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## **Historical Perspective and Fundamentals of Clinical Research in Nigeria**

**\*Akinyemi R.O.<sup>1</sup> and Ogunniyi A.<sup>2</sup>**

<sup>1</sup>*Neuroscience and Ageing Research Unit, Institute for Advanced Medical Research and Training, College of Medicine, University of Ibadan, Ibadan, Nigeria.*

<sup>2</sup>*Department of Medicine, College of Medicine, University of Ibadan, Ibadan, Nigeria.*

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### **ABSTRACT**

Research may be defined as any activity that generates new knowledge and a better understanding of natural phenomena, while ‘scientific research’ uses scientific methods to explore and discover new facts and uses the new knowledge to solve practical problems and explain natural phenomena. Scientific research dates back to many centuries. The earliest reports of research are found in the Egyptian papyrus dating back to 17th century BC. The beginning of documented medical research in the West African sub-region and indeed Nigeria in the 19th century and much of 20th century (pre-independence Nigeria) is traceable to the writings of the Nigerian pioneers of modern medicine. The research process is an iterative cyclical procedure that includes a set of activities undertaken to test a hypothesis - a tentative statement about the relationship between two or more variables. In clinical research, the principles of good research practice are expected to be maintained throughout the research process. These principles include the pursuit of research excellence with integrity, respect for ethics and rigorous maintenance of professional standards, honesty and transparency, openness and accountability, supporting training and acquisition of skills, multidisciplinary collaboration and public engagement

**Keywords:** *Clinical Research; Fundamentals; History; Nigeria; Africa*

\*Author for correspondence: Email: [rufusakinyemi@yahoo.com](mailto:rufusakinyemi@yahoo.com); Tel: + 234 8033 704 384

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### **INTRODUCTION**

‘Research’ may be defined as any activity that generates new knowledge and a better understanding of natural phenomena, while ‘scientific research’ uses scientific methods to explore and discover new facts and uses the new knowledge to solve practical problems and explain natural phenomena (Salako, 1998). Simply put, research is an organized process of finding solutions to perceived problems and usually begins with either a simple observation or an unusual experience. The World Health Organization (WHO) has defined “Health Research “as “a process for obtaining systematic knowledge and technology which can be used for the improvement of the health of individuals or groups. It provides basic information on the state of health and disease of the population, aims to develop tools to prevent and cure illness and mitigate its effects and attempts to devise better approaches to healthcare for the individual and community” (W.H.O., 1992). According to the United States Department of Health and Human Services, research is “a systematic investigation, including research development, testing and evaluation, designed to develop or

contribute to generalizable knowledge” while the Belmont Report defines research as “any activity designed to test a hypothesis, permit conclusions to be drawn and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships)” (DHHS, 2018). According to the DHHS, a human subject is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.

Scientific research dates back to many centuries (Ogunniyi et al, 2015). The earliest reports are found in the Egyptian papyrus dating back to 17th century BC. Hippocrates of Kos (460BC – 370 BC was generally regarded as the father of Medicine. Edward Jenner (1749-1823) will be remembered for his invention of the smallpox vaccine which was a scourge at that time; Alexander Fleming (1881-1955) discovered Penicillin which provided cure for bacterial infections; Alfred Nobel (1833-1896) discovered dynamite which was used for blasting rocks and made possible construction of roads through tunnels etc. He instituted the

Nobel Prize in 1895 in recognition of academic, cultural and/or scientific advances. The Nobel Prize represents the hallmark of excellence in research and innovation. Fredrick Banting (1891-1944) and Charles Best (1899-1978) discovered insulin in 1921 and won the Nobel Prize for their work in 1923 (Ogunniyi et al, 2015).

## **PIONEERS OF MEDICAL RESEARCH IN NIGERIA**

The beginning of documented medical research in the West African sub-region and indeed Nigeria in the 19th century and much of 20th century (pre-independence Nigeria) is traceable to the writings of the Nigerian pioneers of modern medicine namely: James Beale Africanus Horton (1858), Obadiah Johnson (1884); John Randle (1888), Sodeinde Leigh – Sodipe (1892) and Oguntola Sapara (1895), all of whom qualified in medicine from English and Scottish medical schools in the nineteenth century in the years shown in parentheses (Adeloye, 1977).

Africanus Horton, in an 1859 MD thesis submitted to the University of Edinburgh on ‘the medical topography of the West Coast of Africa including sketches of its botany’ described plants with medicinal properties including the bark of the mangrove tree for treating fevers, castor – oil plant to promote secretion of milk in women and several others (Horton, 1859). Fifteen years later in 1874, Horton published a remarkable work, ‘The diseases of the tropical climate and their treatment’ in which he provided detailed descriptions of tropical disorders he had encountered in his practice, including therapeutic approaches and post – mortem examination findings when available. These diseases included ague or intermittent fever (malaria fever), chronic splenitis with hypertrophy (tropical splenomegaly syndrome), chronic rheumatic disorders (believed to be sickle cell disease) and guinea worm disease (dracunculiasis) (Horton, 1879).

Obadiah Johnson also submitted a thesis for the MD degree of the University of Edinburgh in 1889 titled ‘The Therapeutics of West Africa’ in which he described the practice of traditional and herbal medicine in ‘Sierra Leone and Lagos within the Yoruba country (Johnson, 1889). Johnson also described the common occurrence of twinning in Nigeria as well as some specific diseases – rheumatism (sickle cell disease), hydrocoeles and malaria fever. The treatise described a medicine – man as ‘a botanist’ who used leaves, roots and barks of trees to prepare his drugs. Johnson further averred that skillful, sound and scientific analysis of specimens of the traditional pharmacopoeia of the West African herbalist with the active participation of practitioners of scientific medicine would be required for any useful drug to emerge. This treatise probably laid the foundation for the scientific approach to traditional African medicine, a domain that is currently gaining grounds in the sub – region with introduction of courses on herbal medicine in medical schools and full support of regional bodies and policy makers, including the foremost regional West African Health Organization.

John Randle, also trained in Edinburgh, however did not write a medical thesis but is reputed to have written one of the earliest communications on cancers among Africans which aimed at correcting the misconception that malignancies were

uncommon among blacks (Randle, 1910). Leigh – Sodipe graduated from the medical school at Newcastle – upon – Tyne in 1892 and obtained an MD from Durham University five years after (Leigh – Sodipe, 1897). He was a strong advocate of scientific approach to the art of medicine prevalent in West Africa at the time, stating in his thesis that ‘the mere knowledge or the simple fact of seeing and becoming acquainted with a thing is not science; to see, find out or attempt to find out and know the rationale of cause and effect are the principles of science’. Oguntola Sapara qualified in Medicine in 1895 following training in London and Edinburgh. He was most famous for his public health translational strategies that led to the control of small box outbreak in the early 1900s (Adeloye, 1977).

Embedded in the products of the searching and scientific minds of these astute Nigerian pioneers of medicine are core nuggets of scientific enquiry which laced their routine work as orthodox medical practitioners. Most important was their passionate quest to apply the principles of scientific enquiry and modern medicine to the practice of native African traditional and herbal medicine with a view to scientifically validating the good aspects thereof, and enriching the world of medicine with original products from the rich African pharmacopoeia. This remains an unaccomplished task for contemporary medical scientists.

## **FUNDAMENTALS OF CLINICAL RESEARCH**

Clinical research is carried out to generate knowledge useful to improving medical care or the public health and thus serve the common or collective good. Clinical research may involve administration of drugs, removal of body tissues or fluids, exposure to varying conditions, alteration of diet or environment, interviews or surveys, simple observation, administration of questionnaires, review of medical records etc. The design may be qualitative and/or quantitative, descriptive (cross-sectional surveys; case reports, case series) or analytical (observational and experimental (interventional) or mixed methods involving a combination of different methods such as qualitative and quantitative approaches.

### **Types of Observational Studies**

**Cohort study:** This involves a group of subjects followed over time for defining the incidence and investigating potential causes of a condition. It can be prospective (investigator chooses a sample group and measures characteristics in each subject over a period of time that might predict outcomes) or can be retrospective (same as prospective, except all data collection and follow-up has happened in the past; only possible if adequate data is available).

**Cross-sectional study:** This is similar to cohort studies except all the measurements are made at one time point with no follow-up. The purpose of cross-sectional study is to describe variables and their distribution patterns (prevalence). The strength of cross-sectional study lies in the fact that it is fast and inexpensive since there is no follow-up or waiting time to evaluate outcomes.

**Case-control study:** There are two groups of people examined for the same outcome; Group 1 – “cases” or a population of people with a certain disease and Group 2 – “controls” or a population of people without that same disease. The purpose of this study is to compare prevalence of risk factor(s) in subjects with the disease (cases) versus subjects without the disease (controls).

**Experimental study:** This study evaluates the effects of an intervention including

- Behavior modification (eg. a walking program to improve weight loss)
- Drug (eg. a new investigational drug or studying a drug for off-label use – subject to FDA regulations)
- Device (eg. a new investigational stent – subject to FDA regulations)

The main strength of experimental study is that it demonstrates causality.

### Phases of Experimental Studies

**Phase I:** Unblinded studies of a small number of healthy volunteers to test safety of treatment (can sometimes use people with the disease).

**Phase II:** Randomized studies of relatively small number of people with the disease to test dose ranges and/or efficacy of treatment.

**Phase III:** Randomized studies of large number of people with the disease to test efficacy of treatment on pre-selected outcomes

**Phase IV:** Large experimental studies or observational studies conducted after treatment has been approved by the FDA to assess performance of treatment (called Post-Market Studies)

### THE RESEARCH PROCESS

The research process is an iterative cyclical procedure that includes a set of activities undertaken to test a hypothesis - a tentative statement about the relationship between two or more variables. A hypothesis is a specific, testable prediction about what you expect to happen in a study. The research process involves such processes as definition of an hypothesis – driven research question(s), description of the methodological approach to answering the questions, collection of data, collation, cleaning storage and analysis of the datasets, writing the results and report of the research and refinement of the research question and generation of new research questions. In all these processes, highest ethical standards must be rigorously kept.

### GOOD RESEARCH PRACTICE

In clinical research, the principles of good research practice are expected to be maintained throughout the research process. These principles include the pursuit of research excellence with integrity, respect for ethics and rigorous maintenance of professional standards, honesty and transparency, openness and accountability, supporting training and acquisition of skills, multidisciplinary collaboration and public engagement. (MRC, 2014)

### CONCLUSION

In this review, we have briefly summarized the historical development of research, explored the early years of medical research in Nigeria and reviewed fundamental principles of types of clinical research, the iterative research process and elements of good research practice.

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