediatric endocrinology centre for long-term management, genetic counselling, and assessment of potential co-existing hypopituitarism.

Figure 3: Additional clinical photograph of the patient during the NICU admission.

Discussion

This case report illustrates several key clinical and contextual lessons relevant to the management of CHI in resource-limited settings in sub-Saharan Africa.

First, macrosomia in a term neonate without maternal diabetes should strongly prompt consideration of CHI. Large-for-gestational-age neonates born to non-diabetic mothers who develop persistent hypoglycaemia represent a high-risk group in whom CHI must be systematically excluded.2,6 Unlike transient hypoglycaemia in infants of diabetic mothers, which typically resolves within 24–48 hours with feeding and dextrose supplementation, CHI-related hypoglycaemia is sustained and escalating (Arnoux et al., 2010; Rosenfeld et al., 2019).

Second, the requirement for a GIR exceeding 8 mg/kg/minute is a well-validated clinical marker of hyperinsulinism and should serve as a trigger for urgent hormonal profiling (Arnoux et al., 2010; De Leon & Stanley, 2017; Rosenfeld et al., 2019). In this case, the GIR requirement escalated to 12.5 mg/kg/minute before biochemical confirmation was obtained on day 15. While sequential exclusion of commoner diagnoses (sepsis, IDM, adrenal insufficiency) contributed to this delay, earlier diagnostic evaluation with a critical hormonal sample, including serum insulin, C-peptide, cortisol, and free fatty acids during a hypoglycaemic episode that could have shortened the diagnostic interval and potentially reduced the duration of neurotoxic hypoglycaemia exposure.

Third, the hormonal profile in this case was biochemically consistent with CHI. A serum insulin of 4.3 µU/mL during hypoglycaemia (expected value in normal physiology: <2 µU/mL) constitutes a non-suppressed insulin level.4 Co-existing with a markedly elevated serum C-peptide of 1,043 pmol/L, which is co-secreted with insulin in equimolar amounts and reflects autonomous beta-cell secretory activity. This profile confirms endogenous hyperinsulinism and excludes exogenous insulin administration (Lord & De León, 2013). The severely low serum cortisol (<27 nmol/L) raises the possibility of concomitant hypopituitarism or adrenocortical insufficiency, which can co-exist with CHI in syndromic forms of the condition, and warrants further investigation at a specialist centre.

Diazoxide, a potassium channel activator that inhibits pancreatic insulin secretion by opening ATP-sensitive potassium channels on beta cells, is recommended as first-line treatment for diazoxide-responsive CHI by the 2023 International Consensus Statement on the Diagnosis and Treatment of Hyperinsulinism (Galcheva et al., 2019). The standard starting dose is 5–15 mg/kg/day in two to three divided doses, titrated by glycaemic response (Arnoux et al., 2011). Response is defined as the ability to maintain normoglycaemia (blood glucose ≥3.5 mmol/L) for at least 12 hours without intravenous

glucose. In this case, diazoxide produced a clinically meaningful and rapid reduction in hypoglycaemic episodes, supporting a diazoxide-responsive phenotype, which is most commonly associated with mutations other than the KATP channel genes ABCC8 and KCNJ11 (Arnoux et al., 2011; Galcheva et al., 2019). Diazoxide-unresponsive CHI — typically caused by diffuse KATP channel mutations, requires escalation to somatostatin analogues (octreotide) or, ultimately, near-total pancreatectomy, which were beyond the diagnostic and surgical capacity of this centre (Khalil El Ouadghiri et al., 2025; Yarhere & Jaja, 2023).

Several resource-related challenges merit explicit discussion. Glucagon was limited to a single dose due to family financial constraints, precluding its use as sustained bridging therapy during the diagnostic phase. Genetic testing, [18F]-fluoro-L-DOPA PET scanning (used to differentiate focal from diffuse CHI prior to surgical intervention), and subspecialty paediatric endocrinology consultation were unavailable at this centre. These limitations have been similarly documented in case reports from Nigeria, Morocco, and other African contexts (Krawczyk et al., 2022; Yarhere & Jaja, 2023). Advocacy for inclusion of diazoxide on national essential medicines lists, establishment of regional referral pathways, and investment in neonatal endocrine diagnostic capacity are critical policy priorities.

The concurrent EONS diagnosis complicated the clinical picture, as hypoglycaemia is a recognised complication of neonatal sepsis. However, the rapid normalisation of inflammatory markers by day three — while severe hypoglycaemia persisted and escalated in its GIR requirement — directed clinical attention toward a primary metabolic aetiology. Clinicians should maintain a high index of suspicion for CHI even when concurrent sepsis is identified, particularly when hypoglycaemia is disproportionate to the severity of infection and persists beyond antimicrobial initiation.

Conclusion

Congenital hyperinsulinism should be considered in any term or near-term macrosomic neonate presenting with persistent or recurrent hypoglycaemia unresponsive to standard enteral feeds and glucose supplementation. A glucose infusion rate requirement exceeding 8 mg/kg/minute is a clinical red flag mandating urgent hormonal evaluation with a critical sample. Early biochemical profiling, including serum insulin, C-peptide, cortisol, and free fatty acids obtained during a hypoglycaemic episode is essential for confirmation of diagnosis and initiation of targeted therapy. Oral diazoxide is effective, accessible, and represents an appropriate first-line treatment for diazoxide-responsive CHI that can be initiated without specialist support. This case reinforces the urgent need for expanded access to neonatal hormonal assays, paediatric endocrinology expertise, and essential medicines in sub-Saharan Africa to reduce the preventable morbidity and mortality associated with this treatable condition.

Declarations

Ethics approval and consent to participate: This case report was approved by the Mbeya Regional Referral Hospital and no further Institutional Ethics Review was required. Written informed consent was obtained from the patient's parents/legal guardians prior to case documentation and publication.
Consent for publication: Written informed consent for publication of this case report and de-identified clinical photographs was obtained from the patient's parent/legal guardian.
Availability of data: All relevant clinical data supporting the findings of this case report are contained within this manuscript.
Competing interests: The authors declare that they have no competing interests.
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Response and lessons learned from Marburg Virus Disease outbreaks in Africa: A Systematic Review

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Abstract

Introduction: Marburg virus disease (MVD) is a highly virulent haemorrhagic fever caused by Marburg virus, with recurrent outbreaks across Africa associated with high case fatality rates (CFRs). Despite decades of outbreaks, comprehensive evidence on response strategies and lessons learned remains dispersed. This systematic review synthesizes available evidence on outbreak response, public health interventions, and lessons learned from MVD outbreaks in Africa from 1975 to 2025.

Methods: A systematic search was conducted in multiple databases to identify studies reporting MVD outbreaks and response measures in Africa. Studies were screened and data extracted on outbreak epidemiology, transmission dynamics, clinical and public health responses, community engagement, lessons learned, challenges, and policy implications.

Results: Twenty-three studies met inclusion criteria, spanning outbreaks in Uganda, Tanzania, Rwanda, Angola, Ghana, Equatorial Guinea, Kenya, and DRC. Outbreaks ranged from isolated cases to large epidemics, with CFRs between 21% and 100%. Transmission was predominantly through zoonotic spillover from Egyptian fruit bats, followed by human-to-human transmission via direct contact, unsafe caregiving, and traditional burial practices. Key response strategies included rapid case detection, isolation, contact tracing, infection prevention and control (IPC), risk communication, and coordinated multisectoral interventions. Persistent challenges included delayed outbreak recognition, limited laboratory capacity, weak surveillance, and socio-cultural barriers. Lessons learned emphasize the importance of early detection, strengthened IPC, healthcare worker protection, community engagement, and coordinated national and international response systems. Policy implications highlight the need for robust surveillance, rapid response teams, laboratory capacity, culturally sensitive risk communication, and regional collaboration to improve preparedness and mitigate future outbreaks.

Conclusion: Effective MVD outbreak response depends on integrated approaches combining robust surveillance, strong infection prevention and control, timely diagnostics, coordinated multisectoral action, and meaningful community engagement. Strengthening health system preparedness, enhancing laboratory capacity, and incorporating culturally sensitive communication strategies are critical for improving outbreak response and resilience in Africa.

Keywords: Marburg Virus Disease, outbreak response, lessons learned, Africa

Background

Marburg virus disease (MVD) is a severe, highly virulent haemorrhagic fever caused by the Marburg virus, a member of the Filoviridae family (WHO 2024). Since its first recognition in 1967, MVD has been

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associated with recurrent outbreaks in several African countries, including Angola, Uganda, the Democratic Republic of Congo (DRC), Kenya, Tanzania, Rwanda, Equatorial Guinea and Ghana (Mmbaga et al. 2024; Kinyenje, Hokororo, Ngowi, Kiremeji, Mnunga, Nagu, et al. 2024; Idris, Adesola, and D'Souza 2023; Sibomana and Kubwimana 2024; Gashugi et al. 2025; Adjei et al. 2025).

Case fatality rates (CRFs) have reached as high as 88% in some outbreaks, underscoring its significant epidemic potential and the substantial threat it poses to fragile health systems. Over the past decades, Africa has experienced multiple MVD outbreaks of varying magnitude and severity. Recent outbreaks in Uganda (Siya et al. 2019; Nyakarahuka et al. 2017; Mbonye et al. 2012), Angola (Jeffs et al. 2007), Tanzania (Bulimbe et al. 2023; Mmbaga et al. 2024; Kinyenje, Hokororo, Ngowi, Kiremeji, Mnunga, Nagu, et al. 2024), Equatorial Guinea (Oduoye et al. 2023) and Rwanda (Absolomon et al. 2025) have highlighted persistent vulnerabilities in outbreak preparedness and response.

These outbreaks have exposed critical gaps in early detection systems, surveillance infrastructure, laboratory capacity, infection prevention and control (IPC) practices, case management and risk communication strategies. Healthcare workers have frequently been disproportionately affected, reflection weaknesses in IPC implementation and occupational safety measures. Additionally, delayed case identification, limited community engagement, sociocultural practices, and mistrust in health authorities have contributed to sustained transmission in some settings.

Despite repeated outbreaks and growing global health attention, response effort across countries have varied considerably in speed, coordination, and effectiveness. While some outbreaks were rapidly contained through coordinated multisectoral actin, others were characterized by delayed recognition, high mortality, and strained health services. Lesson learned from these outbreaks remain dispersed across outbreak reports, observational studies, qualitative research, and grey literatures. To date, no comprehensive systematic review has been synthesized the available evidence on response measures and documented lessons learned from MVD outbreaks in Africa.

This systematic review therefore aims to synthesize existing evidence on response strategies and lessons learned from MVD outbreaks across Africa. Specifically, it seeks to answer the question: *How have African countries responded to Marburg virus disease outbreaks, and what lessons have been learned?* Through consolidating available evidence for over fifty years from 1st January 1975 to 31st July 2025, this review will provide an evidence-based understanding of surveillance systems, case management approaches, IPC measures, risk communication strategies, and preparedness mechanisms implemented during MVD outbreaks. The findings are expected to inform policymakers, public health practitioners, and health systems stakeholders by identifying best practices, persistent gaps, and context-specific strategies for strengthening preparedness and response to future MVD outbreaks in Africa.

Materials and Methods

Study design

This review was registered with PROSPERO (ID: CRD420251039508) and followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines.

Search Strategy

A comprehensive literature search was conducted in various databases. Eligible sources included journal articles and WHO reports. Keywords used in the search strategy included: Marburg Virus Disease (MVD), outbreak response, preparedness, lesson learned, and Africa. Boolean operators ("AND", "OR") were used to refine search combinations.

Eligibility criteria
Studies were included if they report MVD outbreaks in African countries, describe responses strategies, outbreak investigations, preparedness measures, or health system implication and provided lesson learned or recommendations for policy and practice. Studies focusing exclusively on laboratory virology without response implications were excluded.

Study selection
All identified records were imported into Covidence for screening and removing duplication. Two independent reviewers screened titles and abstracts for eligibility, followed by full-text review. Discrepancies were resolved through discussion between reviewer pairs.

Data extraction and quality checks
Data extraction was conducted using a standardized data extraction template developed to ensure consistency and completeness across all included studies. The template captures key information on study characteristics, outbreak context, methodological approaches, outbreak epidemiology, response strategies, and major findings.

Variables
Extracted variables included bibliographic information (authors, title, year of publication, source type and Digital Object Identifier (DOI), study objectives, study design, country and geographic location of the outbreak, year of the outbreak occurrence, study population, sample size where applicable. Detailed outbreak characteristics recorded including the number of cases, number of deaths, CRFs, index case description, primary mode of transmission, detection and surveillance mechanisms, laboratory diagnostic capacity, and the time from case detection to laboratory confirmation.

Information on response and intervention measures was also extracted, such as case management approaches, contact tracing strategies, IPC measures, community engagement activities, risk communication, and coordination mechanisms among national and international partners. Qualitative insights were documented, including cultural beliefs, traditional healing practices, key lessons learned, challenges encountered during outbreak response, best practices, policy implications, and research gaps identified in the studies.

Synthesis methods
Extracted data were organized and analysed according to key thematic areas. Seven, thematic areas were identified. They included outbreak epidemiology and context, transmission dynamics and risk factors, public health and clinical response strategies, community engagement and coordination, lessons learned, challenges and Policy and future preparedness implications. The synthesis involved tabulating results from included studies. Findings were then analysed descriptively across seven identified themes

Results
The study selection process is illustrated in **Fig 1** where a total of 22 studies met the selection criteria.

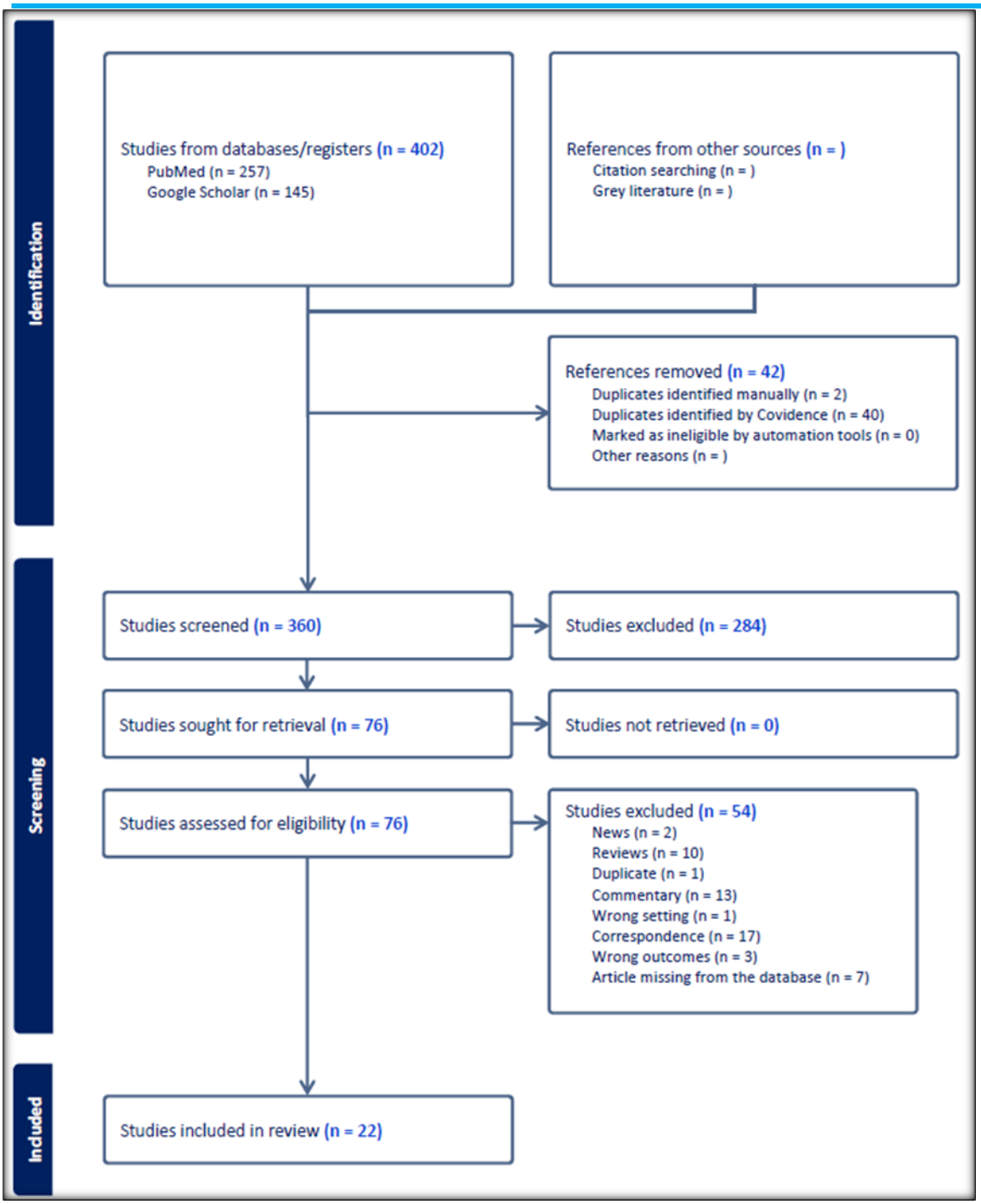

Figure 1: PRISMA diagram

Study Characteristics

Table 1 summarizes the characteristics of 23 studies included in this systematic review, spanning publications from 1982 to 2025 and covering multiple MVD outbreaks across Africa. The included studies demonstrate substantial diversity in geographical distribution, study design, outbreak magnitude, and reported outcomes. Majority of studies were conducted in East and Central Africa,

particularly Uganda, Tanzania, Rwanda and DRC. Angola and Equatorial Guinea were also represented. Uganda contributes to the highest number of studies, indicating both recurrent outbreaks and active documentation of response experience in the country. Outbreak periods ranged from 1980 in Kenya to 2025 in Tanzania and Rwanda. Majority of articles reviewed were qualitative by design (7/22) followed by case reports (6/22) and cross-sectional designs (5/22) while longitudinal and mixed method articles had 2 each. Reported outbreaks varied considerably, ranging from single confirmed cases in Uganda to large outbreaks in Angola in 2005 with 158 confirmed cases as well as in Rwanda in 2024 with 64 confirmed cases. Case fatality rates also varied widely, from 21% in Rwanda to 100% in isolated case reports in Uganda. Notably high CFRs were reported in Angola (88%) and multiple Tanzanian outbreaks (67%).

Table 1: Study characteristics

	Author (Year)	Country	Year of Outbreak	Study Setting	Study Type	Sample Size	Study Population	Total Confirmed/Probable/Suspected Cases	Total Deaths Reported	CFR (%)
1.	Absolomon (2025)	Rwanda	2024	Hospital	Observational study	N/A	General population	56 confirmed cases	12	21
2.	Adjei (2025)	Ghana	2022	Not stated	Qualitative study	10	Quarantined healthcare workers	N/A	N/A	N/A
3.	Adjemian (2011)	Uganda	2007	Mining setting	Case report	4	Miners	4 confirmed	1	N/A
4.	AgbohHNK (2024)	Ghana	2022	Hospital-based	Cross-sectional survey	15	Clinical and non-clinical health workers	N/A	N/A	N/A
5.	Borchert (2007)	DRC	1998–2000	Hospital-based	Longitudinal survey	48	Healthcare workers	6 confirmed	4	N/A
6.	Branda (2025)	Tanzania	2025	Community	Cross-sectional survey	N/A	General population	N/A	N/A	N/A
7.	Bühler (2014)	Sub-Saharan Africa (Angola, DRC, Uganda)	1995–2007 (Multiple FHF outbreaks)	Hospital-based	Qualitative study	40	Healthcare workers	N/A	N/A	N/A
8.	Colebunders (2004)	DRC	1999	Community	Observational study	N/A	General population	N/A	N/A	N/A
9.	Colebunders (2007)	DRC	1998–2000	Hospital-based	Cross-sectional survey	77	General population	51 confirmed; 26 probables	N/A	78
10.	Englert (2019)	Uganda	2000–2012	Hospital-based	Qualitative study	N/A	Healthcare workers	N/A	N/A	N/A
11.	Gashugi (2025)	Rwanda	Sept-24	Hospital	Report	64 cases	General population	64 confirmed	15	23
12.	Grolla (2011)	Angola	Apr–Jun 2005	Hospital	Cross-sectional survey	388 patients	General population	130 positive samples	N/A	N/A
13.	Jeffs (2007)	Angola	Mar–Nov 2005	Hospital	Cross-sectional survey	N/A	General population	158 confirmed	329	88

14.	Kinyenje (2024)	Tanzania	Mar–Jun 2023	Hospital	Observational study	N/A	Not specified	9 cases	6	67
15.	Knust (2015)	Uganda	Oct-12	Hospital & Community	Case report	N/A	General population	9 confirmed; 11 probables	15	58
16.	Mbonye (2012)	Uganda	Oct-12	Hospital	Case report	N/A	General population	14 confirmed; 5 probable; 11 suspected	7	50
17.	Mmbaga (2024)	Tanzania	Mar–Jun 2023	Hospital & Community	Case report	N/A	General population	8 confirmed; 1 probable	6	67
18.	Musyani (2025)	Tanzania	2023	Community & Hospital	Retrospective surveillance document review	N/A	General population	8 confirmed; 1 probable	6	67
19.	Nyakarahuka (2017a)	Uganda	2014	Community & Hospital	Case report	N/A	Not specified	1 confirmed	1	100
20.	Nyakarahuka (2017b)	Uganda	2007 & 2012	Community	Mixed methods	740	Adults	N/A	N/A	N/A
21.	Siya (2019)	Uganda	2017	Community-based	Cross-sectional qualitative study	60	Adult men and women (≥25 years) in farming & livestock communities	N/A	N/A	100*
22.	Smith (1982)	Kenya	1980	Hospital & limited community exposure	Outbreak investigation	2 confirmed cases; 207 contacts; 224 sera	Adults; healthcare workers; contacts	2 confirmed	1	50

Table 2 represents a thematic synthesis of response strategies implemented across African countries affected by Marburg virus disease, highlighting major responses and lessons learned. In general, it illustrates that successful MVD outbreak control depends on a comprehensive approach that integrates technical, social, and systemic components rather than isolated interventions. Across MVD outbreaks, 11, sub-thematic areas were identified. They included early detection, surveillance, and rapid response, IPC, health system preparedness and capacity building, community engagement and risk communication, cultural beliefs and practices, healthcare worker protection and psychosocial support, laboratory capacity and diagnostics, coordination, partnerships, and international support, one health and zoonotic risk management, research, innovation, and data systems as well as policy, preparedness, and health system resilience.

Findings have revealed that, lessons learned from MVD outbreaks are multidimensional, with strong interconnections across surveillance, health systems, and community-level factors. A consistent pattern across four out of twenty-two studies is that early detection and rapid response form the foundation of effective outbreak control. Delays in identifying index cases were repeatedly

associated with increased transmission and higher case fatality. The findings shows that IPC remains a cornerstone of outbreak management, particularly in preventing nosocomial transmission. Four articles (4/22) reported the importance of IPC, However, persistent gaps in IPC adherence, availability of personal protective equipment, and healthcare worker training indicate systemic weaknesses in resource-limited settings. These gaps are closely linked to broader issues of health system preparedness, where countries with prior outbreak experience or stronger infrastructure demonstrated more effective and coordinated responses.

Three out of twenty-two articles reported the central role of community engagement and risk communication. Trust, timely information sharing, and involvement of community actors such as community health workers significantly improved case detection, reporting, and adherence to control measures. At the same time, cultural beliefs and traditional practices, were reported in three out of 22 articles; they included burial rituals and reliance on traditional healers, which influenced transmission dynamics, emphasizing the need for culturally sensitive interventions rather than purely biomedical approaches. A total of three out of 22 articles indicated the importance of protecting healthcare workers, not only through IPC measures but also by addressing psychological stress, fear, and stigma, which can undermine response efforts.

Similarly (3/22), laboratory capacity and diagnostics emerge as critical enablers of rapid response, with innovations such as mobile laboratories significantly reducing turnaround time for case confirmation. Few articles (2/22) reported lessons learned about coordination and partnerships, particularly with international organizations such as World Health Organization (WHO) and Centres for Disease Control and Prevention (CDC). These organizations were consistently identified as essential for mobilizing resources, technical expertise, and logistics. The integration of One Health approaches highlighted the need to address zoonotic transmission at the human–animal–environment interface.

There were only two articles documented the integration of one health approaches. Strengthening research, innovation, and data systems is fundamental to improving Marburg Virus Disease outbreak response. Only 2 studies (2/22) studies showed that clinical documentation, standardized data collection tools, and real-time data sharing enhance the quality and usability of outbreak information, enabling more informed decision-making. Additionally, the integration of research during outbreaks, including the use of experimental therapeutics and operational research that supports the generation of critical evidence for improving case management and reducing mortality. Policy, Preparedness, and Health System Resilience was documented by 3 out of 22 articles as key for future outbreak prevention and control (**Table 2**).

Table 2: Thematic Synthesis of Lessons Learned from Marburg Virus Disease (MVD) Outbreaks

S/N	Sub-Theme	Description of Lessons Learned	Key References
1	Early Detection, Surveillance, and Rapid Response	Early identification of index cases, timely reporting, and rapid deployment of response teams were critical to limiting outbreak spread. Delays significantly increase transmission.	Vida Mmbaga et al., 2024; Atuganile Musyani et al., 2025; Barbara Knust et al., 2015; Luke Nyakarahuka et al., 2017
2	Infection Prevention and Control (IPC)	Strong IPC measures such as isolation, PPE, safe burials and hygiene were essential to prevent nosocomial transmission. Countries with prior outbreak experience or stronger infrastructure demonstrated more effective and coordinated responses.	Erick Kinyenje et al., 2024; Robert Colebunders et al., 2004; Marc Borchert et al., 2007; Barbara Knust et al., 2015

3	Health System Preparedness and Capacity Building	Prepared health systems with trained staff, equipped laboratories, isolation units, and emergency coordination systems improve outbreak outcomes. Prior outbreak experience strengthens response.	Yves Gashugi et al., 2025; Francesco Branda et al., 2025; Erick Kinyenje et al., 2024
4	Community Engagement and Risk Communication	Effective communication, community sensitization, and engagement of local leaders and CHWs enhanced trust, reporting, and adherence to control measures.	Herman Nuake Kofi Agboh et al., 2024; Atuganile Musyani et al., 2025; Francesco Branda et al., 2025
5	Cultural Beliefs and Practices	Cultural beliefs (e.g., witchcraft) and practices (e.g., burial rituals, traditional healing) influence transmission and care-seeking; integrating these into response strategies is crucial.	Aggrey Siya et al., 2019; Elizabeth Englert et al., 2019; Marc Borchert et al., 2007
6	Healthcare Worker Protection and Psychosocial Support	Protecting healthcare workers through PPE, training, and mental health support is essential; fear, stigma, and burnout can hinder response efforts.	George Adjeisah Adjei et al., 2025; Gashaija Absolomon et al., 2025; Marc Borchert et al., 2007
7	Laboratory Capacity and Diagnostics	Rapid diagnostics (PCR), mobile laboratories, and reduced turnaround time are critical for timely case confirmation and outbreak control.	Sylvain Grolla et al., 2011; D. H. Smith et al., 1982; Gashaija Absolomon et al., 2025
8	Coordination, Partnerships, and International Support	Strong national coordination and collaboration with partners (WHO, CDC, MSF) enhance technical capacity, logistics, and outbreak response effectiveness.	Robert Colebunders et al., 2004; Francesco Branda et al., 2025
9	One Health and Zoonotic Risk Management	Addressing zoonotic transmission through One Health approaches was essential, particularly in high-risk environments involving bats and human–animal interactions.	Aggrey Siya et al., 2019; Yves Gashugi et al., 2025
10	Research, Innovation, and Data Systems	Strengthening clinical data systems, documentation, and research (including experimental therapies) improves outbreak response and evidence generation.	Silja Bühler et al., 2014; Gashaija Absolomon et al., 2025
11	Policy, Preparedness, and Health System Resilience	Investment in surveillance, preparedness frameworks, IPC policies, and sustainable health systems is key for future outbreak prevention and control.	Francesco Branda et al., 2025; Erick Kinyenje et al., 2024; Vida Mmbaga et al., 2024

Discussion

This systematic review synthesizes evidence from 22 studies spanning over five decades on MVD outbreaks in Africa. This review has documented that, timely integration of surveillance, clinical care, IPC) and community interventions are important for effective outbreak control. Consistent with previous outbreak reports, the findings show that, although response capacity has improved over time. Persistence structural and sociocultural challenges continues to influence transmission dynamics and outcomes (Musyani et al. 2025; Kinyenje, Hokororo, Ngowi, Kiremeji, Mnunga, Samwel, et al. 2024; Mmbaga et al. 2024).

A key finding is the critical importance of early detection and rapid response. Delays in identifying index cases and initiating control measures were repeatedly associated with increased transmission and higher CFRs, particularly in setting with weak surveillance systems (Knust et al. 2015;

Mmbaga et al. 2024; Nyakarahuka et al. 2017). In contrast , countries with prior outbreak experience, such as Uganda, demonstrated more rapid and coordinated responses, highlighting the value of preparedness, institutional memory, and established rapid response systems (Nyakarahuka et al. 2017; Mbonye et al. 2012).

Infection prevention and control remains a cornerstone of MVD outbreak management, particularly in preventing nosocomial transmission. However, this review identified persistence gaps in IPC implementation, including inadequate PPE supply, limited training, and poor adherence to protocols (Colebunders et al. 2004; Borchert et al. 2007; Kinyenje, Hokororo, Ngowi, Kiremeji, Mnunga, Nagu, et al. 2024). These gaps contributed to the proportionate burden of infection among healthcare workers observed in several outbreaks. Strengthen IPC is one of the lessons learned as it is essential for patient safety and protects the healthcare workers during outbreaks.

Community engagement and risk communication emerged as equally critical component of outbreaks response. Studies consistently showed that, involving community leaders, community healthcare worker, and trusted local persons in the community improved early case reporting, adherence to control measures, and overall outbreak containment (Agboh, Adjei-Okai, and Adjei 2024; Branda et al. 2025; Musyani et al. 2025). Conversely, sociocultural practices such as traditional burial rituals, beliefs in supernatural causes of illness, and reliance on informal healthcare provides contributed to delayed care-seeking and sustained transmission (Englert, Kiwanuka, and Neubauer 2018; Siya et al. 2019; Borchert et al. 2007). These findings imply the need for culturally sensitive approaches that can integrate community perspective into Marburg virus disease response strategies.

Health system preparedness and capacity were also key determinants of outbreak outcomes. Countries with stronger infrastructure, including trained personnel, functional isolation units, and effective coordination mechanisms, demonstrated more efficient response and lower CFRs (Gashugi et al. 2025; Kinyenje, Hokororo, Ngowi, Kiremeji, Mnunga, Nagu, et al. 2024). In contrast, weak health systems were associated with delayed detection, inadequate case management, and higher mortality. Laboratory capacity further influenced response effectiveness, with rapid diagnostic tools and mobile laboratory significantly reduced turnaround time for case confirmation and facilitating timely isolation (Grolla et al. 2011; Absolomon et al. 2025).

The importance of coordination and partnership was evident. Multisectoral collaboration involving governments and international partners such as the WHO and CDC and Prevention enhanced technical capacity, logistics, and overall response effectiveness (Colebunders et al. 2004; Branda et al. 2025). However, reliance on external support is some settings highlights the need for sustainable national capacity building and stronger health system ownership. It was noted that, the integration of One Health approaches and research system remains limited despite the zoonotic nature of MVD. Only few studies highlighted the importance of addressing transmission at the human-animal-environment interface, particularly in relation to exposure to Egyptian fruit bats (Siya et al. 2019; Gashugi et al. 2025). Similarly, embedding research within outbreak responses such as operational research, standardized data systems and evaluation of experimental therapeutics, was identified as an important but underutilized strategy for improving evidence-based decision-making (Absolomon et al. 2025).

This systematic review has important policy and practice implications particularly on strengthens surveillance systems, including community-based surveillance as essential component of early detection. Investing in IPC systems and healthcare workers protection should be prioritized as part of health system resilience. Risk communication strategies must be culturally appropriate and community-driven to build trust and improve compliance. Furthermore, regional collaboration and cross-border preparedness mechanisms are critical given the transboundary nature of MVD outbreaks. Despite these contributions, this review has limitations. The heterogeneity of included studies,

variations in methodological approaches, and inconsistent reporting limited by the ability to perform quantitative synthesis. Additionally, reliance on published literature may have excluded relevant insights from grey literature and outbreak reports on captured in indexed databases. Underreporting of outbreaks, particularly in earlier decades, may also affect the completeness of the evidence.

Conclusion

This systematic review highlights that, lessons learned from MVD outbreaks in Africa are interconnected across surveillance, health system, and community domains which call for a need to have a comprehensive and integrated response approach in place prior to outbreak occurrence. Early detection and rapid response are fundamental, as delays in identifying index cases consistently lead to increased transmission and higher mortality, emphasizing the importance of strengthening surveillance systems such as community-based detection and rapid laboratory confirmation. Infection prevention and control remains a critical yet inconsistently implemented component, with gaps in PPE availability, training, and adherence contributing to health care workers infection and nosocomial spread. Protecting healthcare workers both physically and psychologically is therefore a key priority.

Community engagement and culturally sensitive risk communication are essential for improving trust, timely reporting, and adherence to control measures. Neglecting local beliefs and practices, such as traditional burial rituals, can sustain transmission. Health system preparedness, including trained personnel, functional isolation units, and diagnostic capacity, has been documented to significantly influence outbreak outcomes. Decentralized and mobile laboratory systems further improve the timeliness of case confirmation.

Coordination and partnership enhance resource mobilization and technical capacity, although reliance on external support highlights the need for stronger national ownership and sustainability. Integrating One Health approaches and strengthening research and data systems remain underutilized but critical for addressing zoonotic risks and supporting evidence-based decision-making. Collectively these findings reinforcing that effective MVD outbreak control depends on resilient heath systems, coordinated action, and strong community involvement.

Declaration

The authors have nothing to declare.

Author contributions

BE: Conceptualization and drafted the manuscript, MC: data screening, extraction and manuscript review, ED: data screening and extraction, AJ: data screening and extraction, GPM: data screening and extraction, AML; extraction and manuscript review. All authors have read and approved the final manuscript.

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Competing interests
None declared.

Ethical approval
Not applicable.

Data availability
All data supporting the findings of this systematic review are derived from published studies and publicly available sources included in the review. The datasets generated and analysed during the current study are available from the corresponding author upon request.

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Evaluation of Product Quality Management Practices of Regional Prime Vendors: Compliance, Shelf-Life, and Supply Consistency. A Case Study of Tanga Region

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Abstract

Introduction: Health is a fundamental determinant of quality of life and depends on strong infrastructure, reliable pharmaceutical supply chains, adequate financing, skilled health workers, and evidence-based policies. In Tanzania, despite reforms from a push to a pull supply-chain model, healthcare facilities continue to experience medicine stock-outs, limited budgets, and procurement inefficiencies. When medicines are unavailable at the Medical Stores Department (MSD), facilities often rely on private suppliers, resulting in higher costs and increased administrative burdens. To address these challenges, the Government introduced the Prime Vendor System (PVS), known as *Mshitiri*, which was piloted in Dodoma in 2011 and scaled nationally in 2018 to complement MSD. The system aimed to improve procurement efficiency, transparency, affordability, and medicine availability.

Methods: This cross-sectional analytical study assessed product quality management practices among Prime Vendors in Tanga Region. A total of 277 respondents, including pharmacists, laboratory personnel, facility in-charges, and other healthcare workers, participated. Data were collected through structured questionnaires and documentary reviews. The Prime Vendor Performance Index (PVPI) assessed product quality, order fulfillment, shelf-life compliance, delivery lead time, delivery-point compliance, and communication.

Results: Findings demonstrated high compliance with procurement and contractual requirements. About 99.28% of respondents confirmed that procurement was initiated only after MSD reported stock-outs, while 91.34% reported adherence to bimonthly procurement cycles. Product quality was also rated highly: 91.3% reported that medicines were free from physical damage, 93.9% confirmed clear labeling, and 93.5% confirmed that expiry dates and batch numbers were clearly indicated. Shelf-life management was generally effective, with 88.81% reporting that they had never received expired medicines and 70.40% confirming that near-expiry products were replaced. Spot checks of tracer commodities further showed over 90% compliance in packaging, labeling, and shelf-life requirements.

Conclusion: Overall, the findings indicate that the Prime Vendor System has strengthened medicine availability and quality assurance in Tanga Region. High compliance with procurement procedures, product integrity, and shelf-life standards demonstrates that PVS is a viable complement to MSD. Continued monitoring, enforcement of minimum shelf-life requirements, and sustained quality assurance are recommended to maintain and improve the system's long-term effectivenes

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Introduction

Health is universally recognized as a fundamental determinant of quality of life, dependent on strong infrastructure, dependable supply chains, adequate financing, and evidence-based policies. In Tanzania, the Ministry of Health underscores that sustainable health outcomes require integrated systems that combine infrastructure, financing, and research-supported practices (Tanzania 2025)

In Low- and Middle-Income Countries (LMICs), pharmaceutical supply chains have emerged as a critical component of health system strengthening. International partners such as USAID emphasize strategies including financial support, staff training, improved procurement and distribution, and enhanced data transparency to promote efficiency and accountability (Fenta 2016). Reliable access to essential commodities, pharmaceuticals, diagnostics, and medicines aligned with national treatment guidelines is a prerequisite for patient trust and attendance at health facilities (MoHCDGEC 2017).

Tanzania's supply chain has transitioned from a push to a pull model, yet systemic challenges persist. Frequent stock-outs at facilities level, limited facility budgets, and inefficiencies in end-to-end management continue to undermine service delivery (Tanzania 2017). When out of stock is observed, facilities procure from private vendors, incurring high transactional costs and facing risks of inefficiency and non-transparency (Mbwasi et al. 2022).

To address these gaps, the Government introduced the Prime Vendor System (PVS), locally known as *Mshitiri*, as a complementary mechanism to MSD. Piloted in Dodoma in 2011 and scaled nationwide in 2018, PVS has demonstrated improvements in procurement efficiency, cost reduction, and transparency (Kuwawenaruwa et al. 2021). In 2021, the President's Office for Regional Administration and Local Government (PORALG) directed regions to establish four procurement lots to strengthen resilience and mitigate risks of MSD stock-outs

Materials and Methodology

Study Design

This study adopted an analytical cross-sectional design with a quantitative approach. The design was appropriate as it enabled the assessment of Prime Vendor (PV) practices and performance indicators across multiple health facilities in the Tanga Region between January and December 2025 and data collection period were from May to June 2026. By capturing data at a single point in time, the cross-sectional approach facilitated measurement of relationships between vendor practices and system performance indicators without variable manipulation.

Study Population

The study population consisted of health facilities in the Tanga Region that actively procure commodities through the Prime Vendor System (PVS), including the Regional Referral Hospital, councils hospitals, health centers, and dispensaries. Participants were drawn from healthcare workers directly engaged in supply chain functions such as facility in-charges, pharmacists, storekeepers, laboratory personnel, radiographers, procurement officers, and other staff working in pharmacy or store sections, as well as suppliers and vendors, specifically regional vendor contract managers and supply chain officers. These groups were deliberately included because they represent the core stakeholders in the supply chain ecosystem and are directly responsible for the operationalization and performance of the PVS. (Kuwawenaruwa et al. 2021) (Wiedenmayer et al.

2019). These studies support the inclusion of health facilities and healthcare workers and justify the inclusion of vendors and contract managers.

Sample Size and Sampling

The sample size was calculated using Cochran's formula for proportions, with parameters set at a 95% confidence interval (Z = 1.96), maximum variability (p = 0.5), and a margin of error of 5% (e = 0.05). Substituting these values yielded an initial sample size of $n_0 = 384$. Given that the total number of public health facilities in the Tanga Region represents a finite population (N), the finite population correction (FPC) was applied to adjust the sample size accordingly. After applying the correction and incorporating a 10% allowance for non-response, the final sample size was determined to be 277 respondents. This sample was proportionally distributed across councils and facility levels to ensure representativeness of the Regional Referral Hospital, district hospitals, health centers, and dispensaries (Cochran 1977).

Study Approach

The study deployed a quantitative research approach. Before data collection, informed consent was obtained, and strict confidentiality protocols were followed. Ethical clearance was secured from St. John's University.

Data collection and data processing

In May 2026, enumerators were trained for three days to ensure the tools' validity, followed by pre-testing in three facilities of Chamwino District Council in Dodoma Region.

A face-to-face interview was conducted from May to June 2026 with all purposefully selected respondents using a guided and constructive questionnaire containing both open-ended and closed-ended questions. All quantitative data were electronically collected using the ODK application, where data collectors entered the information/data they collected directly into the Tablet using the electronic tool. The ODK application allowed online and offline data entry with GPS coding. Also, documentary evidence was reviewed for the period of January-December 2025. This ensured accuracy and efficiency in data capture.

Dependent Variables

The dependent variable for this study was the Prime Vendor Performance Index (PVPI), a composite measure constructed from the PVS Monitoring Framework. The index was expressed as a percentage score (0–100%) and derived from weighted indicators reflecting key dimensions of vendor performance. The indicators and their respective weights were: product quality (25%), order fulfillment (40%), shelf-life compliance (10%), delivery lead time (15%), delivery point compliance (5%), and communication quality (5%). This composite index provided a standardized and measurable outcome variable for assessing vendor performance across facilities. Based on the PVPI score, facilities were categorized into four performance levels: Excellent (95–100%), Good (80–94%), Satisfactory (65–79%), and Poor (<65%). This classification enabled systematic comparison of vendor practices and facilitated interpretation of performance trends across the study population.

Independent Variables

The independent variables were defined and operationalized based on the Prime Vendor System (PVS) Monitoring Framework. Product Quality Management was measured as the compliance of supplied commodities with physical, labeling, and shelf-life standards, expressed through a quality score (0–25%) and shelf-life compliance rate. Order Fulfillment Practices captured the extent to which ordered items were delivered fully and accurately, measured by the fulfillment rate (%). Delivery Performance assessed the timeliness of deliveries relative to contractual lead times, measured in average delivery days. Finally, Communication Practices reflected responsiveness, transparency, and documentation quality, measured using a communication index score. These constructs provided quantifiable dimensions of vendor practices, enabling systematic analysis of their influence on the Prime Vendor Performance Index (PVPI).

Data Analysis

Data were analyzed using Binary Logistic Regression to identify factors associated with the perceived positive impact of the Prime Vendor System (PVS) on medicine availability, with logistic regression selected due to the categorical nature of the dependent variable (positive vs. negative impact). Independent variables included delivery lead time, product quality at delivery, and communication practices, and results were reported as Odds Ratios (OR) and Adjusted Odds Ratios (AOR) with 95% confidence intervals. Quantitative data were cleaned and validated in Microsoft Excel and analyzed using SPSS Version 25, where descriptive statistics such as means, standard deviations, frequencies, percentages, fulfillment rates, and lead-time averages were generated and presented in tables and graphs to illustrate patterns of vendor practices. A weighted scoring system was applied to construct the Prime Vendor Performance Index (PVPI), while inferential analysis included Pearson correlation and multiple linear regression to examine relationships between variables. Statistical significance was set at $p < 0.05$.

Results

A total of 277 health workers participated in the study. The majority (57.8%) were aged 31–40 years, followed by 25.3% aged 18–30 years, while 17.0% were above 40 years. By sex, 63.5% were male and 36.5% female. Nearly half (49.8%) had 1–5 years of professional experience, 27.1% had more than 15 years, 15.5% had 6–10 years, and 7.6% had 11–15 years of experience. In terms of facility type, 53.1% of respondents were from health centers, 33.2% from district council hospitals, 11.2% from dispensaries, and 2.5% from the regional referral hospital. Regarding professional cadres, pharmacists constituted the largest group (21.7%), followed by laboratory personnel (19.1%) and health facility in-charges (18.8%). Health secretaries accounted for 9.8%, procurement officers 8.7%, while the remaining 22.0% comprised other support cadres involved in supply chain and inventory management.

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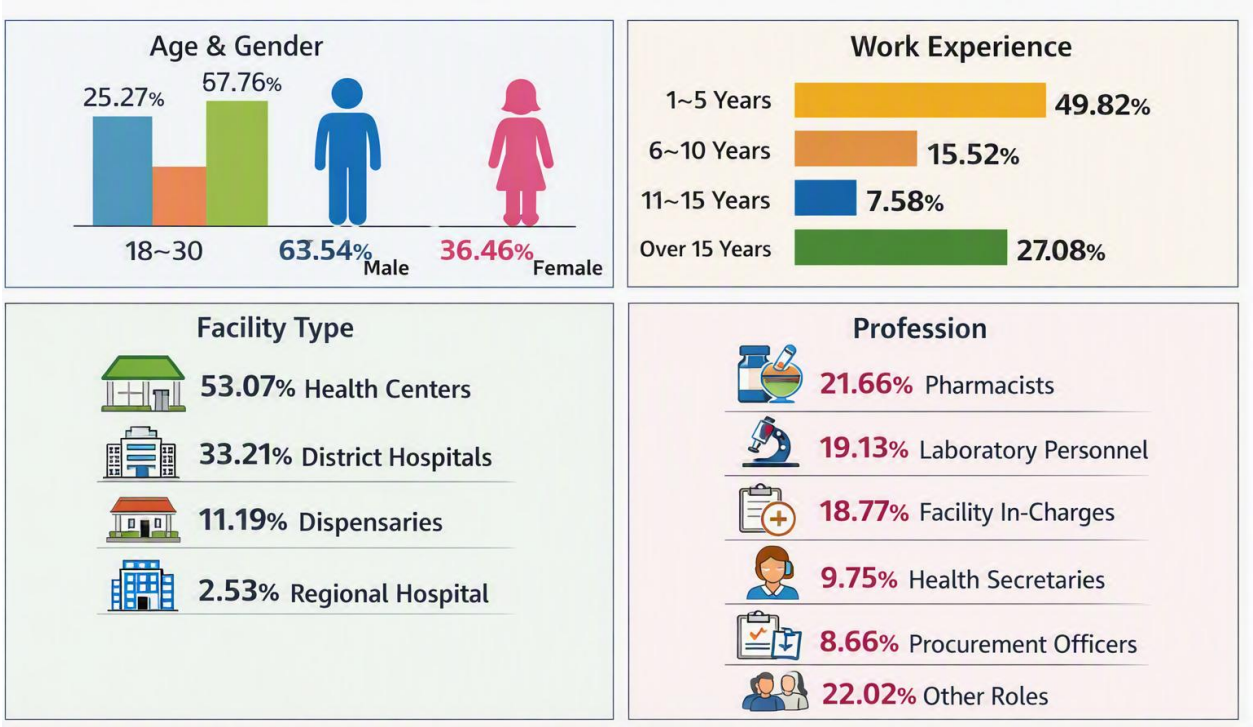

Figure 1; *Demographic of Study Respondents (N= 277)*

The demographic distribution revealed a predominantly young workforce, with 57.76% of respondents aged 31–40 years, suggesting a group likely adaptable to innovations such as the electronic procurement system (NeST). The gender composition, 63.54% male and 36.46% female, reflects the historical gender balance within Tanzania's health supply chain professions. Analysis of aggregate data showed no significant differences in the experience of the Prime Vendor System (PVS) across gender or professional roles, indicating that operational challenges and successes are uniformly experienced throughout the workforce. The high representation of pharmacists (21.66%) and laboratory personnel (19.13%) underscores that the primary users of the PVS are those most directly responsible for inventory management and quality assurance, reinforcing the system's relevance to technical cadres central to supply chain performance.

Table 1: *Respondents' General Information (n=277)*

Variable	Frequency	Percent (%)
Age		
18-30	70	25.27
31-40	160	57.76
>40	47	16.97
Sex		
Male	176	63.54
Female	101	36.46
Experience category		
1-5	138	49.82
6-10	43	15.52
11-15	21	7.58

>15	75	27.08
Facility Type		
Regional Referral Hospital	7	2.53
District Council Hospital	92	33.21
Health Centre	147	53.07
Dispensary	31	11.19
Role of the Respondent		
Pharmacist	60	21.66
Laboratory personnel	53	19.13
Health Facility In-Charge	52	18.77
Health Secretary	27	9.75
Procurement Officer	24	8.66
Other	61	22.02

The Product Quality Management Practices of Prime Vendors

This section presents findings that sought to evaluate the product quality management practices of Prime Vendors. The analysis focused on key dimensions of vendor performance, including procurement and compliance practices, physical product quality at the point of delivery, shelf-life management, and quality assurance and handling procedures. These components collectively provide insight into how effectively Prime Vendors uphold product integrity and regulatory standards throughout the supply chain, ensuring that commodities delivered to health facilities meet acceptable quality and safety requirements.

Procurement and compliance practice

The results demonstrate strong compliance with product quality management practices among Prime Vendors. Nearly all respondents (99.28%) reported that procurement was initiated only after notification of stock unavailability from the Medical Stores Department (MSD), and 91.34% confirmed adherence to the approved quarterly procurement cycle. Procurement quantities were determined using both facility consumption data and stock status information (98.92%), while 99.28% affirmed compliance with contract specifications. Importantly, all respondents (100%) indicated that commodities supplied were registered and approved by the Tanzania Medicines and Medical Devices Authority (TMDA), underscoring consistent adherence to regulatory standards.

Table 2: Procurement and compliance practice (n=277)

Variable	No n (%)	Yes. n (%)
Health commodities are procured from the Prime Vendor only after receiving an Out-of-Stock (OS) notification from MSD	2(0.72)	275(99.28)
Orders to the Prime Vendor follow the approved quarterly procurement cycle	24(8.66)	253 (91.34)
Procurement quantities are based on both facility consumption data and stock status data.	3(1.08)	274(98.92)
All supplied commodities must comply with the specifications stated in the Prime Vendor contract	2(0.72)	275(99.28)
The Prime Vendor supplies commodities that are registered and approved by TMDA for use in Tanzania	0(0.00)	277(100.00)

Physical Product Quality at the Delivery Point

The findings indicate strong agreement among respondents regarding the physical quality of commodities supplied by Prime Vendors. A majority (91.3%) agreed or strongly agreed that medicines delivered were free from physical damage such as breakage, leakage, or cracks, while only 1.8% expressed disagreement. Similarly, 88.5% confirmed that packaging materials adequately protected products during transportation, with minimal disagreement reported. Product labeling was also positively rated, with 93.9% agreeing or strongly agreeing that labels were clear, readable, and correctly written according to guidelines. In terms of batch numbers and expiry dates, 93.5% of respondents affirmed that these details were clearly indicated, with only 0.4% disagreeing. Regarding product integrity, 91.3% agreed or strongly agreed that medicines showed no observable changes in color, smell, or form, while 1.1% disagreed. For medical supplies such as gloves, gauze, and intravenous fluids, 93.1% of respondents agreed or strongly agreed that they met acceptable physical quality standards, with disagreement reported by less than 1%.

Table 3: Physical Product Quality at Delivery Point (n = 277)

Variable	SDSAGR	DSAG	Neutral	AGR	SAGR
	n (%)	n (%)	n (%)	n (%)	n (%)
Delivered medicines are free from physical damage (breakage, leakage, cracks)	2(0.72)	3(1.08)	19(6.86)	163(58.84)	90(32.49)
Packaging materials adequately protect products during transportation	1(0.36)	4(1.44)	27(9.75)	164(59.21)	81(29.24)
Labels are clear, readable, and correctly written as per guidelines	2(0.72)	0(0.00)	15(5.42)	163(58.84)	97(35.02)
Batch numbers and expiry dates are clearly indicated on all products.	0(0.00)	1(0.36)	17(6.14)	154(55.60)	105(37.91)
There are no observable changes in the color, smell, or form of medicines supplied	0(0.00)	3(1.08)	21(7.58)	167(60.29)	86(31.05)
Medical supplies (gloves, gauze, fluids) meet acceptable physical quality standards	0(0.00)	2(0.72)	17(6.14)	179(64.62)	79(28.52)

Shelf-Life Management Practices

The findings revealed that the majority of respondents (88.81%) reported never receiving expired medicines from the Prime Vendor, while 11.19% indicated that they had. With respect to medicines supplied with less than six months of remaining shelf life, 33.21% of respondents acknowledged receiving such commodities, whereas 66.79% had not. Regarding replacement practices, 70.40% of respondents stated that expired or near-expiry products were replaced upon notification, while 29.60% reported that replacements were not provided.

Tanzania Journal of Health Research
Volume 27: Issue 5 (2026) https://dx.doi.org/10.4314/thrb.v27i5.14

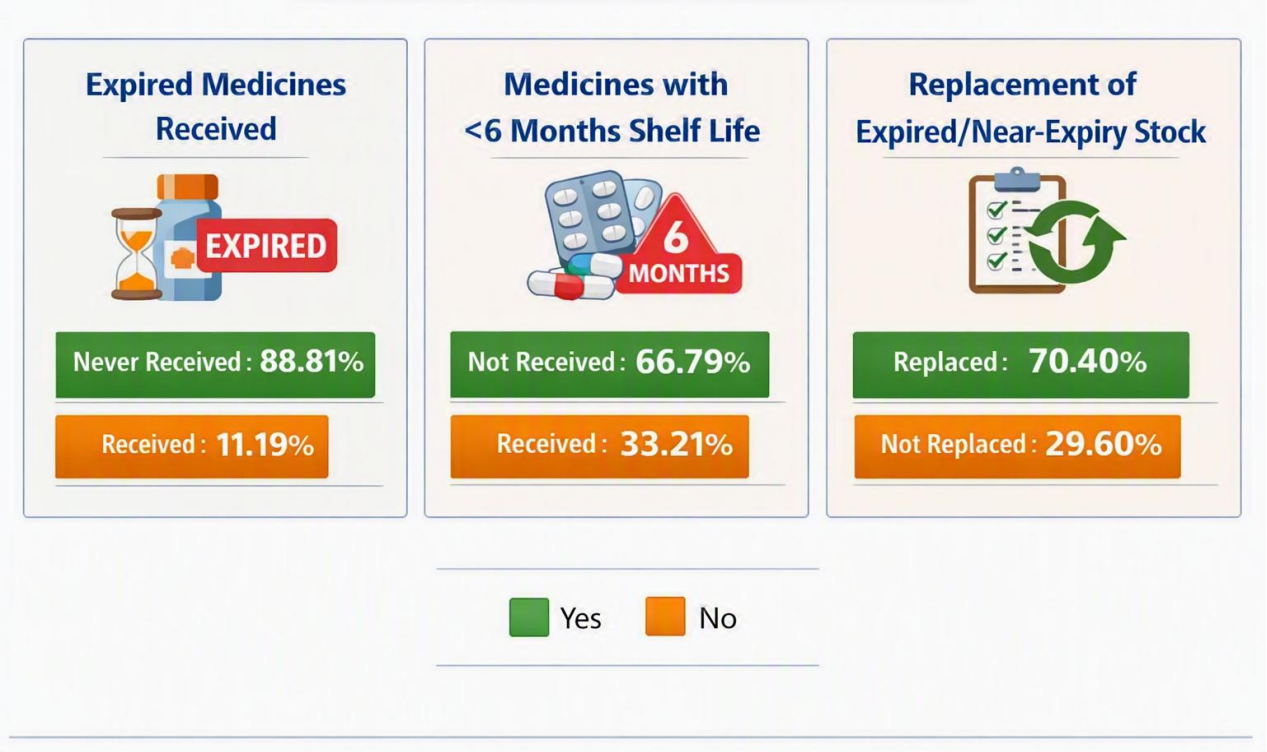

Figure 2: Shelf- Life Management Results (N= 277)

Practice Assessment

The results show that most respondents agreed the Prime Vendor consistently supplies medicines with adequate remaining shelf life, with 60.7% agreeing and 20.9% strongly agreeing. A smaller proportion (16.6%) remained neutral, while only 1.8% expressed disagreement. On the reliability of shelf-life information, 65.0% agreed and 26.0% strongly agreed that the information provided was accurate, with 7.9% neutral and less than 1.1% disagreeing.

Regarding the effect of shelf-life issues on medicine availability, 57.0% agreed, and 16.3% strongly agreed that such issues rarely affected availability. Neutral responses accounted for 16.6%, while 10.1% disagreed.

Table 4: Practice Assessment — Shelf-life Implementation (n = 277)

Variable	SDSAGR	DSAG	Neutral	AGR	SAGR
	n (%)	n (%)	n (%)	n (%)	n (%)
The Prime Vendor consistently supplies medicines with adequate remaining shelf life	3(1.08)	2(0.72)	46(16.61)	168(60.65)	58(20.94)
Shelf-life information provided by the Prime Vendor is accurate and reliable	2(0.72)	1(0.36)	22(7.94)	180(64.98)	72(25.99)
Shelf-life issues rarely affect medicine availability	12(4.33)	16(5.78)	46(16.61)	158(57.04)	45(16.25)

at this facility					

Quality Assurance & Handling Practices

The findings indicate that most respondents perceived strong adherence to appropriate transportation and quality assurance practices by Prime Vendors. A majority (78.7%) agreed or strongly agreed that medicines were delivered under suitable transportation conditions, while only 5.4% expressed disagreement. For cold-chain commodities, 60.3% of respondents agreed or strongly agreed that deliveries included evidence of temperature control, though 23.8% remained neutral and 15.9% disagreed. Regarding the resolution of reported quality issues, 71.9% agreed or strongly agreed that such issues were addressed promptly, with 23.8% neutral and 4.3% disagreeing. Similarly, 66.1% of respondents confirmed the existence of clear procedures for reporting product quality problems, while 24.6% were neutral and 9.4% disagreed.

Table 5: Quality Assurance & Handling Practices (n = 277)

Variable	SDSAGR	DSAG	Neutral	AGR	SAGR
	n (%)	n (%)	n (%)	n (%)	n (%)
Medicines are delivered under appropriate transportation conditions	4(1.44)	11(3.97)	44(15.88)	167(60.29)	51(18.41)
Cold-chain products are delivered with evidence of temperature control	16(5.78)	28(10.11)	66(23.83)	117(42.24)	50(18.05)
Quality issues reported to the Prime Vendor are resolved on time	2(0.72)	10(3.61)	66(23.83)	150(54.15)	49(17.69)
There are clear Procedures for reporting product quality problems	5(1.81)	21(7.58)	68(24.55)	141(50.90)	42(15.16)

Product Spot-Check (Tracer Items)

The findings revealed consistently high compliance with product quality standards across all tracer items. For Amoxicillin and Co-trimoxazole, most respondents rated packaging, physical appearance, labeling, and shelf-life as "mostly" or "full" compliance, exceeding 90% in each category. Similar patterns were observed for Paracetamol and Diclofenac, with over 90% of respondents reporting "mostly" or "full" compliance in packaging, labeling, and shelf-life. Benzyl Penicillin and Ceftriaxone injections also demonstrated strong performance, with the majority rating all quality indicators within the "mostly" and "full" categories. For fluids (Ringer's Lactate, D5%, and Normal Saline), compliance remained high, with more than 90% of respondents indicating "mostly" or "full" adherence to packaging and physical quality standards. Overall, responses across all tracer items confirmed that Prime Vendors consistently met acceptable product quality benchmarks, with minimal reports of non-compliance.

Table 6: Product Spot-Check on Tracer Items (n = 78)

Variable	Non	Minimal	Partially	Mostly	Full
	n (%)	n (%)	n (%)	n (%)	n (%)
Quality of Packaging for Amoxicillin Caps, Syrup, DT / Co-trimoxazole Tabs, Syrup	3(3.85)	2(2.56)	2(2.56)	27(34.62)	44(56.41)
Physical Appearance/ Color change for Amoxicillin Caps,	3(3.85)	1(1.28)	1(1.28)	29(37.18)	44(56.41)

Syrup, DT / Co-trimoxazole Tabs, Syrup					
Labels and Labelling for Amoxicillin Caps, Syrup, DT / Co-trimoxazole Tabs, Syrup	4(5.13)	1(1.28)	1(1.28)	31(39.74)	41(52.56)
Shelf-life remaining at time of delivery for Amoxicillin Caps, Syrup, DT / Co-trimoxazole Tabs, Syrup	5(6.41)	1(1.28)	1(1.28)	29(37.18)	42(53.85)
Quality of Packaging for Paracetamol Tabs, Syrup/ Diclofenac Tabs & Injection	4(5.13)	1(1.28)	2(2.56)	29(37.18)	42(53.85)
Physical Appearance/Color change for Paracetamol Tabs, Syrup/ Diclofenac Tabs & Injection	4(5.13)	1(1.28)	1(1.28)	30(38.46)	42(53.85)
Labels and Labelling for Paracetamol Tabs, Syrup/ Diclofenac Tabs & Injection	4(5.13)	1(1.28)	2(2.56)	28(35.90)	43(55.13)
Shelf-life remaining at time of delivery for Paracetamol Tabs, Syrup/ Diclofenac Tabs & Injection	4(5.13)	0(0.00)	1(1.28)	30(38.46)	43(55.13)
Quality of Packaging for Benzyl Penicillin Injection/ Ceftriaxone Injection	4(5.13)	1(1.28)	2(2.56)	27(34.62)	44(56.41)
Physical Appearance/Color change for Benzyl Penicillin Injection/ Ceftriaxone Injection	4(5.13)	1(1.28)	0(0.00)	31(39.74)	42(53.85)
Labels and Labelling for Benzyl Penicillin Injection/ Ceftriaxone Injection	4(5.13)	1(1.28)	1(1.28)	29(37.18)	43(55.13)
Shelf-life remaining at time of delivery for Benzyl Penicillin Injection/ Ceftriaxone Injection	4(5.13)	1(1.28)	0(0.00)	31(39.74)	42(53.85)
Quality of Packaging for Fluids (RL, D5%& NS)	5(6.41)	1(1.28)	1(1.28)	29(37.18)	42(53.85)
Physical Appearance/ Color change for Fluids (RL, D5%& NS)	5(6.41)	1(1.28)	1(1.28)	27(34.62)	44(56.41)
Labels and Labelling for Fluids (RL, D5%& NS)	5(6.41)	1(1.28)	0(0.00)	29(37.18)	43(55.13)
Shelf-life remaining at time of delivery for Fluids (RL, D5%& NS)	5(6.41)	1(1.28)	1(1.28)	31(39.74)	40(51.28)
Quality of Packaging for Gloves/ Cotton wool/ Gauze	3(3.85)	1(1.28)	0(0.00)	33(42.31)	41(52.56)
Physical Appearance/ Color change for Gloves/ Cotton wool/ Gauze	2(2.56)	1(1.28)	0(0.00)	32(41.03)	43(55.13)
Labels and Labelling for Gloves/	2(2.56)	1(1.28)	1(1.28)	30(38.46)	44(56.41)

Cotton wool/ Gauze					
Shelf-life remaining at time of delivery for Gloves/ Cotton wool/ Gauze	2(2.56)	1(1.28)	0(0.00)	32(41.03)	43(55.13)

The results are presented across four dimensions of product quality management practices. Procurement and compliance practices showed near-universal adherence (≥99%), physical product quality at delivery was consistently rated above 91% agreement, shelf-life management practices demonstrated strong compliance with 88.81% reporting no expired medicines, and quality assurance procedures showed 78.7% agreement on appropriate transportation and 71.9% agreement on timely resolution of issues. Spot checks confirmed tracer item compliance above 90% across packaging, labeling, and shelf-life indicators.

Discussion

Procurement and Compliance Practices: The study findings demonstrate that procurement from Prime Vendors was largely initiated following notification of stock unavailability from the Medical Stores Department (MSD), and that procurement adhered to quarterly cycles and contractual specifications. This reflects the system's alignment with national procurement regulations and the Public Procurement Act, ensuring transparency and accountability in medicine acquisition. Such compliance is consistent with the Prime Vendor System Implementation Manual (2022), which emphasizes adherence to approved procurement cycles and contract management to safeguard public funds and ensure timely supply

Physical Product Quality at Delivery: Respondents overwhelmingly agreed that medicines delivered were free from physical damage, adequately packaged, and properly labeled, with clear batch numbers and expiry dates. These findings highlight the robust quality assurance mechanisms embedded in vendor contracts and monitored by regional health authorities. Evidence from the Jazia Prime Vendor System pilot in Dodoma confirms that vendor supplies were of assured quality, with packaging and labeling standards comparable to those of the Medical Stores Department (Wiedenmayer et al. 2023)

Shelf-Life Management Practices: The majority of respondents reported never receiving expired medicines, though some noted receipt of products with less than six months of shelf life. Importantly, most facilities confirmed that expired or near-expiry commodities were replaced upon notification. This practice reflects adherence to quality assurance and risk mitigation protocols, ensuring that medicines supplied remain safe and effective throughout their use. The Prime Vendor System guidelines mandate shelf-life monitoring and replacement mechanisms to maintain confidence in the supply chain.

Quality Assurance and Handling Procedures: Respondents indicated strong agreement that medicines were delivered under appropriate transportation conditions, including cold-chain monitoring for temperature-sensitive products. Furthermore, most agreed that reported quality issues were resolved promptly, and that clear reporting procedures were in place. These findings underscore the importance of accountability and vendor responsiveness, which have been identified as critical success factors in the performance of the Jazia Prime Vendor System (Kuwawenaruwa et al. 2020)

Product Spot Check: The spot check findings revealed consistently high compliance with product quality standards across tracer items, with the majority of respondents rating packaging, physical appearance, labeling, and shelf-life as either "mostly" or "full" compliance. These results suggest that Prime Vendors are effectively maintaining product integrity at the point of delivery, which is critical for ensuring patient safety and sustaining trust in the supply chain. Comparable evaluations of the Jazia Prime Vendor System in Dodoma similarly reported high compliance with packaging and labeling standards, reinforcing the reliability of vendor-managed procurement in Tanzania (Mikkelsen-Lopez et al. 2014)

Conclusion

This study demonstrates that Prime Vendors in Tanga Region consistently uphold product quality management practices, with compliance rates exceeding 90% across procurement, product integrity, and labeling standards. Shelf-life management was effective, as 88.81% of respondents reported never receiving expired medicines and 70.40% confirmed replacements for near-expiry commodities. Quality assurance practices were also strong, with 78.7% agreement on transportation conditions and 60.3% agreement on cold-chain monitoring. Spot check results confirmed tracer item compliance above 90% in packaging, labeling, and shelf-life. Collectively, these findings reinforce the Prime Vendor System as a reliable complement to MSD, strengthening medicine availability and trust in the supply chain. Sustained monitoring and stricter enforcement of shelf-life thresholds are recommended to ensure long-term effectiveness.

List of Abbreviations

MSD – Medical Stores Department
PVS – Prime Vendor System
TMDA – Tanzania Medicines and Medical Devices Authority
PMORALG – Prime Minister's Office Regional Administration and Local Government
PORALG – President's Office – Regional Administration and Local Government
GDP – Good Distribution Practices
PVPI – Prime Vendor Performance Index
RL – Ringer's Lactate
NS – Normal Saline

Declaration

Ethical Consideration

Ethical clearance was obtained from St John's University of Tanzania. Permission from the Regional Administrative Secretary of Tanga for data collection was given. Written informed consent was sought from all participants before data collection. Confidentiality and anonymity were observed, and voluntary participation was enhanced. Data are securely stored and used solely for academic purposes.

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Development of a Patient Safety Model for Independent Midwifery Practice Implementation

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Abstract

Introduction: Patient safety is a key concern in independent midwifery practices in Indonesia, especially in regions like Tangerang that face contextual and systemic limitations. These include decentralized governance, limited infrastructure, and professional isolation, which collectively compromise the quality of maternal and newborn care. The purpose of this research is to analyze the available patient safety models and frameworks in the practice of midwifery as well as ascertain the critical matters to patient safety to assist in forming a tailored model of separate midwifery practices for Indonesian midwives.

Method: This study applied a Systematic Literature Review (SLR) using PRISMA 2020 guidelines. From 24,342 initial records retrieved from Scopus, 25 studies were selected based on their relevance to patient safety models in midwifery, following a structured screening and eligibility assessment process.

Result: Findings revealed persistent and interrelated challenges such as high psychological burden among midwives, non-adherence to clinical protocols, limited access to evidence-based practice (EBP) resources, inadequate interprofessional communication, cultural insensitivity, and fragmented care. While existing models, such as resilience frameworks, continuity of care approaches, and structured communication tools, have demonstrated effectiveness in high-resource settings, their applicability in Indonesia is limited by contextual misalignment, resource constraints, and regulatory fragmentation.

Conclusion: The study emphasizes the urgent need for a regionally adapted patient safety model that integrates culturally sensitive, community-based approaches with enhanced access to EBP, structured collaboration across healthcare actors, and resilience-building strategies for midwives. By aligning global best practices with local realities, this model offers a practical framework for improving safety outcomes in independent midwifery care and ensuring maternal and neonatal well-being in decentralized healthcare systems.

Keywords: patient safety, midwifery, safety models, Indonesia

Introduction

Patient safety in midwifery has become an urgent global concern, particularly in independent practices such as those in Tangerang, Banten Province, where decentralized governance, limited infrastructure, and professional isolation pose unique risks to care quality (Finnajakh, Maharani and Lestari, 2021; Elliott-Mainwaring, Phillips and Bowie, 2023). The circumstances unfolding here can be illuminated by the Swiss Cheese Model of accident causation as mentioned by Reason (2000), which portrays patient safety failures as arising from several overlapping protective strata, including clinician competencies, established safety procedures, system-level resources, and mechanisms of patient transfer. Research conducted in India (Khapre, Naik and Mudey, 2015) and Nepal (Marasini, Shrestha and Chaudhary, 2023) documents significant deficiencies in the occupational health and safety expertise and implementation among health care personnel. Non-

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physician cadres frequently interpret OHS in strictly protective terms, show limited familiarity with infection control committees, and generally undervalue chemical and ergonomic risks. Although the utilisation of personal protective equipment is widespread, adherence is typically driven by directive orders instead of an understanding of the underlying hazards; moreover, the valuation of protective gear shows divergent levels of endorsement among occupational groups, and incidents that compromise safety are routinely underreported.

Other literature in OHS scope, such as Fadhel and Alqurs (2025) emphasises that the construction of a robust safety model is a multidimensional challenge, necessitating the convergence of strategic leadership and Total Quality Management (TQM). In hospitals constrained by limited resources, these dimensions become pivotal for the deployment of occupational health and safety (OHS) practices. The findings indicate that the safeguarding of patients and healthcare workers is contingent not merely upon adherence to clinical guidelines but equally upon the articulation of the organisational mission, the sophistication of managerial systems, and the iterative cycle of quality enhancement.

Midwives' safety and performance face intertwined challenges, from low PPE compliance due to resource and cost barriers (Mirong et al., 2023), to performance gains linked with strong OHS measures (Iskamto et al., 2020), heightened risks in conflict areas without legal protection (Putri & Afifah, 2024), and rapid post-training knowledge decline (Bardosono et al., 2018), underscoring the complex, multifaceted nature of developing an effective patient safety model.

Although numerous patient safety models have been developed internationally, their effectiveness remains context-dependent, as highlighted by Eri et al. (2020), who emphasized the need for woman-centered and locally adaptable frameworks. A study conducted by Herlina et al. (2021) in Bogor showcased the effectiveness of a custom model within a tailored intervention that enhanced midwives' safety-related competencies, illustrating the need for interventions to be aligned with national standards of practice. Also, models such as the UK Professional Midwifery Advocate (PMA) from Whatley (2022) which combine supervision and staff support offer valuable solutions that could be modified for Indonesian conditions to assist midwives located in regions of relative professional solitude. In this study, there are two reserch qestions addressed.

1. What existing patient safety models and frameworks are currently applied in midwifery practice?
2. What are the main challenges affecting patient safety in independent midwifery practice?

Therefore, this systematic literature review aims to address and analyze key safety issues and existing frameworks in order to provide region-specific recommendations for their improvement towards the incorporation of comprehensive enhancement mechanisms for maternal newborn care in independently practiced midwifery in Tangerang.

Method

In this systematic literature review (SLR) performed within the framework of PRISMA 2020 (Page *et al.*, 2021), it aimed to identify, screen, and assess peer-reviewed literature on patient safety models in midwifery. A comprehensive search using "patient AND safety AND model AND midwifery" as keywords was conducted in the Scopus database which yielded 24,342 records initially. The phrase "midwifery" narrowed down the results to 49 articles; from these, 25 were deemed eligible after relevance assessment, full-text evaluation and eligibility verification. Only those studies addressing model development or evaluation concerning midwifery safety were considered while ignoring non-empirical, non-peer-reviewed works.

Data were extracted regarding authorship, publication year, location, safety challenges presented in the practice setting, type of models pertaining to the study's methodology, implementation steps taken towards applying them., and limitations provided by the authors. This enabled comparability among existing patient safety models and their suitability for independent midwifery practices situated in areas such as Tangerang, Indonesia. The synthesis is proposed as a

starting point for developing a region-specific model designed for the operational realities of Praktik Mandiri Bidan.

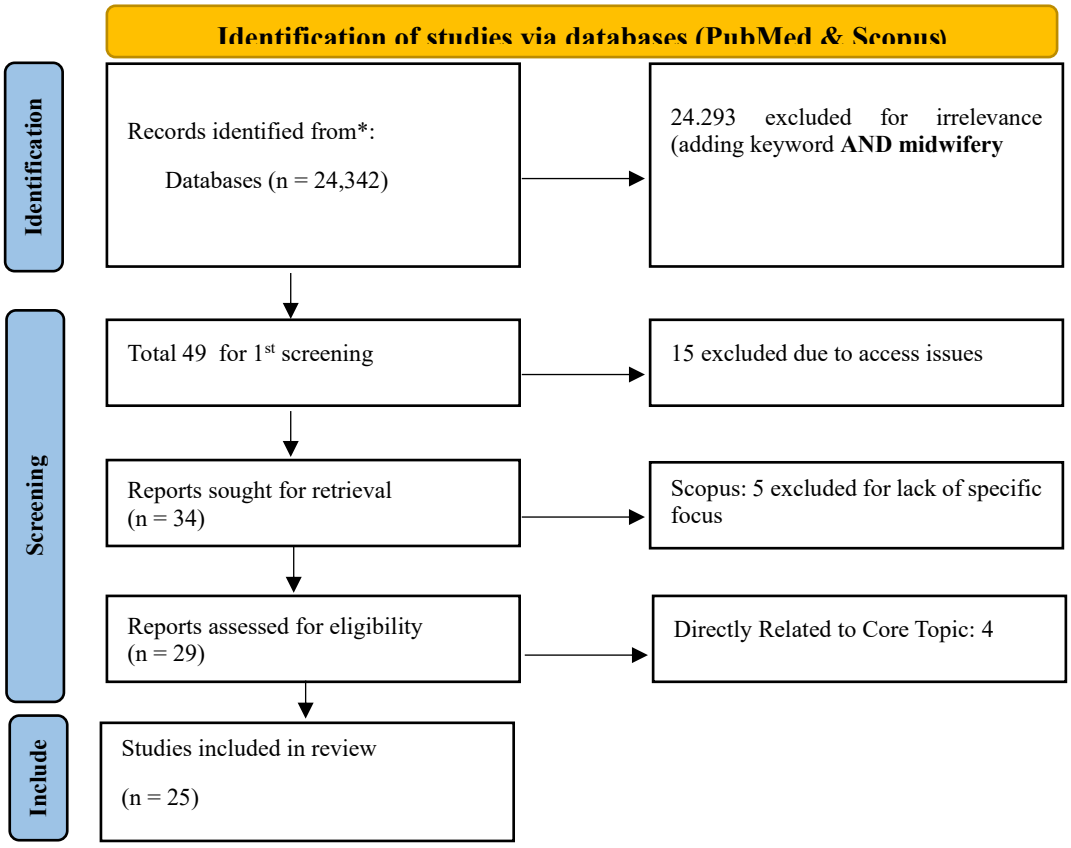

Figure 1. Screening Process Using Prisma

Results

The 25 studies investigated are shown in Table 1. The Table is constructed to provide a detailed comparative overview of existing studies that explore patient safety within the context of midwifery care. Its central aim is to consolidate varied academic insights into a coherent, accessible format that allows readers to trace the trajectory of empirical and theoretical advancements in this field. Each row in the table represents a specific study, capturing not only its research objective and context but also the specific safety challenges it addresses, ranging from stress-related risks and communication failures to policy implementation gaps and structural inequities. This layout supports a thematic understanding of how patient safety issues are experienced and managed across different healthcare systems, from acute care hospitals in Australia to community-based midwifery services in the UK and Ethiopia.

In addition, the table shows what models or frameworks have been used or developed in each study based on resilience psychology, communication theory, or principles of continuity of care. Including methodological details like whether a study used cross-sectional surveys, realist evaluations, or mixed methods approaches enables the table to capture appreciation of how patient safety models are formulated and tested in different settings. This is especially important for scholars and practitioners who want to adapt or replicate successful interventions in comparable settings such as Indonesian independent midwifery practices. Moreover, the comparison of implementation strategies demonstrates how each model is translated into policies

or programs including training programs, digital tools, community engagement, and interdisciplinary collaborations.

Alongside demonstrating the existing models, the table also addresses concerns and gaps highlighted by the original authors, which include generalizability issues, infrastructural limitations, low response rates, cultural dissonance, and restricted applicability of certain frameworks in specific socio-political contexts. The documentation of these constraints encourages self-reflection on the part of the user rather than mindlessly accepting models as a "given" and invokes deeper engagement with submitted works which is vital for areas like Tangerang which face resource constraints clinically diverse cultures, along with fragmented healthcare systems characterized by centralized politics or southern governance structures demanding context-tailored customized strategies instead of "off-the-shelf" solutions.

Ultimately, this table performs more than a descriptive function, it is an analytical tool that distills a body of literature into actionable insights for the development of a new, locally grounded patient safety model. It demonstrates how existing evidence can inform the design of an adaptive framework that acknowledges the realities of independent midwifery practice while drawing from global innovations. The inclusion of outcomes and implementation strategies helps to illuminate pathways for future research and policy design, bridging theory and practice. As such, Table 1 not only supports the academic rigor of the systematic literature review but also enhances its practical relevance for healthcare stakeholders aiming to improve maternal and newborn safety through evidence-based, scalable, and culturally aligned models.

Table 1. Overview of Studies Used

Author/ Year	Purpose of Study	Research Context	Challenges Identified	Existing Models/Frameworks
(Elliott and Fry, 2021a)	To explore psychological capital of nurses/midwives and its impact on patient safety attitudes	Acute health facilities, Sydney, Australia	High stress linked to adverse events; resilience impacts patient safety	Psychological Capital Questionnaire (PCQ-24), Safety Attitudes Questionnaire (SAQ)
(Whybrow *et al.*, 2020)	To assess implementation of antenatal hypertension guidelines and identify strategies for reducing severe hypertension and related morbidity	Multicenter study in NHS hospitals, UK	Non-adherence to antihypertensive medication; lack of patient education; inconsistency in BP target setting	NICE Hypertension in Pregnancy Guidelines (2010)
(Rayment-Jones *et al.*, 2023)	To identify mechanisms in midwifery care that reduce or exacerbate health inequalities for women with social risk factors	UK NHS settings with continuity models of care in community and hospital-based midwifery	Stigma, discrimination, perceived paternalistic and surveillance-based care	UK's NHS Long Term Plan for continuity of care
(Taye *et al.*, 2024)	To assess the implementation of evidence-based practice (EBP) in midwifery and factors associated with it	Public hospitals, Central and South Gondar Zone, Ethiopia	Limited EBP resources, lack of training, poor internet access	None directly referenced, focused on EBP practices
(Fox *et al.*, 2023)	To assess nurse practitioners' views on registered nurse	Healthcare facilities in Australia, focusing	Concerns about role overlap, patient	Health Professionals Prescribing Pathway (HPPP)

	prescribing in a partnership model	on RN-NP partnerships	safety, and risk of medication errors	
(Tai *et al.*, 2024)	To analyze the role of inherent requirements (IRs) in supporting or limiting diversity in nursing and midwifery education	Australian universities offering nursing/midwifery courses	IRs create barriers for diverse students, particularly those with disabilities	Inherent Requirements of Nursing Education (IRONE)
(Fletcher *et al.*, 2019)	To explore pregnant women's preferences for birth settings in England	National survey conducted with pregnant women in England	Limited access to various birth settings; desire for partner's overnight stay and higher baby safety	No specific models reviewed; focused on discrete choice experiments for preference analysis
(McCalman *et al.*, 2024)	To explore experiences of First Nations women in culturally tailored continuity of midwife care	Three maternity services in Victoria, Australia	Lack of cultural safety, fragmented care, and unresponsive systems	RISE framework, "Birthing on Country"
(Cummins *et al.*, 2024)	To evaluate the Midwifery Antenatal and Postnatal Services (MAPS) model and its alignment with Quality Maternal Newborn Care framework	Six maternity sites in New South Wales, Australia	Limited knowledge of MAPS; challenges in continuity of care for intrapartum period	Quality Maternal Newborn Care (QMNC) framework
(Christianson, Lehn and Velandia, 2022)	To develop a gender ethics protocol to address gender-related ethical dilemmas in midwifery	Midwifery ethics context, primarily focused on structural and individual ethical dilemmas	Power imbalance in healthcare, lack of gender-focused ethics in midwifery	Gender Ethics Model for Midwifery (GEMM)
(Hall *et al.*, 2023)	To identify health system factors promoting positive childbearing experiences	Public health system in Australia	Fragmented care, lack of continuity, and need for respectful, individualized care	Quality Maternal and Newborn Care (QMNC) framework
(Turienzo *et al.*, 2021)	To assess experiences of care among women at increased risk of preterm birth receiving continuity of midwifery care vs. standard care	POPPIE pilot trial in the UK, with women at risk of preterm birth	Limited midwifery support, lack of continuity in standard care	Continuity of Midwifery Care model, with specific risk group inclusion
(Dencker *et al.*, 2020)	To validate a revised childbirth experience questionnaire (CEQ2) focusing on decision-making and midwifery support	Maternity settings, Gothenburg, Sweden	Limited midwifery support and decision-making inclusion; variation in childbirth experiences	Original Childbirth Experience Questionnaire (CEQ)
(Lippke *et al.*, 2019)	To examine the impact of communication on patient safety in gynecology and obstetrics	Two maternity clinics in Germany	High risk of preventable adverse events (pAEs) due to communication errors	Health Action Process Approach (HAPA) and SACCIA model

(Offerhaus *et al.*, 2020)	To compare outcomes of caseload midwifery care vs. regular midwife-led care	Midwifery in the Netherlands, focusing on continuity of care	Higher referral rates in regular care, fragmented care	Cochrane MLCC model, with focus on continuity

Challenges of Patient Safety

Patient safety in midwifery practice is a fundamental issue, especially in independent diverse healthcare environments. Ensuring safe, high-quality care for women and newborns necessitates tackling several difficulties, including the management of high-risk medical conditions and the promotion of efficient communication and continuity of care. In recent years, patient safety models in midwifery have concentrated on addressing these challenges through systematic frameworks, protocols, and cooperative practices. Nonetheless, the efficacy and adaptability of these models may differ markedly due to restrictions such as resource limitations, population heterogeneity, and compliance issues. This study examines the significant problems in patient safety in midwifery, evaluating how current models strive to reduce risks and improve treatment quality as it could be seen in Table 2.

Table 1 in this study serves as a structured synthesis of previous research efforts that have explored various dimensions of patient safety in midwifery care. The inclusion of this table is intended to contextualize the discussion by mapping how different studies, across diverse settings such as Australia, the UK, Ethiopia, and the Netherlands, have investigated safety issues, responded to those issues through theoretical models or frameworks, and assessed their impact. By summarizing the purpose, setting, challenges, and methodology of each study, this table provides a panoramic view of the existing academic landscape on midwifery-related safety initiatives. It highlights not only the growing academic concern for improving maternal and newborn outcomes but also the nuanced approaches taken to understand and resolve systemic barriers in different health systems.

In presenting these studies, the table underscores the recurring patterns of safety challenges encountered globally, such as psychological stress among midwives, the absence of cultural sensitivity, lack of continuity in care, and communication failures that often result in adverse outcomes. Each entry in the table details how specific models, ranging from the Psychological Capital framework to continuity-based community care and gender ethics protocols, have been proposed or assessed to mitigate these challenges. The methods used, whether cross-sectional surveys, realist evaluations, or mixed-methods analyses, reveal the rigor and diversity of the approaches employed. This enables readers to critically evaluate how applicable and transferable certain findings or interventions might be to localized contexts such as independent midwifery practices in Indonesia.

Additionally, Table 1 serves as a diagnostic lens through which gaps in the literature become evident. It identifies limitations frequently cited by the original researchers, including low generalizability, infrastructural inadequacies, and lack of inclusivity in existing models. These documented gaps reinforce the argument that patient safety interventions must be both evidence-based and context-specific. For example, while shared decision-making tools may work effectively in NHS hospitals, they may require cultural and operational adaptation to be relevant for midwives operating independently in decentralized Indonesian health systems.

Table 2. Challenges of patient safety

Challenges	References
High Stress and Psychological Burden	(Elliott & Fry, 2021)
Non-Adherence to Guidelines and Medication	(Whybrow *et al.*, 2020)
Stigma and Discriminatory Care Practices	(Rayment-Jones *et al.*, 2023)
Limited Evidence-Based Practice (EBP) Resources	(Taye *et al.*, 2024)
Role Overlap and Medication Error Risks	(Fox *et al.*, 2023)
Barriers to Diversity in Education	(Tai *et al.*, 2024)
Limited Access and Birth Setting Preferences	(Fletcher *et al.*, 2019)

Lack of Cultural Safety	(McCalman *et al*., 2024)
Fragmented and Discontinuous Care	(Cummins *et al*., 2024); (Offerhaus *et al*., 2020)
Power Imbalance and Ethical Dilemmas	(Christianson *et al*., 2022)
Inadequate Communication	(Lippke *et al*., 2019); (Bendowska & Baum, 2023)
Understaffing	(Turner *et al*., 2024)
High Variation in Care Practices	(Lundsberg *et al*., 2020)
Reduced Support During COVID-19	(Van Manen *et al*., 2021); (Riddell *et al*., 2022)
Limited Access to Ultrasound and Training	(Vinayak *et al*., 2021)
Insufficient Continuity of Care	(Turienzo *et al*., 2023); (Turienzo *et al*., 2021)
Need for Obstetrician Involvement	(Morr *et al*., 2021)

Table 2 presents a synthesized account of the persistent challenges affecting patient safety in midwifery, particularly within independent and community-based care contexts. Perhaps the most significant issue is the mental strain midwives face, which has been associated with diminished resilience and a heightened likelihood of negative outcomes (Elliott & Fry, 2021). The lack of adequate organizational support systems exacerbates this vulnerability, underscoring the need for integrated wellness programs alongside resilience training. No less disturbing is the ongoing non-compliance with clinical standards, especially with regard to the neglect of antenatal hypertension where deficient guideline adherence coupled with inadequate patient education compromises safety (Whybrow *et al*., 2020).

These gaps in care are made worse by the continued presence of stigma and discriminatory policies, particularly towards vulnerable populations, which undermine trust. This gap also worsens existing inequities in health (Rayment-Jones *et al*., 2023). In addition to these issues, structural limitations such as a lack of accessible evidence-based practice (EBP) resources, which is common in remote or low resource areas where midwives work without proper training and digital tools (Taye *et al*., 2024), hinder the quality of care provided. Also, role ambiguity or vague responsibility definitions regarding shared responsibilities between nurses and midwives can increase clinical error risk, indicating a need for stronger boundary for defined professional roles, improved teamwork, and coordination (Fox *et al*., 2023). These gaps are further widened by inequalities education; the midwifery training system has exclusionary inherent requirements that deny access to disabled or marginalized applicants. This narrowing workforce undermines diversity, inclusivity and representation not only within midwifery but within the care offered (Tai *et al*., 2024).

Limitations regarding the preferred setting for giving birth and insufficient accommodation to involve family members constitute systemic inadequacies that detract from women's experiences during childbirth (Fletcher *et al*., 2019). First Nations women report receiving unwelcoming, culturally inadequate care which indicates that cultural safety is still underdeveloped. Overall, this gap in culturally competent care during labor interferes with continuity in patient-provider interactions, disrupts the relationship between patients and providers, and negatively impacts care quality (Cummins *et al*., 2024). Lastly, unresolved ethical dilemmas along with unresolved intra-team communication issues often lead to coordination breakdowns during high-risk situations which remains commonplace (Christianson *et al*., 2022; Lippke *et al*., 2019).

Midwifery practices within lone practitioner models are facing challenges attributed to chronic understaffing that has been persistently connected to increased risk of adverse events (Turner *et al*., 2024). Moreover, considerable divergence in clinical approaches due to absence of coherent legal frameworks or guiding documents leads to inconsistent outcomes in patient care (Lundsberg *et al*., 2020). These issues reveal gaps related to governance structure as well as uniform training protocols systemically. Echoing these findings, the COVID-19 pandemic has further exposed these weaknesses by facilitating swift shifts towards home births and discontinuity while constraining institutional support (Van Manen *et al*., 2021; Riddell *et al*., 2022).

There is a lack of trained personnel in ultrasound and diagnostic tools because of the persistent technological constraints, especially in low resource areas. This, coupled with the lack of

adequate care for high-risk pregnancies, adds to the already existing clinical delays and reduces chances for prompt action (Vinayak *et al*.,2021). Furthermore, there are noticeable gaps in the defined roles of caregivers as illustrated through continuous dependence on obstetricians during midwife-led deliveries during cases of fetal distress which raises concerns about midwifery preparedness for critical care systems (Turienzo *et al*., 2023; Turienzo *et al*., 2021) and (Morr *et al*., 2021).

Discussion

This review illustrates that safety in midwifery care stems from a complex interplay of clinical, structural, educational, and sociocultural factors (Elliott and Fry, 2021b; Hall *et al*., 2023) and (Turienzo *et al*., 2021; Rayment-Jones *et al*., 2023) (Taye *et al*., 2024), Such challenges as stress and burnout, role ambiguity, insufficient continuity of care, and ineffective interprofessional collaboration are not confined to a single nation or economy. Rather, they are global and systemic in nature. From the perspective of the Swiss Cheese Model (Reason, 2000), these challenges represent numerous "holes" in the midwifery care safety nets or defences. When these holes coincide, the possibility of negative consequences for mothers, newborns, and midwives rises substantially.

The review demonstrates the distinct difficulties that arise in contexts such as Tangerang, Indonesia, where independent midwives function on the periphery with scant institutional integration. In contrast to midwives based in higher-resource countries where collaborative frameworks and embedded support systems are available, Indonesian midwives in more decentralized settings deal with professional isolation, inadequate training opportunities, poor referral infrastructure, and little-to-no escalatable care pathways. The absence of standardized protocols along with solo practice digital monitoring systems, and psychosocial support systems increases the danger of solo practice. This analysis indicates that regardless of which country these issues arise in, the problems may be diverse but their cumulative impact, compromised maternal and newborn safety, is worrying for all countries. Hence, designing contextually appropriate and operationally feasible safety interventions requires studying global issues within local frameworks as well as understanding local realities.

The psychological load of midwives remains an ever-growing issue when looking at safety as it is one of the most paramount burdens to mental health… as midwives work in isolation without adequate professional support (Elliott-Mainwaring, Phillips and Bowie, 2023). This coupled with lack of resilience leads to increased clinical mistakes. In addition, failure to adhere clinically such as in antenatal hypertension management implies not only provider-side gaps but also low patient education levels (Whybrow *et al*., 2020). Furthermore, the stubborn persistence of social stigma and discrimination in maternal care centered on client demographics breaches ethical values about trust and autonomy within midwifery care (Rayment-Jones *et al*., 2023). These matters continue to bring into sharp focus the need for a true culture of humility grounded care that elevates patients' needs above clinical mandates.

Inadequate fragmentation of care pathways permits frequent disruption within the continuum of antenatal care, intrapartum, and postnatal care. In this context, literature fails to capture the full scope of occupational health risks associated with the practice of midwifery. The risks include physical hazards, such as standing for extended periods, repetitive motions, psychosocial stressors such as role ambiguity, emotional labour, stigma, as well as ergonomic inadequacies like poorly designed workstations or delivery rooms (Iskamto *et al*., 2020; Mirong *et al*., 2023). Each category of risk not only endangers the midwives' safety and long-term health but also poses significant risks to patient safety due to the increased likelihood of fatigue-related errors, intervention delays, and deterioration of care, as well as damage to the quality of interpersonal care (Bardosono *et al*., 2018; Putri and Afifah, 2024).

Gaps in continuity-of-care models illustrate how most midwives find it difficult to maintain contact throughout the perinatal period (Cummins, Catling and Homer, 2018; Offerhaus *et al.*, 2020). The gap in continuity diminishes relational trust and coordination which threshold early detection of complications and timely referrals within a multidisciplinary framework. Infrastructural deficits exacerbate these gaps, including insufficient diagnostic tools, limited access to evidence-based practices (EBPs), weak digital infrastructure, as was prominently noted in studies conducted in Ethiopia and Indonesia (Vinayak *et al.*, 2021; Taye *et al.*, 2024). Guided by these constraints, complex decisions increase clinical risk alongside professional burnout for midwives due to lack of resources, support frameworks, and decision-making aids.

Models like the Psychological Capital framework, SACCIA communication approach, gender ethics protocols, and culturally embedded continuity-of-care plans, propose relatively viable approaches to tackling patient safety issues (Christianson, Lehn and Velandia, 2022). Despite lacking consideration for Indonesia's decentralised and under-resourced setting, these frameworks medicalised culturally and sociologically relevant issues which resulted in Indonesia's fragmented health system lacking in institutional infrastructural support. In the context of the Swiss Cheese Model (Reason, 2000; WHO, 2021; Flin et al., 2006), these frameworks omit important dimensions of hazard identification, risk control, and safety culture, thereby creating critical gaps, or "holes" in the layered defences. Other perspectives offer industrial and occupational safety (OHS) frameworks, which argue that gaps like these need to be bridged by context-specific models aligned with OHS principles, requiring integration of strategic leadership, Total Quality Management (Fadhel & Alqurs, 2025) and a sustained, permeating safety culture.

Global crises such as the COVID-19 pandemic have exposed significant gaps in patient care and safety infrastructure, with midwives facing rapidly changing clinical guidelines and limited institutional support (Van Manen *et al.*, 2021; Riddell *et al.*, 2022) Lundsberg et al. (2020) and Morr et al. (2021). Viewing these disruptions from an OHS perspective shows how external shocks align several weaknesses such as resource scarcity, procedural instability, and role conflicts (Lundsberg et al., 2020; Morr et al., 2021) within the Swiss Cheese Model's layers of defense, thereby compromising both patient risk and the autonomy of midwifery practice.

Moving beyond the frameworks brought in from outside the country, there is an immediate call for a patient safety model which is regionally grounded within Indonesia's context and addresses the realities of decentralized midwifery practice. Furthermore, this model should enhance culturally responsive care as it relates to local customs that builds trust between midwives and the communities they work with.

To improve maternal involvement and mitigate avoidable complications within the region, approaches should be directed towards the following areas: fostering risk detection and prevention systems, enhancing communication and coordination of care alongside psychosocial support to sustain midwives' resilience. Congruent within the boundary of the Swiss Cheese Model (Reason, 2000), these approaches serve as supplementary defensive strategies aimed at aligning gaps within system vulnerabilities. Integrating principles of OHS like The Hierarchy of Controls (NIOSH, 2015), alongside the Safety Culture (Flin et al. 2006), these approaches also cover identifying the hazards, risk control, and sustaining the workforce well-being thereby ensuring safety within the midwifery care integrates clinical quality and occupational safety.

Remaining within the confines of the Swiss Cheese Model (Reason, 2000), these approaches focus on additional layers of defence aimed at filtration-system lapses. Also integrating OHS principles like the Hierarchy of Controls (NIOSH, 2015) and Safety Culture (Flin et al., 2006), these approaches fill the gap on the identification and control of hazards and risks as well as the well-being of the workforce, thus ensuring that midwifery care balances clinical quality and occupational safety. Improvements to communication workflows can lessen fragmentation and staffing risks at peak demand periods through midwife and clinical board staff scheduling flexibility. Safety-aligned, practice-based resources promote global safety compliance and equitable access. There are

persistent gaps in knowledge and compliance in the use of PPE (Khapre, Naik and Mudey, 2015; Marasini, Shrestha and Chaudhary, 2023), along with the need for integrated strategic leadership and TQM in safety systems (Fadhel & Alqurs, 2025), that emphasise the need for midwifery patient safety innovations to augment occupational protective safety for the workforce.

Conclusion

This review shows that patient safety in midwifery is shaped by interrelated psychological, clinical, and systemic factors, especially in decentralised and under-resourced regions. In Tangerang, where midwives operate with considerable autonomy within a bounded system, safety enhancement necessitates improved continuity of care, access to up-to-date clinical information, and well-planned inter-service level coordination. Protecting maternal-neonatal outcomes and midwives' well-being can be achieved through the incorporation of these safety culture–centred stressors. This study advances Occupational Health and Safety in the context of independent midwifery practice by embedding these locally tailored elements into the model, thereby defending patients while improving the safety and efficiency of the healthcare workforce.

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Tanzania Journal of Health Research
Volume 27: Issue 5 (2026) https://dx.doi.org/10.4314/thrb.v27i5.16

Fathers' Involvement in Childcare Practices and Its Determinants: A Case Study of Fathers with Under Five Children in Njombe Region, Tanzania

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Abstract

Background. Father involvement benefits child and maternal outcomes, but participation is limited by norms such as social pressure from peers, relatives and community as seen overly involved in childcare and being dominated by their partner and barriers such as lack of time and experience in childcare due to spending most time at work. This study applied the Extended Theory of Planned Behavior (ETPB) to identify predictors of fathers' childcare intention and past behaviour in Njombe, Tanzania.

Methodology. A cross-sectional survey was conducted using multi-stage cluster sampling in Njombe and Makete districts. Three wards per district and two villages per ward were randomly selected via a lottery system. From a calculated sample size of 422, a total of 372 eligible fathers with a child under five were randomly selected and successfully completed the study. Data were collected through face-to-face interviews using structured questionnaires. Analyses included reliability testing, descriptives, and multiple linear regression.

Results. Participants had a mean age of 32.29 (±7) years. Most respondents were married (73.2%, n=270), had primary education (50%, n=186), and were farmers (58%,n=214) and had only one child under five years (70.4%,n=262). The full Intention model showed strong fit (R^2 = 0.664; adj. R^2 = 0.645; $F(17,311)$ = 36.124, $p < .001$). SN (β = 0.341, $p < .001$), PBC (β = 0.303, $p < .001$), and Past Behaviour (β = 0.304, $p < .001$) were positive predictors; Attitude was not significant ($p = .663$). For Past Behaviour, the full model explained 54.2% of variance (R^2 = 0.542; adj. R^2 = 0.520; ΔR^2 = 0.259, $p < .001$). Intention positively predicted behaviour (β = 0.525, $p < .001$); PBC was not significant.

Conclusion. Fathers' intentions are primarily driven by social expectations and perceived control rather than individual attitude. The strong intention-behavior suggests that fathers' involvement in childcare is associated with reduced child stunting risk. Interventions should move beyond individual education toward community-wide norm shifting and practical skill-building in male-friendly settings to overcome traditional barriers.

Background

In today's world, fathers are more involved in childcare and household chores than in previous generations (Churchill et al., 2023). Though mothers continue to be primarily involved in childcare practices, they spend more time on these activities (Lachance-Grzela & Bouchard, 2010). Participation of fathers in childcare practices is important to both women's and child wellbeing. For mothers it helps them to increase participation in the workforce and challenges traditional gender roles (Pinho &

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Gaunt, 2024). Globally some studies show that father's involvement in childcare is important and vital for child wellbeing and development as it leads to better cognitive skills, emotional regulation and overall health (Allport et al., 2018; Rollè et al., 2019). Supportive policies and cultural changes have resulted in increased fathers' involvement in developed countries, where fathers spend more time with their children, engage in stimulating activities and assume more responsibility all of which positively impact child development (Peterson, 2014; Schober, 2015).

In many Sub-Saharan African settings, fatherhood is organized by patriarchal norms that position men as household heads and primary providers and women as main caregivers, which limits fathers' routine participation in childcare (Rabie & Tomlinson, 2020; Jorosi-Tshiamo et al., 2013; Makusha & Richter, 2014). Evidence from Kenya, Ethiopia, Botswana, South Africa, and Namibia shows these norms continue to constrain day-to-day paternal caregiving (Alemayehu & Fenet, 2019; Makusha & Richter, 2014; Le Roux & Lesch, 2023), although studies from Uganda, Nigeria, and Kenya indicate that when fathers' roles extend beyond provision, engagement can improve children's nutrition, development, and health (Muoghalu & Eboiyehi, 2019; Nyqvist & Jayachandran, 2017; Rakotomanana et al., 2021; Sonkola et al., 2021).

In Tanzania specifically, fathers are widely positioned as providers and decisionmakers while daily caregiving is framed as women's work; postpartum traditions can exclude men from early care; and time poverty from income-earning further reduces availability—factors that collectively weaken perceived control over participation (Alsager et al., 2024; Mahiti et al., 2017; Shaban et al., 2025). And evidence shows that intentionally engaging men in childcare can increase men's knowledge, shift gender attitudes, and raise domestic time (Galvin et al., 2023; Jeong et al., 2023; Rothstein et al., 2023). Despite the growing recognition of the importance of fathers' involvement in childcare practices there is a continued need for understanding and promoting active paternal participation, especially in rural settings (Jeong et al., 2023; Martin et al., 2021).

In Tanzania communities, traditional gender roles create barriers against fathers' involvement in infant and young childcare (Rothstein et al., 2023). These barriers result in low knowledge and skills regarding childcare practice among fathers, influencing their involvement intentions and behaviors (Aubel, 2012; Aubel & Alvarez, 2011). Existing studies highlight that men's involvement in maternal and child health remains limited, particularly in rural areas where traditional gender roles are more pronounced. Paternal involvement is a critical yet underutilized lever in stunting prevention; active fatherhood has been shown to significantly improve child dietary diversity and overall development (Jeong et al., 2023**).**

In the Njombe region, where stunting affects about 63% of children, research on fathers' involvement in childcare remains scarce (TDHS-MIS, 2022). Existing studies primarily focus on maternal care, leaving the father's role under explored (Altare et al., 2016; Berenge & Muhimbula, 2023; Mwaseba et al., 2016). While some literature identifies traditional gender roles as barriers to paternal care, these studies only confirm the existence of such norms (Gibore & Bali, 2020; Rothstein et al., 2023). A gap remains regarding the internal decision-making of these fathers specifically, why fathers adhere to or bypass traditional norms depending on the situational context (Mwaseba & Kaarhus, 2015).

This study evaluates factors influencing fathers' involvement in childcare practices by utilizing the extended Theory of Planned Behavior (TPB), including past behavior. The extended theory of planned behavior TPB suggests that a person's intention to perform a behavior is influenced by their attitude, subjective norms, and perceived behavioral control, with the addition of past behavior to enhance predictive power.

Tanzania Journal of Health Research
Volume 27: Issue 5 (2026) https://dx.doi.org/10.4314/thrb.v27i5.16

CONCEPTUAL FRAMEWORK

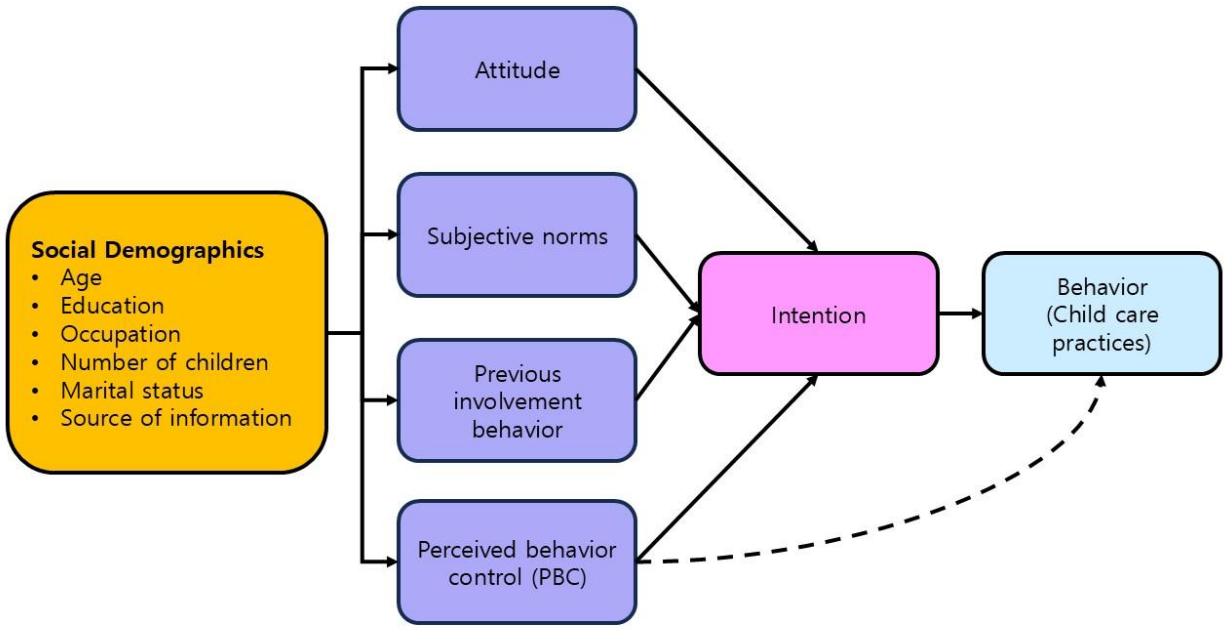

Figure 1: The conceptual framework of the theory of planned behavior and modified to suit the research objectives. Source: Adapted model from Ajzen (2002)

Methods

Study Setting

The study was conducted in Njombe region involving two districts which are Makete and Njombe DC districts. Njombe region has a population of approximately 889,940 and is largely inhabited by the Bena, Kinga and Wanji ethnic groups. Makete District, located in the southern highlands of Tanzania, covers an area of approximately 5,800 square kilometers with population around 109,160 people where 52,180 males and 56,980 females with mixed ethnic group such as Kinga, Wanji, Bena, Nyakyusa and Sangu. People primarily engage in smallholder farming, cultivating crops and raising livestock (NBS, 2022). Njombe DC, located in the central part of the Njombe Region, spans approximately 3,153 square kilometers with population of about 109,131 people where 52,044 males and 57,267 females. Bena is ethnic group which is most present and people primarily depend on agriculture, cultivating crops and supplemented by small-scale industries like tea processing and wood milling (NBS, 2022).

Study design and population

A cross-sectional study was conducted to assess factors influencing fathers' involvement in child-care practices through data collection at a single point in time. Data were collected from July 2025 to September 2025 in the selected villages within Njombe DC and Makete districts.

Sampling procedures

Both purposive sampling and simple random sampling methods were employed to recruit fathers with children under five for the study. Participants were eligible for inclusion if they were male, aged 18–45 years, permanent residents of the selected villages, and having at least one child under five years of age, to ensure the sample reflects the active child-rearing generation currently engaging in childcare practices in study area. Individuals were excluded if they were temporary visitors, unable to provide informed consent, or possessed chronic physical or mental illnesses that precluded active childcare participation to ensure that father's involvement reflects personal choice rather than physical or legal inability. In cases where fathers had multiple children under five, the responses referred to the youngest child as the index child. The Njombe region was purposefully selected due to its high rates of stunting among children under five. According to the Tanzania Demographic and Health Survey (TDHS-MIS, 2022), Njombe reports a stunting prevalence of about 63%, one of the highest in the country.

The study employed a multi-stage cluster sampling technique to ensure an unbiased representation of the study area. In the first stage, all administrative wards in the two districts were listed: 12 wards in Njombe DC and 23 wards in Makete DC. Using a simple random sampling (lottery) approach, three words were selected from each district, totaling six wards. This random selection was prioritized over specific criteria like size or accessibility to eliminate selection bias and ensure every ward had an equal probability of inclusion. In the second stage, a sampling frame of all villages within the six selected wards was established. Random selection was achieved through a lottery system. In each ward, the names of all constituent villages were written on identical slips of paper, folded, and placed in a container then drew two slips per ward. Two villages were selected from each ward, resulting in a total of 12 study villages.

The final stage involved the selection of households. A full list of all households in the villages was obtained from village registry with the assistance of local leaders. From this list, households were screened to identify those meeting the inclusion criteria. All the eligible households were listed from the village registry and subjected to simple random sampling method using lottery system was then applied to these filtered lists to select the final participants utilizing a blinded lottery system based on unique household identification numbers to ensure an unbiased sample where unique household IDs were drawn from a container, ensuring every eligible household had an equal probability of selection. If a selected household had more than one eligible father, only one was randomly selected to participate.

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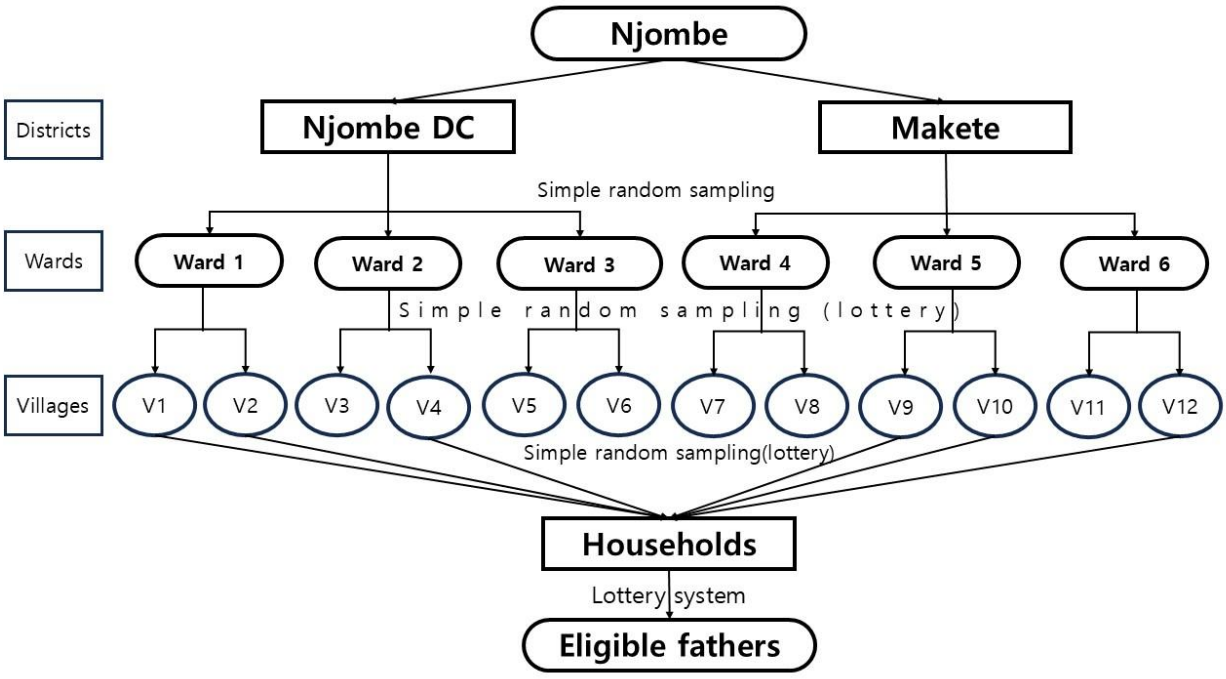

Figure 2; flow chart showing sampling procedure

Sample Size

The total number of fathers with under-five children who participated in the study was determined using the sample size formula developed by Cochran for unknown population based on the fact that the population size of the fathers with under-five children in the study area is not known;

$$\boldsymbol{n = \frac{z^2 qp}{e^2} \pm 10\%\ AF}$$

Where:

n = initial sample size
z = Z-value for a 95% confidence level (1.96)
p = estimated proportion of fathers with under-five children
e = margin of error (0.05)
AF= attrition factor
The calculation is as follows:

$n = \frac{1.96^2 * 0.5 * 0.5}{0.05^2}$

= 384

In order to cater for non- response rate, the sample size was increased by 10% (Fisher et al., 1991).

= 384 + 384(10%) =422

Of the calculated sample size of 422, a total of 372 fathers successfully completed the survey, yielding a response rate of 88.2%

Data collection

Construction and administration of a Questionnaire

The study utilized a structured questionnaire adapted from a combination of validated scales and theoretical framework was based on the Extended Theory of Planned Behavior (TPB). The core TPB constructs, Attitude, Subjective Norms, and Perceived Behavioral Control were operationalized using

the validated scales developed by Issa (2021), alongside the original framework by Ajzen (2002). On paternal roles, the tool was expanded to include measures of Paternal Identity and Gender Ideology, adapted from the PACOTIS (Parental Cognitions and Conduct Toward the Infant Scale) and WIAF (What I Anticipate as a Father) scales as utilized by Ross-Plourde, et al (2022). In Past Behavior and the Intentions were specifically adapted from the Multiple Indicator Cluster Survey (MICS) module for 'Care for Child Development' and the work of Issa (2021).

Modification was made to pivot these sections from general reproductive health to nutritional involvement. The Attitude section was modified from general reproductive health views ad clinic attendance to focus on the father's role in child nutrition, domestic support during pregnancy, and child-health decision-making. Subjective Norms were expanded to measure perceived community stigma regarding tasks traditionally viewed as mother's duties, such as bathing or feeding. Perceived Behavioral Control was adjusted to assess a father's confidence in balancing active caregiving and demands of work responsibilities. In Intentions and Past Behavior were modified from general household engagement and clinic accompaniment to father-specific physical tasks, including feeding, bathing, and the immunization and monitoring of child growth.

To ensure its effectiveness, the questionnaire was pre-tested with 12 fathers with children under five in Mbeya rural and the language of the questionnaire was refined to ensure clarity, cultural appropriateness, and conceptual equivalence. Two enumerators received comprehensive training on question delivery and response recording to ensure consistent data collection. Finally, the questionnaires were administered through face-to-face interviews at fathers' home and men's gathering areas from morning hours.

Socio-Demographic factors

Information on socio-demographic factors of the study participants was collected using pretested questionnaire administered. The collected data included age, education, marital status, occupation, number of children under five, fathers' awareness of male involvement, information source and spouse employment.

Attitudes

This multidimensional concept was assessed with 12 items developed in the questionnaire. Included the group such as gender ideology, importance of the role of father and perceived consequences of father involvement. Fathers indicated their level of agreement with each statement on scale ranging from 1 (strongly disagree) to 5 (strongly agree). Sample item: "a father's involvement in antenatal care visits is important for the well-being of both the mother and child"

Subjective norms

This concept was assessed with 16 items, which were developed to assess subjective norms associated with father involvement in childcare practices. This scale measures both perceived norms and motivation to comply with norms. Fathers indicated their level of agreement with each statement on a scale ranging from 1 (not at all) and 5 (very much) for perceived norm 1 (strongly disagree) to 5 (strongly agree) for motivation to comply with norms. Sample item: "How much do people who are important to you expect you to participate in childcare?"

Perceived behavior control

This concept was assessed with 8 items, which were developed to assess perceived behavior control associated with father involvement in childcare practices. Fathers indicated their level of agreement

with each statement on scale ranging from 1 (very unlikely) to 5 (very likely). Sample item: "actively participate in daily childcare tasks such as feeding, bathing, or playing with your child"

Behavior intention

This concept was assessed with 8 items, which were developed to assess behavior intention associated with father involvement in childcare practices. The scale measure included items related to direct care (e.g., bathing, playing with the baby) and indirect care (e.g., washing baby clothes, buying baby items). Fathers indicated their level of agreement with each statement on a scale ranging from 1 (very unlikely) and 5 (very likely). Sample item: "How likely are you to actively participate in daily childcare tasks such as feeding, bathing, and playing with your child?"

Past behavior

This concept was assessed with 8 items which were developed to assess past behavior associated with father involvement in childcare practices. The scale measure included items related to past involvement in childcare care activities (e.g., bathing, playing with the baby, changing diapers). To distinguish between past behavior and current/recent behavior during field data collection, the study employed time-bound recall and frequency-based scaling. In the field, we use specific local milestones (e.g., since the last harvest or since the child's last clinic visit) to make the respondent's memory to a defined retrospective period. Fathers indicated their level of agreement with each statement on a scale ranging from 1 (never) and 5 (always). Sample item: "In the past six months, how often have you participated in feeding your child under five years old?".

Data Analysis

Compilation and Coding

All items from the study questionnaire were cleaned and coded where Likert scale items and demographic items were translated to numeric values for statistical analysis. The data aggregated by tallying individual item score to find the composite mean of score for extended theory of planned behavior (ETPB) constructs (attitude, SN, PBC, Intention and past behavior). Data analysis was conducted by using IBM SPSS Version 25.0 where descriptive and inferential statistics were used. Descriptive statistics include frequency, percent, mean, standard deviation and minimum and maximum which show in socio-demographic and composite construct scores. construct score mean was calculated by individual item scores within a construct were summed and then divided by the total number of items in that section.

Inferential statistics include two multiple regression analyses, where first analysis on predicting Intention, the composite mean for Intention as the Dependent Variable (DV). The Independent Variables (IVs) included the composite means for Subjective Norms, Perceived Behavioral Control, Attitude, and Past Behavior, while adjusting for socio-demographic and media exposure controls. The second analysis on predicting Behavior, the composite mean for Past Behavior as the DV. The IVs were the composite means for Intention and Perceived Behavioral Control, maintaining the same socio-demographic controls. With results presented in the form of a coefficient table, showing the model used to predict fathers' intention and fathers' behavior in ETPB.

Results

Socio-Demographic characteristics of the respondents

A total of 372 fathers with children under five years were recruited for the study. The majority 55.9% (n=208) were aged between 31-45 years. Half respondents had attained primary school education 50% (n=186). Majority of respondent were married 73.2% (n=270) and work as farmers 58% (n=214). More than two-thirds respondent 70.4% (n=262) had one child under five years, radio was the most prevalent source of information 52.2% (n=187). Table 1

Table 1 Socio-Demographic Characteristics of Study Participants

Variable		N	%
Ward	Isapulano	40	10.80
	Iwawa	44	11.80
	Kidegembye	67	18.00
	Lupalilo	66	17.70
	Matembwe	70	18.80
	Mtwango	85	22.80
Age group			
	Young adult (18-30)	164	44.09
	Middle adult (31-45)	208	55.91
Education status			
	No education	17	4.6
	Primary education	186	50.0
	Secondary education	141	37.9
	Higher education	28	7.5
Marital status			
	Single	54	14.6
	married	270	73.2
	cohabited	28	7.6
	Divorced	13	3.5
	widowed	4	1.1
Occupation	Farmer	214	58.0
	Trader	86	23.3
	Civil servant	23	6.2
	Transport (drivers)	17	4.6
	Skilled trades (carpenter, mason, mechanic, saloon)	27	7.3
	Other (pastor, security)	4	1.1
Number of Children			
	1	262	70.4
	2	94	25.3
	3	11	3
	4	5	1.4
Fathers' male involvement awareness			

	Yes	277	74.7
	No	94	25.3
Source of information			
	Radio	187	52.2
	Television	102	26.4
	Social media	71	18.3
	Magazine	10	2.6
	Relatives and friends	67	17.4
	Health facilities	32	8.3
	Community channels (school, religious, NGO, seminar)	13	3.3
Spouse's Employment Status			
	Full-time	109	30.1
	Part-time	117	32.3
	Unemployed	136	37.6

Descriptive Statistics

The consistency of the study items was assessed using Cronbach's alpha. Internal consistency for the constructs ranged from marginal to acceptable, with past Behavior showing the highest reliability (α = 0.775). The items for measuring attitude included 11 items, and items measuring perceived behavior control included 5 items, showed marginal consistency (α = 0.583 and α = 0.601, respectively); this is probably given the multi-dimensional concept and limited items per subscale. For Attitude, item for financial support and for PBC, the items regarding domestic tasks were the primary contributors to low reliability. All items were positively phrased, thus requiring no reverse-coding. For the Attitude construct, an initial 12-item scale yielded a reliability of alpha = 0.578, which was improved to alpha = 0.583 after the deletion of one item. For Perceived Behavioral Control (PBC) construct was refined from an initial 7-item set (alpha = 0.457) to a final 5-item scale, achieving a marginal consistency of alpha = 0.601 through the deletion of two items

Table 2: Descriptive statistics of interest composite variables

Composite variable	N	Mean	SD	Min	Max	Cronbach's alpha
Attitude	372	4.10	0.41	2.91	5.18	0.583
Subjective Norms	372	3.43	0.60	1.63	4.63	0.732
Perceived Behavioral Control	372	3.52	0.67	1.00	5.00	0.601
Intention	372	3.57	0.64	1.00	5.00	0.741
Past Behavior	372	3.16	0.71	1.00	4.60	0.775

Multiple Linear Regression Predicting Behavioral Intention

After controlling for socio-demographic factors, the inclusion of ETPB constructs significantly improved the model, explaining 66.4% of the variance in fathers' intentions ($\Delta R^2 = .664$). In the final model, Subjective Norms (β = 0.341), Past Behavior (β = 0.304), and Perceived Behavioral Control (β = 0.303) emerged as the significant predictors of intention. While demographics like marital status were significant initially, only Higher Education (β = 0.080) and Social Media exposure (β = 0.073) remained

significant in the presence of ETPB variables. Attitude did not significantly predict intention in any stage of the model. Table 3 displays the coefficients for father's intentions.

Table 3 Multiple Regression Models Predicting Fathers' Intention to Engage in Childcare

	Model 1			**Model 2**		
Predictor	**B**	**SEB**	**β**	**B**	**SEB**	**β**
Demographic / Control variables						
Age	−0.007	0.005	−0.072	−0.001	0.003	−0.010
Education	0.092	0.048	0.100	**0.075** *	0.031	**0.080** *
Marital status	**0.154**	0.051	**0.156** **	0.008	0.035	0.008
Occupation	−0.009	0.032	−0.014	0.029	0.021	0.048
Number of Children under 5	0.087	0.053	0.085	0.019	0.035	0.019
Fathers' awareness of male involvement	**−0.334**	0.106	**−0.209** ***	0.047	0.072	0.029
Spouse employment	−0.024	0.039	−0.032	0.023	0.026	0.030
Media exposure (Radio = reference)						
Television	**−0.264** ***	0.076	**−0.192** ***	**−0.113** *	0.050	**−0.082** *
Social media	**0.252** **	0.087	**0.157** **	**0.118** *	0.058	**0.073** *
Magazine	0.334	0.195	0.090	0.088	0.130	0.024
Relatives/Friends	0.163	0.086	0.102	0.110	0.057	0.069
Theory of Planned Behaviour variables						
Attitude	—	—	—	0.022	0.051	0.015
Subjective Norms	—	—	—	**0.360** ***	0.047	**0.341** ***
Perceived Behavioural Control	—	—	—	**0.280** ***	0.037	**0.303** ***
Past Behaviour	—	—	—	**0.267** ***	0.041	**0.304** ***
Model R^2	**.213**			**.664**		
ΔR^2 (vs. previous model)	—			**.451**		

Dependent variable = Intention. Model 1 includes socio-demographic. Model 2 adds TPB constructs (Attitude, Subjective Norms, PBC, Past Behavior). Significance: *p*<.05 (), *p*<.01 (), ***p*<.001 ()**. Model 2 fit: *F* (17, 311) =36.124, *p*<.001; adj. R^2=.645.

Multiple Regression Models Predicting Past Fathers' Involvement Behavior

The full regression model explained 54.2% of the variance (ΔR^2= .542) in past father's involvement behavior, intention was a significant predictor of past behavior involvement (β = 0.525). Among the control variables, marital status (β = 0.125), remained a significant positive predictor, while fathers' awareness of male involvement (β = −0.137), and spouse's employment (β = −0.083) were associated with lower involvement. Table 4 displays the coefficients for father's past behavior in childcare practices.

Table 4 Multiple Regression Models predicting past fathers' involvement behavior

	Model 1			**Model 2**		
Predictor	**B**	**SEB**	**β**	**B**	**SEB**	**β**

Demographic / Control variables						
Age	−0.003	0.005	−0.031	0.001	0.004	0.012
Education	0.013	0.052	0.012	−0.045	0.042	−0.043
Marital status	**0.238***	0.055	**0.211***	**0.141**	0.045	**0.125**
Occupation	−0.058	0.034	−0.084	−0.052	0.028	−0.075
Number of Children under 5	0.038	0.058	0.033	−0.022	0.046	−0.019
Fathers' awareness of male involvement	**−0.476***	0.115	**−0.262***	**−0.249**	0.094	**−0.137**
Spouse employment	**−0.094**	0.043	**−0.108**	**−0.072**	0.035	**−0.083**
Information source *(Radio = reference)*						
Television	**−0.187**	0.082	**−0.119**	−0.014	0.067	−0.009
Social media	0.178	0.095	0.098	0.013	0.077	0.007
Magazine	0.414	0.212	0.098	0.206	0.171	0.049
Relatives/Friends	0.161	0.094	0.088	0.066	0.076	0.036
Theory of Planned Behaviour variables						
Perceived Behavioural Control	—	—	—	0.080	0.053	0.076
Intention	—	—	—	**0.598***	0.060	**0.525***
Model R^2	**.283***			**.542***		
ΔR^2 (vs previous)	—			**.259***		

DV = composite mean of Past Behavior. Model 1 includes socio-demographic. Model 2 adds Perceived Behavioral Control and Intention. Significance codes: $p<.05$ = **; $p<.01$ = **; $p<.001$ = ***. Model 2: R=.736, R^2=.542, adj. R^2=.520; ΔR^2=.259; *F*-change (2,313) =88.538, $p<.001$

Discussion

This study shows that the Extended Theory of Planned Behavior (ETPB) is a useful model for predicting father involvement in Njombe, Tanzania. The finding that Subjective Norms and Perceived Behavioral Control (PBC) are significant associated with intention suggests a way to address high child stunting rates. When fathers help with childcare, they share the domestic workload. This may allow mothers additional time for breastfeeding, preparation of proper food for the child, increased participation in economic activities which promote child's health and nutrition. Additionally, when fathers are involved, household resources are more likely to be used for the child's health and nutrition, which is essential for reducing chronic malnutrition. (Saaka et al., 2023)

Fathers' intentions to participate in childcare appear closely tied to the social expectations they face in their communities. This may indicate that a father's willingness to participate in childcare is not just a matter of personal volition but is shaped by social conformity within the community. In rural Tanzanian settings, masculinity is mainly defined by the provider role; breaking this norm to perform childcare tasks carries the risk of social stigma and a loss of respect from peers. While parents and spouses may provide positive encouragement for fathers to move beyond the traditional role, negative norms were more commonly reported in relation to peers and the wider community. These

findings are consistent with Mahiti et al. (2017), who studied fathers in rural Dodoma, Tanzania, and Jacob et al. (2025), who focused on married men in the Kanam communities of Nigeria. Both studies found that cultural expectations often discourage men from caregiving despite their position as primary decisionmakers. These patterns suggest that shifting social norms may be important for stunting reduction efforts in Njombe; when the community mindset becomes more supportive of fathers' involvement in childcare, fathers may be more likely to participate in health-seeking behaviors and household hygiene practices. Such involvement may support healthier child environments in settings with high malnutrition risk.

Fathers' intentions in Njombe may also reflect how confident they feel about performing childcare tasks and how much control they perceive over their time and resources. This suggests that a father's intention may be influenced not only by social pressure, but also by perceived competence and access to resources. Low perceived behavioral control (PBC) may be related to the gendered upbringing common in rural Tanzania, where boys are rarely socialized to perform caregiving tasks. This may contribute to a skills gap in which fathers intend to help but feel less competent in tasks like bathing or soothing an infant.

Additionally, the seasonal nature of agriculture in the Southern Highlands may be associated with work demands that limit a father's perceived control over time. This is coherent with a study by Basil and Ndijuye (2019) in Kilosa District, Tanzania, which found that many fathers are occupied with economic activities for over 12 hours a day, keeping them away from their children. This may reflect a practical constraint where fathers perceive limited time to engage in caregiving even when they recognize its importance. Improving PBC may therefore involve practical childcare skills and realistic time-planning support; these approaches may help fathers feel more able to contribute to timely feeding and caregiving when mothers are occupied with other duties which may contribute to stunting reduction efforts.

This pattern suggests that prior involvement may be linked to stronger intentions, possibly because repeated experience builds confidence and makes caregiving feel more normal or manageable. Experience may function as a learning process through which fathers become more comfortable with childcare tasks and less concerned about social judgment. Fathers who have been involved with previous children may have already navigated skills-related barriers and stigma around roles traditionally viewed as feminine. This is supported by Shaban et al. (2025), who found that young fathers in Arusha, Tanzania, are increasingly transitioning from passive to active roles while negotiating patriarchal norms. Their study reported that when fathers gain experience through targeted programs, they report stronger bonding and higher confidence in caregiving. In the same way, fathers with prior practice may be more likely to support feeding practices and health-monitoring for younger siblings. This suggests that encouraging early involvement among first-time fathers may help establish routines of participation, potentially supported through practical, skill building workshops and peer-mentorship programs where experienced fathers teach first-time fathers that may influence norms and build confidence and collaborative couples counselling (Jenkinson, 2016).

The weak role of attitudes in this model may indicate that favorable views alone are not sufficient when social expectations and day-to-day constraints remain strong. In rural Tanzanian communities, personal attitudes may be less influential when patriarchal structures and social conformity are strong. Evidence from Kilgallen et al. (2025) in Northwestern Tanzania suggests that although younger fathers may hold more egalitarian views, they may face sanctions from elders for performing domestic tasks or taking children to clinics.

In regions like Njombe, where respect for seniority is a deeply rooted cultural value, fathers may downplay their positive attitudes to avoid conflict with family members or community

gatekeepers. Thus, positive attitudes may not reliably correspond to intention when stigma and structural barriers (such as long work hours) remain. Additionally, the low reliability (α = 0.52) of the attitude scale in this study may have reduced its ability to detect an association, which may partly explain the non-significant result. From a child stunting perspective, this suggests that attitude-focused messaging alone may be insufficient, and interventions may need to focus more on norms and practical supports that enable fathers' involvement in childcare practices linked to nutrition and child health.

The intention–behavior link observed in this study suggests that when fathers report stronger intention to be involved, they also report higher involvement in caregiving practices. This pattern may reflect that fathers with stronger intention are more likely to report participating in tasks such as supervising handwashing, bathing the child, and supporting dietary diversity. This may relate to fathers' beliefs that their involvement matters for maternal and child health (Fletcher et al., 2024). The association between intention and reported caregiving may be relevant for stunting reduction because involvement in behaviors such as ANC accompaniment, complementary feeding support, and participation in growth monitoring may contribute to more consistent care during the first 1,000 days. Sharing responsibilities may also be linked to reduced maternal workload and more stable caregiving routines, which may support child health.

The negative association between fathers' awareness of male involvement and both intention and behavior may reflect how the awareness item is understood and how information is delivered. This suggests that fathers may know the concept but still lack practical guidance for translating awareness into action in rural settings. Male involvement messaging may not be well matched to the cultural and social realities of rural Tanzania, especially if it emphasizes clinic accompaniment or family planning more than daily childcare tasks (Mapunda et al., 2022).

In addition, knowledge alone may not be sufficient to overcome social barriers; without guidance on how to balance caregiving with traditional expectations, awareness may not correspond to behavior change. This is consistent with Omobowale et al. (2023), who found that even when men understood the need for active involvement, their participation remained conditional and shaped by social visibility and stigma. Similarly, Vermeulen et al. (2016) observed that some men with positive attitudes still maintained a passive role in practice. This contrasts with studies where greater knowledge was associated with greater involvement, suggesting a possible gap in how involvement is promoted and practiced across settings (August et al., 2016; Chahalis et al., 2021).

Spouse employment may be linked to lower opportunities for fathers to build routine, independent childcare involvement. In rural Njombe, women's work often includes farming, trade, and services near the home, which may allow mothers to keep children physically close during work (Mwakalasya et al., 2024). When children remain in mothers' constant care, fathers may have fewer chances to develop solo caregiving routines, which may be associated with lower confidence in tasks like soothing a crying child or preparing food. In addition, if a woman's employment corresponds to higher earnings than her husband, this may be associated with feelings of insecurity that could coincide with reduced father involvement in childcare, as a way to protect status. This is consistent with Nkwake (2015) in Uganda, which found that fathers who earned less than their spouse were less involved in childcare. Together, these patterns suggest that in rural dual-income households, father involvement may be shaped by both the closeness of mothers to children during work and the dynamics of perceived economic roles within the family.

Study limitations

The cross-sectional nature of this study limited us from drawing causal relationship conclusions with confidence. We could not confirm increase of subjective norm causes future increase in intention. Other limitations included potential biases in self-reported data, which could lead to overestimation of involvement levels to align with what is socially acceptable, and measurement consistency, while most scales were acceptable attitudes measure with lower reliability which require a careful interpretation of non-significant findings of attitude as lower reliability weaken a variable's relationship with others.

Conclusion

Fathers' involvement in childcare within the Njombe region is not merely a matter of individual choice, but outcome of social structures, past experiences, and perceived capability. While the Extended Theory of Planned Behavior (ETPB) provides a useful framework, the findings reveal that in rural Tanzania, subjective norms and perceived behavioral control are strongly associated with father's intention. The significance of past behavior suggests that once the initial cultural barriers are broken, involvement becomes a self-reinforcing routine. Conversely, the non-significance of attitude highlights a critical suppression effect, where personal egalitarian beliefs are often stifled by generational resistance and fear of societal judgment.

Eventually, these findings indicate that fathers are a resource in the fight against child stunting. When fathers move from passive providers to active caregivers participating in ANC visits, growth monitoring, and hygiene practices they provide a vital nutritional safeguard that reduces the maternal workload and ensures consistent care. To achieve lasting improvements in early childhood development, the focus must shift from changing individual minds to transforming community-wide norms. By creating a social environment that validates and supports caregiving as a core component of modern Tanzanian manhood, we can unlock the potential of paternal involvement to improve nutritional outcomes and ensure the healthy growth of the next generation.

Policy implication

The strong influence of perceived behavioral control and past behavior suggests that interventions must move beyond general health education and focus on building specific, practical caregiving skills. The Government, in partnership with other stakeholders such as NGOs, should implement on training for fathers. These programs should teach specific skills such as practicing responsive caregiving, proper infant hygiene (including bathing and changing diapers), and identifying early signs of childhood illness. Rather than relying solely on traditional clinic settings, these skills should be taught in male-friendly spaces like local marketplaces, sports gatherings, or through religious institutions using practical demonstrations. Furthermore, since this study found that social norms and traditional hierarchies often block father involvement, community leaders and village elders must be engaged to lead norm-shifting campaigns. By using communication channels such as community radio and public meetings to redefine active caregiving as a sign of a strong and responsible father and can remove the fear of social stigma. These policy actions will ensure that fathers in Njombe are equipped to provide the consistent care and nutritional support necessary to reduce child stunting and improve long-term health outcomes.

Declarations

Ethical Consideration

Ethical approval was obtained from the National Institute for Medical Research (NIMR/HQ/R.8a/Vol.IX/5039) while permission to undertake the study was obtained from Sokoine

University of Agriculture (SUA/ADM/R.I8I1379). Written informed consent was obtained for all subjects. Permission was also obtained from relevant administrative offices. Data confidentiality and privacy were maintained throughout the research process. Anonymity was maintained by using participant identification codes instead of names on all research instruments, with the code-to-name key stored in a separate, secure location. Data confidentiality was ensured by conducting interviews in private settings and training all enumerators on privacy standards. All physical data is stored in locked cabinets, while electronic data is maintained in password-protected, encrypted databases.

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Physician Volunteering and Health System Gaps in Morocco: A Qualitative Study

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Abstract
Background: In resource-constrained health systems, informal mechanisms often emerge to address shortages in human resources and territorial inequities in access to care. In Morocco, medical caravans and mobile health initiatives rely heavily on physicians' voluntary engagement. However, limited research has examined how this engagement contributes to health system functioning and equity.
Objective: To explore physicians' voluntary engagement as a response to health system gaps and human resource shortages in Morocco.
Methods: This exploratory qualitative study was conducted with eight physicians working in public hospitals in the Fes region. All participants had experience in medical caravans, mobile health units, or outreach interventions in remote rural areas. Data were collected through semi-structured interviews and analysed using inductive thematic analysis. The analysis focused on physicians' motivations, professional identity, and perceptions of health system constraints.
Results: Physician volunteering was described as both an ethical commitment and a pragmatic response to structural deficiencies in healthcare delivery. Four interrelated dimensions emerged: empathic and humanitarian drivers, professional and ethical responsibility, sociocultural and religious values supporting solidarity, and awareness of systemic constraints. These constraints included shortages of specialists, limited infrastructure, and unequal territorial distribution of services. Participants viewed volunteering as a temporary way to bridge access gaps in underserved areas. However, they also emphasized the structural limits of such initiatives.
Conclusion: Physician volunteering constitutes an informal yet significant component of healthcare delivery in Morocco. It partially mitigates human resource shortages and territorial inequities. Integrating voluntary medical engagement into broader health workforce and equity strategies may strengthen its contribution to health system responsiveness in underserved settings.
Keywords: Physician volunteering; Human resources for health; Health system gaps; Access to care; Morocco; Qualitative research

Introduction

Volunteering has become an increasingly visible component of health system functioning in many low- and middle-income countries, particularly in contexts characterized by structural shortages of human resources and persistent territorial inequities in access to care. According to the State of the World's Volunteerism Report, millions of individuals worldwide engage annually in unpaid activities that contribute to social cohesion and the reduction of inequalities (Volunteers, 2018). In

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the health sector, such engagement often complements formal healthcare delivery systems, especially were public services face resource constraints.

Beyond its social value, volunteering has also been conceptualized as a contributor to public health outcomes. A meta-analysis of cohort studies found that regular volunteering is associated with improved psychological well-being and reduced mortality risk (Jenkinson *et al.*, 2013). While these findings highlight individual-level benefits, growing attention has been directed towards understanding volunteering as a structural component of service delivery in under-resourced health systems.

In this regard, the voluntary involvement of qualified health professionals including physicians, represents a specific form of "professional skills volunteering." A recent scoping review of 144 studies indicates that physicians constitute the most frequently studied group in health-related volunteering initiatives (Strkljevic *et al.*, 2024). Existing literature identifies multiple drivers of such engagement, including altruistic values, professional identity, moral and religious commitments, and opportunities for clinical development. However, beyond individual motivation, volunteering increasingly functions as a supplementary human resource mechanism in contexts facing workforce deficits.

In many countries of the Global South, health professional volunteering is embedded within broader strategies aimed at mitigating access gaps in underserved regions. In Morocco, despite recent reforms to expand health coverage, the health system continues to face a structural shortage of medical human resources and a strong urban concentration of services (Al Hassani, Achhab & Nejjari, 2024). Rural and mountainous areas remain disproportionately affected by limited access to specialists and essential healthcare services.

To address these disparities, the Ministry of Health and Social Protection has developed mobile service delivery models, including mobile medical units, temporary hospitals, and specialized medical caravans. These interventions are designed to provide intensive packages of curative, preventive, and health promotion services in remote areas. Medical caravans have been legally institutionalized under Law No. 131-13 regulating medical practice, which provides a framework for physicians' participation in temporary missions (Royaume du Maroc, 2015). Public authorities, local governments, and non-governmental organisations including the Mohammed V Foundation for Solidarity, regularly organize such initiatives, often reaching thousands of beneficiaries within short timeframes (Mansouri, 2025).

Despite their institutionalization, these interventions rely heavily on the voluntary engagement of physicians from both public and private sectors, frequently outside their formal working hours. National campaigns such as "Riaya" further illustrate how voluntary medical mobilization is integrated into seasonal public health responses (Ministry of Health and Social Protection, 2023). In practice, physician volunteering constitutes a recurrent mechanism through which the health system attempts to mitigate territorial inequities and temporary service shortages.

However, while medical caravans and outreach initiatives are increasingly visible within the Moroccan health landscape, limited research has examined how physicians' voluntary engagement operates as a response to systemic health workforce constraints. International studies highlight that professional volunteering is shaped not only by individual motivations but also by organisational and structural determinants, including workforce distribution, institutional culture, and policy frameworks (Strkljevic *et al.*, 2024). Understanding this interaction is particularly important in resource-constrained settings where voluntary engagement may partially compensate for structural deficits.

The present study addresses this gap by exploring physician volunteering as an informal yet significant mechanism within the Moroccan health system. Drawing on qualitative interviews with physicians involved in medical caravans and mobile health initiatives, the study examines how voluntary engagement is articulated in relation to professional identity, sociocultural values, and

systemic health workforce challenges. By situating physicians' motivations within the broader context of human resource shortages and access inequities, this research aims to contribute to discussions on health system strengthening, workforce planning, and equitable service delivery in underserved settings.

From a public health perspective, physician volunteering can thus be understood not only as an expression of individual altruism but also as a form of informal health system supplementation that reflects both resilience and structural vulnerability within healthcare delivery.

Conceptual and Theoretical Framework

Analyzing physician volunteering within resource-constrained health systems requires a framework capable of articulating both individual motivations and structural determinants. In this study, interpretation of the findings draws primarily on prosocial motivation theory, while situating it within the broader context of health workforce challenges and access inequities.

Prosocial motivation theory provides a well-established lens for understanding why individuals voluntarily invest time, effort, or professional skills for the benefit of others. Batson's empathy–altruism hypothesis (Batson, 2014) posits that helping behaviour arises from empathic concern for others' well-being rather than from self-interested calculations. Empathy is defined as the capacity to perceive and emotionally respond to another person's vulnerability, thus constitutes a central driver of prosocial action.

Penner, Dovidio, Piliavin, and Schroeder (Penner. *et al.*, 2005) further conceptualize prosocial behaviour as a multilevel phenomenon shaped by intrapersonal factors (values, emotions, moral beliefs), interpersonal influences (social norms, relational ties), and structural opportunities (organisational settings and institutional contexts). Within this perspective, prosocial motivation is not solely an individual disposition, but a dynamic process embedded in social identity and contextual conditions. This multilevel dimension is particularly relevant in healthcare, where professional roles are normatively anchored in care ethics and responsibility towards vulnerable populations.

Grant (Grant, 2008) defines prosocial motivation as "the desire to expend effort to benefit other people," highlighting empathy, moral values, professional identity, and perceived social impact as core drivers. In health professions, where therapeutic relationships and social responsibility are central to professional identity, these dimensions often reinforce one another. Grant and Berg (Grant & Berg, 2011) further demonstrate that "other-oriented" occupations are more likely to sustain prosocial engagement because moral meaning is deeply integrated into professional practice.

Within the literature on medical volunteering, several studies confirm that physicians' engagement in humanitarian or outreach activities is frequently motivated by compassion, commitment to social justice, and the desire to address inequalities in access to care (Martiniuk *et al.*, 2012) (Rovers *et al.*, 2016) . Omoto and Snyder (Snyder et Omoto, 2008) describe volunteering as a sustained process influenced by identity formation, perceived usefulness, and belonging to a broader moral community. These frameworks emphasize that volunteering is not merely episodic altruism, but a socially embedded practice shaped by values, identity, and institutional environments.

Applying prosocial motivation theory to the Moroccan context allows for an integrated interpretation of physicians' engagement. Participants' narratives reflect empathic concern for underserved populations, strong professional identification with public service and health equity, and sociocultural values rooted in solidarity and mutual aid. At the same time, their engagement unfolds within a health system characterized by human resource shortages, uneven territorial distribution of services, and high unmet needs.

In this sense, prosocial motivation operates not only at the individual level but also as a mediating mechanism between structural constraints and professional action. Physicians'

voluntary participation in medical caravans and mobile initiatives can be interpreted as a response that bridges personal values and systemic gaps. The theory thus enables the articulation of four interrelated dimensions emerging from the data: empathic drivers, normative and cultural values, professional identity, and awareness of structural health system limitations.

By mobilising prosocial motivation theory within a health systems perspective, this study situates physicians' voluntary engagement at the intersection of individual agency and institutional context. This approach allows for a nuanced understanding of medical volunteering as both a moral commitment and an adaptive response to human resource deficits in resource-constrained settings.

Methods

Study design

This study adopted an exploratory qualitative design grounded in an interpretive approach. A qualitative methodology was considered appropriate to capture in-depth, context-sensitive insights into physicians' voluntary engagement within a health system characterized by human resource shortages and territorial inequities. The aim was not statistical generalization but analytical understanding of the mechanisms linking individual motivations to systemic health workforce challenges.

Participants

Semi-structured interviews were conducted with eight physicians working in public hospitals in the city of Fes. The choice of Fes was justified by its position as a major regional health hub in the Fes-Meknes region, where university and public hospitals regularly mobilize physicians for medical caravans, mobile health units, and outreach interventions targeting remote and underserved areas. Focusing on physicians from this region allowed the study to explore volunteering practices in a context marked by both specialized medical resources and persistent territorial inequalities in access to care.

Participants were purposively selected based on their substantial experience in medical volunteering, including participation in medical caravans, mobile health units, outreach initiatives in remote rural areas, or humanitarian actions led by the Ministry of Health or local associations. A purposive sampling strategy was employed to ensure diversity in age, professional experience, medical specialty, workplace, and type of voluntary engagement. They were aged between 33 and 58 years, and their volunteering experience ranged from 5 to 25 years.

Recruitment continued until thematic saturation was reached. Saturation was assessed progressively during data collection and preliminary analysis. After the sixth interview, the main analytical categories had already been identified. The seventh and eighth interviews confirmed the same recurring patterns related to empathic motivation, professional responsibility, sociocultural and religious values, and awareness of health system constraints, without generating substantially new themes. This indicated that sufficient thematic depth had been achieved for the exploratory purpose of the study.

Table 1. Characteristics of the participants.

Gender	Age	Medical specialty	Workplace	Experience in volunteering (years)	Type of voluntary engagement
Male	45	Ophthalmology	Hassan II University Hospital, Fes	12	Medical caravans, rural outreach activities
Male	38	Emergency medicine	Al Ghassani Hospital	8	Mobile units, seasonal campaigns

Male	52	Cardiology	Hassan II University Hospital	20	Specialized interventions, screening activities
Male	58	Surgery	Ibn Al Khatib Hospital	25	Humanitarian missions, NGOs
Male	40	Dentistry	Al Ghassani Hospital	10	Ministry of Health medical caravans
Male	47	General medicine	Ibn Al Khatib Hospital	15	Specialized outreach in remote areas
Female	36	Otorhinolaryngology (ENT)	Hassan II University Hospital, Fes	6	Medical caravans
Female	41	Gynecology	Al Ghassani Hospital	9	Medical caravans

Procedure

Interviews were conducted between March and May 2025. They took place face-to-face in private offices within participants' workplaces, ensuring confidentiality and a calm environment. Each interview lasted between 45 and 75 minutes.

All interviews were audio-recorded with participants' consent and transcribed verbatim. Interviews were conducted in French. The transcripts were first analysed in their original language in order to preserve participants' meanings, expressions, and contextual nuances. For reporting purposes, selected illustrative quotations were translated into English after the completion of the thematic analysis. The translation aimed to maintain semantic equivalence rather than a literal word-for-word correspondence. Translated quotations were reviewed against the original French transcripts to ensure accuracy and consistency of meaning.

An interview guide was developed based on existing literature on medical volunteering and prosocial motivation theory. The guide was reviewed by the research team before data collection to assess the clarity, relevance, and logical sequencing of the questions. Minor wording adjustments were made to improve clarity. However, no separate pilot interview was conducted. The interview guide explored previous volunteering experiences; personal, professional, and social motivations; perceptions of volunteering within the Moroccan health system; barriers and facilitators to voluntary engagement; and the perceived impact of volunteering on professional practice and personal development. Attention was paid to themes related to health system functioning, workforce shortages, and territorial inequities in access to care.

Table 2. Interview guide used in the study

Theme	Main questions
Volunteering trajectory	Can you describe your initial experiences of volunteering in the health sector?
Motivations	What motivates you to participate in medical volunteering activities?
Personal and professional dimensions	To what extent is your voluntary engagement linked to your professional identity?
Barriers	What obstacles or constraints do you encounter when participating in these activities?
Impacts	How does volunteering influence your practice, your perception of the profession, or your personal development?
System perception	How do you perceive the role of volunteering within the Moroccan health system?
Suggestions	What could be improved to encourage greater physician engagement in medical volunteering?

Data analysis

Data were analysed using inductive thematic analysis following the approach described by Braun and Clarke (Braun & Clarke, 2006). This approach was appropriate because it allowed themes to emerge from participants' accounts while remaining attentive to the broader theoretical framework of prosocial motivation and health system constraints.

The analytical process involved five stages: familiarization with the data through repeated reading of transcripts; initial line-by-line coding; grouping codes into broader analytical categories; development of overarching themes; and interpretation of themes in relation to prosocial motivation theory and health system context.

Initial codes were generated inductively from the interview transcripts and remained close to participants' narratives. Similar codes were then compared and grouped into broader analytical categories. These categories were progressively refined into themes by examining their recurrence across interviews, their internal coherence, and their relevance to the research objective. The final themes were not predetermined but emerged through repeated comparison across participants' accounts. They were later interpreted in relation to prosocial motivation theory and the structural challenges of the Moroccan health system.

Coding was conducted manually by the primary researcher. Qualitative data analysis software was considered; however, manual coding was preferred because of the relatively small sample size and the exploration nature of the study. This approach allowed close engagement with the transcripts and facilitated a nuanced interpretation of participants' meanings, expressions, and contextual details.

To enhance analytical rigor, emerging codes, categories, and themes were discussed iteratively with a senior researcher experienced in qualitative health systems research. Discrepancies were resolved through discussion until consensus was achieved. Field notes taken during and after interviews were also used to support interpretation and contextualize the data.

Reflexivity was maintained throughout the research process. The researcher acknowledged her professional background in the health and social sector, which facilitated contextual understanding while requiring careful attention to avoid interpretive bias. Reflexive notes were used to document analytical decisions, contextual impressions, and potential assumptions during the coding and theme development process. This analytical approach enabled a nuanced understanding of how physicians' voluntary engagement is shaped by both individual motivations and structural health system constraints.

Results

The thematic analysis of the eight interviews identified four major themes structuring the motivations of physicians engaged in volunteering within the Moroccan health sector: (1) empathic and humanitarian motivations, (2) professional and ethical motivations, (3) social, cultural, and religious motivations, and (4) motivations related to the structural context of the health system. Together, these themes reflect the complexity of the individual and collective drivers underpinning physicians' voluntary engagement and shed light on the prosocial mechanisms shaping their decisions.

1. Empathic and Humanitarian Motivations

All participants expressed motivations strongly rooted in empathy, the desire to alleviate suffering, and the willingness to contribute to improving the well-being of vulnerable populations. Several physicians described volunteering to "restore meaning" to their daily practice and to go "beyond the technical act" in order to reconnect with the human dimension of care.

One participant stated:

> *"I chose to engage in volunteering because I wanted to give a more human meaning to my practice, to reach patients who have no one."*

This motivation was particularly evident among physicians who had worked in rural or underserved settings, where they reported being deeply affected by patients' extreme vulnerability:

> *"When you see the conditions in which some families live, you cannot remain indifferent. You feel a human obligation to help."*

Empathy thus emerges as a central driver of engagement, reinforced by direct exposure to suffering and barriers to healthcare access.

2. Professional and Ethical Motivations

A second form of motivation relates to physicians' professional identity and the ethics of care. Participants perceived volunteering as a natural extension of their social role and professional responsibilities, often referring to a "moral duty" inherent in the medical profession.

As one general practitioner explained:

> *"When you are a doctor, you cannot limit yourself to the office or the hospital. You have a duty towards people, especially those who cannot come to us."*

Several physicians also described volunteering as an opportunity to strengthen clinical skills, adaptability, and practical experience in non-conventional settings:

> *"Medical caravans allow us to learn differently. We work under difficult conditions and think differently. It is real learning."*

For some specialists, volunteering offered a more humane and less bureaucratic practice environment than hospital settings, fostering a more direct relationship with patients:

> *"In caravans, we rediscover real medicine, the medicine of contact and listening, without administrative pressure."*

3. Social, Cultural, and Religious Motivations

Many physicians explained their engagement by referring to their upbringing, family values, or early socialization in associations or youth movements. Volunteering was thus perceived as a natural continuation of transmitted values.

One participant with a background in scouting noted:

> *"Since childhood, I was raised in a culture of mutual aid and volunteering. For me, it is normal to do something for others."*

Others emphasised the influence of Moroccan cultural norms of solidarity and benevolence (al-khayr, al-iḥsān), as well as the religious dimension of volunteering:

> *"In our culture and religion, helping others is a core value. A physician should set an example in this regard."*

These social, cultural, and spiritual dimensions anchor volunteering in a broader conception of the physician's role that extends beyond paid employment.

4. Motivations Related to the Structural Context of the Health System

Finally, physicians' motivations were also embedded in the structural context of the Moroccan health system, characterized by persistent territorial inequalities, shortages of human resources, and limited access to specialized care in remote areas.

Several participants indicated that their engagement stemmed from a deep awareness of these systemic constraints:

> *"When you work in the public sector, you see the system's limits every day. So when you can do something more, even outside work hours, you do it."*

For some physicians, volunteering represented a way to compensate for the absence of public services in certain regions:

> *"We know there are areas where people have never seen a specialist. That is why we go to fill a gap."*

Volunteering was thus perceived both as a humanitarian act and as a pragmatic response to structural deficiencies.

Physicians' motivations for volunteering are organized around four complementary dimensions: empathic motivations centered on alleviating suffering; professional motivations rooted in the ethics of care; social motivations nourished by cultural, family, and religious values; and structural motivations linked to unmet needs within the health system. These motivations interact and reinforce one another, structured by a strong sense of social usefulness and a deep commitment to vulnerable populations.

Discussion

The findings indicate that physician volunteering in Morocco operates at the intersection of individual motivation and structural health system constraints. While participants' narratives strongly align with the multidimensional dynamics described by prosocial motivation theory, the data also reveal that voluntary engagement functions as an adaptive response to systemic workforce and access gaps.

Consistent with Batson's empathy–altruism hypothesis (Batson, 2014), physicians described empathic concern as a primary driver of engagement. Direct exposure to vulnerable populations and visible inequalities in access to care appeared to trigger a moral imperative "not to remain indifferent." International evidence similarly demonstrates that compassion and concern for underserved communities are central motivations among physicians involved in humanitarian and outreach activities (Martiniuk *et al.*, 2012) (Rovers *et al.*, 2016). The Moroccan findings reinforce this pattern, suggesting that empathy constitutes a foundational mechanism sustaining voluntary medical action across diverse contexts.

Professional identity further reinforces this engagement. In line with Grant's conceptualization of prosocial motivation (Grant, 2008), participants perceived volunteering as a natural extension of their ethical and professional responsibilities. Several physicians described rediscovering a patient-centred form of medicine less constrained by administrative pressures. Comparable findings have been reported in studies of international medical missions, where volunteering is framed as a reaffirmation of professional meaning and social responsibility (Caldron *et al.*, 2018) (Kim *et al.*, 2019). These dimensions illustrate how professional ethics and perceived social impact sustain long-term voluntary involvement.

Sociocultural and religious values also play a structuring role. Consistent with Penner et al.'s multilevel model (Penner. *et al.*, 2005), participants' engagement reflects internalized norms of solidarity, mutual aid, and moral obligation. Similar patterns have been documented in settings where religiosity and community cohesion strongly shape volunteering practices (Sallam *et al.*, 2018) (Gianisa & Le De, 2018). . In the Moroccan context, such values reinforce physicians' readiness to contribute beyond formal contractual obligations.

However, beyond these motivational dimensions, the study highlights the structural role of volunteering within the Moroccan health system. Participants consistently described their engagement as a response to shortages of specialists, insufficient infrastructure, and territorial inequities in healthcare distribution. These findings resonate with analyses of fragile and resource-constrained health systems, where voluntary or community-based initiatives partially compensate for institutional deficits (Iqbal, Rabrenovic et Li, 2019) (Glenton *et al.*, 2013; Maes, 2016). In this sense, physician volunteering may be interpreted not only as an expression of altruism but also as an informal human resource supplementation mechanism.

This dual nature raises important health systems considerations. While medical caravans and outreach initiatives temporarily mitigate access gaps, reliance on voluntary engagement may also reflect underlying workforce distribution imbalances and systemic vulnerabilities. Volunteering can enhance responsiveness and flexibility, yet its episodic and discretionary character may limit

continuity of care and long-term sustainability if not embedded within coordinated planning frameworks.

From a health workforce perspective, integrating voluntary medical engagement into broader human resource strategies may enhance its impact. Structured coordination, monitoring mechanisms, and clearer institutional recognition could strengthen alignment between voluntary initiatives and national health equity goals. At the same time, policymakers must remain attentive to the risk that informal supplementation mechanisms become substitutes for structural investment in permanent workforce distribution and infrastructure development.

Overall, the findings suggest that physician volunteering in Morocco reflects both resilience and constraint within the health system. It embodies strong ethical commitment and sociocultural solidarity, while simultaneously revealing persistent gaps in equitable service provision. Understanding this interplay between agency and structure is essential for designing policies that support voluntary engagement without reinforcing systemic dependency.

This study offers one of the few qualitative explorations of physician volunteering within the Moroccan health system, providing in-depth insight into how individual motivations intersect with structural workforce challenges. The use of semi-structured interviews enabled rich contextual understanding, and the integration of prosocial motivation theory within a health systems lens strengthened analytical coherence.

Nevertheless, certain limitations should be acknowledged. The sample was limited to eight physicians from a single region, which may restrict transferability to other contexts. Although thematic saturation was achieved, broader geographic diversity could further illuminate regional variations in voluntary engagement. Social desirability bias may also have influenced participants' narratives, given the positive social valuation of volunteering within the medical profession. However, the consistency of themes across interviews and their alignment with international literature support the credibility of the findings.

These results have important implications for health workforce policy and system strengthening. Medical volunteering should be formally acknowledged within national human resources for health strategies. Institutional recognition mechanisms such as structured accreditation of voluntary hours, integration into continuing medical education frameworks, or formal recognition by professional councils, could enhance motivation while aligning voluntary engagement with national health equity objectives. Establishing a national registry or coordination platform for medical volunteering may also improve transparency and strategic workforce planning.

Stronger governance and coordination mechanisms are required to ensure coherence and sustainability. Improved collaboration between the Ministry of Health and Social Protection, regional health authorities, professional bodies, and civil society organisations would facilitate better planning, geographic targeting, and evaluation of medical caravans and mobile initiatives. Developing standardised monitoring and evaluation frameworks could strengthen accountability, assess impact on access to care, and reduce duplication of interventions.

Logistical and organisational support should also be reinforced, particularly in remote and underserved areas. Ensuring adequate equipment, transportation, administrative support, and integration with local primary healthcare structures would enhance the quality, continuity, and safety of care delivered during voluntary missions. Structured collaboration with community health workers and social services could further improve referral pathways and follow-up mechanisms.

At the same time, policymakers should carefully balance the institutionalisation of volunteering with long-term structural investment. While physician volunteering can temporarily mitigate territorial inequalities and workforce shortages, it should complement rather than substitute sustained recruitment, equitable distribution of health professionals, and infrastructure development. Embedding voluntary initiatives within broader health system strengthening and

universal health coverage efforts would help ensure that they reinforce, rather than mask, systemic gaps.

Future research could extend this work by incorporating comparative regional analyses, mixed-methods designs, or policy-level investigations to better assess the sustainability and systemic implications of physician volunteering in Morocco and similar settings.

Conclusion

This study highlights physician volunteering as both an ethical commitment and an adaptive response to structural constraints within the Moroccan health system. Physicians' voluntary engagement reflects strong professional identity, sociocultural solidarity, and empathic concern, while simultaneously responding to persistent territorial inequities and workforce shortages.

By conceptualizing physician volunteering as an informal human resource supplementation mechanism, this research contributes to understanding how individual agency intersects with systemic health system challenges. Recognizing, coordinating, and strategically integrating voluntary engagement within broader workforce and equity strategies may enhance health system responsiveness in underserved settings.

At the same time, ensuring that voluntary initiatives complement structural investment in permanent workforce distribution remains essential for sustainable and equitable health system development.

Declarations

Ethical considerations

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki and Moroccan legislation on the protection of individuals participating in biomedical research. The protocol received a favorable opinion from the Oujda Biomedical Research Ethics Committee (CERBO), reference 27/2024, dated 2 August 2024. All participants received detailed information about the study objectives and procedures and provided written informed consent prior to participation. Anonymity, confidentiality, and the right to withdraw at any time without consequence were guaranteed.

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An analysis of the Level and Factors Influencing Adolescent Mothers' Resilience to Gender-Based Violence in Shinyanga Region, Tanzania

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Abstract

Introduction: Gender-Based Violence (GBV) remains a pervasive public health and human rights issue in Tanzania, with adolescent mothers particularly vulnerable. Despite numerous interventions, limited attention has been paid to understanding how adolescent mothers develop resilience in the face of such violence.

Objective: This study examined the level of resilience among adolescent mothers and the factors influencing adolescent mothers' resilience to GBV in Shinyanga region, Tanzania.

Methods: A cross-sectional research design, along with a mixed-methods approach, was adopted, integrating a household questionnaire survey (n = 202) with qualitative data collected through focus group discussions (FGDs) and key informant interviews. Quantitative data were analyzed using SPSS version 25, while qualitative data were subjected to content analysis.

Results: Results: The findings revealed low resilience among adolescent mothers. Multiple linear regression analysis showed that resilience was positively associated with higher education level (β = 0.304, P< 0.001), social support (β = 0.240, P< 0.05), and financial support (β = 0.276, P<0.001). Conversely, living arrangement (β = -0.160, P < 0.05) and age at first birth (β= -0.214, P< 0.01). were negatively significantly associated with resilience among adolescent mothers. Qualitative findings complemented these results by revealing that adolescent mothers with higher education level and stronger family or community support in-terms of financial and social capital were better able to cope with violence and seek assistance. Participants in FGDs emphasized that emotional encouragement from parents helped them withstand abusive situation. Conversely, adolescent mothers who lacked family support or experienced early childbearing reported greater dependence on parents and limited ability to respond to violence.

Conclusion: There is a need for joint programs involving family, community, government, and non-government institutions to provide social, economic, and psychological support to enhance adolescent mothers' resilience to GBV.

Key words: Adolescent mothers, gender-based violence, resilience, social supports, regression analysis

Introduction

Gender-based violence (GBV) remains a human rights concern at both the national and international levels (Villiers, 2018). It affects adolescents, particularly adolescent mothers (Ovejas, 2025). Moreover, 30 percent of girls including adolescent mothers worldwide have been subjected to either non-partner sexual violence or physical and sexual violence within intimate relationship (WHO, 2024). Furthermore, about 10.4 percent of adolescents experience GBV, with adolescent mothers at higher

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risk (Bali, Sembiah, & Burman, 2024). Adolescents mothers are vulnerable to abusive behaviors that they may normalize in romantic relationships (Ovejas, 2025). These intersecting forms of violence and structural disadvantage disrupt the education and future opportunities of adolescent mothers. Many survivors drop out of school due trauma, stigma, or responsibilities related to nearly motherhood. This limits their chances for skill development, employment, and empowerment (Kassanga & Lekule, 2021).

In Africa, particularly Sub-Saharan Africa, studies show that 28 percent of adolescents (15-19 years) and 29 percent of adolescent mothers (20-24 years) had experienced physical or sexual intimate partner violence (Wado et al., 2021). These experiences are strongly influenced by early pregnancy, gender inequality, poverty, and sociocultural norms, which collectively increase their vulnerability. In Tanzania, 37.2 percent of women aged 15to 49 have ever experienced either physical or sexual violence (URT, 2022). Rates of physical and sexual violence vary across the country, with Shinyanga among the regions with the highest levels, ranging from 36 percent to 64.2 percent (URT, 2022). Nonetheless, harmful traditional practices, values, and norms that still exist in the region have contributed to the increasing of GBV among adolescent mothers, as a result of harmful practices, Shinyanga region is one of the leading regions with 59 percent of early marriage (URT, 2020). Despite the existence of legal and policy frameworks such as the Law of Marriage Act (1971), the Child Act (2009), the Domestic Violence Act (2010), and the National Action Plan to End Violence Against Women and Children (2017–2022), gender-based violence against women and girls including adolescent mothers remains highly prevalent in Tanzania, particularly in Shinyanga region (UNFPA, 2021).

In this context, adolescent mothers' resilience is critical to protecting them from the harmful effects of adversity such as GBV due the fact that they face early parenthood, social stigma, economic hardship, educational disruption, and increased exposure to GBV. Resilience studies offer a new approach to addressing GBV against women and children. they focus on promoting the qualities that enable individuals to face adversity and overcome violent situations (Mantler et al., 2024). This allows some individuals to adapt and maintain positive functioning in the face of severe adversity, while others facing the same challenges have negative outcomes (Namy et al., 2017).

Despite the well-documented risks associated with gender-based violence (GBV) including school dropout, early pregnancy, sexually transmitted infections, poor academic performance, and violent behavior, many adolescent mothers in both rural and urban Tanzania continue to function adaptively despite these adversities (Pfeiffer, Ahorlu, Alba, & Obrist, 2017). Existing literature, however, has largely focused on the prevalence of GBV and institutional responses, such as the roles of One Stop Centres (OSCs) and police gender desks (Mntambo & Bwikizo, 2024), as well as the physical, psychological, and social health consequences of GBV among adolescents (Cherewick et al., 2022; Pfeiffer et al., 2017; Villiers, 2018). Comparatively little attention has been paid to adolescent mothers as a distinct and highly vulnerable group facing intersecting challenges related to age, motherhood, and socioeconomic marginalization. Consequently, there remains a critical gap in understanding the level of resilience and the factors that influence resilience to GBV among adolescent mothers. This study seeks to address this gap by identifying resilience enablers, with the aim of informing policymakers and stakeholders in developing targeted mechanisms to better support adolescent mothers affected by GBV.

Conceptual framework

This study was guided by the socio-ecological framework of resilience from a multi-layered social-resilience framework by Obrist, Pfeiffer & Henley (2010), in examining adolescent mothers' resilience to GBV in Shinyanga Region. The model provides a powerful lens for understanding the resilience of an individual to GBV. By considering multiple levels of influence and the interaction between risks and resources (capital).

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The conceptual framework (Figure 1.0) positions gender-based violence (GBV) as a major threat to the well-being of adolescent mothers. The framework assumes that exposure to GBV at the family, community, and societal levels negatively affects the physical, psychological, and social health of adolescent mothers. However, the impact of GBV is influenced by key determinants of resilience, including economic capital, social capital, human capital, and demographic characteristics.

Economic capital, such as access to income, employment opportunities, and financial resources, enables adolescent mothers to meet basic needs and reduce dependency, thereby strengthening their ability to cope with and resist GBV. Social capital, reflected in family support, peer networks, and community relationships, provides emotional, informational, and practical assistance that enhances adaptive capacity. Human capital, including education, skills, and knowledge, equips adolescent mothers with problem-solving abilities, awareness of rights, and improved decision-making skills, which are essential for responding to violence. Demographic variables, such as age, marital status, living arrangements, and age at first birth, shape individual vulnerability and access to supportive resources, thereby influencing resilience outcomes.

The presence of these determinants strengthens resilience among adolescent mothers by enabling them to mobilize available resources and adopt coping strategies that help them withstand or overcome GBV. Conversely, the absence or limited availability of these moderating factors increases vulnerability, exposing adolescent mothers to adverse health and social outcomes associated with GBV. Therefore, the study emphasizes competence as a result of resilience, whereby high resilience can lead to positive outcomes such as recovery and empowerment, while low resilience can lead to incompetence making it possible for GBV exposure.

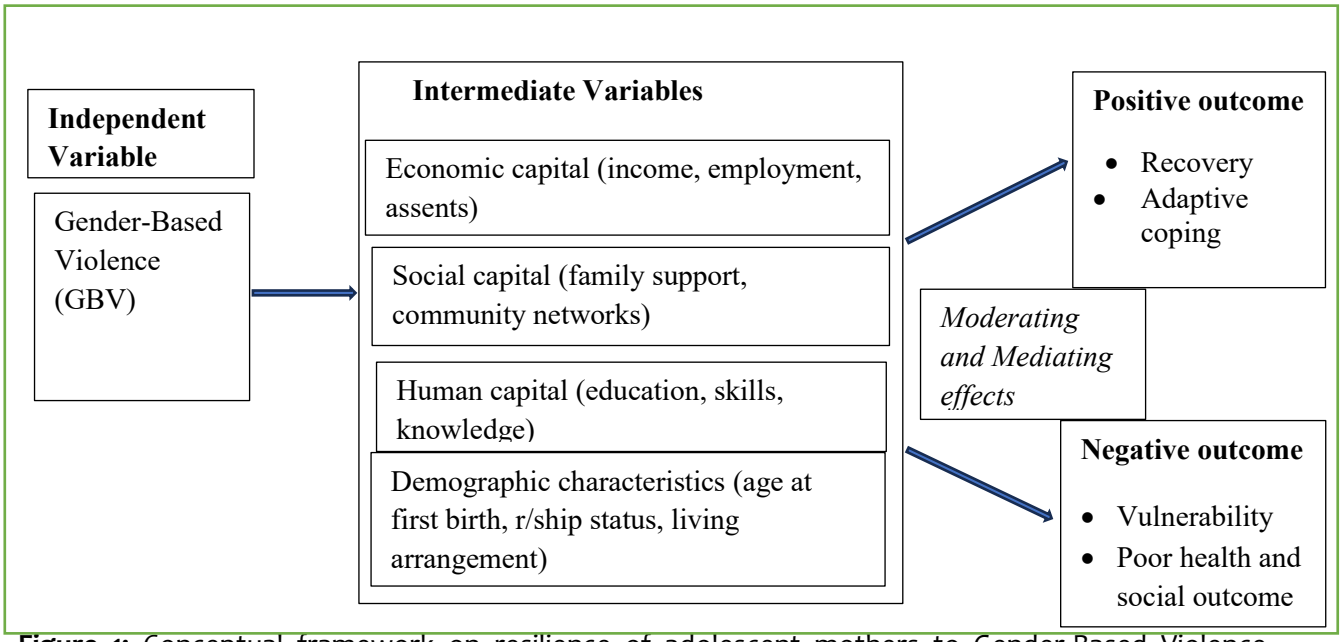

Figure 1: Conceptual framework on resilience of adolescent mothers to Gender-Based Violence adapted from Obrist, Pfeiffer & Henley (2010) social resilience framework.

Materials and Methods

Study Area

The study was conducted in Shinyanga Region, located between 31°–35° East longitude and 2°–3° South latitude in Tanzania's Lake Zone. The region borders Simiyu to the east, Tabora to the south, Kigoma

to the west, Kagera to the northwest, and Mwanza to the north (NBS, 2013). Shinyanga is among the regions with a high prevalence of gender-based violence (GBV), including child marriage and intimate partner violence. Reports indicate a child marriage prevalence of 64% in Shinyanga, and approximately 78% of married women have experienced violence, compared to 44% nationally (URT, 2022; World Bank Report, 2022). Shinyanga and Msalala Districts were randomly selected (See Figure 2). Three wards from each district were purposively selected based on GBV prevalence, and one village from each ward was included in the study.

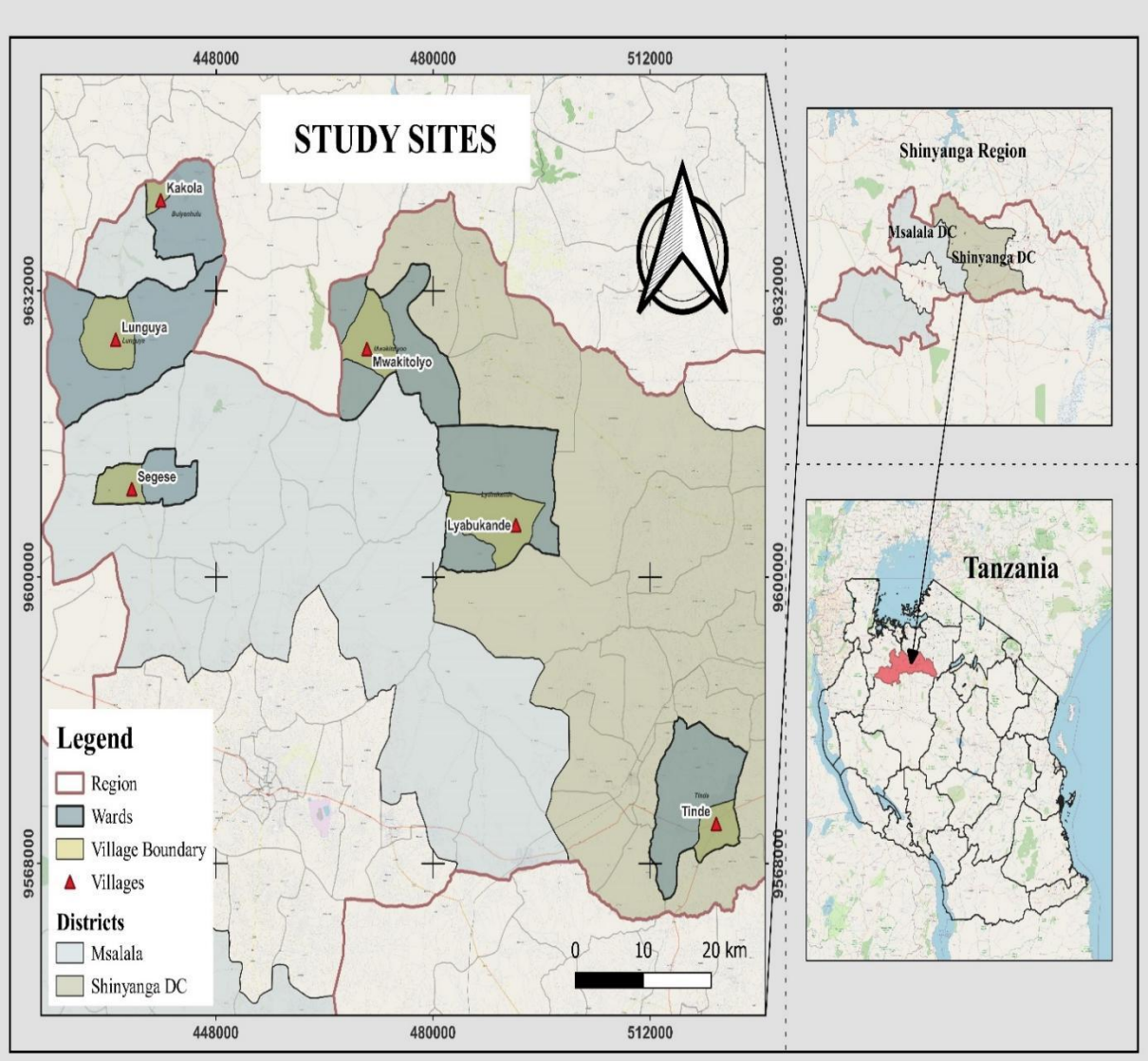

Figure 2: *location of the studied villages in Shinyanga Region*
Source: UDOM, GIS LAB (2024)

Research Design

The study adopted a cross-sectional mixed-methods design integrating quantitative and qualitative approaches. This design enabled data collection at a single point in time to assess resilience levels and associated factors, including social support, financial support, age at first birth, and education among

adolescent mothers. The mixed-methods approach, with greater emphasis on quantitative data, enhanced a comprehensive understanding of resilience to gender-based violence.

Targeted Population, Sample Size, and Sampling Techniques

The study targeted adolescent mothers aged 15–19 who had given birth at least once. Key informants included police gender desk officials, health officers, and NGO representatives working with adolescents. The inclusion criteria of this study were adolescent mothers aged between 15 and 19 years, had at least one child and had been residing in Shinyanga Region for at least six months prior to the study. Also, participants required to be willing to participant and able to provide informed consent or assent. Adolescents who were outside the specified age range, pregnant but had not yet given birth, temporarily residents of the region, severely ill, or un able to provide informed consent/ assent were excluded from the study. Sample size for this study was determined using the Cochran's (1963) formula..

$$n = \frac{(Z_{\alpha}/2)^2 P(1-P)}{\lambda^2}$$

Whereby, n = sample size, P= percentage of adolescent mothers experiencing GBV, and λ= sampling error: since P was not known for the study population, its value was assumed to be 50%, which ensures the maximum sample size (Amin, 2005; Nwako & Nwoke, 2009). Using a 95% confidence interval for the estimated population proportion, a 10% sampling error, design effects of 2 (n×2) (Kisinza et al., 2008) and a 5% non-response rate the formula provided a sample size of 202 respondents for this study. Accordingly, probability sampling using systematic random sampling was applied to select adolescent mothers from household lists obtained from village and community welfare officials. Systematic random sampling ensures a maximum sample, reduces bias, and makes the selection procedures more efficient (Makwana et al., 2023). Purposive sampling was used to select wards, villages, and key informants for qualitative data collection.

Data Collection Methods and Procedure

Quantitative data were collected through face-to-face interviews using structured questionnaires with both closed- and open-ended questions, administered by the researcher and two trained assistants. Questions gathered information on the issues of adolescent mothers' resilience and gender-based violence. Additionally, Qualitative data were collected to complement quantitative findings. Six Focus Group Discussions (FGDs) were conducted, with one FGD held in each of the six selected villages. The FGDs involved adolescent mothers who met the study inclusion criteria and were purposively selected to ensure diversity of experiences related to GBV exposure, coping mechanisms, and social support systems. Each FGD consisted of 8–10 participants and was facilitated using a checklist.

Key Informant Interviews (KIIs) were conducted with district social welfare officials, police desk officers, and three representatives from NGOs, namely SHIDEFA+, Thubutu Africa Initiative (TAI), and Rafiki SDO. These were knowledgeable and provided important information about the prevalence of GBV, types of GBV encountered by adolescent mothers, and social, economic, and psychological support provided to adolescent mothers.

All FGDs and KIIs were conducted in Kiswahili by a researcher and trained research assistants at private, convenient locations to ensure confidentiality and encourage open discussion. Each FGD lasted approximately 60–90 minutes, while each KII lasted 30-60 minutes. Prior to participation, written informed consent was obtained from all participants. With participants' permission, all discussions and interviews were audio-recorded and supplemented with field notes to enhance data completeness and accuracy.

Data Analysis

Quantitative data were analysed using IBM SPSS version 25, employing descriptive statistics and inferential analysis. Resilience was measured using a 10-item scale adapted from the Connor-Davidson Resilience Scale with a 5-point Likert scale (Davidson, 2018). Exploratory Factor Analysis using Principal Component Analysis confirmed construct validity (KMO = 0.714; Bartlett's test $\chi^2 = 1352.7$, $p < 0.001$). Components with eigenvalues> 1 and factor loadings ≥ 0.40 were retained to generate composite resilience scores. Respondents scoring below the mean were categorized as having low resilience, while those scoring at or above the mean were classified as having high resilience.

Table 1: Descriptive Statistics of Resilience Scores (n= 202)

Variable	Minimum	maximum	Mean	Std. deviation
Resilience score	-2.018	2.339	0.000	1.00

However, Multiple linear regression analysis was conducted to examine associations between resilience and socio-demographic and psychosocial variables, including age at first birth, relationship status, education, living arrangement, marriage of the respondent's parent, financial support, and social support.

The logistic model used to determine the factors that influence resilience is given in the equation hereunder;

$Y = \beta o + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \cdots + \beta_k X_k + \varepsilon$

Where:

Y = the dependent variable (resilience score of adolescent mothers)

β_o = the intercept (constant)

$\beta_1, \beta_2 \ldots, \beta_k$ = regression coefficients for each predictor

X_1, X_2, ----------, X_k = independent (predictor) variables (age at first birth, educational level, etc.)

ε =error term.

Additionally, qualitative data from focus group discussions and key informant interviews were analysed through content analysis (Assarroudi et al., 2018). Following the process of summing the information into condensed meaningful units, coding, defining, and naming themes, and reporting. The findings were then integrated with quantitative results in the results section through triangulation, providing deeper explanation and contextual meaning to the statistical association.

Results

Socio-Demographic Characteristics of Respondents

This study involved 202 respondents (adolescent mothers), whereas 41.6 percent were 19 years old, while, very few (3.5 percent) were 15 years old. In addition, 57.4 percent were in the age group of 18-19 years and 42.6 percent were in the age group of 15-17 years. Furthermore, 76.7 percent of the respondents started childbearing before 18 years old, while 23.3 percent started childbearing after 18 years old. In terms of educational level, 58.9 percent had primary education, 29.7 percent had secondary education, and 11.4 percent had no formal education. In terms of relationship status, nearly half of the respondents (48.5 percent) were single, while 26.2 percent were in relationships but not married. Only 15.4 percent were married, and 9.9 percent were divorced or separated. 46.0 percent were lived with parents while 54.0 percent were lived with either husbands, relatives, or friends. In

addition, 48.5 percent were in a polygynous marriage, while 51.5 percent were in a monogamous marriage of the respondent's parents. These results are presented in Table 2.

Table 2. Social Demographic Characteristics of the Respondents (n=202)

Variable	Frequency	Percent
Age of respondent		
15 years	7	3.5
16 years	38	18.8
17 years	41	20.3
18 years	32	15.8
19 years	84	41.6
Age at first birth		
Less than 18 years old	155	76.7
More than 18 years old	47	23.3
Level of education		
None	23	11.4
Primary education	119	58.9
Secondary education	60	29.7
Relationship status		
Married	31	15.4
In a relationship but not married	53	26.2
Single	98	48.5
Divorced or separated	20	9.9
Living arrangement		
With parents	93	46.0
Others (husbands, relatives or friends)	109	54.0
Types of marriage by parents		
Polygyny	98	48.5
Monogamy	104	51.5

Source: Field data (2024)

Resilience Level to GBV among Adolescent Mothers in Shinyanga, Tanzania.

In examining resilience levels among adolescent mothers, the study first sought to determine the prevalence of sexual, physical, and emotional violence among adolescent mothers in the study area. The findings (Figs 3, 4, and 5) show that 84.0 percent reported sexual violence, 82.0 percent reported physical violence, and 92.6 percent reported emotional violence. Participants described their experiences with Gender-Based Violence. During the Focus Group Discussion (FGD) in Mwakitolyo village, one participant said,

> *"Physical abuse is undoubtedly a prevalent occurrence in our communities and families. I was married, but I later divorced. During our marriage, my husband would frequently hit or slap me, injuring my leg and head, even though I wasn't at fault. Also, at one time, my mother-in-law threw me out of the house and told me to go away from their family. I was so troubled by this habit that I ultimately decided to end my marriage with my husband." (FGD participant, 19 years, February 2024).*

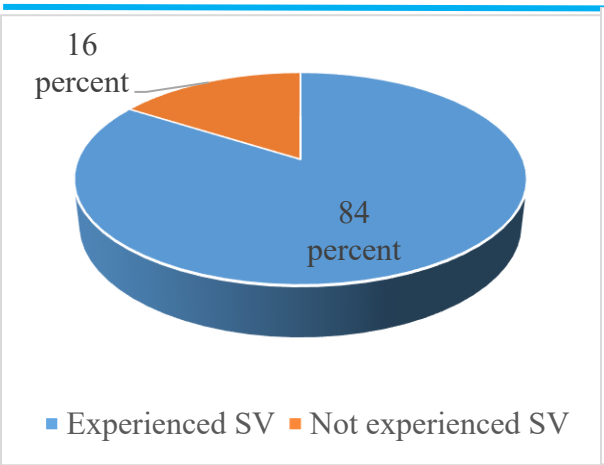

Figure 3. Prevalence of sexual violence

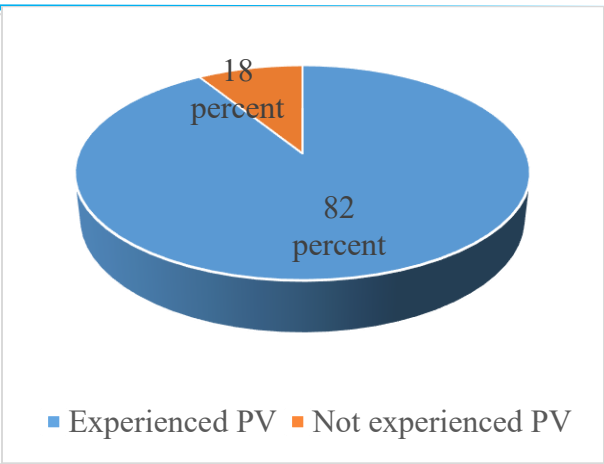

Figure 4. Prevalence of physical violence

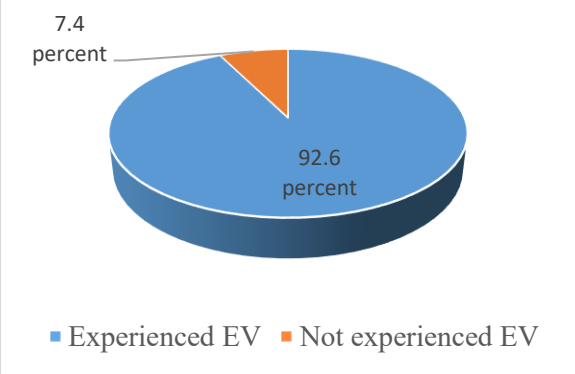

Figure 5. Prevalence of emotional violence.
Source; Filed data 2024
Key: SV=Sexual Violence: PV= Physical Violence and EV= Emotional Violence

Regarding resilience among adolescent mothers, the findings (Table 3) reveal that 64.4 percent of the respondents had low resilience scores, compared with 35.6 percent who had high resilience scores.

Table 3. Resilience Level against GBV among Adolescent mothers (n=202)

Resilience level	Mean score	Frequency	Percent
Low	<0.000	130	64.4
High	>=0.000	72	35.6

Source: Field data (2024)

3.3 Factors associated with Resilience of Adolescent Mothers to GBV in Shinyanga, Tanzania.

A multiple linear regression analysis was performed to examine the factors associated with resilience among adolescent mothers, with resilience treated as a continuous outcome variable. The predictors included age at first birth, relationship status, educational level, financial support, social support, living arrangement, and parental marriage. The findings in Table 3 demonstrate that education level, financial support, and social support were positively significantly associated with resilience among adolescent mothers, while age at first birth and living arrangement were negatively significantly associated with resilience among adolescent mothers. The study also found that respondents' parents were not significantly associated with the resilience of adolescent mothers in the study area.

The results (Table 3) show that education level was found to be a strong positive predictor of resilience (β= 0.304, P< 0,001). This quantitative result was reinforced by focus group discussions conducted at Mwakitolyo village, whereby participant who had plans to return to school expressed greater optimism and determination to improve their lives, and she said that;
"Despite having a child, I want to return to school. Because education will make my child and me live better lives. That's what makes me strong." (FGD participant, 17 years, February 2024)
Similarly, Key informants highlighted that education empowers adolescent mothers and reduces feeling of hopeless, saying that;
"Adolescent mothers with some educations are more resilient. They can find different alternative ways of surviving to manage abuses." (Social welfare officer, Tinde village, February 2024).

In terms of social support, the findings (Table 3) revealed that social support was a significant positive predictor of resilience (β = 0.240, P< 0.05). This finding was also supported by one of the participants during focus group discussion as follows;
*"This year I finished form four (husband) and got married to my husband, who helps me in getting some basic needs. Sometimes my parents also help me when I need something. I have never experienced any form of violence, except for minor misunderstandings that sometimes happen between my husband and me. (*FGD participant, Tinde village, February 2024).

In terms of financial support, the regression model in Table 3 showed that financial support exhibits significantly higher resilience scores to GBV among adolescent mothers (β = 0.276, P<0.001).

For age at first birth, the finding (Table 3) indicates a significant negative relationship with resilience (β = -0.214, P < 0.01). indicating that adolescent mothers who gave birth at a young age tend to have lower resilience scores to GBV than those who gave birth slightly later. This result was supported by qualitative findings from focus group discussions in Segese village, whereby one of the participants had the following to say;
"Since I dropped out of school, I have been struggling myself. Sometimes I could not have anyone to talk to, I could hardly know to whom I should go to because anyone, even my mother's response would mostly be, 'You will be all right" or "it is okay". Sometimes I felt like people started to avoid me because of the young parental hood." (FGD, participant, Segese village. February 2024).

Similarly, during a key informant interview in Segese village, a healthcare provider emphasized that younger adolescent mothers are more likely to experience psychological distress and low confidence when dealing with gender-based violence. She said that;
"Girls who give birth before 18 years have a very hard time coping. They are still developing mentally and emotionally. Many of them lack self-esteem and resilience." (Healthcare provider, Segese village, February 2024).

This study also found that living arrangement was significantly associated with resilience (β = -0.160, P < 0.05) (Table 3). The negative sign of the coefficient suggests that adolescent mothers living with others rather than their parents were associated with lower resilience. This finding was also reinforced by a focus group discussion in Segese village, whereby one of the participants had the following to say;
"I'm living with my uncle. I am always insulted. They regularly remind me that I brought shame to the family because of the pre-marital childbearing. (FGD participant, Segese village, February 2024).

Conversely, a key informant also noted: *"Some girls live with relatives who treat them badly. This affects their self-worth and resilience."* (Social welfare officer Segese village. February 2024).

Meanwhile, the results (Table 3) of this study show that relationship status (β = -0.119, P = 0.072) and parental marriage (β = -0.076, P = 0.332) were not significantly associated with adolescent mothers' resilience in the study area.

Table 3: Factors Influencing Resilience of Adolescent Mothers (n=202)

Variables	B	SE	β	t	Sig.	95%CI For EXP(B)	
						lower	Upper
Age at first birth	-0.506	0.193	-0.214	1.986	.009**	-0.884	-0.125
Relationship status	-0.275	0.152	-0.119	-1.807	.072	-0.575	0.025
Education level	0.622	0.152	0.304	4.106	.000***	0.323	0.921
Financial support	0.241	0.038	0.276	4.414	.000***	0.126	0.356
Social support	0.535	0.174	0.240	3.083	.002**	0.193	0.877
Living arrangement	-0.321	0.131	-0.160	-2.256	.015*	-0.579	-0.063
Marriage by Parents	-0.151	0.155	-0.076	0.973	.332	-0.458	-0.153
Constant	0.555	0.279	.	1.986	.0.048	0.004	1.106

Note: *=P<0.05, **= p<0.01 and ***=p<0.001, SE= Standard Error. B = Unstandardized Coefficient, β = Standardized Coefficient.

Source: Field data (2024)

Discussion

This study highlighted the level and factors associated with resilience of adolescent mothers to gender-based violence in the Shinyanga region. The quantitative data suggest that adolescent mothers have experienced GBV, including sexual, physical, and emotional violence, indicating the prevalence of these forms of violence in the study area. The prevalence of these forms of GBV is associated with socio-cultural norms, such as the patriarchal system, which perpetuates men's dominance over women. However, the government's efforts to eliminate these violations are outlined in the Shinyanga Regional Strategy of 2020, which campaigns to end violence against women and children (URT, 2020).

These societal norms and practices promote violence, and as norms uphold gender-based inequality, women and children are disproportionately the victims and most at risk of experiencing sexual, physical, and emotional violence in their homes and communities. This finding is consistent with Nuwabaine et al, (2023) in Rwanda and Nwafor et al, (2023), which indicates similar situations on the prevalence of sexual, physical, and emotional violence among adolescents. This makes GBV, especially the physical violence, common, particularly in rural areas where women and children are victims of the violence.

This aligns with the theme of the types of violence experienced, which emerged strongly during qualitative coding as several participants reported experiencing sexual, physical, and emotional violence. This is evidence of how physical and other types of violence occur among adolescent mothers. The impact of physical brutalities and beatings on women is profound and far-reaching, affecting their physical health, mental well-being, social relationships, and economic stability. Therefore, addressing physical and other violence against adolescent mothers requires comprehensive efforts to promote gender equality and challenge society's attitudes and norms that perpetuate violence.

The findings of this study showed that most adolescent mothers had a low level of resilience to GBV. This could possibly be attributed to inadequate social, financial, and psychological support from family and community members. This was also reported by the World Bank (2022), that most

adolescent mothers in Shinyanga and other parts of the low-income settings come from economically disadvantaged households and lack independent income. This limits adolescent mothers' coping skills and emotional strength, making them susceptible to GBV. Similar patterns have been observed across Africa, in Ethiopia, for example, Abebe & Bekele (2021) observed that adolescent survivors of sexual and intimate partner violence demonstrate heightened psychological distress and significantly lower resilience scores. In Malawi, Phiri et al., (2022) demonstrated that persistent low resilience among GBV-exposed adolescents, including heightened symptoms of depression and anxiety.

Additionally, Manori et al,. (2025) in Sri Lanka noted that adolescents who have experienced sexual abuse had weakened social and emotional coping capacity. Collectively, this body of evidence shows that GBV remains a critical barrier to resilience among adolescents across the continent, highlighting the need for targeted interventions to strengthen adaptive coping, emotional safety, and supportive social environments. Conversely, studies in most developed countries have shown different results; for instance, studies (Jardim et al., 2021; Lou et al., 2018) highlighted that most adolescents in developed countries had a high level of resilience.

The possible explanation for the difference is that the cultural, societal, and economic disparities that exist, as well as the use of different instruments and approaches to gauge resilience levels among adolescents, can result in different resilience outcomes. As in this study, the population considered adolescent mothers, unlike other studies that considered different populations. Therefore, building resilience of young girls, particularly young mothers, against acts of violence in developing countries, including Tanzania, requires new social, economic, cultural, and political motivations to enable them to access mobile resources.

The current study, using multiple linear regression analysis, identified predictors of resilience to GBV among adolescent mothers. The findings indicated that adolescent mothers with higher levels of education were more likely to have high resilience compared to their counterparts. This can be explained by the fact that adolescent mothers with complete primary and secondary education have knowledge and skills that help them to demonstrate stronger coping capacities and adaptability to life challenges compared to those with lower education or non-formally educated adolescent mothers. Education may enhance problem-solving skills, self -confidence, and access to information, all of which contribute to resilience to GBV.

This result is supported by earlier findings in Tanzania, such as those by Kassanga & Lekule (2021), which noted that adolescent mothers with more schooling have better coping skills and higher aspirations after GBV. Similarly, a study in Kenya by Obara & Banyard (2025) revealed that schooling fosters self-efficacy, problem-solving ability, and future orientation, enabling adolescent mothers to better manage stressors such as gender-based violence, stigma, and economic hardship. Also, Jones et al,(2021) in Ethiopia found that education increased adolescents' capacity to navigate institutional support systems, strengthening resilience. These findings underscore education as both a psychological and structural resilience resource, highlighting the importance of school retention and re-entry policies for adolescent mothers in the study area.

In terms of social support, the study revealed that adolescent mothers who received social support were more likely to have high resilience. This implies that receiving social support, such as encouragement, care, and comfort, can help adolescent mothers cope with adversity. During focus group discussions, this study observed that adolescent mothers who made sure to have social support from their husbands, parents, or community had a high degree of resilience, which shielded them from GBV events. This finding is consistent with the studies (Kuo et al., 2022; Mampane, 2014; Terrazas-carrillo, 2024). That showed a linkage between social supports and improved individual psychological functioning. Further noting that individuals with a strong social support network are less likely to have low resilience (Zhang et al., 2022). This points to the importance of social support that adolescent

mothers need from parents, family members, organizations, and the community at large to build their resilience to GBV.

The study also found that adolescent mothers who received financial support from parents or guardians, husbands, friends, relatives, and community members to handle GBV-related incidents were more likely to have high levels of resilience compared to their counterparts. According to this study, GBV incidents included emotional abuse, sexual assault, physical abuse, unwanted pregnancy, and the like. Financial support can facilitate access to health services, including reproductive health care, but also reduce dependence on potentially abusive partners or family members. Similar studies (Rava et al., 2023; van Breda & Theron, 2018) have also contended that financial support is crucial for fostering adolescent resilience. This helps adolescent mothers to access necessary medical care and mental health support, which can mitigate the effects of GBV. Thus, reducing GBV exposure among adolescent mothers.

Furthermore, the current study revealed that adolescent mothers who gave birth at an earlier age are less likely to demonstrate high resilience than those who gave birth at a relatively older adolescent age. The possible explanation for this is that the biological, psychological, and social unpreparedness that often accompanies very early motherhood can contribute to this result. This study shows that the majority (76.7 percent) of adolescent mothers gave birth before 18 years old, which has negative impacts on their education, livelihood, and health. This finding concurs with what was reported by UNFPA (2023), that early childbirth exposes girls to heightened vulnerability, including school dropout, economic dependency, stigma, and increased risk of gender-based violence, all of which undermine resilience. The study by Nyundo & Emmelin (2020) in Tanzania reported that adolescent pregnancy has been consistently linked to social exclusion and mental health challenges, which restrict young mothers' ability to develop effective coping strategies. These conditions weaken the protective mechanisms that promote resilience, such as self-efficacy, optimism, and access to support networks. The finding aligns with Chirwa et al., (2023), who reported that young adolescent mothers in Sub-Saharan Africa experience higher psychological distress and lower coping capacity compared to older adolescent mothers. However, from a resilience perspective, exposure to severe adversity at an early age reduces the ability to positively adapt, especially when protective factors are limited (Masten, 2018). These results highlight the need for interventions that strengthen protective resources, such as education continuation, psychosocial support, and economic empowerment, for adolescent mothers across age groups, while simultaneously addressing the structural determinants that limit their long-term well-being.

This study found that living arrangement was significantly associated with resilience to gender-based violence (GBV) among adolescent mothers, with those living with parents demonstrating higher resilience compared to those living with others. The negative standardized coefficient indicates that residing away from parental households, such as with intimate partners, relatives, or non-family members, is linked to reduced capacity to cope with and recover from GBV experiences. The evidence from qualitative findings revealed that many adolescent mothers were subjected to verbal abuse, emotional neglect, or even physical violence by relatives or guardians due to shame and stigma associated with early pregnancy. Such environments perpetuate secondary victimization, where the adolescent mother is repeatedly traumatized even after the initial experience of GBV. Additionally, studies (Danpho & Thommachot, 2025; Manori et al., 2025) noted that adolescents living with parents are more likely to disclose experiences of violence, access psychosocial support, and be shielded from exploitative or violent relationships. Furthermore, Yoon (2022), had a similar view that parental presence has been shown to mitigate the psychological impacts of sexual and intimate partner violence by fostering a sense of safety and social belonging, which are critical components of resilience. In contrast, adolescent mothers living with others, as in this study, 54 percent of adolescent

mothers were either living with husbands or sexual partners, relatives, and friends. The possible explanation for this is that, in Shinyanga, adolescent mothers leave their parental homes due to parental disappointments, and stigma associated with premarital pregnancy. In such cases, adolescents migrate to partners' homes, relatives' households, or mining areas for work. Parental rejection following adolescents' pregnancy has been reported in several regions of Tanzania (Baraka et al., 2022; Machange & Temba, 2024). This exposes them to intimate partner violence, power imbalances, and economic dependency, all of which undermine resilience to GBV. This finding is consistent with studies by Bussemakers & Kraaykamp,(2020) and Khan &Akram, (2025), which indicates that cohabitation with partners at a young age and non-parental living increase vulnerability to repeated violence and limit adolescents' autonomy in seeking help or exiting abusive relationships. These findings underscore the importance of household context in shaping GBV and strengthening resilience among adolescent mothers.

Conclusion

This study concludes that adolescent mothers in the study area experience high levels of Gender-based violence (GBV), encompassing sexual, physical, and emotional forms, which substantially undermines their overall well-being. Despite continued exposure to violence, the general level of resilience among adolescent mothers was low, indicating limited capacity to cope with, adapt to, or recover from GBV-related adversities. Importantly, the findings demonstrate that resilience is not an inherent trait but is strongly shaped by social and structural factors. Higher levels of education, along with access to social and financial support, were found to significantly enhance resilience, underscoring the protective role of human capital development and supportive social networks in strengthening adolescents' adaptive capacity in the face of violence. Conversely, living arrangement and age at first birth were negatively associated with resilience to GBV. Adolescent mothers living with partners or relatives exhibit lower resilience, likely due to increased exposure to intimate partner violence, as well as psychological violence, economic insecurity, and reduced emotional support. Similarly, age at first birth emerged as a significant vulnerability factor, reflecting the compounded effects of disrupted education, social stigma, and premature assumptions of adult responsibilities, all of which constrain adolescent mothers' ability to cope with GBV. These findings highlight the need for targeted policy and programmatic interventions. Strengthening the implementation of the National Plan of Action to End Violence Against Women and Children (NPA-VAWC) is critical to ensure that prevention and responses services adequately address the specific needs of adolescent mothers. Efforts also should focus on promoting education re-entry opportunities, economic empowerment initiatives, and community-based psychosocial support services to enhances resilience and reduce vulnerability to GBV and calls for further research on resilience to GBV among both female and male adolescents.

Declarations

Ethical considerations

Research permit for this study was obtained from the University of Dar es Salaam research review committee. Permission to conduct the study was also obtained from the Shinyanga regional and district administrative authorities. Informed consent was obtained from all participants prior to data collection. For respondents under 18 years, assent was obtained in addition to consent from parents or guardians. Participants were informed about the voluntary nature of participation, confidentiality of their responses, and their right to withdraw from the study at any time without consequences.

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The Relationship Between Psychosocial Therapy and Drug Abuse Relapse Among Adolescent Students in Public Secondary Schools in Tanzania

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Abstract
Background: Drug abuse relapse among adolescents remains a major public health concern in secondary schools. This study examined the relationship between psychosocial therapy and drug abuse relapse among adolescent students in public secondary schools in Tanzania.
Objective: The study aimed to determine the level of provision of psychosocial therapy, determine the prevalence of drug abuse relapse, and to examine the relationship between psychosocial therapy and drug abuse relapse among adolescent students.
Design and setting: A correlational, cross-sectional design was used in 10 public schools across Temeke and Kinondoni Municipalities, Dar es Salaam Region, Tanzania.
***Methods*:** Data were collected using structured questionnaires from 132 respondents (100 adolescent students, 20 discipline teachers, and 12 school counsellors). An independent t-test was used to compare drug abuse relapse by sex, while Spearman's Rank Order Correlation Coefficient was used to determine the relationship between psychosocial therapy and drug abuse relapse.
***Results*:** The results showed that the provision of psychosocial therapy among adolescents was moderate, at 43.1%. Moreover, the study found the high prevalence of drug abuse relapse, which was 59.09%. The Spearman correlation showed no statistically significant relationship between psychosocial therapy and drug abuse relapse ($r = 0.0793$, $p = 0.366 > 0.05$).
***Conclusion*:** The psychosocial therapy provision was moderate, and drug abuse relapse was high among adolescent students; also, no significant relationship was found between the two. The findings suggest that the current provision of psychosocial therapy is insufficient in preventing relapse among adolescents. The study recommends strengthening psychosocial therapy services and enhancing preventive drug education from family to school levels to reduce drug abuse and relapse among adolescents.
Keywords: *Psychosocial therapy, drug abuse relapse, adolescent students*

Introduction

Adolescent drug use is a serious concern and a major public health issue worldwide (Sedibe & Hendricks, 2021). Early experimentation with tobacco, alcohol, and other drugs is associated with both immediate and long-term threats to healthy adolescent development, including educational, social, and health consequences (Abedi et al., 2019), and drug abuse is associated with a significant share of morbidity and mortality during adolescence (Khan et al., 2019). In the United States, an estimated 75.6% of young people under 18 years report having used addictive substances such as cigarettes, alcohol, marijuana, or cocaine at least once (Bersamin et al., 2017), while more recent trends point to rising use of Ketamine, ecstasy, and methamphetamine among adolescents elsewhere (Lee et al.,

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2018). Understanding the risk of relapse after treatment is therefore critical for developing effective substance misuse prevention policy.

Psychological therapy has gained prominence as a response to this problem. Steele et al. (2020) described psychological therapy as an implicit or explicit therapeutic contract in which a person seeking to resolve problems in living, relieve symptoms, or pursue personal growth engages with a psychosocial practitioner. Its aims include decreasing vulnerability, reducing the impact of stressful events, minimising symptoms, improving quality of life, enhancing treatment adherence, and changing maladaptive behaviour patterns (Vázquez et al., 2020). Psychological interventions are effective for drug users in a range of settings (Harvey & McKay, 2017); for example, family-oriented therapy has been associated with reduced drug-use behaviour and improved family functioning among adolescents (Vázquez et al., 2020) and may be more effective than other approaches at preventing relapse when it provides adolescents with sustained guidance and counselling (Azmi et al., 2019). Evidence from Bangladesh similarly shows that structured, supervised treatment pathways for adolescents who use drugs are associated with better outcomes than unsupported approaches (Khan et al., 2019), and Barasa (2013) found that effective guidance and counselling in schools helps prevent drug abuse. Together, this evidence suggests psychosocial therapy should be prioritised for adolescents who abuse drugs, but it remains unclear whether such therapy is associated with lower relapse specifically among adolescents in secondary schools.

In Tanzania, drug use among adolescents is reported to be rising both in and out of school (Mavura et al., 2022). Most adolescents who experiment with substances do not progress to regular use, but some develop more chronic problems that persist into adulthood; adolescents who receive support from family, school, and community are less likely to engage in drug abuse and more likely to develop positive outcomes (Simbee, 2015). Data from the Drug Control and Enforcement Authority (DCEA) covering 2018-2022 show that Dar es Salaam, Arusha, Pwani, Kilimanjaro, and Tanga are the leading regions for adolescent drug relapse cases in secondary schools, with the trend increasing year on year (DCEA, 2022). Tanzania has responded with sober house centres offering treatment and consultation, and with Medically Assisted Therapy (MAT), also known as Opioid Against Therapy (OAT) (Simbee, 2015); in Dar es Salaam, Muhimbili National Hospital, Temeke, and Mwanayamala Regional Referral Hospital offer methadone treatment for opioid addiction (Mavura et al., 2022)

Despite this local burden, few studies examine the relationship between psychosocial therapy and drug abuse relapse among Tanzanian adolescents specifically. Existing Tanzanian evidence has established relapse prevalence (Mavura et al., 2022; Simbee, 2015) and the correlates of drug use more broadly but has not directly tested whether the level of psychological therapy provision is statistically associated with relapse in this population. This addresses that gap by examining the relationship between psychosocial therapy provision and drug abuse relapse among adolescent students in public secondary schools and using validated relapse-prevention theory (Marlatt & Gordon, 1985) as its analytic frame.

Objectives of the Study

The general objective of this study was to examine the relationship between psychosocial therapy and drug abuse relapse among adolescent students in public secondary schools in Tanzania. The specific objectives were to; determine the level of provision of psychosocial therapy among adolescent students in public secondary schools, determine the prevalence of drug abuse relapse among adolescent students in public secondary schools and examine the relationship between psychosocial therapy and drug abuse relapse among adolescent students in public secondary schools.

Study's Hypothesis

H1: There is a statistically significant relationship between psychosocial therapy and drug abuse relapse among adolescent students in public secondary schools.

Theoretical Framework

The Relapse Prevention Model (RPM) is considered an essential part of drug abuse treatment. Marlatt and Gordon proposed the RPM model in 1985, which stated that high-risk situations, coping skills, outcome expectations, the abstinence violation effect, lifestyle factors, and urges and desires all contribute to drug abuse relapse (Larimer et al., 2004). Furthermore, the theory includes a wide range of specific and global intervention strategies that enable therapists and patients to address each stage of the drug abuse relapse process (Menon & Kandasamy, 2018). The RPM proposes therapies such as identifying specific high-risk situations for each patient and improving the patient's skills for dealing with those situations, increasing the patient's self-efficacy, dispelling myths about drug effects, managing lapses, and restructuring the patient's perceptions of the relapse process (Walitzer et al., 2018).

1Conceptual Framework of the Study

The conceptual framework shows the relationship between psychosocial factors as the independent variable and drug abuse relapse among adolescent students as the dependent variable. Figure 1 summarises it below.

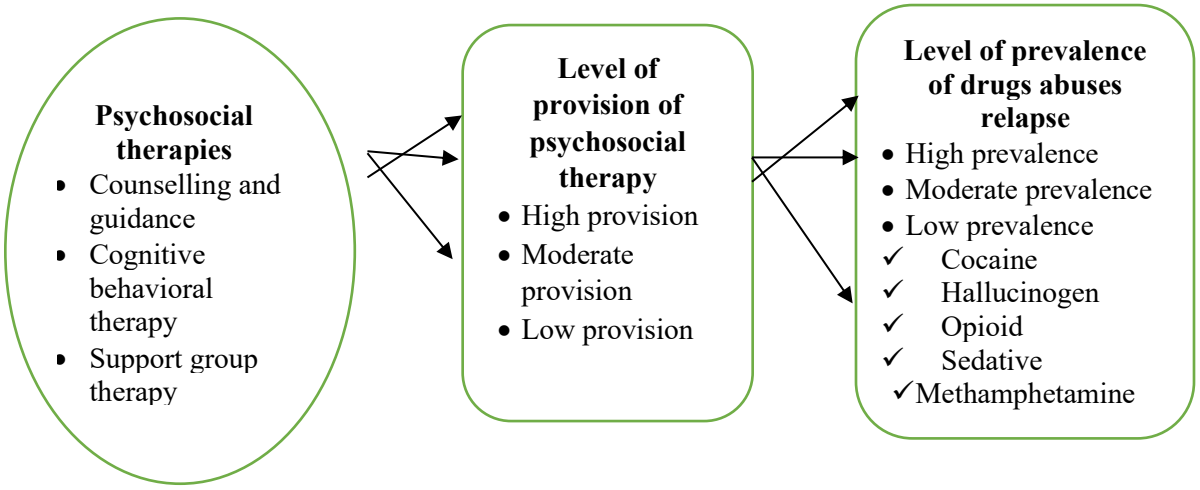

Figure 1: Conceptual Framework on the Relationship between Psychosocial Therapies and Drug Abuse Relapse ***Source****: Modified from Kabisa et al. (2021)*

Figure 1 shows the relationship between psychosocial therapies such as counselling and guidance, cognitive behavioural therapies, and support group therapy that are provided in the researched schools. The figure also shows the level of provision of these psychosocial therapies, whether it is provided at high, moderate, or low levels. Finally, the figure shows the prevalence of drug abuse relapse, whether high, moderate, or low. This prevalence can be in cocaine, hallucinogens, opioids, sedatives, and methamphetamine. Generally, the conceptual framework shows that the provision of psychosocial therapies at a high, moderate, or low level has a direct relationship to drug abuse relapse among adolescent students.

Materials and Methods

Research Approach

This study employed a quantitative research approach. The quantitative approach relies on statistical analysis, including inferential statistics, hypothesis testing, and mathematical exposition (Creswell & Creswell, 2017). The study examined the relationship between psychosocial therapy and drug abuse relapse among adolescent students.

Research Design

A correlational research design, which is a non-experimental design, was used to investigate the relationship between psychosocial therapy and drug relapse among adolescents in secondary schools. A correlational design is a technique for determining the relationship between two or more variables (Creswell & Creswell, 2017).

Study Area

This study was conducted in Dar es Salaam region because it is a leading region that involves a higher number of drug abuse relapses among adolescent students in secondary schools than the other regions in Tanzania (DCEA, 2022). Similarly, Dar es Salaam region is the leading region with a higher number of sober houses than the other regions, while Temeke and Kinondoni municipalities have a high number of drug abuse adolescents and sober houses. (DCEA, 2022). Data in Table 1 provide a summary of the leading regions for drug abuse relapse among students over five consecutive years.

Table 1: *Leading Region for Relapse Drug Abuse for the Students from 2018-2022*

Year	2018		2019		2020		2021		2022		
Region	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**Total**
Dar es salaam	132	27	137	29	142	32	118	32	241	42	932
Arusha	161	6	163	12	150	16	142	27	171	18	866
Pwani	71	9	73	8	67	12	60	13	93	15	421
Kilimanjaro	72	5	70	5	77	8	81	9	70	12	409
Tanga	35	2	30	6	39	3	41	4	45	8	213

Source: DCEA (2023)

Targeted Population of the Study

Secondary school discipline teachers, school counsellors, and adolescent's students constituted the targeted population. Adolescent students were included because they are the group directly affected by drug abuse and drug abuse relapse. Discipline teachers were included because they manage discipline cases involving adolescent students and provide guidance where necessary, while school counsellors were included as the respondents responsible for providing psychological therapy to students who had relapsed.

Sample size

The population of secondary school students with a documented history of drug relapse in Temeke and Kinondoni municipalities was 164 (DCEA, 2022). Using Cohen et al.'s (2018) sample size table for a population of this size, with a 5% margin of error and 95% confidence level, the required probability sample of students was 132. Because full access to all 164 students in this population could not be secured, a final sample of 100 students was obtained through simple random sampling. To supplement the students' self-reported data and provide corroborating, informant-level perspective on the

provision of psychosocial therapy, 20 discipline teachers and 12 school counsellors were purposively added, giving a combined study sample of 132 respondents overall.

Table 2: ***Summary of Sample Categories (n=132)***

Category	Number of respondents
Adolescent Students	100
Discipline Teachers	20
School Counsellors	12
Total	**132**

Source: Field Data, 2023

Sampling Techniques

Simple random sampling technique was used to select 100 adolescent students from Form One to Form Four with a documented history of substance use relapse, drawn from ten (10) secondary schools across the two municipalities. Purposive sampling was used to select the 10 schools (5 in Temeke and 5 in Kinondoni) that had received psychosocial therapy services in response to drug abuse, the 20 discipline teachers who were directly involved in managing drug relapse, and the 12 school counsellors who provided psychosocial therapy (drawn from the 10 schools, two of which had two counsellors each).

Methods of Data Collection

Data were collected using structured questionnaires administered to students, teachers, and counsellors. Data for this study were gathered using a structured questionnaire for students, teachers, and counsellors. Using this method of data collection allowed the researcher to collect a large amount of data from respondents (Cohen et al., 2018). To obtain responses on the provision of psychosocial therapy, the researcher adapted and employed the Psychosocial and Lifestyle Questionnaire (PLSQ), which contains 13 items from Smith et al. (2023). The Cronbach's alpha coefficient was 0.960, indicating that all 13 questionnaire items had excellent internal consistency. Likewise, to obtain the prevalence of drug abuse relapse, the researcher adapted and employed the Drug Abuse Relapse Questionnaire (DARQ), which contains 19 items. The Cronbach's alpha coefficient was 0.965, indicating that all 19 questionnaire items had excellent internal consistency

Results

This study collected the respondents' background information from public secondary schools in Tanzania. The information was based on gender, age, educational level, and working experience of the respondents. Some 132 questionnaires were distributed and collected from respondents. Table 3 provides a summary of the respondents' demographic characteristics.

Table 3: Respondent Characteristics based on Gender, Age, and Working Experience

Criteria		Male		Female		Total	
Ages/all respondents		F	%	F	%		%
	11-15	17	12.87%	08	6.06%	25	18.93%
	16-20	38	28.78%	09	6.81%	47	35.6%
	21-25	09	6.81%	07	5.3%	16	12.12%
	26-30	08	6.06%	04	3.03%	12	9.09%

	31>	14	10.06%	18	13.63%	32	24.24%
Total		86	65%	46	35%	132	100%
Education/teachers and counsellors							
	Diploma	00	00%	00	00%	00	00%
	Degree	07	21.87%	20	62.5%	27	84.37%
	masters	02	6.25%	03	9.37%	05	15.63%
Total		09	28.12%	23	71.87	32	100%
Work experience							
	Less than 5	5	15.62%	7	21.87%	12	37.5%
	5-10	6	18.75%	11	34.37%	17	53.12%
	10>	1	3.12%	1	3.12%	02	6.25%

Key, F=Frequency, %=Percentage
Source: Field Data, 2023.

Based on data in Table 3, male respondents were 86 (65%), while female respondents were 46 (35%), making a grand total of 132 respondents who participated in this study. In terms of the highest educational background for discipline teachers and counsellors, the data show that 27(84.37%) had a bachelor's degree, while 05(15.23%) had a master's degree; none of them had a diploma. The data also show that 12 (37.5%) of discipline teachers and counsellors had less than five years of working experience, while 17(53.12%) were within 5-10 years of working experience, and lastly, 02(6.25%) had more than ten years of working experience. Therefore, the majority of discipline teachers and counsellors had between 5 and 10 years of working experience.

The Provision of Psychosocial Therapy among Adolescent Students

The provision of psychosocial therapy was measured by using the Psychosocial and Lifestyle Questionnaire (PLSQ), a scale widely used for measuring individuals who have been provided with psychosocial therapy after being affected with drugs abuses or drug abuse relapse. The scale consisted of 13 items, and the average scores were computed from all 13 items using a 4-point Likert scale format ranging from strongly disagree to strongly agree, as seen in Table 4.

Table 4: ***Participant Frequencies and Percentages on Psychosocial Therapy Provision (N=132)***

	SD		D		A		SA	
Items	F	%	F	%	F	%	F	%
Feeling comfortable when other people care relapsed one	21	15.9%	34	25.75%	43	32.57%	34	25.75%
Social gathering reduces relapsed students' stress	22	16.6%	38	28.78%	44	33.33%	28	21.21%
Loving friend who comforted a relapsed one	17	12.8%	12	9.09%	93	70.45%	10	7.57%
Feeling happy to show personal problems to experts	28	21.21%	27	20.45%	58	43.93%	19	14.39%
Feeling comfortable when peers are guided towards having good manners	18	6.06%	31	23.48%	49	37.12%	34	25.75%

Feeling comfortable when parents guide towards good manners	14	10.60%	29	21.96%	52	39.39%	37	28.03%
Talking about any problems to parents or expertise	31	23.48%	24	18.18%	48	36.36%	29	21.96%
Caregivers have nothing to contribute to social well-being	40	30.30%	42	31.81%	31	23.48%	19	14.39%
Caregivers have a great contribution to social well-being	18	13.63%	29	21.96%	44	33.33%	41	31.06%
Sober houses have nothing to help me with emotional well-being	58	43.93%	38	28.78%	14	10.60%	22	16.6%
Sober houses make great contributions to help emotional well-being	11	8.33%	23	17.42%	61	46.21%	37	28.03%
Guidance and counselling are helpful for psychological well-being	06	4.54%	11	8.33%	97	73.48%	18	13.63%
Guidance and counselling are not helpful for psychological well-being	21	15.9%	95	71.96%	08	6.06%	08	6.06%

Source: Field Data 2023.
KEY SD=Strong disagree D=Disagree A=Agree SA=Strong Agree F=Frequency %=Percentage.

Table 4 shows that 43(32.57%) of respondents strongly agreed that they felt comfortable when other people cared for them. Some, 44(33.33%), agreed that social gatherings reduced stress. The majority, 93(70.45%), agreed on the love of friends who comfort them. Therefore, the majority of respondents agree that the provision of psychosocial therapy, especially through social gatherings, and that parents and friends have a great contribution to reducing their social problems. The findings further show that 61(46.21%) agreed and 37(28.03%) strongly agreed that sober houses have a great contribution to help with emotional well-being. The other 97(73.48%) agreed that guidance and counselling were helpful for psychological well-being. Meanwhile, 95(71.96%) disagreed that guidance and counselling were not helpful for psychological well-being.

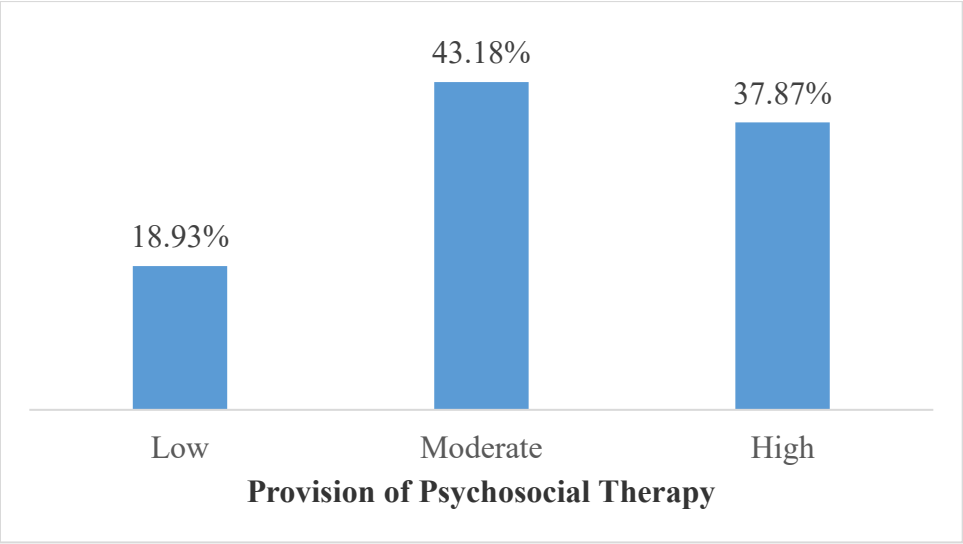

Figure 2: Provision of Psychosocial Therapy Provision
Source: Field Data, 2023

Figure 2 shows that moderate provision of psychosocial therapies was most common (43.18%), followed by high provision (37.87%) and, lastly, low provision (18.93%) among adolescent students in secondary school. Therefore, the alternative hypothesis, which stated that there is high provision of psychosocial therapy among adolescent students in public secondary schools, is rejected; the null hypothesis was accepted, as moderate and low combined dominated how psychosocial therapies were provided.

Psychosocial Therapies Provided

Respondents were given a chance to pick more than one kind of psychosocial therapy that was provided at their schools. Table 5 summarizes items of psychosocial therapies.

Table 5: Psychosocial Therapy Provided at Secondary Schools (n=132)

Item	Frequency	Percentage %
Guidance and counselling	58	43.9%
Cognitive behavioral therapy	27	20.45%
Emotion-focused cognitive therapy	17	12.8%
Psychoeducation therapy	11	8.3%
Social support therapy	9	6.8%
Peer support therapy	7	5.3%
Motivation and rewards therapy	3	2.7%

Source: Field Data, 2023

Table 5 shows that there were various psychosocial therapies that were provided in the researched schools. The findings show that guidance and counselling was reported to have been provided by 43.9%, whereas cognitive behavioral therapy was reported by 20.45%. Furthermore, emotion-focused cognitive therapy was reported to have been provided by 12.8%. Also, some 8.3% reported on psychoeducation therapy provision, and social support therapy accounted for 6.8%. The findings further show that those who reported peer support therapy were 5.3% and, lastly, motivation and rewards therapy was said by 2.7% to have been provided.

Prevalence of Drug Abuse Relapse among Adolescent Students in Public Secondary Schools

The prevalence of drug abuse relapse was measured by using the Drug Abuse Relapse Questionnaire (DARQ). The scale is widely used to measure the degree of patients' relapse after attending methadone clinics and psychosocial therapies by health experts. The scale consists of 19 items using a 4-point Likert scale format ranging from Strongly disagree to Strongly agree, as summarized in Table 6.

Table 6: Participants' Response Frequencies and Percentages on Drug Abuse Relapse (N=132)

	SA		A		D		SD	
	F	%	F	%	F	%	F	%
After recovery, I/relapsed students drink out of control	28	21.9%	58	43.9%	34	25.7%	12	9.0%
After recovery, I/they used methadone	30	22.7%	59	44.6%	36	27.2%	7	5.3%
After recovery, my/peers strongly encouraged them to use drugs	12	9.0%	97	73.4%	12	9.0%	11	8.3%
Overall, I/they influenced drug abuse relapse	27	20.4%	68	51.5%	16	12.1%	21	15.9%
Influence of family issues/conflict in drug abuse relapse undeniable	13	9.8%	76	57.5%	37	28.0%	6	4.5%

I/they feel proud when smoking	11	8.3%	86	65.1%	11	8.3%	9	6.8%
Feeling confident when I/they use drugs for sleeping	46	34.8%	58	43.9%	7	5.3%	21	15.9%
I/they feel trapped and stuck, like there is no way out until they use drugs again	12	9.09%	68	51.5%	27	20.4%	25	18.9%
I/they feel angry or frustrated	7	5.3%	12	9.0%	74	56.0%	39	29.5%
Relapsed students have poor eating habits	5	3.78%	58	43.9%	62	46.9%	7	5.3%
I/they get irritated or annoyed with my friends	7	5.3%	33	25.0%	59	44.6%	28	21.2%
I/they feel confused after use of the drug	11	8.3%	58	43.9%	8	6.0%	46	34.8%
I/they feel things don't work out well for them	28	21.2%	70	53.9%	14	10.6%	19	14.3%
I/they feel nervous or unsure of my ability to stay sober	10	7.5%	25	18.9%	87	65.9%	10	7.5%
I/they have trouble sleeping	28	21.2%	65	49.2%	34	25.7%	5	3.7%
I/they have long periods of serious depression	11	8.3%	78	59.0%	37	28.0%	6	4.5%
I/they don't really care what happens	3	2.2%	30	22.7%	62	46.9%	37	28.0%
I/they feel things are so bad that I might as well drink	10	7.5%	87	65.9%	24	18.1%	11	8.3%
I/they are not able to think clearly	25	18.9%	72	54.5%	24	18.1%	11	8.3%

Source: Field Data, 2023.
Key: SD=Strongly Disagree, D=Disagree, A=Agree, SA=Strongly Agree, F=Frequency, %= Percentage

Table 6 shows that the majority of the respondents strongly agreed and agreed that, after recovery, the relapsed students were out of their control. The results show that the majority of participants, 58(43.9%), agreed. The findings also reveal that the majority of the respondents, 59(44.6%), agreed that after recovery they were using methadone. The findings also revealed that the majority of the respondents, 62(46.9%), disagreed; they didn't really care what happened. The findings further revealed that the majority of the respondents, 87(65.9%), agreed that relapsed students felt things were so bad that they might as well drink. It was further revealed that the majority of the respondents, 72(54.5%) had agreed that they were not able to think clearly.

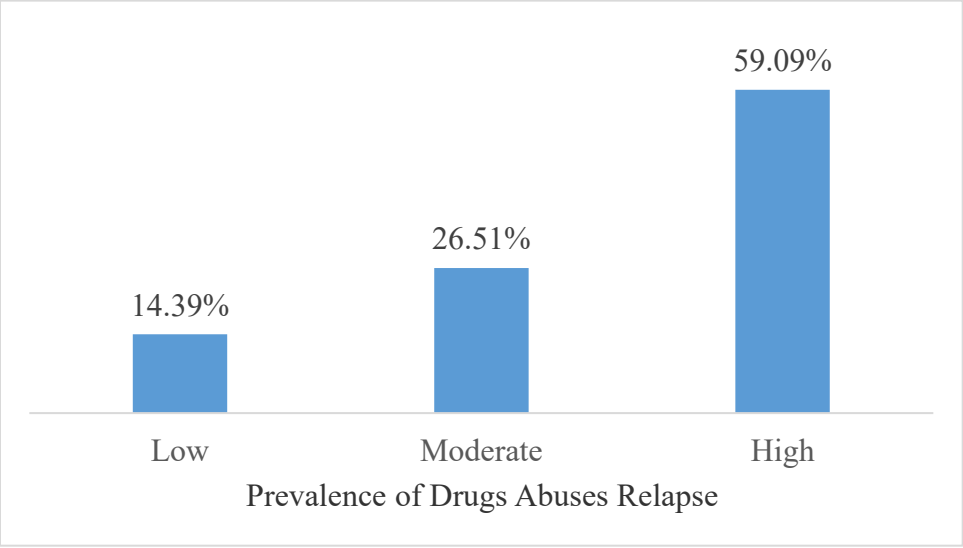

Figure 3: The Prevalence of Drug Abuse Relapse
Source: Field Data 2023

The findings from Figure 3 above reveal that there is a high prevalence of drug abuse relapse by 59.09 relapse dominating among adolescent students. Thus, the alternative research hypothesis that stated there is a high prevalence of drug abuse relapse was accepted.

Drug Abuse Relapse in terms of Sex

An independent t-test was used to measure mean differences between male and female adolescent students. The logic was to determine sex differences in drug abuse relapse. The data in Table 4.5 show the mean differences between males and females, where the mean is an average of the given numbers, calculated by taking the sum of all observations divided by the total number of observations. Table 7 also shows the standard deviation between means differences of male and females, which indicates the variability of the data set collected in the field; it tells an average of how far each value lies from the mean. The findings are summarized in Table 7 below.

Table 7: ***Drug Abuser Relapse in Terms of Sex (N=132)***

Sex of Respondent	Mean	Std Deviation	P-value
Male	2.36	0.57	.001
Female	1.76	0.61	.001

Source: Field Data, 2023

Table 7 reveals that male adolescent students had a higher number of relapses into drug abuse than female adolescent students, with mean differences and standard deviations being M=2.36, SD=.57 for males, and M=1.76, SD=.61 for females. Both male and female adolescent students had a p-value of .001. Therefore, after attending various methadone clinics and receiving psychosocial therapies, a higher number of male adolescent students relapsed into using various kinds of drugs than female students.

The Leading Types of Drug Abuse Relapse for Adolescent Students

Descriptive statistics were used to determine which types of drugs adolescent students relapse into. The logic of determining this was to know which kind of drugs students relapsed to. The data are summarized in Table 8.

Table 8: ***Types of Drug Abuse Relapse for Adolescent Students in Response Frequency and Percentage (n=132)***

Types of Drug Abuse	Frequency	Percentage
Marijuana	37	28%
Heroine	33	25%
Cocaine	29	21.90%
Methamphetamine	16	12.10%
Sedative	10	7.57%
Substance abuse	5	3.78%
Hallucinogen	2	1.51%
Total	132	100.00%

Source: Field Data, 2023

The findings show that Marijuana was considered the leading kind of drug abuse that respondents relapsed to, which constituted 37(28%) of responses; heroin followed, with 33(25%) of drugs abuses relapse. Also, the findings indicated that cocaine was shown by 29(21.90%) for drug abuse relapse; methamphetamine was shown by 16(12.10%) for drug abuse relapse. The findings further show that sedatives were identified by 10(7.57%) for drug abuse relapse; substance abuse was pointed out by 5(3.78%) regarding drug abuse relapse. The least was hallucinogens, shown by 2(1.51%) responses on drug abuse relapse.

The Relationship between Psychosocial Therapy and Drug Abuse Relapse among Adolescent Students

Psychosocial therapy was tested as an independent variable, and drug abuse relapse among adolescent students in public secondary schools was tested as a dependent variable using Spearman's Rank Order Correlation Coefficient. The results are summarized in Table 9.

Table 9: Spearman's Rank Order Correlation Coefficient between Psychosocial Therapy and Drug Abuse Relapse among Adolescent Students in Public Secondary Schools (n=132)

	Spearman's Rank Order Correlation Coefficient (r)	Level of significance
Psychosocial therapies	0.0793	0.366

Source: Field Data, 2023

The results, as indicated in Table 9, reveal that there is no significant relationship between the provision of psychosocial therapy and drug abuse relapse among adolescent students in public secondary schools. The results show r=.0793, where the p-value is .366>0.05. Therefore, the hypothesis that started that there is a statistically significant relationship between psychosocial therapy and drug abuse relapse is rejected, and the null hypothesis is accepted.

Discussion

Provision of Psychosocial Therapy

This study is consistent with that conducted by Manos (2013), who found that there was average provision of psychosocial therapy among drug abuse relapse students in secondary schools. The study further revealed, however, that the provision of psychosocial therapy has a great contribution to enhancing the health and performance of the students. Moreover, Jhanjee (2014) revealed that cognitive behavioral therapy, motivational interviewing, and relapse prevention appear to be effective for many drugs of abuse. Meanwhile, the findings of this study are concurrent with those conducted by McGovern et al. (2022), who found that the provision of psychosocial therapy for the parents is more effectiveness on reducing the frequency of the drugs abuses relapse, especially in alcohol.

Therefore, the intensification of the provision of psychosocial therapy among adolescents is one of the best ways of raising their awareness and consciousness of the best way of getting rid of the problem of drug relapse. For that matter, in Tanzania, the Ministry of Health, Community Development, Gender, Elderly and Children [MoHCDGEC] (2022) maintains that psychosocial care and support illustrate a continuum of services and facilitation that addresses social, emotional, and psychological problems to safeguard the well-being of individuals, their families, and communities.

Nevertheless, the study findings are contrary to those provided by Alsubaie (2023), who found that there is low provision of psychosocial therapy provision which involves both education and

training, with the aim of improving their health after relapsing. Meanwhile, the British Psychosocial Society (2018) found that there is low provision of psychosocial interventions among drug relapse patients, such as a user-centered counselling style for eliciting behavior change by helping clients to get rid of the problem of drug relapse. To that extent, the provision of psychosocial therapy among adolescent students is considered helpful for maintaining their health, improving their academic involvement, and reducing the possibility of students engaging in drug abuse relapse.

On the specific therapies provided, guidance and counselling was most common, consistent with Serah et al. (2018), who found that guidance and counselling contributes to reducing drug abuse among adolescents. Moreover, Alghamdi (2023) reported that cognitive therapy has a great contribution to the mental restructuring of the patient, which helps them to get rid of drug abuse. In the same vein, Alamdarloo et al. (2019) revealed that cognitive behavioral therapy has reduced depression, anxiety, and stress for adolescent patients. Furthermore, Zaidi (2020) emphasized that social support increases interconnectedness between family and societal members, which facilitated reduction of the drugs addicts among adolescents. In a similar tone, Koob (2013) provided that rewards, motivation, and addiction bring new hope for patients, which has a significant impact on reducing relapse among patients. In that regard, Satinsky et al. (2021) indicated that peer support has positive impacts on reducing drug relapse among drug users in low- and middle-income countries. Therefore, psychosocial therapies are considered to have contribution on helping drug abuse patients gain mental awareness, which ultimately helps them become psychologically well.

Prevalence and Types of Drug Abuse Relapse

The findings of this study are concurrent with those conducted by Kabisa et al. (2021), who found a higher prevalence of relapse, with 59.9% of patients relapsing into substance use disorders after attending various methadone clinics. This suggests that the contribution of psychosocial therapies had less impact on reducing the number of patients engaging in relapse. Ramsewak et al. (2020) found a higher percentage of relapse among users within five years of abstinence, whereby 57.5% of participants had a positive family history of substance use disorders. The findings also found that Cannabis was the most commonly abused substance, and 76.2% were introduced through curiosity about drugs.

In that context, Yamashita et al. (2021) provided that the reasons for drug abuse relapse among patients might be caused by different factors, which include peers' influence, family support, environment, and other factors. Meanwhile, Malik et al. (2023) found that self-efficacy, social support, personality traits, and stigma have a significant role in causing addiction relapse among patients. Therefore, there is a need to build high self-efficacy, high self-esteem, and positive personality traits that will help patients to have a strong conscience of abstaining from drug abuse by any means.

On substance type, the findings are related to those of Haney et al. (2013), who found that 49% of participants relapsed the first day active marijuana became available. Also, tobacco cigarette smokers (75%) who were not abstaining from cigarettes were far more likely to relapse than non-cigarette smokers (OR=19, $P<0.01$). The findings also showed that the majority of the respondents relapsed to using Marijuana after completing this psychosocial therapy (White et al., 2015). Therefore, this is an indication that patients are still relapsing into their former condition of using Marijuana. Thus, deliberate effort should be made, such as strict supervision by subjective norms, when a patient has completed therapy and gets out of the rehabilitation center.

The findings of this study are also concurrent with those conducted by Ramsewak et al. (2020), who found that the highest number of relapses were found in cannabis, which contained 76.2%, followed by alcohol, amphetamine, inhalants, and opioids, which had a lower percentage of relapse simultaneously. The majority of patients who relapsed were coming from nuclear or single-substance

family backgrounds. Furthermore, the findings are in line with those of Sau et al. (2013), who reported that 59.1% of patients relapsed to heroin after being treated in methadone clinics. Therefore, several patients are not persisting in their new form or style of living without using drugs again.

Male students in this report had significantly higher relapse that female students. The findings of this study are concurrent with those conducted by Kabisa et al. (2021), who found that the majority of participants 84.1% for males and only 15.9% for females) relapsed into substance abuse after being treated in methadone clinics and rehabilitation centers. The findings were also consistent with those provided by Helmy et al. (2016) that relapse was more common among male than female addicted patients, which was caused by weak willpower, bad friends, family problems, pressure at work, and physical problems. Furthermore, the findings are consistent with those conducted by Bhandari et al. (2021), who found that 94.7% of students had relapsed in drug use after abstinence. Therefore, male patients seem to be a vulnerable gender category for relapse after being discharged from psychosocial therapies. Intensive help, like cognitive restructuring services, after discharge from rehabilitation centers should be given to such patients to reduce the chance of relapse.

Relationship between Psychosocial Therapy and Drug Abuse Relapse

The findings of this study fall in line with those conducted by Nagy (2022), that there are no statistical differences between psychosocial therapy in addiction management and drug abuse relapse among inpatients of the psychiatric institute at Ain Shams University Hospital; through multivariate analysis, the findings revealed that x^2= 12.525, p = .166; thus, thus majority of the students had not relapsed after obtaining psychosocial therapy. Meanwhile, the findings are similar to those of Mohamed (2021), who reported that there is no statistically significant relationship between psychosocial therapy and drug abuse relapse among drug users/dealers, where the findings showed p=0.176>0.05. Hence, the provision of psychosocial therapies does not reduce the chances of drug abuse relapse.

However, the findings are inconsistent with those concluded by Malik et al. (2023) that psychosocial factors such as self-efficacy, social support, personality traits, and stigma have a significant role in causing addiction relapse. Yet the findings are further inconsistent with those of Azmi et al. (2018), who revealed that psychosocial factors such as self-efficacy, peer support, family support, and community support have a direct relationship with drug abuse relapse among adolescents after being involved in rehabilitation centers. It is also worth noting that Mohamed et al. (2022) revealed that there is a positive significant correlation between psychosocial therapy, such as self-efficacy and social support, and treatment motivation among adult patients in drugs. This means that psychosocial therapy has nothing to contribute to preventing relapse in drug abuse among human beings, including adolescent students.

Meanwhile, Kardas (2023) found that cannabis use (p=0.005), late treatment initiation (p=0.001), less psychosocial (p=0.006), outpatient (p=0.003), and inpatient (p=0.001) treatment history were associated with relapse before one month. Therefore, cannabis users were approximately 5 times more likely to relapse in less than a month. This suggests that psychosocial therapy has no contribution to reducing or preventing relapse among adolescents. Therefore, the current study's findings differ from the findings of that study because it is stated that it has no contribution towards reducing the possibility of students relapsing.

Conclusion

The provision of psychosocial therapy among adolescent students was moderate (43.18%), while drug abuse relapse was high (59.09%). No statistically significant relationship was found between

psychosocial therapy and relapse (r = .0793, p=.366 > .05). Given the non-experimental, cross-sectional design of this study, this finding should not be read as evidence that current psychosocial interventions are ineffective; rather, the combination of a lack of detected association with a relapse rate suggests that current provision may be insufficient in scope or intensity and warrants further evaluation, ideally with validated instruments and a longitudinal design. Strengthening psychosocial therapy services and implementing comprehensive, continuous drug education from family to school levels, for example through a spiral curriculum that revisits and reinforces key messages across school years, is recommended to support sustained behavioral change among adolescents.

Implications

The findings carry important implications for policy, practice, and research in adolescent mental health and substance use prevention. The moderate provision of psychosocial therapy alongside a high relapse rate suggests a need to strengthen the scope, intensity, and quality of counselling and psychosocial support services in schools. Interventions should move beyond basic provision to include structured, evidence-based approaches targeting relapse prevention, coping skills, and behavioral change. At the policy level, there is a need for stronger integration of school-based mental health services within national health and education systems, including capacity building for school counsellors and teachers. Practically, collaboration between families, schools, and community stakeholders should be enhanced to provide a supportive environment that reinforces recovery and reduces relapse risk. The findings also point to the value of comprehensive and continuous drug education, including spiral curricula that reinforce learning over time and promote sustained awareness among adolescents.

Future Directions

Future research should adopt mixed-methods approaches, combining quantitative scales with qualitative interviews, to capture relationships between psychosocial therapy and drug abuse relapse among adolescents. There is also a need to examine the effectiveness of specific evidence-based psychosocial interventions, such as cognitive-behavioural therapy, motivational interviewing, and peer support programs within school settings. Also, expanding research to include diverse populations such as out-of-school youth and adolescents in different sociocultural contexts would enhance generalisability. Future studies should explore moderating and mediating factors, including family dynamics, peer networks, mental health status, and socioeconomic conditions, to provide a more comprehensive understanding of relapse mechanisms. Finally, intervention-based studies evaluating integrated school–family–community models are recommended to identify sustainable strategies for reducing drug abuse relapse among adolescents.

Declarations

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Ethical approval and consent to participate

Institutional review board approval was obtained from the University of Dar es Salaam, ref. No.AB3/12(B) dated 3rd July 2023 on behalf of the Tanzania Commission for Science and Technology (COSTECH). Informed consent form from research participants was signed. Parental informed consent was obtained for some of the participants aged below 18 years; confidentiality and the right of withdrawal were also adhered to and maintained for all participants.

Disclosure statement
No competing interests between authors.

Data Availability
Data will be accessed upon request.

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Assessment of factors associated with knowledge of antimicrobial resistance among patients attended referral hospitals in Dodoma region, Tanzania

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Abstract

Introduction: Antimicrobial resistance (AMR) occurs when microorganisms including bacteria, viruses, fungi, and parasite develop mechanisms that protect them from the effects of antimicrobial drugs designed to kill them or inhibit their growth. Antimicrobial resistance (AMR) has emerged as one of the top ten global public health threats, contributing to an estimated 4.95 million deaths annually, with 1.27 million deaths directly attributed to bacterial AMR alone. Despite these efforts, AMR remains a critical challenge in Tanzania because of deep-rooted behavioral and systemic factors. While clinical data show rising resistance patterns in regional hospitals, there remains a disconnect between national policy and patient-level behavior

Methods: The study employed hospital based analytical cross-sectional design to assess factors associated with antimicrobial resistance among adult patients attended referral hospitals in Dodoma region. Written Informed Consent was requested before the administration of the questionnaires to the respondents. A verified structured questionnaire tool (English version) was used to assess factors associated with KAP of patients.

Results: A total of 407 participants were enrolled in this study. The median age was 38 years and interquartile range (IQR) of 26-52. Nearly half of the 188 participants (46.2%) were over 40 years old. Most participants were female, 237 (58.2%) and lived in urban areas 339 (83.3%). Levels of education were varied: 133 (32.7%) had a primary education and 127 (31.2%) had a university or college education. For occupation, 192 (47.2%) were self-employed.

Conclusion: The findings of this study show that knowledge of antimicrobial resistance (AMR) is not uniformly distributed among the participants. It is suggestively influenced by socio-demographic factors. Participants aged 30 to 39 years, females and those with higher levels of education exhibited better understanding of AMR compared to other groups.

Keywords: Antimicrobial resistance, Knowledge, Patients, Referral hospitals and Dodoma region

Introduction

Antimicrobial resistance (AMR) occurs when microorganisms such as bacteria, viruses, fungi and parasites no longer respond to medicines that were previously effective (Md. Abdus Salam, 2023). As a result, standard treatments become less effective, infections may persist and the risk of transmission, severe illness, disability and death increases. Although AMR is a natural evolutionary phenomenon, its emergence and spread have been dramatically accelerated by human activities,

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including the misuse and overuse of antimicrobials in healthcare, agriculture, livestock settings and the environment (Antibiotic Resistance Threats in the United States, 2019; Taylor, 2016).

AMR has emerged as one of the top ten global public health threats, contributing to an estimated 4.95 million deaths annually, with 1.27 million deaths directly attributed to bacterial AMR alone (Murray et al., 2022). The crisis is particularly acute in low- and middle-income countries, including those in sub-Saharan Africa, where a high burden of infectious diseases is compounded by fragile healthcare systems and unregulated access to medicines (Murray et al., 2022). Without urgent and coordinated action, AMR is projected to cause up to 10 million deaths annually by 2050 and may substantially reduce global economic output (Atalay & Abebe Gelaw, 2024).

In Tanzania, AMR is a growing clinical challenge, with studies reporting high resistance to commonly used first-line antibiotics such as ampicillin, amoxicillin and trimethoprim-sulfamethoxazole (Azabo et al., 2022). This challenge is intensified by widespread self-medication and the ease of obtaining antibiotics without prescription (Mudenda et al., 2023). Nationally, the government has launched the National Action Plan on Antimicrobial Resistance (2023–2028), which emphasizes a One Health approach to strengthen surveillance and promote rational antimicrobial use across human and animal health sectors (Frumence et al., 2021).

Despite these efforts, AMR remains a critical challenge in Tanzania because of deep-rooted behavioral and systemic factors. While clinical data show rising resistance patterns in regional hospitals, there remains a disconnect between national policy and patient-level behavior (Frumence et al., 2021). Inappropriate antibiotic use, including self-medication has been documented in the community (Kheder, 2013). However, evidence on the specific socioeconomic and behavioral factors associated with AMR knowledge among patients in Dodoma Region remains limited. Most studies in Tanzania have focused on healthcare providers or laboratory-based resistance profiles, with relatively few studies examining patient knowledge, attitudes and practices regarding AMR in central Tanzania (Sindato et al., 2020). This limited evidence constrains the design of targeted public health interventions needed to improve antimicrobial use and reduce misuse among patients in Dodoma Region.

Therefore, this study aimed to determine factors associated with knowledge of AMR among patients attending referral hospitals in Dodoma Region, Tanzania.

Material and Methods

Study design, population and site

The study employed hospital based analytical cross-sectional design to assess factors associated with antimicrobial resistance among adult patients attended referral hospitals in Dodoma region (Benjamin Mkapa Hospital (BMH), Mirembe National Mental Health Hospital (MNMH) and Dodoma regional Referral Hospital (DRRH)) for two (2) months from May to June 2025. These referral hospitals provide specialized outpatient and inpatient services and serve as core centers for health services in Dodoma Region and neighboring regions, making them suitable for assessing factors associated with antimicrobial resistance.

Data collection method and tools

The study had three days of training and orientation for the research assistants concerning the study and how data were going to be collected. A verified structured questionnaire tool (English version) was translated into Swahili for easy administration to the interviewer.

Validity

The content validity of the research tool was checked by the AMR expert with good experience in quantitative research methods. Another expert was also asked to review each question to determine if they addressed the research objectives. The feedback from experts was analyzed and compared to determine the degree of content validity for each question. Modifications suggested were considered before pre-testing and data collection.

Reliability of the instrument

A pre-test to check the reliability of the tool was done with respondents with similar criteria as the study sample and appropriate modifications were made. The data collection tool was pre-tested through the pilot study with some patients (10% of the sample size). The purpose of pre-testing was to verify the adequate collection of desired information as well as ensure consistence of the questions. In the pre-testing process, minor corrections were made before conducting the study.

Sample size estimation and sampling technique

The sample size was determined using the Kish and Leslie (1965) formula for estimating a single population proportion in cross-sectional studies: $n = Z^2P(1-P) / d^2$

Where:

- n = minimum required sample size
- Z = standard normal deviate corresponding to a 95% confidence level (1.96)
- P = estimated prevalence of adequate knowledge of antimicrobial resistance among the target population
- d = margin of error (precision), set at 5% (0.05)

Since there was limited published evidence on the prevalence of adequate knowledge of antimicrobial resistance among patients attending referral hospitals in Dodoma Region, a conservative prevalence estimate of 50% (P = 0.5) was used.

Substituting the values:

- $n = (1.96^2 \times 0.5 \times 0.5) / (0.05^2)$
- $n = 384.16$

The minimum required sample size was therefore 384 participants. To account for non-response and incomplete questionnaires, 10% was added:

- $nf = 384 + (0.10 \times 384)$
- $nf = 422.4 \approx 423$

Thus, the final target sample size was 423 participants. A total of 407 participants completed the interview and were included in the final analysis, yielding a response rate of 96.2%.

Sampling Technique:

A systematic random sampling technique was employed to recruit participants from Benjamin Mkapa Hospital, Dodoma Regional Referral Hospital, and Mirembe National Mental Health Hospital. Eligible adult patients attending outpatient services during the study period were selected systematically after providing informed consent. The first participant was selected randomly, followed by recruitment of every kth eligible patient until the desired sample size was attained. Sample allocation was proportional to patient attendance volume at each hospital.

Inclusion and Exclusion Criteria

Inclusion Criteria:

- Adult patients aged 18 years and above.
- Attending selected referral hospitals during the study period.
- Able to communicate in Swahili or English.
- Willing to provide written informed consent.

Exclusion Criteria:

- Critically ill patients are unable to participate.
- Patients with severe cognitive or communication difficulties.
- Patients who declined participation or withdrew consent

Measurement of Knowledge on AMR

Knowledge on antimicrobial resistance was assessed using a structured questionnaire consisting of knowledge-related items. Each correct response was assigned one point, while incorrect and "not sure" responses were assigned zero points. Individual scores were summed to generate a composite knowledge score. Participants scoring at or above the predetermined cut-off (preferably the median score or ≥80%, depending on the authors' analytical approach) were categorized as having good knowledge, while those below the cut-off were categorized as having poor knowledge. The dichotomized variable was used in regression analyses.

Data analysis

Data from the kobo toolbox were extracted in excel format and imported into STATA Version 17. Data were checked, cleaned and analyzed using STATA. Descriptive statistics summarized data using frequencies and proportion for categorical and median using interquartile range. Categorical variables were summarized as proportions and were analyzed using the Pearson's Chi-Square test to test statistical differences among the various groups. The p-value of less than 0.05 was considered statistically significant with their respective 95% confidence interval (CI) were calculated to measure the strength of associations. Modified Poisson regression models used to analyze crude risk ratio and Adjusted Risk Ratio (ARR) of factors with knowledge domain.

Results

Socio-demographic characteristics among patients attending referral hospitals in Dodoma region

A total of 407 participants were enrolled in this study. The median age was 38 years and interquartile range (IQR) of 26-52. Nearly half of the 188 participants (46.2%) were over 40 years old. Most participants were female, 237 (58.2%) and lived in urban areas 339 (83.3%). Levels of education were varied: 133 (32.7%) had a primary education and 127 (31.2%) had a university or college education. For occupation, 192 (47.2%) were self-employed. This is presented in table 1 below.

Table 1: Socio-demographic characteristics among patients attending referral hospitals in Dodoma region (N=407)

Characteristics	n	%
Sex		
Male	170	41.769
Female	237	58.230
Age (Years)		
Median (IQR)	38 (26-52)	

18-29	133	32.678
30-39	86	21.130
>40	188	46.191
Residence		
Rural	68	16.707
Urban	339	83.292
Educational level		
No schooling	23	5.651
Primary	133	32.678
Secondary education	124	30.466
University /college Education	127	31.203
Occupation status		
Unemployed	156	38.329
Self employed	192	47.174
Employed	59	14.496

Knowledge of antimicrobial resistance among patients attending referral hospitals in Dodoma region (N=407)

Figure 1 shows, 64.86% **of patients had good knowledge**, while **35.14% had poor knowledge**. This shows patients with good knowledge was more prevalent among patients with poor knowledge.

Fig 1: Knowledge of antimicrobial resistance among patients (N=407).

Descriptive statistic of Knowledge on antimicrobial use among patients attending referral hospitals in Dodoma region (N=407)

Figure 2 show most participants, 350 (86%) agreed that antimicrobial resistance has an effect on human health and 61.4% agreeing that AMR occurs when antimicrobials become less powerful that don't work well. Regarding the causes of AMR, **61.4**% of the participant agreed that AMR occurs when microbes become resistant to antimicrobial agents, whereas **30.7**% disagreed and **7.9**% were unsure, however large proportion of participants had misconceptions about AMR, **70.3**% agreed that AMR occurs when the human body becomes resistant to antimicrobials, Furthermore, half of the participants **51.4**% agreed with the incorrect statement that AMR only affects people with serious infections in hospitals.

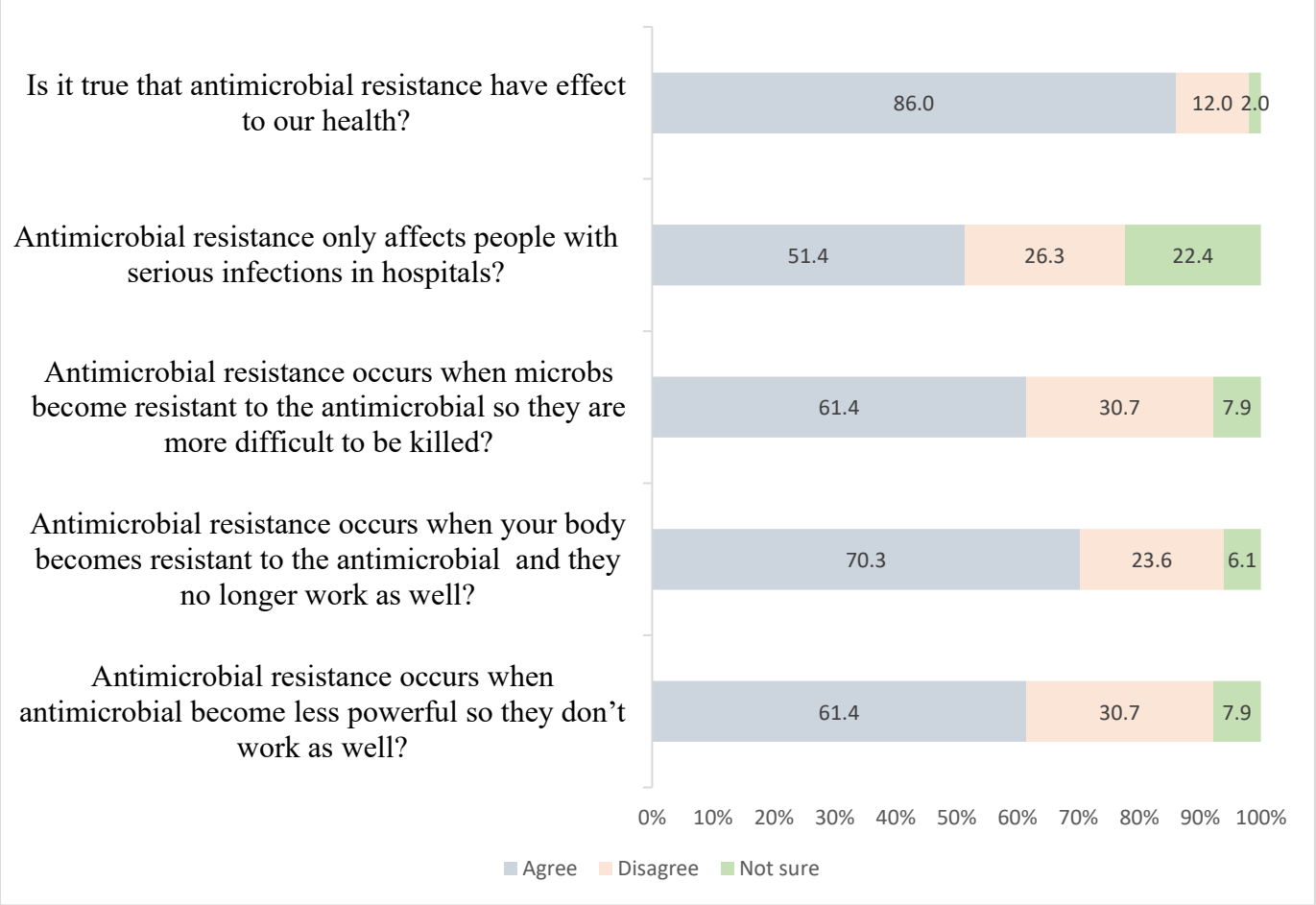

Fig 2: Descriptive statistic of Knowledge on antimicrobial use among participants(N=407)

Antibiotic use and related information among patients

Table 2, show information on antibiotic use among 407 patients attending referral hospitals in the Dodoma region, the majority of participants 254 (62.4%) had taken antibiotics within the last month, while 80 (19.7%) had used them within the last six months and 70 (17.2%) had taken antibiotic more than one year ago. Regarding sources of antibiotics, half of the participants (52.8%) obtained antibiotics through healthcare professionals and 192 (47.2%) obtained them from pharmacies, more than half pf participants (60.2%) reported having used antibiotics without a prescription (self-medication), and 235 (57.7%) reported received advice on how to take antibiotics from a health worker.

Table 2: Antibiotic use and related information among patients attending referral hospitals in Dodoma region (N=407)

Variables	Categories	Frequency n %
The last time to take antibiotics	In the last month	254 (62.41)
	In the last 6 months	80 (19.66)
	More than a year ago	70 (17.20)
	Don't know	3 (0.73)
The sources of antibiotics (More than one answer is possible)	Pharmacy	192 (47.17)
	Healthcare professional	215 (52.83)
	Friends or family/Online	0 (0)
	Other	0 (0)
Ever used antibiotics without prescription (self-medication with antibiotics)	Yes	245 (60.20)
	No	162 (39.80)
Getting advice from a doctor, nurse or pharmacist on how to take antibiotics	Yes	235 (57.74)
	No	172 (42.26)

Factors associating with knowledge of Antimicrobial Resistance (AMR)

Table 3 show, Age was significantly associated with AMR knowledge, patients aged 30-39 years had 1.2 times good knowledge of AMR, compared to those aged 18-29 years (ARR = 1.25, 95% CI 1.11-1.41, p < 0.001). Female patients had 1.62 higher knowledge of AMR compared to males (ARR = 1.62, 95% CI 1.02-2.60, p = 0.043). Regarding education, patients who attained educations had significantly knowledge of AMR compared who had no formal education, those with primary education had 2.2 more likely to have good AMR knowledge (ARR = 2.26, 95% CI 1.03-4.95, p = 0.042), Similarly, participants with secondary education had 2.8 times higher AMR knowledge (ARR = 2.81, 95% CI 1.28-6.16, p = 0.010), while those with university/college education had 3.5 times higher knowledge of AMR (ARR = 3.51, 95% CI 1.61-7.68, p = 0.002).

Table 3: Associating factors of knowledge towards AMR among patients referral hospitals in Dodoma region (n = 407).

Variable	Knowledge on AMR	
	ARR (95%CI)	**P-value**
Age (Years)		
18-29	1.00	
30-39	1.25 (1.111, 1.414)	**<0.001**
>40	1.15 (0.980, 1.344)	0.071
Sex		
Male	1.00	
Female	1.62 (1.015, 2.601)	**0.043**
Residence		
Rural	1.00	
Urban	1.18 (0.909, 1.520)	0.218
Educational level		
No schooling	1.00	
Primary	2.26 (1.030, 4.947)	**0.042**
Secondary education	2.81 (1.280, 6.155)	**0.010**
University /college Education	3.51 (1.608, 7.676)	**0.002**
Occupation status		

Unemployed	1.00	
Self employed	0.57 (0.236, 1.399)	0.223
Employed	0.44 (0.180, 1.074)	0.071
Have you ever taken antimicrobial without a prescription from a healthcare professional?		
No	1.00	
Yes	0.93 (0.835, 1.029)	0.157
Getting advice from a doctor, nurse or pharmacist on how to take antibiotics		
No	1.00	
Yes	0.765 (0.570, 1.026)	0.073

Discussion

Associating factors of knowledge towards AMR

The study observed the lower adjusted risk ratios (ARR) of good knowledge towards AMR among patients aged 18-29 years compared to those aged 30-39. Similarly, another study reported that health workers under 30 years of age had a slightly lower knowledge rate, while those aged 30 years and above had higher knowledge of AMR (Jahromi et al., 2025). This low knowledge to young population as compared to those aged from 30-39 years could be less internet access, because internet is the major source of information regarding AMU and AMR where there is a vast majority of information regarding the antimicrobial use and antimicrobial resistance are spread from various sources (Tsuzuki et al., 2020) as compared to young adults who depend mostly from education systems and radio as seen in the study reported from Seira Leone (Kamara et al., 2025) Also, the observed low knowledge in the young population could be because they didn't get this as basic knowledge to their education system, but also less experience in antibiotic use, whether for themselves or in taking care of those who use antibiotics. (Waaseth et al., 2019)

Our study findings are contrary to a study conducted in Bangladesh, which reported that the age group of 18–30 years showed improved knowledge compared to other age groups, but participants' gender had no substantial effect on their AMR knowledge (Azim et al., 2023).

This could be explained by the participants' educational backgrounds and exposure to medical information, our studies was conducted among the general populations individual from the community who attended the healthcare services at the tertiary hospitals without considering their educational background and exposure to medical educations, the level of knowledge among young university students still is high in the studies conducted in Nigeria and Malaysia (Akande-Sholabi & Ajamu, 2021; Ting wei Tiong, 2020)

This emphasizes the necessity to raise the campaigns regarding antimicrobial use and microbial resistance to society through our education systems, formulation of AMR clubs in schools, and the young population, which has been shown to have a low level of knowledge, to increase their level of awareness through media such as Radio and TV that focus more on youth.

This study also described that female patient had a higher ARR of AMR knowledge compared to males. A study conducted in Zambia reported that Male participants were less likely to have good knowledge towards AMU and AMR compared with females (Mudenda et al., 2023).

This could be explained by the behaviour which is shown in a lot of females to be concerned about their health compared to men, due to this health-seeking behaviour, predispose more women to acquire more knowledge about AMR from medical professionals during their frequent visits to healthcare facilities (Mramba et al., 2025; Waaseth et al., 2019). The study done in Ilala, Kibaha and Kilosa districts in Tanzania gives the opposing results that the Awareness and knowledge

of antimicrobial use and resistance were similar between males and females and also no significant difference in the same with age (Sindato et al., 2020). Furthermore, these findings necessitate spreading education to all genders equally so that they can reduce hurdles regarding the prevention of AMU and AMR among the general population, because the whole society will be aware of the effects of AMU and AMR without regard to specific gender only.

Our study reported that respondents with formal education had higher knowledge on antimicrobial resistance than those without formal education, such that, as the level of education increases, the more knowledge on AMR is raised. Similar results were reported by the study conducted in Turkey, which found that the antibiotic knowledge level of the participants with a postgraduate degree was found to be significantly higher than that of high school and primary school graduates or the uneducated (Ozturk et al., 2019)

This could be attributed to the ability of those people with higher knowledge to have access to credible and reliable sources of information from their various reputable sources, and some of them to learn from them in school. Therefore, this could raise concern that more focus regarding the knowledge should be on people at the general population, for those people with only primary education or those who do not have formal education regarding the AMU and AMR.

Conclusion

The findings of this study show that knowledge of antimicrobial resistance (AMR) is not uniformly distributed among the participants. It is suggestively influenced by socio-demographic factors. Participants aged 30 to 39 years, females and those with higher levels of education exhibited better understanding of AMR compared to other groups. This pattern suggests that increased maturity, possible exposure to health-related responsibilities and higher educational attainment may enhance an individual's capacity to access, interpret and apply health information.

Study limitations

We cannot establish causal effect between factors and outcome of interest due to the study design.

Abbreviations

AMR – Antimicrobial resistance
ARR - Adjusted Risk Ratios
BMH - The Benjamin Mkapa Hospital
KAP – Knowledge, attitude and practices

Declarations

Ethical approval

Before conducting this study, an ethical clearance letter was obtained from University of Dodoma Institutional Research Review Ethics Committee (IRREC) with the reference number MA.84/261/86/160 dated 19th March 2025. The study also obtained a written permission to conduct the study in these institutions. Participants were asked to provide written informed consent before the interviewer administered the questionnaire. No penalty or mistreatment was applied to the participants who refused to participate or who decided to withdraw somewhere in the middle of the study. The consent form contained a full explanation of the benefits and risks of the study to participants and assurance of voluntary participation (participants can refuse to participate at any time during the interview) and provided assurance of confidentiality by maintaining anonymity.

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Availability of data and materials:
All data for this study has been included in this manuscript. No extra data available elsewhere.

Authors' contributions:
SSM designed the study, collected data, wrote the study report and manuscript. **HI** designed the study, wrote the study report, analyzed data and wrote the manuscript. **SSK** collected data and wrote the study manuscript. **MM** designed the study, wrote the study report and study manuscript. **SAK** collected data and analyzed data. **EM** analyzed data. **SJ** wrote the first draft of study proposal and report. **MK** supervised report and manuscript writing. **AM** supervised report and manuscript writing. **BL** report and manuscript writing. **JRN** report and manuscript writing. **AB** report and manuscript writing.

Competing interests:
No competing interests

Consent for publication:
No person, institution or organization will be allowed to disseminate/publish part or full of this study results without the written consent and permission of the principal investigator or the affiliated institution.

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Culture-Confirmed Meningitis in a Tertiary Hospital in Central Morocco (2017–2019): A Retrospective Single-Center Study

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Abstract

Introduction: Meningitis remains a major global health concern, particularly in low- and middle-income countries where bacterial forms continue to cause high morbidity and mortality despite vaccination programs. In Morocco, national immunization against *Haemophilus influenzae* and *Streptococcus pneumoniae* has reduced pediatric incidence, yet the disease persists due to vaccine-resistant serotypes and opportunistic infections. Updated local data are essential to guide surveillance and prevention strategies**.** This study aimed to describe the epidemiological characteristics and culture-confirmed etiologies of meningitis among hospitalized patients investigated for suspected meningitis in a tertiary hospital in central Morocco between 2017 and 2019.

Methods: We conducted a retrospective, single-center study based on laboratory records of cerebrospinal fluid (CSF) samples collected from hospitalized patients undergoing lumbar puncture for clinical suspicion of meningitis. Pathogen identification relied on conventional culture and biochemical methods. A confirmed case was defined as a CSF sample with a positive bacterial or yeast culture. Statistical analyses were performed using the Chi-square test, with $p < 0.05$ considered significant

Results: A total of 1,087 CSF samples were analyzed, of which 103 (9.5%) were culture-positive. Culture positivity varied across hospital services, with the highest proportion observed in intensive care units ($p < 0.001$). *Neisseria meningitidis* (55.3%) and *Streptococcus pneumoniae* (32%) were the most frequently isolated bacterial pathogens, while yeasts accounted for a smaller but clinically relevant proportion of isolates (11.7%).

Conclusion: In this tertiary hospital setting, culture-confirmed meningitis was predominantly caused by *N. meningitidis* and *S. pneumoniae*. Given the retrospective, single-center design and the reliance on culture-based diagnostics, these findings should not be extrapolated beyond the study setting. Strengthening routine data collection and integrating molecular diagnostic methods may improve etiological detection and clinical interpretation.

Keywords: meningitis, Morocco, *Neisseria meningitidis*, *Streptococcus pneumoniae*, cerebrospinal fluid, hospital epidemiology

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Introduction

Meningitis is a disease found worldwide in various forms, including bacterial, viral, fungal, and parasitic. It is most commonly of viral or bacterial origin (World Health Organization, 2023). Viral meningitis presents mild symptoms, and recovery occurs spontaneously (Kohil et al., 2021). The incidence of the disease is usually unknown, except during epidemics. Bacterial meningitis is a severe infectious disease characterized by inflammation of the protective membranes surrounding the brain and spinal cord. Bacterial meningitis is an important cause of morbidity and mortality worldwide (World Health Organization, 2023). Indeed, 1 in 10 people who get this type of meningitis die and 1 in 5 have severe complications (World Health Organization, 2023). People who recover often end up with serious sequelae, such as cerebral palsy, epilepsy, blindness, and deafness (Edmond et al., 2010; Subbarao et al., 2023). The bacteria responsible for the highest proportion of meningitis cases in all regions of the world were *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* (Oordt-Speets et al., 2018; Ikken et al., 2020). Other bacterial species such as *Klebsiella* spp, *Streptococcus agalactiae*, *Escherichia coli*, and *Mycobacterium tuberculosis* have been reported in several studies (Pelkonen et al., 2020; El Kareh et al., 2020).

In 2019, there were 2.51 million instances of meningitis globally across all age groups, with 1.28 million cases affecting children under 5 years old (GBD Collaborators, 2023). Despite progress in prevention, bacterial meningitis persists worldwide, especially in developing countries (GBD Collaborators, 2019). Bacterial meningitis incidence and mortality rates are the highest in 26 African countries stretching from Senegal to Ethiopia (Bwaka et al., 2019). In addition, several countries in the Middle East and Africa have experienced recurrent epidemics of meningococcal meningitis. Saudi Arabia has reported outbreaks associated with mass gatherings, while Sudan is part of the African "meningitis belt" where meningococcal epidemics remain endemic (Teleb et al., 2013). In Morocco, meningitis is one of the main problems in public health. The country experienced two important epidemics in 1967-1968 and 1988-1989 (Ministry of Health of Morocco, 2025).

During the period from 2004 to 2009, 4,983 suspected cases of meningitis were reported in 11 Moroccan hospitals, including 1,844 cases aged less than 5 years, 629 cases aged between 5 and 10 years, and 592 cases aged ≥11 years; for the remaining 1,878 cases, the age was not available (Braikat etal., 2012). To minimize the incidence of bacterial meningitis, a mass vaccination targeting *Haemophilus influenzae* and *Streptococcus pneumonia* was introduced respectively in 2007 and 2010 in Morocco (Ministry of Health of Morocco, 2025). The introduction of these two vaccines has probably significantly reduced the occurrence of meningitis, especially in children under 5 years of age (Braikat et al., 2012). However, meningitis still poses a significant health problem for people all over the world due to the replacement of vaccine-resistant pneumococcal serotypes and the advent of bacterial strains with lower sensitivity to antibiotic therapy (de Beek et al., 2021).

The present study described the epidemiological characteristics and culture-confirmed etiologies of meningitis among hospitalized patients investigated for suspected meningitis in a tertiary hospital in central Morocco over a three-year period (2017–2019). By focusing on laboratory-confirmed cases and explicitly acknowledging the scope and limitations of the study design, this work contributes descriptive data relevant to the local hospital setting and highlights priorities for improving meningitis surveillance and diagnostics.

Materials and Methods

Study design and setting

This study was a retrospective, single-center, laboratory-based analysis conducted at a hospital in central Morocco. It included cerebrospinal fluid (CSF) samples processed in the microbiology laboratory between January 2017 and December 2019. Data were extracted retrospectively from

laboratory registers. The retrospective analysis was performed in 2024 after complete verification and digitization of the microbiological records. This timeframe represents the most recent period with consistent cerebrospinal fluid (CSF) sampling and validated culture results before significant organizational and epidemiological changes (including the COVID-19 pandemic).
The study population consisted of hospitalized patients who underwent lumbar puncture because of clinical suspicion of meningitis, and whose CSF samples were sent to the microbiology laboratory for analysis during the study period. Because the study was based on laboratory records, clinical data at the patient level were not systematically available, and the unit of analysis was the CSF sample rather than the individual patient.

Inclusion and exclusion criteria
Inclusion criteria

- CSF samples collected between January 2017 and December 2019.
- Samples obtained from hospitalized patients investigated for suspected meningitis.
- Samples with a documented culture result (positive or negative).

Exclusion criteria

- CSF records with incomplete laboratory information (e.g., missing culture result).
- Duplicate samples from the same clinical episode could not be reliably identified using laboratory records alone and were therefore not excluded.

Case definitions

- **Suspected meningitis**: any hospitalized patient for whom a CSF sample was collected following clinical suspicion of meningitis. Detailed clinical criteria (signs, symptoms, CSF cytochemistry) were not retrievable from laboratory records.
- **Confirmed meningitis:** any CSF sample yielding a bacterial or yeast pathogen on conventional culture.

CSF collection and laboratory procedures
During the study period, a total of 1,087 CSF samples were collected from patients hospitalized with clinical suspicion of meningitis. The germs were isolated using several culture mediums, including Chapman agar, Cetrimide agar, blood agar, and Sabouraud + chloramphenicol for fungi or yeasts. The microorganisms were identified based on cultural, morphological, and biochemical characteristics, supplemented with other assays, including Gram coloration, catalase, and emission of gas bubbles.

Variables and outcomes
The primary outcome was culture positivity of CSF samples. Secondary variables included year of sampling, hospital service, patient sex, and identified microorganisms.
Clinical variables such as comorbidities, prior antibiotic use, disease severity, and patient outcomes were not available in the laboratory dataset and were not analyzed.

Statistical Analysis
Data were entered and cleaned using Microsoft Excel 2010 and analyzed using IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA; 2019). Frequencies and percentages were calculated for categorical variables, and associations were assessed using Pearson's Chi-square test. A *p-value* < 0.05 was considered statistically significant.

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Results

Of the 1,087 CSF samples analyzed, 103 were culture-positive, corresponding to a positivity rate of 9.5%. The annual distribution revealed a progressive increase in the culture positivity rate, from 7.4% in 2017 to 11.8% in 2019, whereas the proportion of sterile samples declined from 92.6% to 88.2% (Figure 1).

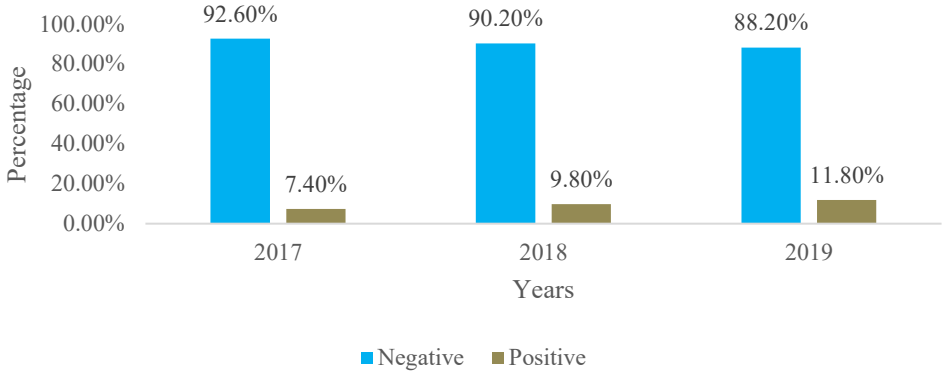

Figure 1: Annual Distribution of Culture-Negative and Culture-Positive CSF Samples

Of all samples, 677 (62.3%) originated from male patients and 410 (37.7%) from females. Positive cultures were detected in 8.9% of males and 10.5% of females. Statistical comparison using the Chi-square test revealed $\chi^2 = 0.789$, df = 1, $p = 0.3752$, indicating no significant association between sex and culture positivity. The distribution of cerebrospinal fluid (CSF) samples and culture positivity rates across hospital services is presented in Table 1. The majority of samples originated from the Neonatal Intensive Care Unit (43.8%), whereas the highest positivity rate was observed in the Intensive Care Unit (31.0%). Similarly, Medical service (19.6%) and Neurosurgery (25 %) displayed elevated positivity**.** Pediatric (14.8%) and Emergency (16.7%) services showed moderate positivity rates. On the other hand, Neurology (5.5%), Cardiology (0%), Gastroenterology (0%), and other services (0%) showed minimal or no positive cultures. The association between hospital service and culture positivity was statistically significant ($\chi^2 = 36.42$; df = 9; $p < 0.001$).

Table 1: Distribution of cerebrospinal fluid (CSF) culture results by hospital service

Units	Total CSF samples (n)	Positive samples (n)	Positivity rate	Proportion of total samples
Neonatal Intensive care	476	20	**4.2%**	43.8%
Pediatrics	263	39	**14.8%**	24.2%
Neurology	181	10	**5.5%**	16.7%
Medical department	112	22	**19.6%**	10.3%
Intensive Care Unit	29	9	**31.0%**	2.7%
Emergency	12	2	**16.7%**	1.1%
Neurosurgery	4	1	**25.0%**	0.4%
Cardiology	2	0	**0.0%**	0.2%
Gastroenterology	3	0	**0.0%**	0.3%
Others	5	0	**0.0%**	0.5%

Among the 1,087 CSF samples analyzed for suspected meningitis, 103 yielded positive cultures. Of these positive cultures, 12 (11.7%) yielded yeasts and 91 (88.3%) yielded bacterial pathogens. The difference in distribution between bacterial and fungal isolates was statistically significant (χ^2 = 60.59, df = 1, p < 0.001).

Table 2: Bacterial Distribution among Positive CSF Cultures

Bacterial species	Observed frequency (n)	Percentage (%)
Neisseria meningitidis	57	62.6
Streptococcus pneumoniae	33	36.3
Pseudomonas putida	1	1.1
Total (bacterial isolates)	**91**	**100**

Neisseria meningitidis was the most frequently isolated bacterial pathogen (62.6%), followed by *Streptococcus pneumoniae* (36.3%) and *Pseudomonas putida* (1.1%). The distribution of bacterial species differed significantly ($\chi^2 = 51.37$, df = 2, $p < 0.001$) **(Table 2).**

Out of the 103 positive cerebrospinal fluid (CSF) cultures, *Neisseria meningitidis* accounted for 55.3% of isolates, *Streptococcus pneumoniae* for 32.0%, yeasts for 11.7%, and *Pseudomonas putida* for 1.0% **(Table 3)**. The distribution of microorganisms varied significantly across hospital services ($\chi^2 = 168.77$; df = 45; $p < 0.001$). In Pediatrics, *N. meningitidis* represented 53.8% of isolates, followed by *S. pneumoniae* (41.0%) and yeasts (5.1%). In Neonatal Intensive Care, *N. meningitidis* accounted for 70.0% of isolates and *S. pneumoniae* for 30.0%. In the Medical Department, *N. meningitidis*, *S. pneumoniae*, and yeasts represented 40.9%, 22.7%, and 36.4% of isolates, respectively. In the Intensive Care Unit, the corresponding proportions were 66.7%, 22.2%, and 11.1%. Overall, bacterial pathogens accounted for 88.3% of positive cultures, whereas yeasts represented 11.7%.

Table 3: Distribution of isolated pathogens by hospital service

Services	*Neisseria meningitidis* n (%)	*Streptococcus pneumoniae* n (%)	Yeasts n (%)	*Pseudomonas putida* n (%)	Total positive (n)
Neonatal Intensive care	14 (70%)	6 (30%)	0 (0%)	0 (0%)	20
Pediatrics	21 (53.8%)	16 (41.0%)	2 (5.1%)	0 (0%)	39
Neurology	5 (50.0%)	3 (30.0%)	1 (10.0%)	1 (10.0%)	10
Medical department	9 (40.9%)	5 (22.7%)	8 (36.4%)	0 (0%)	22
Intensive Care Unit	6 (66.7%)	2 (22.2%)	1 (11.1%)	0 (0%)	9
Emergency	1 (50.0%)	1 (50.0%)	0 (0%)	0 (0%)	2
Neurosurgery	1 (100%)	0 (0%)	0 (0%)	0 (0%)	1
Total	**57 (55.3%)**	**33 (32.0%)**	**12 (11.7%)**	**1 (1.0%)**	**103**

Over the three-year period, *Neisseria meningitidis* remained the leading pathogen isolated from cerebrospinal fluid cultures, accounting for 55.3% of all positive cases. Its annual distribution showed moderate fluctuations, 62.1% in 2017, 51.3% in 2018, and 54.3% in 2019, but the overall trend indicates a stable predominance of meningococcal infections throughout the study period **(Table 4)**. *Streptococcus pneumoniae* ranked second, representing 32.0% of isolates. The proportion decreased slightly over time (from 34.5% in 2017 to 22.9% in 2019).
Yeast isolates represented 11.7% of positive cultures, with a progressive rise from 3.4% in 2017 to 22.9% in 2019. The detection of *Pseudomonas putida* was rare (1%), limited to a single isolate in 2018.

The association between pathogen type and year was not statistically significant ($\chi^2 = 9.82$, df = 6, $p = 0.132$).

Table 4: Annual Distribution of Dominant Pathogens Isolated from Positive CSF Cultures

Year	*Neisseria meningitidis* (n, %)	*Streptococcus pneumoniae* (n, %)	Yeasts (n, %)	*Pseudomonas putida* (n, %)	Total positives (n)
2017	18 (62.1%)	10 (34.5%)	1 (3.4%)	0 (0%)	29
2018	20 (51.3%)	15 (38.5%)	3 (7.7%)	1 (2.6%)	39
2019	19 (54.3%)	8 (22.9%)	8 (22.9%)	0 (0%)	35
Total	**57 (55.3%)**	**33 (32.0%)**	**12 (11.7%)**	**1 (1.0%)**	**103**

Discussion

Despite substantial progress in global vaccination programs and improvements in laboratory diagnostics, meningitis remains a major public-health challenge, particularly in low- and middle-income countries (Villalpando-Carrión et al., 2024). Worldwide, bacterial meningitis continues to cause high mortality and neurological sequelae (World Health Organization, 2025), while the emergence of fungal meningitis has been increasingly reported among immunocompromised patients, those exposed to invasive procedures, or under prolonged antimicrobial therapy (Khalilzadegan et al., 2025). In Morocco, national vaccination campaigns targeting *Haemophilus influenzae* type b (2007) and *Streptococcus pneumoniae* (2010) have reduced pediatric cases, yet the disease persists due to vaccine-resistant strains and post-neurosurgical infections (Abouqal et al., 2022). In this context, retrospective hospital-based analyses remain essential for evaluating local epidemiological dynamics.

Over the three-year period (2017–2019), 1,087 cerebrospinal fluid (CSF) samples were collected, yielding 103 positive cultures (9.5%). This positivity rate is somewhat lower than some African hospital-series, where CSF culture positivity ranged from 20–30% (Barichello et al., 2023). Nonetheless, it aligns with regional patterns in North Africa where robust data are scarce. The progressive rise in positivity from 7.4% in 2017 to 11.8% in 2019 may reflect improved sample collection, enhanced laboratory techniques, or persistent transmission of *Neisseria meningitidis* which remains dominant in the "meningitis belt" (Mazamay et al., 2021). These results demonstrate that despite widespread vaccination efforts, bacterial meningitis remains endemic in central Morocco, underscoring the need for sustained surveillance and local microbiological data.

Among the suspected cases, males accounted for 62.3% and females for 37.7%, a distribution consistent with the well-documented male predominance in bacterial meningitis (Oordt-Speets et al., 2018). Interestingly, in our cohort females exhibited a slightly higher culture positivity rate (10.5%) compared with males (8.9%), although this difference was not statistically significant. Recent meta-analysis shows that approximately 58% of bacterial meningitis cases occur in males (Oordt-Speets et al., 2018), and while many studies report no significant sex differences in incidence, male sex remains a predictor of poorer outcomes (Dias & Brouwer , 2022). Accordingly, the male predominance in suspected cases in our study may reflect higher environmental or occupational exposure, whereas the slightly higher positivity rate in females could signal delayed presentation or more advanced disease at sampling.

The distribution of CSF culture positivity varied significantly across hospital. The highest rates were observed in the Intensive Care Unit (31.0 %), Medical department (19.6 %), and Emergency (16.7 %), whereas Pediatrics registered 14.8 % positivity. In contrast, the Neonatal Intensive Care Unit, which accounted for 43.8 % of all CSF samples, achieved only 4.2 % culture positivity. This contrasting pattern underscores a clear dichotomy between community-acquired meningitis (frequent in Pediatrics and medicine department) and nosocomial or device-associated infections in ICU settings, where the burden of invasive procedures is much higher (Valdoleiros et

al., 2022). The exceptionally low yield in neonatology aligns with literature on neonatal CSF diagnostics in low-resource settings, where empirical antibiotic therapy prior to lumbar puncture and limited culture sensitivity contribute to reduced recovery rates (Zhu et al., 2024). Moreover, the limitations of standard culture in neonates highlight the need for molecular diagnostics to improve etiological yield (Venkatareddy et al., 2025).

Among the 103 culture-positive CSF samples, 12 (11.7%) yielded yeasts and 91 (88.3%) yielded bacterial pathogens. The comparison between bacterial and fungal etiologies demonstrated a highly significant difference in distribution, confirming the predominance of bacterial pathogens in CSF infections. This result is consistent with most African and international surveillance data, where bacterial meningitis remains the leading cause of meningitis, accounting for 80–95% of laboratory-confirmed cases (Barichello et al., 2023; Mazamay et al., 2021).

The predominance of bacterial over fungal etiologies observed in our study mirrors findings from the World Health Organization's 2025 meningitis surveillance, which emphasizes that bacterial pathogens, primarily *Neisseria meningitidis*, *Streptococcus pneumoniae*, and *Haemophilus influenzae*, continue to dominate despite large-scale vaccination campaigns (World Health Organization, 2025). The observed high frequency of bacterial meningitis is consistent with global surveillance data. The Global Burden of Disease Study continues to identify bacterial meningitis as a major cause of neurological mortality and long-term morbidity worldwide, with *Streptococcus pneumoniae* and *Neisseria meningitidis* as the most frequently implicated pathogens in both endemic and epidemic settings (GBD Collaborators, 2023).

Conversely, the 11.7% prevalence of fungal meningitis, while statistically subordinate, represents a clinically significant finding that merits focused discourse. This proportion is substantially elevated compared to rates reported from general populations in high-income nations, where fungal meningitis is predominantly observed in well-defined, immunocompromised subpopulations (Bongomin et al., 2017). The elevated frequency in our setting is a potent indicator of underlying regional health dynamics. It likely reflects the local burden of immunocompromising conditions, such as HIV, poorly controlled diabetes mellitus, and the expanding use of immunosuppressive therapies, all of which are established risk factors for central nervous system (CNS) fungal infections, particularly *cryptococcosis* (Rajasingham et al., 2022).

Thus, the 12 fungal cases in our series should be interpreted not merely as a numerical minority but as a critical signal, potentially revealing vulnerabilities in the screening and management of underlying immunosuppressive states within the community. The highly significant *p-value* ($p < 0.001$) validates the primary etiological distinction within our cohort. However, this statistical clarity should not engender diagnostic complacency. The principal clinical challenge in neuro-infectious diseases often resides in the expeditious and accurate identification of the specific pathogen to initiate targeted, life-saving therapy. The substantial representation of fungal etiology obligates the integration of comprehensive mycological diagnostics, including CSF cryptococcal antigen testing and fungal culture, as a non-negotiable component of the standard workup, especially for patients with subacute presentations or known risk factors for immunodeficiency (Maziarz and Perfect, 2016).

This microbiological profiling of 103 positive cerebrospinal fluid (CSF) cultures provides a detailed and statistically robust depiction of the etiological landscape of central nervous system (CNS) infections within our hospital setting. The data reveal a clear and expected duopoly of classic encapsulated bacteria, with *Neisseria meningitidis* (55.3%) and *Streptococcus pneumoniae* (32.0%) collectively accounting for the vast majority of isolates. This overall distribution is not random, as confirmed by a highly significant Chi-square test, underscoring a distinct epidemiological pattern. The overwhelming predominance of *N. meningitidis* and *S. pneumoniae* is entirely consistent with the global epidemiology of community-acquired bacterial meningitis (CABM), particularly in low-

and middle-income countries (LMICs) where these two pathogens are the leading causes (GBD Collaborators, 2023).

This trend is mirrored in the regional context. Recent data from the Moroccan Meningitis Surveillance Network confirm that *N. meningitidis* and *S. pneumoniae* remain the most frequently isolated bacteria from CSF, with their relative prevalence fluctuating based on age group and vaccination coverage (Ait Mouss et al., 2020). The high proportion of these pathogens in our pediatric (53.8% and 41.0%, respectively) and neonatal intensive care units epitomizes the classic epidemiological pattern of CABM, which disproportionately affects younger age groups (Oordt-Speets et al., 2018).

The highly significant variation in microbial distribution across hospital services unveils distinct clinical and epidemiological narratives. The profile in the medical unit is particularly telling, where a notably high burden of yeast infections (36.4%) was recorded. This starkly contrasts with the pediatric service (5.1% yeasts) and the absence of fungal cases in neonatology. This pattern strongly suggests a high prevalence of opportunistic fungal meningitis, most likely cryptococcosis, among immunocompromised adult inpatients. This is a recognized, serious complication in individuals with HIV, diabetes, or those on immunosuppressive therapy, and its elevated frequency in medical wards aligns with findings from other North African studies reporting a significant burden of cryptococcal meningitis in similar patient populations (Rajasingham et al., 2022). This finding mandates a critical evaluation of routine fungal diagnostics and prophylactic strategies for at-risk adults admitted to our medical services.

The observed heterogeneity in pathogen distribution among hospital services is epidemiologically revealing. Pediatric and neonatal units largely reflected the community-acquired meningitis pattern dominated by *N. meningitidis* and *S. pneumoniae*. In contrast, the medical unit exhibited a markedly higher proportion of yeast isolates (36.4%), likely reflecting opportunistic fungal meningitis among adults with chronic comorbidities or immunosuppression. This finding is consistent with global observations reporting an increasing incidence of *Candida* and *Cryptococcus* meningitis among hospitalized patients receiving corticosteroids, broad-spectrum antibiotics, or invasive interventions (Douglas et al., 2023).

The identification of *Pseudomonas putida*, albeit rare, is clinically relevant. This opportunistic, non-fermenting Gram-negative bacillus is typically associated with nosocomial or post-neurosurgical infections, often linked to biofilm formation on indwelling devices (Baykal et al., 2022). Its presence underscores the importance of infection-prevention protocols in surgical and intensive-care environments.

From a public health perspective, these findings illustrate that bacterial meningitis remains the principal cause of CNS infections in Morocco, but the emergence of fungal meningitis warrants clinical awareness and diagnostic expansion. The co-existence of classical bacterial pathogens and opportunistic fungi reflects the dual burden of community-acquired and healthcare-associated meningitis in middle-income countries undergoing epidemiological transition.

Study Limitations

This study has several limitations inherent to its retrospective and hospital-based design. First, the data were collected from a single tertiary hospital, which may not fully represent the epidemiological profile of the entire Fez–Meknes region. Second, the use of conventional culture methods, while standard, may underestimate certain fastidious or partially treated bacterial infections due to prior antibiotic use before lumbar puncture. The lack of molecular diagnostic confirmation further limits the precision of pathogen identification. Third, clinical variables such as comorbidities, prior treatments, and outcomes were not systematically recorded, preventing correlation between microbiological profiles and patient prognosis. Finally, the relatively small

number of fungal isolates restricts the statistical power to fully characterize their clinical determinants.

Conclusion

This study demonstrates that *Neisseria meningitidis* and *Streptococcus pneumoniae* remain the predominant etiological agents of meningitis in central Morocco, confirming the persistence of classical bacterial meningitis despite vaccination efforts. The detection of fungal agents, accounting for more than 10% of confirmed cases, signals the emergence of opportunistic meningitis in immunocompromised or hospitalized adults. These findings call for sustained vaccination coverage, improved diagnostic infrastructure integrating molecular and mycological testing, and strengthened infection prevention policies in intensive care and neurosurgical units. Establishing a regional meningitis surveillance network that combines clinical, microbiological, and molecular data would facilitate early outbreak detection and guide evidence-based prevention strategies. Further multicentric research is recommended to explore antimicrobial resistance trends and evaluate the effectiveness of ongoing vaccination programs.

Declaration

Ethical Considerations

The study was conducted in accordance with the principles of the Declaration of Helsinki (2013). Authorization for data collection was obtained from the Delegation of the Ministry of Health and Social Protection in Meknes (Authorization No. 6373/24). This retrospective study was based exclusively on anonymized laboratory records collected as part of routine clinical care. No direct patient contact was involved, and no personally identifiable information was accessed during data extraction or analysis. Data confidentiality and privacy were strictly maintained throughout the study. Due to the retrospective nature of the study and the use of anonymized data, the requirement for informed consent was waived.

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Family Burden and Self-Care Practices of Hypertensive Clients: A Cross-Sectional Study in Indonesia

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Abstract

Background: Hypertension is a major risk factor for the development of cardiovascular diseases, with its prevalence continuously increasing each year in Indonesia. This is due to the fact that a heavy family burden can reduce the ability of hypertensive clients to perform optimal self-care practices. The aim of this study is to analyse the relationship between family burden and self-care practices among hypertensive clients in the Public Health Center of Indonesia.

Methods: A cross-sectional design was performed among 191 participants (hypertensive clients and their family members), selected through stratified random sampling. A self-administered questionnaire was used to collect data, including sociodemographic information, the Family Burden Interview Schedule (FBIS) questionnaire, and the Self-Care Behaviour questionnaire, while a sphygmomanometer was used to measure blood pressure in hypertensive patients.

Results: Most of 60.21% of family members experience a moderate level of burden, while 47.12% of hypertension clients demonstrate an adequate level of self-care. Furthermore, there was a significantly relationship between family burden and self-care practices among hypertensive clients (r = -0.176; p-value = 0.010), that indicated more family burden, more self-care practice of hypotensive patients.

Conclusion: Family burden is related with self-care practice of hypertensive patients. Therefore, family burden of hypertensive clients should be well-managed through adequate social support, so that the self-care practices of clients can be effectively improved.

Key words: Family Burden, Self-Care Practices, Hypertensive, Care

Introduction

Hypertension is an increase in blood pressure that can trigger various health complications, particularly cardiovascular diseases. Uncontrolled blood pressure can cause circulatory disorders and damage various organs in the body. In Indonesia, the prevalence of hypertension increased from 25.8% in 2013 to 34.1% in 2018, while Jember Regency ranked third in East Java for the highest hypertension prevalence, reaching 39.18%. Unfortunately, hypertension service coverage in some areas, such as Bangsalsari, remains far below the target, achieving only 10.08% of the expected 100% (East Java Health Office, 2021). One of the main efforts in hypertension control is to enhance patient adherence to treatment and self-care, including maintaining a healthy diet, engaging in regular physical activity, and managing stress.

However, patient adherence remains relatively low due to various factors such as lack of motivation, financial constraints, insufficient family support, and limited knowledge about hypertension management (Agustaria et al., 2022; Susanto et al., 2019; Susanto, Hairrudin, et al., 2024). Additionally, the 2018 Riskesdas report indicated that 32.3% of hypertension patients did not undergo regular treatment, and 13.3% did not take their medication, with reasons including feeling healthy or infrequent visits to healthcare facilities (Ministry of Health of the Republic of Indonesia,

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2018). Therefore, an approach based on education and social support is a crucial strategy to improve patient adherence to self-care practices and prevent further complications.

Family support plays a crucial role in assisting hypertension patients in maintaining their self-care routines. Families can provide physical, emotional, moral, and educational support to encourage adherence to treatment and a healthy lifestyle (Surani et al., 2022; Susanto, Hernawati, et al., 2024). Attention, affection, and motivation from family members can instill a sense of security and boost patients' enthusiasm for self-care. However, long-term care for hypertension patients can also impose burdens on families, including economic, social, physical, and mental challenges. The cost of treatment, transportation to healthcare facilities, and lifestyle adjustments can contribute to family stress (Golics et al., 2018).

Additionally, psychological burdens such as anxiety over the patient's health progression can negatively impact family well-being, disrupt sleep patterns, and reduce emotional stability (Pratiwi, 2022). According to the Self-Care Deficit Nursing Theory (SCDNT) by Dorothea Orem, family support plays a vital role in enhancing a patient's self-care agency, which refers to their ability to independently manage their own health (Juliana, 2023). Families that provide optimal support can help hypertension patients improve adherence to self-care, leading to better blood pressure control and overall quality of life for both patients and their families (Romadhan et al., 2026; Zaiful Rahman et al., 2025). Therefore, understanding the relationship between family burden and self-care practices among hypertension patients is essential for developing effective intervention strategies to enhance patient and family well-being.

Method

This study used a community-based cross-sectional approach (September 2024 - January 2025) in the Bangsalsari Public Health Center, Jember Regency, Indonesia. The population of this study was pairs of hypertensive clients and their family members (N = 6,034). Based on the results of calculations that include the population size (N = 6034), the significance level ($Z1-\alpha / 2 = 1.96$), and the absolute error rate (0.1), the sample size in this study was 191 pairs of hypertensive clients and their family members. The sample size was determined using stratified simple random sampling, which went through two stages: village stratification (stratifying the target population based on the villages within the Public Health Center coverage area) followed by the random selection of hypertensive clients and their family members using random number generators based on the Posyandu registries, with the following inclusion and exclusion criteria.

The sample size was determined using stratified simple random sampling, which went through two stages: village stratification followed by stratification of hypertensive clients and their family members, with the following inclusion and exclusion criteria. Figure 1 was described stratified simple random sampling for selecting samples in this study. The inclusion criteria for hypertension clients were as follows: (1) Clients with a history of adult hypertension who are registered in the Posbindu PTM cohort book, (2) Clients who attended the Posbindu event, and (3) Clients who had at least one family member present at home during the study (spouse, children, parents, siblings, or other family members).

The exclusion criteria for hypertension clients included: (1) Clients with complications from chronic diseases such as diabetes or stroke, and (2) Clients who were unwilling to participate in the study. For the family members of hypertension clients, the inclusion criteria were: (1) Family members living in the same household as the hypertension client, (2) Family members present at home during the Posbindu event, (3) Family members actively involved in the daily care of the hypertension client (such as spouse, children, parents, siblings, or other family members), and (4) Family members who participated in decision-making or accompanied the hypertension client to health facilities. The exclusion criteria for family members included: (1) Family members who were unable to provide information regarding the care of the hypertension client, and (2) Family members who refused to participate as respondents.

This study uses respondents' characteristics questionnaire that contains data on the identity of hypertension clients included questions on age, gender, education, occupation, and duration of hypertension. For family members, the questionnaire covered age, gender, education, occupation, relationship to the client, and income. The measurement of the independent variable (family burden) uses the Family Burden Interview Schedule (FBIS), developed by Pai & Kapur (1981) assessed family burden with 24 questions and a scoring system where higher scores indicated greater burden. The Self Care Behavior questionnaire by Rachmania D, Siswoaribowo A (2022) evaluated self-care practices with responses scored from 1 to 4. In data collection, the researcher coordinated with the nurses responsible for managing non-communicable diseases (NCDs) to request relevant research data. The village nurses provided information on hypertensive clients registered at the Posyandu in each village area. Data collection was conducted with the assistance of Posyandu cadres, who also supported the researcher during the subject selection process.

The collected data were entered into Microsoft Excel 2010 and subsequently analysed using SPSS version 25. Categorical data are presented as percentages, while numerical data with a normal distribution are reported as means and standard deviations. For numerical data with a non-normal distribution, the results are presented as medians, along with the minimum and maximum values. The relationship between family burden and self-care practices in hypertensive patients was analysed using the Spearman's rho statistical test with a significance level of ($p < 0.05$).

Results

Table 1 shows the demographic characteristics of both the 191 hypertensive clients and their family members. The majority of hypertensive clients fall within an average age of 54 years. A significant portion of the respondents, 44.5%, are employed in the agricultural sector, with a higher percentage of females (81.7%) compared to males. Regarding educational background, most client respondents have limited education, with 42.9% having never attended school or not completing elementary school, while only a small percentage have attained a university degree. Furthermore, most respondents have been living with chronic hypertension for more than six months, representing 65.4% of the sample.

For family members, most respondents fall within middle adulthood, with an average age of 48.8 years. A significant proportion of family respondents, 42.4%, are employed in the agricultural sector, particularly as farmers. In terms of gender, there are more male respondents (54.5%) compared to female respondents. Regarding education, most respondents have completed only elementary school, representing 35.1% of the sample. Regarding family dynamics and economics, spouses (husbands and wives) are the primary caregivers for hypertensive clients, accounting for 50.8% of the respondents. Furthermore, the majority of families fall within the middle-income range, with 28.3% earning between Rp 1,500,000 and Rp 2,500,000 per month, and 27.2% earning less than Rp 1,500,000.

Figure 2 showed that the majority of hypertensive clients have high systolic blood pressure with a grade II hypertension category (≥100 mmHg) of 64 (33.5%) patients. Meanwhile, Figure 3 showed that most hypertensive clients have high systolic blood pressure with a grade II hypertension category (≥100 mmHg) of 64 (33.5%) patients.

In this study, family burden was assessed using six indicators. Based on the statistical calculation in Table 2 using the One Sample Kolmogorov-Smirnov test, the result showed that the p-value for the family burden of hypertensive clients was $p<0.001$, indicating a significant difference in the family burden of hypertensive clients, including all of its subdomains (financial burden, disruption of family physical activities, disruption of family recreational activities, disruption of family interactions, impact on family physical health, and impact on family mental health).

Table 3 describes a significant difference in the height of self-care practices. Based on the statistical calculation using the One Sample Kolmogorov-Smirnov test, the result showed that the p-value for the self-care practices of hypertensive clients was $p<0.001$, indicating a significant difference in the

self-care practices of hypertensive clients, including all of its subdomains (physical activity, low-sodium diet, low-fat diet, limiting alcohol and smoking consumption, blood pressure monitoring, medication adherence, weight control, stress management, and doctor visits).
Based on the Spearman's rho correlation test in Table 4, p-value was 0.010, which is less than 0.05, indicating a significant relationship between family burden and self-care practices of hypertensive clients in the working area of Bangsalsari Public Health Center, Jember Regency. The correlation coefficient of -0.186 shows a very weak negative relationship between the two variables. This suggests that as the family burden increases, the self-care practices of hypertensive clients decrease. In conclusion, there is a very weak statistically significant negative correlation between family burden and self-care practices among hypertensive clients.

Discussion

Family Burden and Self-Care Practices of Hypertension Clients in the Working Area of Bangsalsari Public Health Center, Jember Regency

This research conducted 191 pairs of hypertensive clients and their family members in the work area of Puskesmas Bangsalsari, Jember Regency. The results showed a relationship between family burden and self-care practices in hypertension clients in the Bangsalsari Health Center area, Jember. Previous studies suggest that family problems arise from the inability to meet basic needs and suboptimal performance of family health duties (Piola et al., 2020). Families caring for chronic illness patients often bear heavy burdens, such as stress, anxiety, and anger due to the treatment routines they must follow (Kartika et al., 2018). Therefore, high family burden can hinder self-care in hypertension clients, highlighting the need for optimal family support in hypertension care.

Family health status is influenced by the family's ability to provide health care, as families serve as a support system crucial for the success of care programs for family members (Vitaliati, 2021). Previous research has shown a connection between family coping and hypertension management. Good family coping positively impacts the client's health status and helps prevent complications (Febriana & Ningsih, 2024). This indicates that the family's ability to manage both emotional and financial burdens plays an important role in supporting self-care for hypertension clients. Thus, it is essential for families to develop the skills to manage these burdens in order to better support hypertension self-care.Based on the above discussion, it can be concluded that family burden is closely related to self-care in hypertension clients.

The burden felt by the family can affect their ability to provide the necessary support for optimal hypertension management. When families struggle with this burden, their attention to the client's self-care tends to decrease, ultimately worsening the client's health condition. Therefore, it is important for families to have effective coping strategies and adequate support to actively assist in the self-care of hypertension clients and prevent more serious complications.

Family Burden of Hypertension in the Working Area of Bangsalsari Public Health Center, Jember Regency

Research shows significant differences in family burden (financial, physical activity disruption, recreational activity disruption, family interaction disruption, and health impacts). The total family burden score was 50/100, indicating a heavy burden. Previous research Kartika et al., (2018) notes families struggle with caregiving due to lack of information and psychological changes. Dwiyantoro et al., (2022) suggest that family burden management and psychoeducation help in caregiving. Managing family burden in hypertension care is essential for effective care and overall well-being.
The financial burden indicator showed a significant difference in the families of clients in the Puskesmas Bangsalsari work area, Jember Regency.

This is due to most hypertensive clients' families having a monthly income in the medium income category, ranging from Rp1,500,000 to Rp2,500,000, according to BPS (Central Statistics Agency). Previous studies Lestari & Nugroho (2020) show low-income families prioritize basic

needs over healthcare, leading to underutilization of services (Napirah et al., 2019). Raising awareness about using healthcare services regularly is crucial.

The indicator of disruption in family routine activities showed a significant difference. This is due to the total score of disruption in family routine activities being 15, with a maximum value of 24, indicating that the families experienced disruptions that affected their routine activities. Previous research indicated that families with limited time due to caring for clients tend to struggle with performing their regular family activities ((Baik et al., 2021). Therefore, support for the client's family is necessary to help manage time and share roles to ensure the smooth execution of daily family activities.

The indicator of family recreational disruptions showed a significant difference. The total score for family recreational disruptions was 8 out of 16, indicating disruptions in family recreational activities. Financial issues were another factor limiting the family's ability to engage in recreational activities. Previous studies have highlighted the importance of recreation for maintaining emotional balance, reducing stress, strengthening family bonds, and promoting harmony (Maknunah et al., 2018). Therefore, it is crucial for families to engage in simple recreational activities to strengthen relationships and maintain emotional balance.

The indicator of family interaction disruption, significant differences were found, with families scoring 9 out of 20. Poor communication due to busy schedules or differing needs affects interaction (Salawali & Susanti, 2019). Effective communication improves family harmony (Astuti & Triayunda, 2023). The indicator of physical health impact, families scored 4/8, showing physical exhaustion affects family health. Continuous fatigue lowers caregivers' quality of life ((Yustisia et al., 2023). Proper interventions can reduce fatigue and improve quality of life. The indicator of mental health impact, significant differences were noted, with 65.4% of clients experiencing anxiety and stress. Previous studies show caregivers' stress is influenced by the severity of the illness. Emotional support and relaxation techniques help reduce stress (Corchón et al., 2022). Therefore, families need to utilize emotional support, maintain a regular rest pattern, and apply relaxation techniques such as meditation or deep breathing to reduce anxiety and stress.

Self-Care Practices of Hypertension Clients in the Working Area of Bangsalsari Public Health Center, Jember Regency

Research findings show significant differences in self-care practices (physical activity, low sodium diet, low-fat diet, alcohol consumption restriction, smoking cessation, blood pressure monitoring, medication adherence, weight control, stress management, and doctor visits) among hypertension clients in the Bangsalsari Health Center area, Jember. The total self-care score was 46 out of 98, indicating suboptimal self-care. Previous studies highlight that patient knowledge about hypertension, and its complications significantly affects motivation, ability, and attitude toward optimal self-care (Augusto et al., 2022). Thus, more intensive education and support are needed to help clients with hypertension optimize self-care practices.

The indicator of physical activity, the score was 2 out of 5, indicating inadequate activity. Research indicates that many clients, especially older adults, prefer light activities or none at all (Blackburn, 2022). Lack of social support contributes to insufficient physical activity (Belay et al., 2023). Family support is crucial for encouraging physical activity in hypertension care. Regarding a low sodium diet, the score was 10 out of 20, showing inconsistency in adhering to a low sodium diet. Many adults consume excessive salt (Ferencia et al., 2023a). Motivation and family support are essential for clients to maintain a low-sodium diet (Rasnawati et al., 2023). The indicator of low-fat diet, the score was 11 out of 24, indicating inconsistent adherence. Excessive fat intake is linked to higher hypertension prevalence (Ferencia et al., 2023b). Family support in maintaining a low-fat diet can positively impact hypertension management (Mufidah et al., 2023).

Regarding alcohol consumption and smoking, the score was low at 4 out of 10. While no

clients consumed alcohol, many still smoked, especially men. Smoking increases blood pressure and risk of disease (Susanto, Hairrudin, et al., 2024; Umbas et al., 2019). Behavior change, like quitting smoking, is essential for hypertension management (Erman et al., 2021). The indicator of blood pressure monitoring, the score was 2 out of 5, indicating low frequency. Knowledge, understanding, and family support influence adherence to blood pressure monitoring (Lubis, 2023). Regular monitoring, as per Nursing System Theory, requires collaboration between nurses and clients for better health management (Firdaus et al., 2024; Zaiful Rahman et al., 2025). Medication adherence was 5 out of 10, influenced by low education levels. Several factors like education, hypertension duration, and family support impact adherence (Prihatin et al., 2022). Family support is critical for improving adherence (Suryantara & Dewi, 2023).

For weight control, the score was 2 out of 5, indicating low effectiveness. Maintaining a healthy weight (BMI) significantly affects blood pressure (Sari et al., 2023). Family support and education on healthy eating and physical activity are crucial for weight control (Riyadina et al., 2021(Hukmiyah et al., 2025)). Stress management was rated 9 out of 10, indicating good stress control. Adaptive coping mechanisms help manage stress in hypertension clients (Mad Zaini et al., 2022). Family support can help reduce stress through emotional support (Purnama & Putri, 2023). Doctor visits scored 2 out of 5, indicating low frequency of visits. Active participation in chronic disease management programs positively impacts blood pressure stability (Atto'illah et al., 2021). Routine visits to healthcare facilities, aligned with Nursing System Theory, can improve hypertension management through collaboration between healthcare providers and clients.

Conclusion

Family burden is significantly related to self-care practices in hypertensive clients. The higher the family burden, the lower the self-care practices performed by hypertensive clients. Both emotional and financial burdens can hinder the family's ability to provide the necessary support in managing hypertension. Therefore, it is essential for families to have adequate support and effective coping strategies to help hypertensive clients in performing optimal self-care, which ultimately improves the client's quality of life and prevents more serious complications.

Declarations

Ethical considerations

This study received ethical approval from the Health Research Ethics Committee (KEPK) of the Faculty of Nursing, University of Jember, under the reference number 314/UN25.1.14/KEPK/2024. Formal consent was obtained from each participant through signed informed consent forms.

Conflict of interest

There is no conflict of interest in this study.

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Table 1. Distribution of Respondent Characteristics of Hypertension Clients and Their Families (n=191)

Variables	Clients f (%)	Families f (%)
Age (Years)		
x̄ (SD)	54.01 (12.8)	48.8 (13.8)
Occupation		
Farmer	85 (44.5)	81 (42.4)
Housewife	50 (26.2)	26 (13.6)
Entrepreneur	15 (7.9)	52 (27.2)
Unemployed	19 (9.9)	15 (7.9)
Others	22 (11.5)	17 (8.9)
Gender		
Male	35 (18.3)	104 (54.5)
Female	156 (81.7)	87 (45.5)
Level of Education		
Not Completed School	82 (42.9)	34 (17.8)
Elementary School	54 (28.3)	67 (35.1)
Junior High School	12 (6.3)	36 (18.8)
Senior High School	42 (22.0)	50 (26.2)
University	1 (0.5)	4 (2.1)

Duration of Hypertension (Months)		
< 6 Months	66 (34.6)	N/A
≥ 6 Months	125 (65.4)	N/A

Note: f(%) = Number and percentage of respondents, $\bar{x}$ = Mean, SD = Standard Deviation

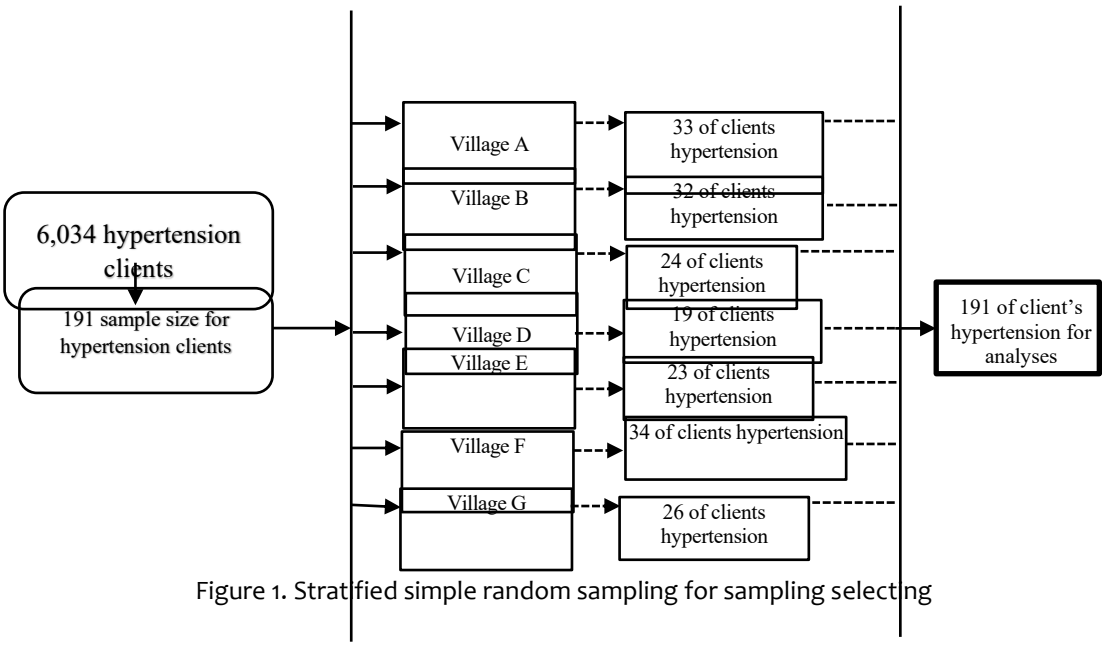

Figure 1. Stratified simple random sampling for sampling selecting

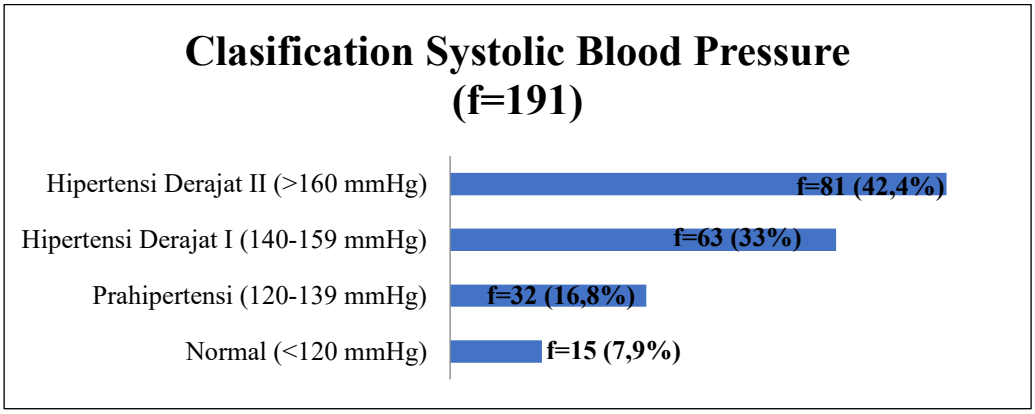

Figure 2. Systolic blood pressure of patients (f=191)

Tanzania Journal of Health Research
Volume 27: Issue 5 (2026) https://dx.doi.org/10.4314/thrb.v27i5.22

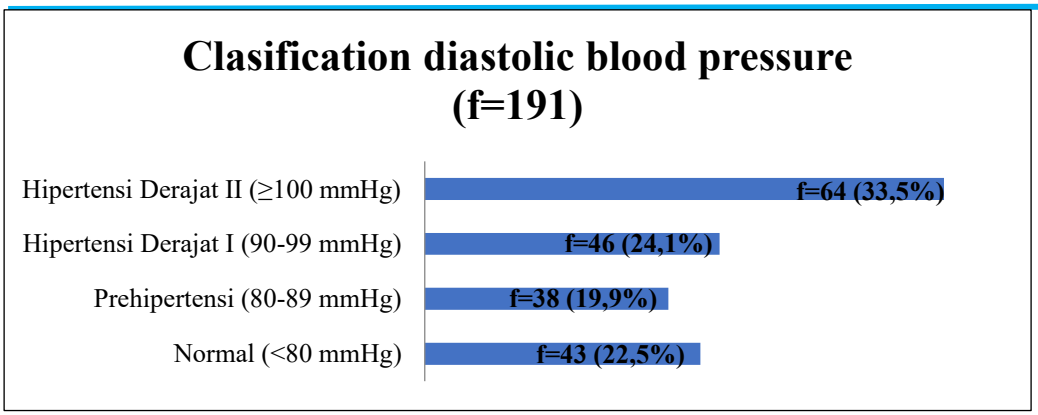

Figure 3. Diastolic Blood Pressure of Patients (f=191)

Table 2. Distribution of Significance Values for Family Burden Indicators in Hypertension Clients (n=191)

Family Burden	x̄	Min - Max	Z	*p-value*
Financial Burden	12.25 (4.10)	7 – 6	0.126	<0.001
Disruption of Family Routine Activities	14.83 (2.81)	7 – 14	0.129	<0.001
Disruption of Family Recreational Activities	7.67 (2.16)	4 – 8	0.185	<0.001
Disruption of Family Interactions	8.52 (1.84)	5 – 11	0.188	<0.001
Impact on Family Physical Health	4.22 (1.31)	2 – 5	0.223	<0.001
Impact on Family Mental Health	3.03 (0.78)	2 – 3	0.412	<0.001
Total	**50.54 (8.41)**	**30 – 56**	**0.049**	**<0,001**

Note: x̄ = Mean, SD = Standard Deviation, Z = One Sample Kolmogorov-Smirnov Test Statistic, and p-value = Significance Value of One Sample Kolmogorov-Smirnov Test.

Table 3. Distribution of the Significance Value of Self-Care Practice Indicators for Hypertension Clients (n=191)

Self-Care	x̄ (SD)	Min - Max	Z	*p-value*
Physical Activity	2.05 (0.92)	1 – 4	0.225	<0.001
Low-Sodium Diet	9.96 (3.32)	4 – 15	0.236	<0.001
Low-Fat Diet	12.09 (3.87)	8 – 21	0.174	<0.001
Limiting Alcohol Consumption and Smoking	3.75 (0.71)	5 – 8	0.487	<0.001
Blood Pressure Monitoring	2.46 (0.89)	2 – 4	0.290	<0.001
Medication Adherence	4.72 (1.78)	2 – 8	0.147	<0.001
Weight Management	2.20 (0.89)	1 – 3	0.277	<0.001
Stress Management	9.64 (2.41)	2 – 8	0.175	<0.001
Doctor Visits	2.18 (0.92)	1 – 4	0.187	<0.001
Total	**45.70 (11.90)**	**39 – 73**	**0.128**	**<0.001**

Note: $\bar{x}$ = Mean. SD = Standard Deviation. Z = One Sample Kolmogorov-Smirnov Test Statistic. and p-value = Significance Value of One Sample Kolmogorov-Smirnov Test.

Table 4. Analysis of the Relationship Between Family Burden and Self-Care Practices in Hypertension (n=191).

Variable	**Md (min-max)**	**r**	***p-value***
Family Burden	50.24 (31.9-71.5)	-0.186	0.010
Self-Care	42.89 (27.4-73.9)		

Note: Md = Median; Min-Max = minimum and maximum values; r = correlation coefficient value; p-value = significance value of the Spearman's rho test

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Perceptions, religious beliefs and the use of herbs in management of Type 2 Diabetes Mellitus in Morogoro, Tanzania

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Abstract

Background : Type 2 diabetes mellitus (T2DM) is a significant public health challenge globally with many patients incorporating different management practices. Proper diabetes management and self-care reduce the risk of complications. However, there is limited understanding of patients' perceptions, religious beliefs, and the use of herbs in the management of T2DM.

Objective: This study aimed to investigate perceptions, religious beliefs, and the use of herbs in management of diabetes in Morogoro, Tanzania.

Methods: A cross-sectional mixed-methods study was conducted from March to June 2024 among 155 patients attending two public health facilities in Morogoro Municipality. Quantitative data were collected through semi-structured questionnaires. Five focus group discussions with T2DM patients and eight In-depth interviews with health care providers and herbalists were conducted. Descriptive statistics was used to describe characteristics of the patients and the use of herbs. Thematic analysis was used to identify perceptions and religious beliefs about T2DM among the focus group participants.

Results: The average duration of respondents to live with diabetes was 8±5years. About 40% of participants reported using herbs, mainly influenced by advice from friends and family. The most commonly herbs were moringa leaves (*Moringa oleifera*) (21%) and sea moss (commonly *Gracilaria spp.)* (29%). Participants expressed varied beliefs about diabetes risk factors including family history of diabetes, unhealthy eating habits, and spiritual factors. Several participants also emphasized that diabetes can be cured through a combination of multiple strategies, including lifestyle changes, prayers, hospital care and herbs. The most commonly herbs were moringa leaves (*Moringa oleifera*), sea moss (commonly *Gracilaria spp.)*, aloe vera (Aloe *vera (L.) Burm. f.*), and black seeds (*Nigella sativa* L.). Participants expressed varied beliefs about diabetes risk factors including family history of diabetes and unhealthy eating habits, and spiritual factors. **Conclusion**: Patients with T2DM use multiple approaches including conventional healthcare, herbs, lifestyle changes, and religious practices, to manage diabetes. Integrating culturally sensitive education and awareness campaigns with healthcare practices can help bridge the gap between traditional or cultural beliefs and scientific understanding to foster informed decision-making and improve diabetes management outcomes in similar settings. Further research is needed to assess the efficacy and safety of commonly used herbs, ensuring their appropriate use alongside conventional diabetes treatments.

Keywords: Herbs, perception, religious belief, diabetes management, Tanzania

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Introduction

The use of herbal medicine in the management of chronic diseases, such as type 2 diabetes mellitus (T2DM), remains a significant component in healthcare, particularly in sub-Saharan Africa. In Tanzania, herbal medicine is often seen as a practical and accessible option for managing chronic diseases, especially in rural and semi-urban areas where healthcare services may be limited (Mujinja & Saronga, 2022). The cost of modern treatments can be prohibitive for many patients, driving them to seek more affordable alternatives through herbs (Taylor, 2022). Also, cultural beliefs play a crucial role, with many people trusting in the healing powers of herbs passed down through generations (Jacob *et al.,* 2024). As a result, patients often turn to traditional healers for holistic treatment, believing that they offer a more personalized approach compared to conventional healthcare (Jamal, 2023).

The continued use of herbal medicine alongside conventional treatment presents both opportunities and challenges. On one hand, it reflects the population's desire to integrate culturally accepted practices into their healthcare regimens (Hsieh, & Kramer, 2021). On the other hand, there are concerns about the safety and efficacy of combining herbal remedies with pharmaceutical treatments, particularly without sufficient scientific validation (Al-Worafi, 2020). Potential risks, such as drug-herb interactions, delayed access to formal medical care, and the use of unregulated remedies, underscore the need for more comprehensive research into herbal medicine use among diabetic patients (Skalli *et al.,* 2022).

Understanding how and why patients use herbs to manage their diabetes is crucial. As it provides valuable insights into patient behavior, adherence to treatment, and the influence of cultural beliefs on healthcare decision-making. Moreover, Spiritual and religious beliefs play an important role in influencing health-seeking behaviors and treatment decisions among diabetic patients. As individuals may view illness and healing from a spiritual perspective, believing that divine intervention, prayer, or faith-based healing practices complements medical treatments (Onyishi *et al.,* 2021). Some patients may perceive diabetes as a test of faith or as a result of spiritual imbalance, affecting patients' readiness to adhere to medical advice (Rajaee, 2024). Religious leaders and traditional healers may also provide guidance regarding illness and healing, potentially influencing patients decision about conventional and alternative treatments.

Despite the continued use of herbal medicine in Tanzania, there is limited evidence on how patient's perceptions of diabetes, cultural practices and religious beliefs influence the use of herbs alongside conventional diabetes treatment. Existing evidence has provided information on traditional medicine use, but less is known about the beliefs and perception that reinforce these practices among patients with T2DM, particularly in Morogoro. Understanding these factors is important for healthcare providers because patients may combine herbal remedies, prescribed medications, lifestyle changes and religious practices without fully discussing these approaches with healthcare professionals.

Therefore, this study aimed to investigate perceptions, religious beliefs and use of herbs among patients with T2DM in Morogoro, Tanzania, with focus on the prevalence and use of herbal medicine use and the cultural, religious and personal beliefs influencing its adoption and perceived role in diabetes management. By exploring these aspects, this study may provide evidence to support culturally sensitive diabetes education and healthcare practices, promote informed treatment decisions and improve the safe management of T2DM.

Methodology

Study area description, design and population

The study applied cross-sectional mixed-methods design, including both quantitative and qualitative research techniques. It was carried out in Morogoro Municipality, a prominent administrative and

economic center within Morogoro region in Tanzania. The Municipality has diverse population engaging in commerce, agriculture and service-related activities. As per 2022 Population Census Morogoro region has an estimated population of approximately three million people, of which 1.2 million reside in the urban areas. The rapid population increase has contributed to the expansion of social infrastructure including health facilities from a total of 309 health facilities in 2005 to about 563 health facilities (55 are health centers, 388 dispensaries, 20 clinics, 18 hospitals,) (MoHCDEC, 2021). The study focused on participants aged 18 years and above, who had been diagnosed with T2DM at least six months prior to commencing of the study. Individuals who had physical disability, pregnant or severely ill were excluded from the study. The study also targeted healthcare providers and herbalists.

Sample size Determination and Sampling procedure

The sample size was estimated using a formula by Kothari (2004)
Whereby;
n = desired sample size
z = standard normal deviation, set at 1.96 corresponding to 95 % confidence interval
P = proportion in the target population estimated to be diabetic in Tanzania is 10.3% (IDF, 2021).
q = (1-p) proportion of the population who are estimated to have the particular characteristics (1-0.103)
d = degree of accuracy desired 5% or (0.05)
Therefore;

$$n = \frac{1.96 \times 1.96 \times 0.103\ (1-0.103)}{0.05 \times 0.05} + 10\%\ \text{contingency} = 155.1 \sim 155$$

Therefore, the study included 155 T2DM patients during quantitative data collection.

Sampling Procedure

This study utilized structured sampling techniques to involve three distinct groups which are T2DM patients', healthcare providers (HCPs) and herbalists. The study was carried out in two major public health facilities in Morogoro Municipality: Morogoro Regional Referral Hospital and Sabasaba Health Center. The facilities were purposively selected because they host specialized diabetic clinics with regular patient attendance, making them appropriate for accessing the target population. From these facilities T2DM patients and health care providers were selected, while herbalists were selected in the community-based setting outside the health care facilities.

T2DM Patients were recruited using systematic sampling where every odd-numbered entry in the daily clinic register was selected. This ensured unbiased selection while accommodating high patient flow. Five Healthcare Providers (HCPs)(three doctors and two nurses) were purposively selected based on experience in diabetes management to participate in Key Informant Interviews (KIIs). Three herbalists were recruited using snowball sampling based on patient referrals. Only actively practicing herbalists involved in diabetes care and willing to participate were included.

Systematic sampling allowed efficient and representative selection of patients in a busy clinic setting. Purposive sampling of HCPs ensured inclusion of expert knowledge, while snowball sampling allowed access to a hard-to-reach population of herbalists. These methods ensured the collection of robust quantitative and qualitative data aligned with study objectives.

Data Collection Methods and Procedures

Data were collected from March to June 2024. Prior to the actual data collection, a pilot survey was conducted in a similar setting to pre-test the questionnaire and interview guides and to assess clarity, relevance, and reliability of the tools. This study employed both quantitative and qualitative data

collection methods. Quantitative data were collected through face-to-face interviews using a semi-structured questionnaire administered to T2DM patients. The questionnaire captured information on socio-demographic characteristics, use of herbal remedies, reasons for use, preparation methods, dosage, sources of advice, and any experienced side effects. The questionnaire was developed based on a review of relevant literature and adapted to the study context. To ensure content validity, the questionnaire was reviewed and the items were assessed for relevance, clarity and completeness. The questionnaire was pretested among T2DM patients with characteristics similar to those of the study participants and were not included in the main study. Feedback from the pretest was used to improve the wording, sequence and clarity of the questions before data collection. The questionnaire was initially prepared in English and translated into Swahili, the language used during interviews. Any discrepancies identified during translation process were resolved before the final version was administered. Interviewers were trained on the study objectives, questionnaire and procedures for maintaining confidentiality and minimizing interviewer bias.

Qualitative data were collected using two approaches which were, Focus Group Discussions (FGDs) which was conducted among T2DM patients to explore shared beliefs, perceptions, and cultural practices related to diabetes management, and Key Informant Interviews (KIIs) were conducted with healthcare providers and herbalists to obtain detailed insights based on their professional experience and specialized knowledge of diabetes management and the use of herbal remedies. A total of five FGDs were conducted, involving 40 participants, with eight participants in each group. The groups were stratified by sex and duration of living with diabetes to ensure homogeneity and encourage open discussion. Two FGDs comprised female participants, two comprised male participants, and one was mixed. Participants were also categorized based on duration of diabetes (≤5 years and >5 years). Data collection continued until saturation was reached, defined as the point at which successive FGDs and KIIs generated no new information, concepts or themes relevant to the study objective.

During Key Informant Interviews (KIIs), a total of eight KIIs were conducted, involving five healthcare providers (three doctors and two nurses) and three herbalists. Healthcare providers were purposively selected based on their experience in managing T2DM patients at the selected health facilities. Herbalists were recruited using snowball sampling, whereby patients who reported using herbal medicine referred to the researchers to practicing herbalists. Interviews were conducted at participants' workplaces or places of practice. All interviews and discussions were conducted in a private setting to ensure confidentiality and were facilitated by trained research personnel. Notes were taken during the interviews, and where permitted, discussions were audio-recorded to ensure accuracy of the collected information.

Data Analysis

Quantitative data were entered, coded, and analyzed using Statistical product and service solutions (SPSS) software for windows version 27. Descriptive statistics were performed and data were presented as frequency and percentages.

Qualitative data from the in-depth interviews (IDIs) and focus group discussions (FGDs) were analyzed manually using thematic analysis. Audio recordings were transcribed verbatim, and the transcripts were reviewed alongside the field notes to ensure completeness and accuracy. Where interviews and discussions were conducted in Swahili, the transcripts were translated into English for analysis and reporting. The transcripts were read repeatedly to familiarize the researchers with the data. Initial

codes were developed based on the study objectives and emerging concepts from the data. Similar codes were grouped into categories and broader themes, which were reviewed and refined to ensure consistency with participants' views. Representative quotations were used to support the findings. Trustworthiness was enhanced through repeated review of transcripts, comparison of findings across different participant groups, and discussion of codes and themes among members of the research team to reach consensus and minimize researcher bias.

Results

Socio-demographic characteristics of the respondents

The demographic characteristics of the respondents indicated that majority of the respondents were from the age range ≥65years (32.3%). Most of the respondents were female (65.8%), married (71.6%) and self-employed (64.5%) (Table 1).

Table1: Socio-demographic characteristics of the respondents

Category	Characteristics	Frequencies	Percentage
Age		**Mean (SD)**	56.66±12.74
	18-64	105	67.7
	≥65	50	32.3
Gender	Male	53	34.5
	Female	102	65.8
Marital Status	Single, Widow/Widower	33	21.3
	Married	111	71.6
	Divorced	11	7.1
Religion	Christian	87	56.1
	Muslim	68	43.9
Education level	University	13	8.4
	Secondary Education	31	20
	Primary Education	100	64.5
	Informal	11	7.1
Occupation	Unemployed	27	17.4
	Self-employed	100	64.5
	Formally Employed	13	8.5
	Retired	15	9.7

Clinical characteristics of participants

The study shows that most participants had lived with type 2 diabetes mellitus (T2DM) for 1–10 years (69.0%), and the majority attended hospital follow-up visits once every two to three months (70.3%). Most were on oral hypoglycemic agents (92.9%), while only a small proportion used insulin (5.8%) or diet control alone (1.3%). Medication non-adherence was reported by 31% of participants, mainly due to unavailability of drugs (41.7%) and hypoglycemia (29.2%). Overall, most participants (85.8%) reported no diabetes-related complications, while 14.2% had complications, mainly Diabetic retinopathy, followed by nephropathy and pulmonary edema (Table 2).

Table 2: Clinical characteristics of participants (N = 155)

Category	Characteristics	n	%
Duration of T2DM			

	1- 5	54	34.8
	6-10	53	34.2
	11-15	34	21.9
	≥15	14	9.0
Hospital visit	Once or twice a month	46	29.7
	Once after every two or three months	109	70.3
Type of medication	Oral hypoglycemia	144	92.9
	Insulin	9	5.8
	Diet only	2	1.3
Skipping of medication	Yes	48	31
	No	107	69
Reason for skipping medication	Hypoglycemia	14	29.2
	Normal blood glucose	7	14.6
	Out of medicine	20	41.7
	Forgot to take medicine	4	8.3
	On other medications	1	2.1
	Tired of taking medications everyday	2	4.2
Presence of complications	No	133	85.8
	Yes	22	14.2
Types of complications			
	Retinopathy	19	86.4
	Nephropathy	2	9.1
	Pulmonary edema	1	4.5

The use of herbal remedies and practices among T2DM Patients

About **40%** of participants reported using herbal remedies, with the majority (**66.1%**) citing advice from friends and family as the main reason for its use. The herbs were mainly sourced from **homesteads** (45.2%). While only **35.5%** of users believed in the effectiveness of herbal medicine, most of the users (**45.2%**) were unsure about its efficacy. Most users (**71%**) co-administered herbs with other medications, and **47%** would recommend herbal medicine to others. However, only **16.1%** of herbal medicine users received advice on maintaining a healthy lifestyle (Table 3).

Table 3: The use of herbal remedies and practices among T2DM Patients

Variable	**Frequencies**	**Percentage**
The use of Herbal remedies		
Yes	62	40
No	93	60
Commonly used Herbal remedies		
Sea moss	18	29
Moringa Leaves	13	21
Chunga	3	4.8
Lemon grass	8	12.9
Tamarind and black plum leaves	2	3.2
Others*	18	29
Reason for herbal medicine use		

advice from friends and family	41	66.1
search for cure	6	9.7
Embedded practice	1	1.6
Advertisement	1	1.6
I know it's a medicine	13	21.0
Source of herbal medicine		
home stead	28	45.2
herbal medicine shops	11	17.7
Market	6	9.7
Farm field	12	19.4
Gift/friend	5	8.1
Advice on maintaining healthy lifestyle		
Yes	10	16.1
No	52	83.9
Effectiveness of the herbal medicine in controlling		
Yes	22	35.5
No	12	19.3
I don't know	28	45.2
Co-administration of medication		
Yes	44	71.0
No	18	29.0
Recommendation of herbal medicine to others		
Yes	29	46.8
No	12	19.4
Not sure	21	33.9

Aloe vera, Cinnamon, Ginger, Neem leaves, java plum, Tamarind, Boswellia serrat, Pomegranate, Chia seeds

Beliefs and Management Practices among patients with Type 2 Diabetes Mellitus

Belief and practices on the causes of diabetes

Participants in the study generally perceived various factors as contributing to the onset of diabetes. Family history was a significant aspect that many believed played a role. Participants who shared this belief mentioned that having close family members, such as grandparents, parents, or siblings, with diabetes made them anticipate that they too would develop the condition. This awareness led some participants to prepare themselves mentally for the diagnosis and to focus on managing the disease when it eventually manifested.

> *"I was not surprised to hear that I had diabetes because it is in my family on both sides. I had to get ready and learn how to handle it because I always thought I would be affected (R1 Male, 41 years).*
>
> *My family has always had diabetes, but I'm not sure why. It was the cause of death ofmany family members, my grandfather, my mother, my aunts, and many of their offspring. We have family members who are diabetic. "(R7 Male, 34years)*

Apart from family history, unhealthy eating habits were cited as another major risk factor for diabetes. Participants stated that part of their condition was a result of increased intake of sugary foods. They expressed concerns about the connection between high sugar meals and an increased risk of diabetes, specifically with regard to sugary drinks that are widely available in the market.

"There are a lot of foods and drinks these days that contain excessive amounts of sugar.… and it's not always possible to prepare meals at home; for example, at work you have to buy fast foods. These foods are unhealthy that cause this disease" (R6 Female, 53 years)

"Because I used to drink too many sugary drinks, I believe that consuming sugary meals is what caused me to develop the disease. When I was thirsty, I used to prefer cold soft drinks; if I had to choose, I would have to take a soft drink" (R2 Male, 64 years)

Concurrently, the herbalists interviewed in the study suggested that the rising prevalence of diabetes is a result of the community moving away from its natural roots

'Diabetes has become common because we have abandoned our traditional ways of living and eating. While conventional medicine is necessary to manage high sugar levels, we use herbs to reconnect the body to its natural state' (KII_ Herbalist 2).

Other participants had spiritual belief about the cause of diabetes. They clarified that mystical factors, such resentment or curses, which are frequently perceived as spiritual assaults, could be the cause of diabetes. These beliefs stemmed from the notion that illness could be a manifestation of negative energy from others, potentially motivated by jealousy. Some also connected the illness to being cursed as a result of transgressions or moral faults.

"Diabetes can be caused by the envy of a friend or family member who casts an evil eye, making you suffer to death, as the disease cannot be cured" (R8 Female, 70 years)

"When you have diabetes, some people believe you've been cursed due to your past wrongdoings. They view you differently, thinking that you must have done something wrong to a friend, and that this illness is a form of punishment or consequence" (R6 Female, 53 years)

Some participants, who struggled to reconcile their lifestyle with their diagnosis, especially those who had actively avoided unhealthy foods or maintained a focus on weight management, tended to attribute their condition to spiritual cause. They believed that despite their efforts to live healthy lives, the disease was inevitable due to them being bewitched.

"I haven't eaten sugary or fatty foods, yet I still got the disease. This makes me believe I must have been bewitched. I think that's what's behind my condition" (R10 Male, 44 years)

Beliefs and practices on the management of the diseases

Most participants consistently highlighted that the management of T2DM largely depends on diet and physical activities, herbal medicine, prayers and hospital care.

"Several people have advised me to exercise regularly as a diabetic, and many have suggested walking barefoot for better health. So, twice a week in the morning, I walk barefoot to become healthier"(R10 Male, 44 years)

"I believe that one day I will no longer have diabetes. That's why I manage my diet, because I trust that with proper diet control, I will be free from this condition."(R5 female, 39 Years)

Several participants also emphasized that diabetes can be cured through a combination of multiple strategies, including prayers, hospital care and herbal medicine. Some used anointed oils or blessed water believing that they will be healed.

"Managing diabetes requires a comprehensive approach, often involving both medical care and additional support like prayers, alternative remedies such as herbal treatments, or a combination of these methods" (R8 Female, 70 years)

"Some days I just wake up with blisters on my feet, I don't know where they are from as I slept fine. I apply anointing oil and go to see a doctor. I also drink blessed water as there is nothing impossible to God" (R10 Male 44 years)

Another one added,

Diabetes can be cured through a combination of medical treatment and prayer, or through medical care alone, depending on your beliefs. If the cause is spiritual, prayers for deliverance may be effective. And if it is a medical condition, the person should seek help from a doctor. Ultimately, the approach depends on individual belief (R8 Female, 70 years)

Others stressed the importance of faith, believing that the ultimate control of health and healing lies with God, as He is the planner of everything in the world.

"Everything in this world occurs according to God's plan. I have come to terms with this illness, and I'm not worried about it."(R3 Female, 59 years)

"I don't let my disease consume my thoughts or dictate my daily actions. As a person, I recognize the importance of being patient in managing this condition. I see this illness as a test from God to evaluate my patience" "(R7 Male, 34years)

The participants express a deep sense of uncertainty and fear regarding their conditions. Some feel a sense of impending mortality as their condition worsens despite ongoing treatment, witnessing others with similar conditions pass away. However, one participant emphasizes resilience, noting that through long-term experience with the disease and interactions with healthcare providers, they have learned how to manage their condition effectively.

"This disease cannot be cured no matter what you do, they are lot of people we have been attending clinic together now they are gone. I know one day it will be me" (R8 Female, 70 years) Every day my condition is getting worse I don't know what to do, maybe my time is about to end" (R2 Male, 64 years)

"I have been with the disease for a long time. I have learned how to manage it as I have met various doctors who taught me how to manage it well" (R6 Female, 53 years)

Other respondents emphasized the need for herbal medicines and remedies as an alternative approach to managing diabetes. They expressed concerns about the long-term use of conventional medications, particularly perceptions that frequent consumption of drugs and regular injections could become toxic or harmful, especially for individuals managing multiple complications. Other participant believes that integrating herbal remedies, such as herbal treatments, could offer a more natural way to support health without the potential side effects of medicines.

"I take my medications every day, alongside other medications for my high blood pressure. I'm concerned that these medications may have long-term side effects, in my body over time (R4 Male, 60 years)

"Oral medications and insulin injections introduce chemicals into the body, while natural remedies help eliminate them (R8 Female, 70 years)

Many highlighted the use of bitter foods and remedies as an alternative way to manage and reduce blood glucose levels. Frequently mentioned remedies include moringa leaves (*Moringa oleifera*), sea moss (commonly *Gracilaria spp.)*, aloe Vera, and black seeds (*Nigella sativa* L.).

Providing a different perspective, herbalists interviewed in this study emphasized that their role is often to provide 'natural' balance that they believe hospital medicine lacks. One herbalist explained:

'We don't tell them to stop the doctor's medicine, but we give them things like moringa because these are foods from the earth. They help the body to naturally wash away the excess sugar that the chemical pills might miss' (KII_ Herbalist 2).

Another herbalist added that their management involves strict dietary advice:

'I tell my clients that if they take my herbs but continue to eat refined sugars and sodas, the herbs will not work' (KII_ Herbalist 1).

These natural remedies are often incorporated into diets or taken in supplemental forms by those seeking alternative or complementary approaches to diabetes management. However, one participant mentioned that herbal medicine was ineffective in treating his condition.

"I take almost anything that I am told it is a medication whether it is food or leaves, maybe one medicine might work. I don't care if it's bitter or unpleasant I just take it" For herbal medicine, I drink boiled moringa leaves or I use sea moss (commonly *Gracilaria spp.)* *to lower my blood sugar" (R8 Female, 70 years)*

"When I first got the disease, I thought I was bewitched. I visited a lot of herbal healers I was given various remedies but I was not cured" (R10 Male 44 years)

"Patients tend to rely on herbal medicine, believing that it is effective. Some diabetic patients come to us with complications, and while we offer them information about medications and self-care strategies, they often disregard our advice. Instead, they listen to their fellows who often contradict what we recommend. As a result, they continue to use herbal remedies"(KII_ Nurse, Female)

Similarly, a clinician noted that the biggest challenge in management is the 'silent' nature of the disease, which leads patients to seek alternative cures.

'Many patients only come to the hospital when the herbs fail or when they develop sores that won't heal. They see the hospital as a last resort rather than the primary place for management' (KII_ Clinician, Male).

Discussion

Most of the study participants perceived that diabetes occurs as a result of a family history. Participants who shared this belief mentioned that having close family members, such as grandparents, parents, or siblings, with diabetes made them anticipate that they too would develop the condition**.** This finding points out perception of T2DM as condition that is mainly hereditary, this is consistent with studies that shows family history as a key determinant of perceived risk of T2DM causations (Airikkala *et al.,* 2023).

However, this belief may lead to simplification of the multifactorial nature of the disease. Interestingly, this narrative was supported by herbalists who suggested that the rising prevalence of diabetes is a result of the community moving away from its "natural roots." This perspective frames

the disease not just as a genetic failure, but as a cultural one where the abandonment of traditional ways of living and eating has left the body vulnerable. Some perceptions may influence how patients understand the role of modifiable behavioral factors in diabetes prevention and management.

Beyond beliefs of hereditary cause, some participants also discussed lifestyle factors, particularly dietary habits, in relation to the causation of diabetes. Some stated that their condition was a result of increased intake of sugary food. This finding highlights a growing awareness of the impact of diet in the causation of diabetes, which is consistent with the findings from other studies emphasizing the detrimental role of high sugar intake and poor dietary choices in the development of T2DM (Kasole *et al.,* 2019; Abdulrehman *et al.,* 2016).

However, while patients focused on the availability of sugary foods, healthcare providers pointed out a deeper challenge: the silent nature of the disease. Clinicians noted that patients often seek medical care only as a last resort when symptoms become severe or complications like sores arise. This suggests that while there is awareness of dietary causes, there is a significant delay in medical engagement due to the asymptomatic nature of early T2DM.

A significant finding was the dual narrative of causation, where biomedical explanations coexist with spiritual attributions such as divine will, envy, or curses. This reflects a cultural framework where health is not merely a biological state but a spiritual one. The attribution of diabetes to supernatural forces aligns with findings in Nigeria by Iregbu *et al*. (2022), where bad fate was cited as a primary cause. From a clinical perspective, these beliefs are critical because they directly influence health-seeking behavior. If a patient perceives their illness as a spiritual trial or a curse, they may prioritize spiritual intercession over pharmacological intervention. This creates a complex management environment where healthcare providers feel their advice is often disregarded in favor of the opinions of peers or traditional beliefs.

Majority of the study participants believed that there are foods and herbs that can be used to treat diabetes. Participants believed that bitterness from these indigenous vegetables, spices and herbs would help to manage and reduce blood glucose levels. In the present study, the herbal medicines and herbs that were used by diabetic patients and local herbalists in the management of diabetes included moringa leaves (*Moringa oleifera*), sea moss and aloe-vera. This finding is similar to the findings of other studies conducted in Tanzania and Kenya (Kasole *et al.,* 2019; Mwanri *et al.,* 2018; Abdulrehman *et al.,* 2016) that identified various herbal remedies including indigenous vegetables, spices, and herbs that were believed to be useful in treating diabetes.

In this study participants indicated misconceptions in management of diabetes that the long-term use of conventional medications, particularly frequent consumption of drugs and regular injections could become toxic or harmful, especially for individuals managing multiple complications. This fear of chemical toxicity is precisely what drives the high prevalence of herbal use. As noted by herbalists, patients believe that natural remedies help eliminate the chemicals introduced by oral medications and insulin injections. This is supported by the clinician's observation that patients often listen to their fellows who recommend herbs over the clinical advice of healthcare providers. Doubt in medical treatment presents a critical barrier to effective diabetes management; this highlights the urgent need for patient-centered education initiatives.

Healthcare providers must implement a more transparent and engaging counseling method, to ensure that patients fully understand the benefits and risks of their treatment options. Findings of the current study are consistent with the study conducted in Ethiopia by Desse *et al.,* 2024 which reported that participants believed that conventional medicine are harmful to their health, these misconceptions led to fear and stress, causing some patients to reduce or discontinue their prescribed medications. Also, finding of this study is supported by other study conducted among Black sub-

Saharan Africans in the Which reported that patients believed that herbs have higher efficacy in controlling blood glucose levels and a wider safety window (Omodara *et al.*, 2022)

The integration of healthcare provider and herbalist perspectives in this study reveals that management is not happening in a vacuum; it is a tug-of-war between clinical advice and beliefs. Therefore, healthcare providers must move beyond just prescribing medicine and engage in transparent counseling that acknowledges these beliefs while explaining the safety of long-term pharmacological therapy. The findings also have important implications for healthcare policy and practices. Healthcare providers should routinely ask patients about herbal medicine use and their beliefs about diabetes in a non-judgmental manner to encourage open communication and reduce the risk of undisclosed herb drug interactions or discontinuation of prescribed treatment.

Diabetes education should address misconceptions regarding the toxicity of long-term medication and provide balanced information on the potential benefits and risks of herbal remedies. At the policy level, culturally sensitive diabetes education should be incorporated into existing diabetes prevention and management programs, with community-based awareness involving health care providers, religious leaders and other influential community members. Strengthening collaboration between conventional healthcare services and appropriate traditional medicine stakeholders may also support safer and more culturally acceptable diabetes management.

Study Limitations

This study has some limitations. The cross-sectional design provides a snapshot of participants' perception, beliefs and herbal medicine use, thus does not allow casual relationships to be established. Participants were recruited from two public health facilities in Morogoro Municipality, which may limit transferability of the findings to patients attending private facilities or those living in other regions and rural settings of Tanzania. Information on herbal medicine use, treatment practices and personal beliefs was self-reported and may have been influenced by recall bias and social desirability bias. Also, the study did not clinically assess the efficacy, safety, dosage or potential herb drug interactions of the reported herbal remedies. Despite the limitations, the mixed methods approach provided complementary quantitative and qualitative evidence and incorporated perspectives from patients, healthcare providers and herbalists, providing a broader understanding of perceptions beliefs and herbal medicine use in diabetes management.

Conclusion

This study highlights the significant role of religious, personal beliefs, perception and practices in managing T2DM in Morogoro, Tanzania. Despite the growing awareness on the causes and management of T2DM, misconceptions such as the harmfulness of conventional medications and spiritual attributions of illness, persist. The misconceptions may complicate the management of diabetes. Thus, patient-centred education should be provided by healthcare professionals who can deliver culturally sensitive intervention that respect cultural beliefs while presenting scientifically grounded information, bridging the gap between cultural beliefs and scientific understanding fostering informed decision-making and improve diabetes management outcomes. To further enhance diabetes management, additional research should be conducted on the efficacy and safety of commonly used herbs, ensuring their appropriate use alongside conventional diabetes treatments. Policies on herbal medicine regulation should be strengthened, and healthcare providers should be trained on culturally competent care.

Declarations

Ethical Clearance

Ethical approval for this study was obtained from the National Institute for Medical Research (NIMR) with a reference number NIMR/HQ/R.8a/Vol.IX/4584. Permission to conduct this study was obtained from the President's Office of Regional Authority and Local Government (PORALG), as well as from respective regional, district, and health facility authorities. The study's aim, procedures, benefits, and potential risks were explained to all potential participants to consent before they were invited to participate. Participants were assured of confidentiality and anonymity, with data handling involving the use of numbers to represent individuals' names.

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Authors' Contributions

All authors contributed to the study's development and design. Data collection, analysis, and interpretation were accomplished collaboratively. Drafting and revision of the manuscript was done with input from all authors. All authors read and agreed upon the final manuscript for submission.

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Exploring the Drivers of Consumer Self-Medication: A Factor Analysis Approach

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Abstract

Introduction: Self-medication has emerged as a common practice across the world, particularly in emerging economies like India. With growing accessibility to over-the-counter drugs, individuals increasingly bypass seeking professional advice, raising concerns about drug misuse and health risks.

Background and Objectives: The study aims to identify and analyze the driving factors behind this behavior, among residents of Punjab, India. The study also examines their implications for public health policies.

Methods: The first-hand study was carried out in the field practice areas associated with pharmacy shops in Punjab. A total of 664 respondents from the Maja, Malwa, and Doaba regions of Punjab were selected using multistage purposive sampling.

Results: By using the exploratory factor analysis, the present study revealed five distinct factors that prominently influence self-medication practices. These factors help in understanding the motivations patterns of self-medication.

Conclusion: The study identifies five characteristics that encourage self-medication amongst the population of Punjab. These factors include: Access Challenges, Marketing and Advisory Influence, Convenience and Self-Reliance, Time and Cost Efficiency, Disclosure Discomfort

Keywords: Factor Analysis, Public Health, Consumer Behavior, Healthcare Access

Introduction

Self-medication is a growing global issue whereby people utilize homemade remedies, natural treatments, or drugs without consulting a professional. "The selection and use of medicines by individuals to address self-identified illnesses or symptoms," the World Health Organization (WHO) defines self-medication (World Health Organization, 1998). Self-medication entails hazards related to improper drug use, side effects, and antibiotic resistance even if it may provide quick relief for minor diseases (Alghadeer et al., 2018).

Over the years, the ideas of self-care, especially self-medication, have changed significantly. Self-medication was sometimes viewed in the 1960s with suspicion, particularly in Western countries where medical systems gave treatment of diseases priority above preventative actions (Lusingu et al., 2004). Due largely to rising health care expenses, restricted access to medical services, and a growing number of over the counter (OTC) drugs, self-medication has been regarded as a necessary component of individual wellness management in recent years (Galán Andrés et al., 2021).

Many factors help to explain the rise in self-medication practices. An individual's decisions to self-medicate are greatly influenced by socioeconomic background, availability of medications, past medication experiences, and cultural influences (Bennadi, 2013). Gender differences also affect self-medication practices; studies indicate that women are more likely than males to self-medicate, ascribed in part to increased health awareness and caring responsibilities (Figueiras et al., 2000). Self-medication practices also vary depending on age, degree of education, job status, and knowledge of medicine (Abay & Amelo, 2010).

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Studies show that older adults, especially those over 60, have more inclination for self-medication, usually depending on previously recommended pharmaceuticals or advice from others rather than medical professionals (Ali et al., 2020). Self-medication is not as common in some geographical areas as in others. Rich countries typically see self-medication as including over-the-counter medications, cold treatments, and dietary supplements. Conversely, in underdeveloped nations, where access to healthcare is more difficult, antibiotics and prescription medications could be used (Saif et al., 2024).

According to a study, most of the respondents prefer purchasing medicines straight from pharmacists without a prescription, acquiring regularly used medications like paracetamol and ibuprofen. As per the research done in Punjab, 73% of Punjabi people in India report self-medication due to being highly influenced by ease, cost-effectiveness, and reliance on their knowledge (Verma et al., 2020). Self-medication carries risks even if it offers advantages, including lessening of the burden on healthcare facilities and quick cures for minor diseases. Medication errors can cause major health problems, including adverse drug reactions, interactions with other drugs, inaccurate self-diagnosis, and the evolution of resistant microorganisms (Tariq et al., 2018). Moreover, bad self-medication habits could postpone required medical consultations, therefore aggravating underlying medical conditions (Kassie et al., 2018).

Objective of the study

This study aims to investigate the key factors influencing consumer self-medication by means of a factor analysis approach. This research also seeks to identify self-medication motivational factors and their implications for public health policies. Comprehending these factors will aid in formulating measures for safe self-medication practices and fostering educated healthcare decisions among consumers.

Review of Literature

According to a study by D. Jato, both main push and pull variables promoting self-medicating are poverty and the low cost of drugs, both of which make up a significant amount of the self-medication trend (Mbako, 2023). Another Sapienza study demonstrates that an unwillingness to visit a doctor and a pharmacy's recommendation are the other factors that push customers towards self-medication (Sigcho & Hurtado, 2023). According to the study conducted by the practicality factor and the assumption of a mild, easily treatable disease, along with the environmental influences of a long-distance relationship with parents (Shabaraya & Ullas, 2021).

The media significantly influences the promotion of self-medication. However, self-medication can result in harmful consequences due to improper use of medicines (Sinulingga, 2020). As per the study conducted by Raina Rahmawati, recommendations from family, friends, and neighbors influence self-medication decisions more. Other factors include dissatisfaction with conventional medicine and the desire to reduce costs (Ephrem et al., 2022).

The current study investigated factors that influence the self-medication behavior among individuals indulged in self-medication. more trust in traditional medicines recommended by friends and family members, irrespective of their socioeconomic and educational backgrounds, and their level of trust is dependent on various factors such as ease of access, perception of a lower cost, and traditional medication side effects. Gaygsz et al. carried out the separate experiment and revealed a strong correlation between governance quality and antibiotic use in Europe. In the field of health care, the study looked at the social and political context. The research examines the links between Europe's socioeconomic status, cultural values, national personality factors, and antibiotic usage (Gaygısız et al., 2017).

Cultural values influenced antibiotic use the greatest, followed by socioeconomic factors and personality attributes (Puvvada et al., 2021). Torres et al. look at a study that shows self-medication (SM) is a global problem with a higher prevalence in low- and middle-income countries (LMICs). Some of the studies reporting factors that affect SM in LMICs were undertaken in Asia, with very few publications from Africa in

general, and notably Sub-Saharan Africa, being reported. Sociocultural health determinants influence SMA behaviors, which are frequently linked to traits such as poor selling and prescribing habits, as well as inadequate safety actions (Torres et al., 2019).

A further study was conducted by Shah et al. to investigate the awareness, knowledge, and perceptions of Nepalese university students. The study found that the most common cause of self-medication was minor illness and the motivation behind previous prescriptions, overconfidence as a result of higher education, knowledge of frequently used medicines, social media marketing, and quick and prompt symptomatic relief from illness. As a result, several studies have suggested that women use more medicines on their own, particularly during hormonal changes and gynecologic issues (Shah et al., 2021).

Mohammed et al. conducted research in Saudi Arabia and reported that health teachers and students spend more time on sites including Facebook, WhatsApp, Telegram, Twitter, and Snapchat to increase health awareness. According to the study, these social media sites are more successful in promoting healthy habits. The research indicates that social media is also an important factor for self-medication selection. According to research performed in Italy, 73.4 percent of respondents said they use the internet to receive antibiotic-related information, and the internet is regarded as the second most important source of healthcare information (Zucco et al., 2018).

The literature review emphasizes several elements affecting consumer self-medication: economic limitations, pharmacological advice, and the view of minor diseases. Self-medication activities depend much on social factors like family, friends, and media. Furthermore, influencing antibiotic use are cultural and economic elements; prescription practices depend on the quality of government. Studies show that self-medication is more common in low- and middle-income nations, mostly motivated by discontent with mainstream treatment, past prescriptions, and overconfidence resulting from increased education. The increase of social media as a main source of health knowledge supports self-medication habits even more.

Materials and methods

To explore the factors motivating self-medication, a descriptive research design was adopted. This section outlines the study population, sampling procedure, and data collection method employed to ensure a focused and reliable analysis.

Research Design

The study employed descriptive research design. Initially, we conducted the study to explore the reasons behind self-medication. The study aimed to determine the factors motivating people to engage in self-medication.

Study population

The current study concentrated on those respondents who are over the age of eighteen and indulged in self-medication for the previous year. The study took place in the Majha, Malwa, and Doaba regions of Punjab, India. The purpose of the study was to look into and comprehend the elements that lead to self-medication in this region.

Sample size and selection

A sample survey was conducted for the purpose of the present study to collect firsthand data from respondents who had engaged in self-medication without the prescription of a registered medical practitioner over the past year. The sample size was determined to be 664 individuals who practiced self-medication from the state of Punjab. This sample size was calculated based on the study population of 2.77 crore (Government of Punjab, 2014), ensuring a 99% confidence interval.

Data Collection

Data collection was conducted using a structured survey method, employing judgmental sampling to ensure the selection of respondents with relevant knowledge and experience in self-medication. A 5-point Likert scale was utilized, allowing respondents to express their levels of agreement or disagreement with various statements. The scale ranged from "Strongly Disagree" (1) to "Strongly Agree" (5), providing a nuanced understanding of participants' attitudes and perceptions. This method facilitated the gathering of rich, ordinal data, enabling researchers to analyze trends and patterns in responses effectively. By employing this approach, we aimed to capture a comprehensive view of opinions on the factors motivating people for self-medication, enhancing the reliability and validity of our findings. The structured format of the Likert scale also made it easier for respondents to articulate their views, contributing to a higher response rate and more meaningful insights.

Table 1 highlights the demographic information of the 664 respondents who participated in self-medication practices over the past year across the six most populated districts of Punjab—Ludhiana, Jalandhar, Hoshiarpur, Faridkot, Amritsar, and Gurdaspur. Selected using a judgmental selection technique, these subjects had data collected via a survey using a questionnaire. The study looks at the basic causes of self-medication behavior employing factor analysis.

Table 1: Demographic Profile of Participants

Demographic Factor	Categories	Number (n)	Percentage (%)
Gender	Male	332	50%
	Female	332	50%
Age Group	18-24 years	133	20%
	25-40 years	398	60%
	41-65 years	133	20%
Educational Background	Primary/Illiterate	166	25%
	Secondary School	199	30%
	Graduate/post-graduate	299	45%
Occupation	Professionals	199	30%
	Students	166	25%
	Laborers	133	20%
	Homemakers	100	15%
	Unemployed	66	10%

Results

Factor analysis, a statistical method used to identify underlying relationships between variables, was applied to the survey data. This method helps in reducing the data to a few significant factors that explain the motivations behind self-medication. Identifying factors motivating people to engage in self-medication: Exploratory Factor Analysis Technique (EFA) was applied for its primary objective to reduce the items into a limited number of factors. After application of EFA, fewer factors were identified as compared to the original factors, but it was discovered to be effective at describing an important portion in the variable among the items.

These variables were used to identify various factors, and the identity of each component was determined through taking into consideration the correlation between the item and that factor. The idea behind factor identification was that the items with the highest correlation with a factor would describe the factor's

conceptual meaning. The factors that were identified were given names according to the set of items or variables that had the strongest correlation with them. The objective of condensing multiple variables into a smaller number of factors was supported by the KMO value of 0.859 (Table 2), which displayed indicators of the applicability of factor analysis (Hair et al., 2010). The hypothesis that the correlation matrix is an identity matrix was rejected considering Bartlett's sphericity test. The null hypothesis was rejected based on the significance value, and the inferences regarding the relationships in the information set that were suitable for EFA were made.

Table 2. KMO and Bartlett's Test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.859
Bartlett's Test of Sphericity	Approx. Chi-Square	4042.449
	df	210
	Sig.	<.001

Furthermore, the information that was gathered to figure out the causes underlying self-medication was on a scale of one to five, with 1 indicating disagreement and 5 indicating agreement. Since there were no distributional assumptions and the data being collected on a Likert scale was discrete, the principal component analysis method was the most appropriate. Five different elements have been identified using principal component analysis (PCA) techniques (Table 3). Taken collectively, each of these factors contributed to nearly 56% of the variations observed among the variables. Given the right number of components eliminated, about 56% of the stated variance can be deemed to be justified.

Table 3. Extraction of Factors Motivating Consumers for Self-Medication

Total Variance Explained									
Component	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	5.53	26.317	26.317	5.526	26.317	26.317	3.283	15.632	15.632
2	2.2	10.49	36.807	2.203	10.49	36.807	2.735	13.025	28.657
3	1.68	7.976	44.783	1.675	7.976	44.783	2.29	10.905	39.562
4	1.29	6.142	50.925	1.29	6.142	50.925	2.128	10.132	49.695
5	1	4.776	55.701	1.003	4.776	55.701	1.261	6.007	55.701
6	0.97	4.596	60.298						
7	0.84	3.994	64.292						
8	0.81	3.846	68.138						
9	0.76	3.609	71.747						
10	0.67	3.207	74.954						
11	0.65	3.072	78.026						
12	0.61	2.909	80.935						
13	0.58	2.778	83.713						

14	0.55	2.624	86.337						
15	0.48	2.298	88.635						
16	0.46	2.191	90.827						
17	0.44	2.072	92.899						
18	0.4	1.886	94.785						
19	0.39	1.848	96.633						
20	0.36	1.691	98.324						
21	0.35	1.676	100						
Extraction Method: Principal Component Analysis.									

For reference, an illustration showing an eigenvalue is provided here. The screen chart in Figure 1 offers a snapshot of the initial loads of factors and indicates that principal component analysis could offer an appropriate clarification as it settled in five iterations.

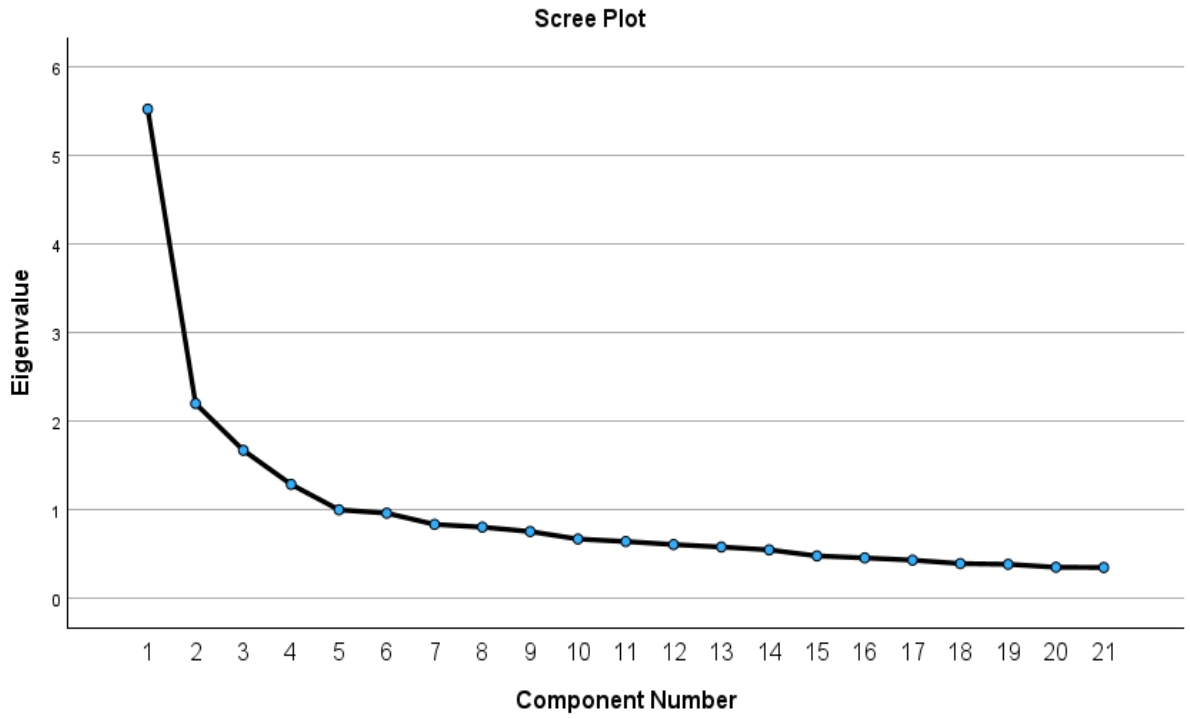

Figure 1: Screen Plot

Communalities which are interpreted as Multiple R2s during multiple regression indicating amount to which any factors elucidate the variance of items were found to be fine, providing additional indication about suitability of results for interpretation (Table 4).

Table 4. Principal Component Analysis

Communalities		
	Initial	Extraction
because of scarcity of time associated to visiting at hospitals	1.000	0.647
In order to get instant relief	1.000	0.741
because it is economical for me	1.000	0.664
As I feel embarrassed while discussing my medical problems	1.000	0.562

because i believe i carry sufficient knowledge about drugs	1.000	0.589
the pharmacy is nearer to my home than the hospital/clinic	1.000	0.599
since I don't want to wait for long patients queues to seek medical help	1.000	0.607
due to lack of trust in medical practioners	1.000	0.279
as the medicines are readily available in the market	1.000	0.452
based on the previous prescription for similar diseases	1.000	0.521
because of inadequate service quality offered by medical practitioners	1.000	0.519
because professional health care are not readily available in my area	1.000	0.605
based upon medication suggested by elderly at home	1.000	0.494
as visiting to a doctor increase my stress level	1.000	0.499
In those cases where illness is not serious enough to consult a doctor	1.000	0.509
Because there is acceptance of Self-Medication in our Society	1.000	0.391
Under the influence of Celebrity endorsements	1.000	0.547
Based upon the suggestions of pharmacists	1.000	0.615
In case if my trusted doctor's prescription is found to be Ineffective	1.000	0.671
After getting influenced with advertisements	1.000	0.633
As for long I have been struggling from a chronic illness	1.000	0.552
Extraction Method: Principal Component Analysis.		

The explanation of the results was approved due to the high confidence in their suitability for principal component analysis. Orthogonal varimax rotation was now used to maximize the variance of the squared loadings of a factor on each item in the factor matrix. Each output variable or item in this rotation tends to be one of the factors, and each factor represents a limited number of things, making it easier to understand the results. Five factors group the variables in a theoretically understandable way, as a review of the rotated component matrix shows (Table 5).

Table 5. Rotated Component Matrix

Rotated Component Matrix					
	Component				
	1	2	3	4	5
because professional health care are not readily available in my area	0.77				
based on the previous prescription for similar diseases	0.686				
because of inadequate service quality offered by medical practitioners	0.672				
as visiting to a doctor increase my stress level	0.634				
based upon medication suggested by elderly at home	0.611				
due to lack of trust in medical practioners					
In those cases where illness is not serious enough to consult a doctor					
In case if my trusted doctor's prescription is found to be Ineffective		0.807			
After getting influenced with advertisements		0.776			
Based upon the suggestions of pharmacists		0.767			

Under the influence of Celebrity endorsements		0.57			
Because there is acceptance of Self-Medication in our Society					
the pharmacy is nearer to my home than the hospital/clinic			0.75		
since I don't want to wait for long patients queues to seek medical help			0.746		
because i believe i carry sufficient knowledge about drugs			0.732		
as the medicines are readily available in the market			0.555		
In order to get instant relief				0.831	
because of scarcity of time associated to visiting at hospitals				0.77	
because it is economical for me				0.768	
As I feel embarrassed while discussing my medical problems					0.697
As for long I have been struggling from a chronic illness					
Extraction Method: Principal Component Analysis.					
Rotation Method: Varimax with Kaiser Normalization.					
a. Rotation converged in 5 iterations.					

Discussion

The study clarifies the key components controlling consumer self-medication. Exploration of factor analysis (EFA) revealed five primary components: access challenges, marketing and advisory influence, convenience and self-reliance, time and cost efficiency, and discomfort disclosure. Each one of these components exhibits significant determinacy and great importance, which clarifies why people self-medicate. Emphasizing the need for targeted regulations to encourage safe medication practices, these results offer significant information for authorities, healthcare professionals, and pharmaceutical corporations. The discussion of every component follows:

Access Challenges

Self-medication mostly results from the difficulty people have obtaining professional healthcare treatments. The study indicates that those who depend on past prescriptions, lack healthcare experts, and receive inadequate quality services are more prone to self-medication. This conduct also depends on family member advice, cultural standards, and stress related to hospital visits, especially that of seniors. These results underscore the need for enhancing healthcare accessibility, inspiring patient confidence in medical experts, and starting community health awareness campaigns to remove challenges to professional treatment.

Marketing and Advisory Influence

This section emphasizes the great impact on self-medication choices of advertising, celebrity endorsements, and pharmacist recommendations. Many consumers base their medical decisions more on advertising messaging and unofficial sources than on professional medical advice. These demands increased attention on consumer education efforts to inspire individuals to self-medicate in the proper manner as well as more regulations on pharmaceutical marketing to ensure advertising is honest.

Convenience and Self-Reliance

Many people prefer self-medication because it is easy. Convenient access to pharmacies, the need to avoid long hospital waits, and confidence in one's own pharmacological expertise all help to drive this practice. This reliance on self-diagnosis raises some health risks. Dealing with this problem calls for public health campaigns stressing the dangers of ill-informed self-medication and the need for getting qualified medical guidance when needed.

Time and Cost Efficiency: Many would more quickly preserve time by simply purchasing over-the-counter drugs and skipping long hospital waiting times. Financial constraints also play a role since, especially for low- and middle-income groups, expensive medical treatments are less accessible. Self-medication entails risks, including inaccurate diagnosis and improper drug use, even if it is convenient and reasonably priced. Policies covering subsidized healthcare, telemedicine services, and pharmacist-led consultations will enable the government to lower these risks and promote safe and informed self-medication free from compromising health.

Disclosure Discomfort

Comfort and privacy issues define most of the self-medication habits. Many people choose to self-manage chronic conditions or feel awkward facing their health problems. This highlights the need for medical facilities to establish nonjudgmental and confidential surroundings where patients feel safe managing their issues. Online health platforms, awareness campaigns, and private consulting services serve to lower discomfort and motivate people to get skilled medical counsel.

Conclusion

The study found the five main elements influencing self-medication: barriers to healthcare access, external influences, convenience and self-perceived knowledge, time and cost efficiency, and privacy and comfort. In contrast to previous studies, this study focused on wide motivations toward the self-medication behavior of individuals. This study highlights deeper issues, such as healthcare shortages, misleading advertisements, constraints on income, and privacy issues. The government may use this study or factors for modifying healthcare policies to promote effective and informed self-medication by expanding telemedicine, reducing hospital wait times, managing advertising medicine, and enhancing pharmacist-led education. This would ensure proper drug use and assist in minimizing threats.

Managing these variables can assist in mitigating the dangers associated with negligent use of drugs and improving access to medical care. For people and others, these findings give a systematic approach for self-medicating. Though people with less education encounter the risk of misuse, the incorrect dosage, and delay in therapy, those with more understanding benefit from making informed decisions. Those who have more medical awareness are more likely to grasp appropriate dosages and any adverse effects, thus ensuring responsible self-medication. On the other hand, lack of knowledge can lead to serious health risks, including drug resistance and long-term complications.

The campaigns for public health ought to concentrate on teaching underprivileged communities to support responsible use of medications. The two types of readily accessible and transparent health information may promote safe practices and help to avoid misuse of drugs. This study ensures that self-medicating is strictly controlled, helpful, and safe by means of organized direction and regulatory assistance. These outcomes ultimately serve to close the discrepancy between individual choices and healthcare policies, therefore ensuring that self-medication remains a safe and wise habit for individuals with the appropriate knowledge and safeguarding others more vulnerable.

Theoretical Implications

Including many behavioral and environmental elements into a methodical analytic framework improves theoretical knowledge of consumer self-medication. This study helps us to better grasp the reasons behind an individual's choice for self-medication. It shows how people are driven toward self-medication by constraints such as restricted healthcare access and expenses, therefore transcending current health models. Unlike other research, it also stresses the part of pharmacist recommendations and advertising, therefore proving that self-medication is not only a personal choice but also shaped by outside circumstances. This study addresses social, cultural, and financial factors as well as provides a better image

of self-medication activities, by means of which these realizations can direct improved laws and medical campaigns to ensure responsible and safe drug usage.

Practical Implications

The findings of this study offer important novel ideas on enhancing medication safety and access to healthcare. Working together, doctors and chemists can make sure over the counter (OTC) medications are easily accessible and incorporate appropriate use rules to prevent abuse. The first may help prevent unsafe self-medication practices and erroneous data by increasing knowledge of the risks involved in purchasing medications from unreliable sources. By educating customers in making appropriate medicine choices, pharmacist-led consultations at retail stores help improve healthcare services and safer self-medication practices. Moreover, online channels can be constant sources of medical knowledge, which would enable people to decide to self-medicate knowingly.

By giving customers competitive prices and quick consultations, expanding telemedicine technologies can help overcome financial and logistical constraints on professional healthcare access. Pharmacists can assure access without compromising confidentiality by offering individuals who respect privacy and discretion covert packaging and home delivery options. These strategies enable the healthcare system to strike a balance between consumer autonomy and medical safety, therefore encouraging appropriate self-medication practices and improving health outcomes.

Managerial Implications

This study emphasizes the need for legislators and healthcare managers to improve consumer education programs and regulatory systems. Healthcare management should prioritize removing access restrictions through improved local pharmacy networks and telemedicine services, which will provide people with better alternatives to self-medication. Pharmaceutical marketing strategies have to follow ethical standards, so they encourage responsible self-medication instead of encouraging ignorant reliance on over-the-counter drugs. Through mobile health apps and artificial intelligence consulting companies that offer quick advice based on symptoms, companies could deliberately spend money on consumer education. Among people who devote time to their optimal health, this approach encourages loyalty to brands and trust among consumers. The government must work together with business partners to create awareness programs so that customers have the knowledge needed to differentiate between safe and unsafe self-medication approaches.

Limitations and scope of future research

The challenges of the study concentrate on its geographic concentration, maybe limiting its general usefulness, and the possibility of participant-biased data production. The population size and study representation determine whether results can be generalized. Technological issues consist of the use of preliminary techniques to prove the potential of further validation by means of assurance processes. Future research might examine shifts in time with data collected over time, look at cross-cultural variations in self-medication motives, and use qualitative methods to advance knowledge. In addition, evaluating the financial and medical consequences of popular self-medication behaviors might produce significant results for health care.

Declaration

Conflict of interest: The authors declare that there is no conflict of interest associated with this study.

Ethics approval

A study of self-medication behavior was reviewed and approved by the Institutional Ethics Committee, Lovely Professional University (IEC-LPU). The committee thoroughly examined the research proposal, ensuring it meets the ethical standards required for research involving human participants. The approval was

granted under reference number LPU/IEC-LPU/2025/1/8, dated 15.02.2025. The committee confirmed that the study poses minimal risk to participants and adheres to guidelines related to informed consent, confidentiality, and participant welfare.

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Developing a Comprehensive Literature Review Chapter for Qualitative Research: An Evidence-Informed Guide for Students and Early-Career Researchers in Low-Income Contexts

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Abstract

Background: Developing a comprehensive literature review chapter is a critical skill for students and early-career researchers conducting qualitative research, particularly in low-income settings where access to resources may be constrained. A well-constructed literature review serves as the foundation for research by situating the study within the existing body of knowledge and identifying gaps that the research seeks to address. However, there is a notable lack of accessible, simplified, and practical guidelines tailored to students and early career researchers in low-resource environments, which hinders their ability to develop proficiency in this essential area.

Objective: To provide a practical and accessible framework for developing a literature review chapter for qualitative research, with particular relevance to students and early-career researchers working in resource-constrained settings.

Methods: This article employed a descriptive methodological approach informed by evidence synthesis, methodological literature on literature reviews, and the author's prior qualitative research experience. Key recommendations from methodological publications and practical examples from qualitative research were reviewed, synthesized, and organized into a framework comprising seven complementary techniques for literature review development.

Findings: The framework identifies seven essential techniques for constructing a literature review chapter: summarizing the literature search, articulating discussions on literature, categorizing bodies of literature, comparing arguments within the literature, exemplifying key arguments or findings, identifying critical gaps and their implications, and positioning research to address identified gaps. The framework emphasizes transparency, critical analysis, contextual relevance, and practical applicability in resource-constrained environments.

Conclusion: The proposed framework offers a simplified and evidence-informed approach to literature review development for qualitative research. Mastering the steps proposed in the framework allows students and early-career researchers to improve the quality, rigor, and scholarly contribution of their research while enhancing participation in global academic discourse.

Keywords: Literature review; Qualitative research; Early-career researchers; Students; Low-income countries; Research methodology; Tanzania; Africa

Introduction

Literature review is an essential component of academic research, serving as a cornerstone for situating a study within its scholarly context. A well conducted literature review provides valuable insights for researchers and helps professionals stay updated with the latest evidence to guide their decisions and improve their work (Paré & Kitsiou, 2017). For researchers, it serves as a clear and reliable

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starting point to synthesize existing knowledge, identifies gaps, and highlights areas for further exploration (Maggio, Sewell & Artino, 2016; Snyder, 2023). Literature reviews are highly regarded because they offer a concise overview of a topic and point to important sources for deeper exploration (Cronin *et al*., 2008). Although they require effort and dedication, completing a literature review greatly benefits the academic community by organizing and summarizing knowledge in a way that is accessible and useful to others.

Students and early-career researchers conducting qualitative research in low-income contexts must develop strong skills in writing literature reviews. A well-crafted literature review enables effective utilization of limited resources while ensuring their contributions are meaningful and relevant to global academic discourse. Literature reviews take three critical forms each with its focus and purpose in research. First, they are often integrated into the introduction and background sections of research proposals, journal articles, or theses. These sections synthesize existing evidence to identify knowledge gaps, thereby constructing a robust justification for the study's necessity (Paré & Kitsiou, 2017).

This synthesis highlights how the research aligns with or diverges from previous studies, ensuring it addresses a relevant and pressing problem. Additionally, the literature review in the introduction and background section may be used to establish theoretical foundation for the study, demonstrating the significance of the research problem, and underscoring the study's potential to contribute novel insights to existing knowledge. It also serves to validate the methods and approaches chosen, linking them to established evidence and practices (Paré & Kitsiou, 2017; Snyder, 2019).

However, this type of literature review is often concise, focusing specifically on framing the objectives of the current study. Despite its brevity, it plays a crucial role in orienting the research within a broader academic and practical context, particularly for researchers working in resource-constrained settings.

Second, a literature review can take the form of a dedicated thesis chapter following the introduction and background sections. This chapter typically begins with a literature search, followed by the extraction and synthesis of relevant evidence. It involves comparing arguments, identifying gaps in existing knowledge, and analyzing their implications in relation to the proposed study. This process not only justifies the current study's objectives but also situates it within the broader academic discourse, highlighting how it aims to address the identified gaps (Paré *et al*., 2015).

Furthermore, this type of literature review goes beyond merely supporting the current study; it provides a critical resource for other researchers interested in the same topic. Offering a comprehensive synthesis of the research evidence in the field facilitates a deeper understanding of the research area and informs future studies. Furthermore, students and early-career researchers can leverage such in-depth literature reviews to create standalone review articles, which can be submitted for publication in scientific journals. Publishing a review article enhances the visibility of their work, contributes to the cumulative knowledge base, and establishes their academic credentials (Snyder, 2019; Xiao & Watson, 2019). Thus, mastering this form of literature review, which is the focus of this article, offers both immediate and long-term benefits, advancing both the researcher's career and the field of study.

The third and final form of literature review is the standalone review article, a comprehensive scholarly work that synthesizes existing knowledge on a particular topic. Standalone reviews are diverse in format and may include, but are not limited to, systematic reviews, narrative reviews, meta-analyses, descriptive reviews, hybrid reviews, critical reviews, and scoping reviews (Grant & Booth,2009; Paré *et al.,* 2015). Each type serves a unique purpose and caters to different research needs, offering distinct methodological approaches and outcomes. Systematic reviews and meta-

analyses, for instance, are highly rigorous and structured, requiring a systematic process for identifying, evaluating, and synthesizing all relevant studies on a topic (Paré *et al*., 2015; Munn *et al*., 2018; Page *et al*., 2021). Scoping and narrative reviews, on the other hand, are less structured and focus on providing a thematic synthesis of existing literature (Paré *et al*., 2015; Munn *et al.,* 2018). Hybrid reviews combine elements from different types of reviews to address complex research questions, while critical reviews emphasize evaluating the quality and robustness of existing literature (Grant & Booth, 2009). Standalone review articles are among the most frequently cited types of academic publications, as they provide a comprehensive overview and serve as a starting point for other researchers. For students and early-career researchers, mastering these reviews can enhance their academic impact and visibility, positioning them as contributors to advancing knowledge in their field. Developing these reviews, particularly systematic and meta-analyses, fosters collaboration, methodological rigor, and subject matter expertise, often laying the foundation for advanced research careers.

Despite the critical role of literature reviews in research, constructing a high-quality review can be a challenging task, particularly for students and early career researchers with limited access to databases, journals, and other academic resources. Existing guides, such as those by Cronin et al. (2008), Paré & Kitsiou (2017), Snyder (2019), and Xiao & Watson (2019), while valuable, often present methodologies that are inaccessible, overly complex, or impractical for researchers operating in low-resource settings. These limitations leave students and early-career researchers in low-income contexts at a disadvantage, often resulting in substandard reviews that fail to meet academic and professional standards. This article addresses these gaps by presenting a practical and accessible framework for developing literature reviews, specifically tailored to researchers in resource-constrained environments. The framework focuses on simplifying the process, prioritizing essential techniques, and leveraging freely available tools and resources. By addressing common challenges, such as limited access to scholarly materials and a lack of methodological guidance, this framework aims to empower researchers to produce comprehensive and impactful literature reviews, thereby enhancing the quality of their contributions to global academic discourse.

Methods

Design

This article was developed using a descriptive methodological approach informed by evidence synthesis and the author's prior qualitative research experience. The article presents an evidence-informed methodological guide rather than primary empirical research. The aim was to identify, synthesize, and present practical techniques that can guide students and early-career researchers in developing literature review chapters for qualitative research, particularly in low-income and resource-constrained settings.

Sources of Evidence

The framework was informed by three complementary sources. First, methodological literature on literature reviews, qualitative research, and evidence synthesis was reviewed, including works by Cronin et al. (2008), Paré and Kitsiou (2017), Snyder (2019), Xiao and Watson (2019), and related methodological publications. Second, examples and lessons were drawn from the author's doctoral research on patient trust in doctors in rural Tanzania (Isangula, 2018), which included extensive literature review development and synthesis. Third, additional contemporary studies addressing research capacity strengthening and qualitative research practices in low-resource settings were consulted to ensure contextual relevance.

Development of the Framework

The identified literature was reviewed to extract recurring recommendations regarding effective literature review writing. Similar recommendations were grouped and synthesized into practical techniques. Through an iterative process of comparison, refinement, and contextual adaptation, seven complementary techniques were identified (detailed below).

Validation and Contextualization

The proposed framework was further refined using examples from published theses and peer-reviewed studies conducted in both high-income and low-income settings. Particular attention was given to ensuring applicability for students and early-career researchers working in environments with limited access to academic resources and methodological support.

Results

Results of the literature synthesis are presented as a practical framework comprising seven complementary techniques for developing a literature review chapter. The framework integrates evidence from methodological literature with practical examples, recommendations, and contextual insights to address common challenges encountered by students and early-career researchers, particularly in low-resource settings. These challenges include limited access to diverse scholarly resources, difficulties in synthesizing and reconciling conflicting evidence, and the need to maintain contextual relevance while engaging with global scholarship.

The framework is grounded in the growing body of literature emphasizing the value of structured, transparent, and adaptive approaches to research and knowledge synthesis in resource-constrained environments (Witter et al., 2023; Isangula et al., 2024). Through the synthesis, seven interrelated techniques were identified as critical for producing analytically rigorous and contextually relevant literature reviews: (1) summarizing the literature search, (2) articulating discussions on literature, (3) categorizing bodies of literature, (4) comparing arguments within the literature, (5) exemplifying key arguments or findings, (6) identifying critical gaps and their implications, and (7) positioning research to address identified gaps (Figure 1).

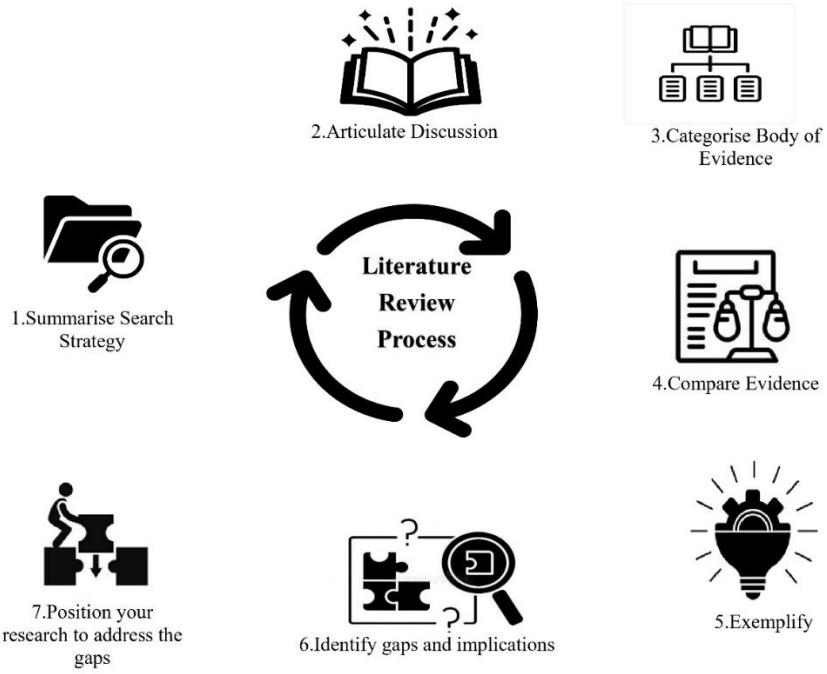

Figure 1: The seven complimentary techniques for literature review process

Collectively, these techniques provide a coherent and accessible framework for strengthening literature review practices and enhancing knowledge generation among students and early-career researchers. Each technique is described in detail in the sections that follow.

Step 1: Summarizing the Literature Search

The first technique in constructing a standalone literature review chapter involves conducting a systematic search of relevant studies and providing a detailed summary of the search strategy. Unfortunately, many theses, both in low-income and high-income contexts, often overlook this critical step. For instance, theses by Matiko (2011) and Mkolo (2029) in Tanzania, and Thiehoff (2025) in the United Kingdom, bypass the explanation of their search strategies, jumping directly to describing the evidence from the literature. While the format of a literature review may be influenced by supervisors, research type, academic writing style, and institutional preferences, summarizing the search strategy ensures transparency, reproducibility, and a solid foundation for the review.

A comprehensive summary of the search strategy typically includes details such as the databases accessed (e.g., PubMed, Scopus, CINAHL, HINARI, Google Scholar, and institutional repositories), regional or context-specific repositories for localized studies, and the inclusion and exclusion criteria aligned with the research objectives. Students and early career researchers may consider prioritization of international and regional databases that offers open access to scholarly articles such as Scientific Electronic Library online (SciELO) and African Journals Online for example.

Additionally, listing keywords, Boolean operators, and search strings used for the search promotes replicability. This level of detail is particularly important for standalone literature review articles, where methodological rigor is essential (Snyder, 2019; Xiao & Watson, 2019). Conversely, if the literature review is integrated within the introduction or background section of a broader study, the search strategy summary may be more concise, focusing on key evidence rather than an exhaustive description. For example, Huang (2023) incorporated an 'overview of existing literature' into the

introduction section of a study conducted in Eswatini, while Nwosu (2021) used an 'objectives and introduction' chapter as a literature review in a study conducted in Uganda. For standalone review articles, adopting frameworks such as PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) can further enhance clarity and adherence to best practices (Page *et al.*, 2021).

Tailoring the depth of the search strategy summary to the purpose and format of the review ensures the methodology supports the study's objectives while remaining accessible and relevant to the intended audience. A simplified version exemplifying a summary of literature search can be seen in Isangula (2018):

> *"The past 30 years have seen increased research in the field of trust in patient-doctor relationships. A search of empirical literature across databases including MEDLINE, Embase, PubMed, Psych Info, CINAHL, Scopus, Google Scholar and the Web of Science, as well as the grey literature, revealed that trust in the patient-doctor relationship has mostly been researched in HICs"* (p48)

Step 2: Articulating Discussions on Literature

The second technique in developing a standalone literature review chapter is to clearly establish that the discussion is exclusively about literature and related scholarly findings. This requires deliberate articulation to ensure the reader understands that the focus is on synthesizing existing research, identifying gaps, and setting the context for the study. The step emphasizes the importance of developing a coherent narrative that highlights trends, and key debates within the field. Several experts have developed tools and resources, such as 'academic phrase banks,' to assist students in constructing discussions for literature reviews effectively.

One notable example is Dr. John Morley's Academic Phrasebank (Morley, 2024), which provides practical phrases for the key sections of a research paper or thesis. This resource is particularly valuable for academic and scientific writers, especially those who are non-native English speakers, as it helps them develop clarity and precision in their writing. These phrases are organized thematically, aiding writers in presenting arguments, discussing findings, and structuring their reviews. When engaging with existing literature, it is essential to use language that reflects the author's active interaction with research body, as this demonstrates an understanding of the field and adds credibility to the discussion. Phrases such as the following are instrumental in achieving this goal:

- "The past decade has seen growing evidence on the subject of…"
- "The literature suggests…"
- "Studies indicate…"
- "Research has shown…"
- "Evidence indicates…"
- "Previous research has..."
- "Current research indicates…"

For instance, a statement like, *"The literature suggests that community engagement is pivotal in the success of public health interventions in low-income regions" (Author, Year)* not only highlights the student or early career researcher's familiarity with the topic but also anchors their argument within established research.

This engagement with literature is exemplified in Isangula (2018), where the discussion of scholarly evidence on patient-doctor relationships is constructed on critical insights from existing studies to underscore its importance in public health. By adopting such an approach, early-career researchers can create literature reviews that are both comprehensive and analytically robust. Isangula (2018), states:

> *"…a large body of literature indicates that patient-doctor communication and provider behavioral interventions have been prioritized in improving patient-doctor relationships."* (p40)

> *"Over recent years, an increased amount of literature has examined the role of patient trust in healthcare seeking, disease management and control. A considerable amount of research suggests that patient trust in doctors' influences patients' willingness to seek and use healthcare, uptake of preventive services and initiation of treatment"* (p49)

Step 3: Categorizing Bodies of Literature

The third technique in developing a robust literature review is organizing the literature into thematic categories, which facilitates structured and coherent analysis. Grouping and categorizing studies based on shared characteristics not only indicate active engagement with the literature but also demonstrate a deep understanding and mastery of the body of research. This process highlights critical patterns and relationships within literature, offering a clear framework for analysis and synthesis (Tranfield *et al.,* 2003; Snyder, 2019).

A thematic approach to organizing literature involves clustering studies based on commonalities such as objectives, methodologies, findings, or trends. For instance, researchers might group studies addressing similar research questions, using analogous methodologies, or contributing to the understanding of recurring themes. This method aids in uncovering connections, contradictions, evolving trajectories within the field, and aligns with what Clarke and Braun (2006) term as *thematic analysis*, which involves identifying, analyzing, and interpreting patterns (themes) within qualitative data.

Applying this concept to a literature review, researchers systematically categorize key findings into themes or subcategories, thus creating an organized narrative that is both comprehensive and analytical. For example, a review on public health interventions in low-income regions might categorize the literature into themes such as those focusing on 'community engagement strategies,' those focusing on 'barriers to implementation,' those focusing on 'cultural considerations,' those focusing on 'outcomes and effectiveness, and those focusing on 'measures of community engagement.' Each category would then be discussed in detail, synthesizing insights and highlighting areas requiring further investigation. This thematic organization, as emphasized by Petticrew and Roberts (2008), enhances the clarity and depth of the review while providing a clear structure for critical analysis. This way, students and early career researchers move beyond summarizing individual studies and instead engage in critical evaluation, drawing attention to the broader discussion of the findings. Isangula (2018) exemplifies this:

> *"Available studies reflect a range of concerns, objectives and approaches, which I broadly categorize into four groups. First, a large body of literature focused on the benefits of patient trust in doctors. Such studies aimed to establish the role of trust in addressing the challenges of healthcare use, disease management and control...*
>
> *There is broad consensus that greater trust in doctors is associated with better patient behaviors and health outcomes. A second body of literature examined factors shaping patient trust in doctors and attempted to understand how trust in patient-doctor relationships may be …. Factors related to the patient, the provider/doctor and the health system were identified as shaping trust in different contexts. A third body of literature reported on interventions to improve patient trust in doctors….*
>
> *These interventions were primarily implemented in North America and sought to address some patient and provider factors that shape trust. Finally, a growing body of literature generated*

measures of patient trust in doctors in PHC settings…. Several 'trust in physicians' scales that aimed to generate evidence on factors that shape trust and trust improvement interventions have been developed and validated in different contexts. Each of these themes is examined in detail." (p48-49)

Step 4: Comparing Arguments in Literature

The fourth and critical technique for writing a literature review chapter involves comparing perspectives and findings. This strategy allows students and early career researchers to highlight both alignments, controversies, and divergences in terms of theories, methods, findings or concepts within the field, demonstrating a nuanced understanding of the subject. By juxtaposing theoretical perspectives, empirical findings, and methodological approaches, researchers can identify commonalities and contradictions, enriching the discussion. For instance, the following statements reflect alignment in the field, pointing to general agreement;

"There are many published studies linking microfinance to women's empowerment. The studies mainly concerned on microfinance role on, poverty alleviation, and socio-economic development through microfinance" (Mengstie, 2022 p1)

"Overall, evidence on factors shaping trust in LMICs versus HICs generally agrees. The patient, provider and health system factors shaping patient trust in doctors in urban and rural areas of Tamil Nadu in India, are similar to those discussed in Australia" (Isangula, 2018 p61).

"There appears to be consensus in some theoretical (and some empirical) literature that trust in institutions (institutional trust) is based on the trustor's knowledge and perception of functional institutional or system arrangements that ensure a trustee upholds the trustor's interest" (Isangula, 2018 p71).

These alignments often serve as a foundation for exploring broader implications, such as policy recommendations or practice improvements. However, an effective literature review also critically examines disagreements, recognizing them as opportunities for further inquiry. Controversies and divergences in terms of findings or concepts within literature are equally important, as they highlight gaps, contradictions, or areas of uncertainty that may warrant additional investigation. For example, the following statement emphasizes contrasting findings*:*

"There are controversies on impact of microfinance on women's economic empowerment. Odell study identified the difficultly of making generalized conclusions taking to consideration the heterogeneity of microfinance interventions. Stewart et al. study in Africa found little impact of microfinance on income of beneficiaries…" (Mengstie, 2022 p1-2).

"There is some debate in social literature concerning trustor, trustee and institutional/system factors that shape how trust is built, sustained and damaged. For example, Luhmann viewed trust in the system (institutional trust) as a requirement for trust in the systems' representatives (interpersonal trust). In contrast, Giddens suggested that trust between 'the flesh-and-blood people' (interpersonal trust) is a requirement for 'trust is in the abstract system' (institutional trust). These views are echoed in Meyer et al, Meyer, and Schilke and Cook" (Isangula, 2018 p71).

"On one hand, symmetrical interpersonal trusting relationships manifest when both trustor and trustee have almost equal or equal decisional power in a trusting situation; for example, some sexual or business relationship. On the other hand, asymmetrical interpersonal trusting

> *relationships manifest in situations of decisional power imbalances (e.g. when one person holds more power in relation to decision making). Patient-doctor or citizen-politician relationships exemplify asymmetrical relationships."* (Isangula, 2018 p73).

Such comparisons allow researchers to delve deeper into the reasons behind these discrepancies, whether due to differences in research design, contextual factors, or theoretical frameworks (Petticrew & Roberts, 2008). As Petticrew and Roberts (2008) suggest, identifying these divergences can guide the development of new hypotheses or innovative methodologies that address unresolved questions. This approach ensures that the literature review is not merely a summary of agreements in the literature to support the current study but a critical and analytical synthesis of controversies and disagreements that advances understanding of the need and approaches employed in the present study.

Step 5: Exemplifying Key Arguments or Findings

A key technique in writing a literature review chapter is the effective use of specific examples to enrich key arguments, findings, and concepts discussed in the review. These examples underscore the practical applications and contextual relevance of the reviewed literature, while providing concrete evidence to substantiate the analysis and demonstrate the practical implications of research findings. Referencing specific studies that illustrate a concept or finding bridges the gap between abstract ideas and their real-world significance, enhancing the credibility and depth of the review (Snyder, 2019).

This approach aligns with the recommendations of Booth, Sutton, and Papaioannou (2016), who emphasize that well-chosen examples can clarify complex arguments and highlight key trends in literature. Moreover, Petticrew and Roberts (2008) suggest that incorporating specific examples ensures a balanced representation of research findings, fostering a more critical and comprehensive synthesis of literature.

A fundamental rule when crafting a literature review is to never leave a scholarly argument unsubstantiated; every claim or observation should be supported by relevant examples from specific studies. This practice not only enhances clarity and depth but also showcase the researcher's engagement with the literature. Following such practices enables students and early career researchers to construct literature reviews that are analytically rigorous and contextually relevant. A notable example of this practice is the work of Isangula (2018), who demonstrates exemplary integration of concrete examples into discussions of arguments, issues, and findings within the literature:

> *"A large body of literature has* ***associated patient trust in doctors with increased acceptance of doctors' recommendations and adherence*** *to prescribed. In the US, Nguyen et al., Piette et al. and Altice et al. found patient trust was associated with increased adherence to therapy for irritable bowel syndrome, diabetes and antiretroviral therapy, respectively.* (Isangula, 2018 p50)

> *"Some definitions* ***place the trustors' beliefs and the trustees' reliability as central concepts****. For example, Simpson defined trust as the '…generalized beliefs and attitudes around the degree to which other people are likely to be reliable, cooperative, or helpful, independent of the specific context or situation in which an interaction… might take place."* (Isangula, 2018 p69-70)

Step 6: Identifying critical gaps and emphasizing their implications

Central to writing the literature review chapter is the identification of gaps in the existing body of literature. This forms the cornerstone of a compelling literature review, as identifying these gaps

establishes the rationale for further research. Without this critical element, the literature review risks becoming a mere summary of existing studies. Gaps in literature can take several forms. *Theoretical gaps* occur when, for example, there are disagreements in theoretical constructs, absence of a unifying theory or the lack of a suitable theory to guide the present study. Theoretical gaps may also arise when too many theories attempt to explain a phenomenon, creating a need for consolidation or integration. Such gaps underscore the importance of theoretical innovation and adaptation to address unique research contexts. For example, Isangula (2018) highlights the absence of an "all-embracing theory" that provides a holistic conceptualization of trust in patient-doctor relationships, emphasizing the need for context-specific frameworks (p74).

In addition to theoretical gaps, *methodological gaps* are common in literature and often justify the adoption of alternative research designs or approaches. These gaps might involve an overreliance on certain methodologies, such as a predominance of quantitative studies when qualitative insights are needed, or vice versa. Methodological gaps can also include imbalances in study settings, with most research being conducted in developed, high-income, or urban contexts while neglecting developing, low-income, or rural areas (Snyder, 2019).

For example, studies on healthcare access frequently focus on rural contexts, leaving urban areas underrepresented despite unique challenges faced by the low-income population in such settings. Data collection techniques can also reflect methodological gaps, with some topics requiring individual interviews to explore sensitive issues, rather than relying solely on focus group discussions (Booth *et al.,* 2016).

Similarly, gaps in participant demographics, such as a focus on specific genders, age groups, profession or socio-economic strata, might necessitate studies that include more diverse populations. For example, Isangula (2018) observed that studies on patient trust in doctors often focus primarily on patients' perspectives, with limited engagement of doctors, despite the therapeutic relationship being a negotiated dynamic between both parties (highlighted below).

Conceptual gaps occur when certain concepts remain understudied or require further exploration to provide a more comprehensive understanding. For instance, Isangula (2018) discusses the ambiguity surrounding factors that shape patient trust in doctors, noting conflicting findings in different settings. According to Isangula (2018), some studies suggest that trust in patient-doctor relationships may be "context-specific", with the possibility that factors influencing trust in high-income countries (HICs) may not manifest similarly in low-income areas (LIAs) such as rural Tanzania (p66). These conflicting, inconclusive, or controversial results highlight the need for additional insights from a specific context or using a particular strategy to resolve ambiguities. Addressing conceptual gaps ensures that the literature review not only identifies what is known but also articulates what remains unknown, guiding future research in meaningful and impactful directions.

Step 7. Positioning your research to address the identified gaps

The final technique in writing a literature review chapter is articulating how your research is positioned to address the identified gaps in the literature. This involves clearly outlining the specific contributions your study intends to make while acknowledging the gaps it does not aim to address. It is important to demonstrate how the proposed research aligns with the unresolved issues in the field, emphasizing its relevance and potential impact. However, not all identified gaps can or should be addressed by a single study. In such cases, providing a justification for why certain gaps remain outside the scope of your research, or proposing the need for future investigations, is essential. This transparency not only strengthens the credibility of your study but also sets realistic expectations for its contributions. Additionally, such reflections can be incorporated into the study's 'limitations' section, where the researcher can acknowledge constraints and recommend future research directions (Snyder, 2019).

Positioning your research to address specific gaps should be seamlessly integrated into the literature review, ideally as the concluding sentences in the paragraphs describing the gaps. For example, Isangula (2018) identifies ambiguity in the literature about factors shaping patient trust in doctors, noting that "potentially conflicting findings in different settings" suggest that trust may be context specific (p66). As noted above, the argument is that factors influencing trust in high-income countries (HICs) might not manifest similarly in low-income areas (LIAs) like rural Tanzania, thus justifying the need for the proposed study to unmask the 'context-specific factors.' This approach demonstrates how a researcher can connect the identified gaps directly to their study's objectives. When students and early career researchers explicitly link the research problem to the gaps in literature, not only do they justify the study's significance but also highlight its contribution to advancing knowledge in the field. Another example from Isangula (2018) indicates how this can be executed:

"The findings of most of the reviewed research do not always include doctors' perspectives. Brennan et al. noted that of 596 studies of trust in patient-doctor relationships, only 18% somewhat engaged patients and providers (doctors, nurses, dentists, allied professionals and other cadres). The nature of trust in therapeutic relationships requires attention to providers rather than patients alone, because both parties shape the interactions and exchanges in the clinical setting. This thesis seeks to investigate the perspectives and experiences of both patients and providers to generate a comprehensive understanding of trust in therapeutic relationships in LIA." (p65)

Following Isangula' examples, students and early career researchers can position their studies to address the identified gaps in literature effectively while maintaining a critical and reflective perspective on their scope and limitations.

Discussion

This article builds on prior qualitative research in rural Tanzania (Isangula, 2018) and similar studies conducted in diverse contexts to propose a practical, straightforward approach to writing a literature review chapter for qualitative theses. This guide is specifically designed for students and early-career researchers in low-income contexts, addressing their unique needs and challenges. Grounded in principles of equity and contextual adaptability, the approach reflects the nuanced realities of low-resource settings, where barriers such as limited research skills, restricted access to scholarly resources, and the absence of simplified guides often impede academic progress (Arunachalam, 2003; Isangula *et al.*, 2024).

Furthermore, students and early-career researchers in low-income settings face significant obstacles, including inadequate infrastructure, financial constraints, and limited access to academic databases. These challenges are compounded by the digital divide, which disproportionately affects their ability to acquire and apply advanced research methodologies (Tijssen, 2007). Additionally, the lack of mentorship opportunities exacerbates the gap between their potential and their ability to produce high-quality research (Isangula *et al*., 2024).

Existing scholarly guides, while invaluable in resource-rich settings, often fail to address these limitations effectively (Snyder, 2019; Xiao & Watson, 2019). Recognizing this gap, this article aims to provide a contextually relevant guide that equips students and researchers with practical tools and strategies to navigate these challenges.

The proposed approach emphasizes practical solutions to overcome barriers of conducting research encountered by students and early career researchers in low income contexts. Strategies

such as leveraging open-access databases, collaborating with institutional libraries, and utilizing regional repositories are highlighted as means to facilitate equitable participation in academic discourse (Petticrew & Roberts, 2008). For example, the emphasis on contextual adaptability enables researchers to tailor their literature review methodologies to their specific environments while maintaining analytical rigor (Isangula, 2018).

A key feature of this guide is its complementary nature; it is not intended to critique existing literature review guides but to address the unique needs of low-income contexts. Nevertheless, the skills and approaches discussed can also benefit students and early-career researchers in high-income settings, supplementing resources such as those by Cronin et al. (2008), Paré and Kitsiou (2017), Snyder (2019), and Xiao and Watson (2019).

It is important to note that a well-crafted literature review is foundational to academic research. It situates new studies within the existing body of knowledge, critically identifies gaps, reconciles contradictions, and positions new research to advance understanding in the field (Snyder, 2019; Petticrew & Roberts, 2008). This process is especially significant in addressing inequities in global knowledge production, ensuring the inclusion of diverse and underrepresented voices.

The guide emphasizes critical skills such as summarizing, categorizing, exemplifying literature, and identifying research gaps that students and early career researchers are equipped with competences to produce literature reviews of high analytical quality, even in challenging environments. These competencies are vital not only for producing literature reviews of high analytical quality but also transferable across disciplines for fostering long-term academic and professional growth (Braun *et al.,* 2019).

For students and early career researchers in low-resource contexts, mastering these skills is essential for meaningful contributions to global academic discourse. This article underscores that a literature review should not merely summarize existing research but should critically engage with the field, systematically categorizing and comparing studies to identify patterns, contradictions, and gaps (Booth *et al.,* 2016). When students and early career researchers integrate these strategies into their work, they are likely to produce literature reviews that are analytically rigorous, contextually relevant, and grounded in principles of equity.

Limitations

The framework was developed through synthesis of methodological literature and practical research experience rather than formal consensus methods such as Delphi techniques. Future studies may validate and refine the framework through expert consultation and application across diverse academic settings.

Conclusion

The article highlights the importance of addressing practical and systemic challenges faced by students and early career researchers in low-income contexts. It provides a simplified, contextually relevant guide that aims to bridge the divide in academic research and foster inclusive in global knowledge production. It presents a systematic approach to constructing an effective literature review chapter, emphasizing key strategies such as summarizing searches, articulating discussions, categorizing literature, comparing arguments, exemplifying findings, highlighting gaps and implications, and positioning research to address them. This approach ensures that students and early career researchers from under-resourced settings can contribute meaningfully to scholarly discourse, advancing knowledge in their fields while addressing inequities in access and participation.

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