An assessment of the supply chain management for HIV/AIDS care and treatment in Kilombero and Ulanga districts in southern Tanzania

DANIEL S. NYOGEA1,2,3*, HALFAN SAID2, GODFREY MWAIGOMOLE3, MARCEL STOECKLE3, INGRID FELGER1,3, CHRISTOPH HATZ1,3, LARS HENNING2, FABIAN FRANZECK1,2, EMILIO LETANG1,4, EVELINE GEUBBELS1 and MARCEL TANNER1,2,3

1Swiss Tropical and Public Health Institute, Socinstr. 57, P.O. Box, 4002, Basel, Switzerland
2Ifakara Health Institute, Dar es Salaam, Tanzania
3University of Basel, Basel, Switzerland
4Barcelona Centre for International Health Research, Barcelona, Spain

Abstract

Background: The Chronic Diseases Clinic Ifakara (CDCI) has been providing HIV care and treatment in Kilombero and Ulanga districts in Tanzania since 2005. Over time, several drug-refilling stations were created through the Tanzanian National AIDS Control Programme (NACP) to provide antiretroviral therapy (ART). Without any specific performance and outcome evaluation, these refilling stations were upgraded to comprehensive HIV care and treatment centres (CTCs). The objectives of this study were to evaluate the supply chain of the CTCs, key aspects of patient management and the coping strategies of the CTC staff and ART patients during stock-outs of drugs and test kits.

Methods: Data were collected through structured interviews with staff in charge of 12 sites and patients on ART during un-announced visits.

Results: All sites reported shortage of rapid tests to diagnose HIV. Seven (59%) CTCs experienced stock-outs of co-trimoxazole drugs. The CDCI and all but one peripheral CTC reported stock-outs of ARV medication. CD4 + T cell count service and second line drugs were available at the CDCI and in two CTCs only. To cope with the stock-out situation CTCs staff had to stop testing for HIV, substitute the treatment regimen depending on drug availability or close the CTC temporarily. Patients coped by skipping ARVs and co-trimoxazole medications.

Conclusion: Access to ART in Kilombero and Ulanga districts has some critical imbalances in the supply chain and management for HIV/AIDS care and treatment. Potential strategies to overcome the barriers are discussed in relation to routine health management information system, investments into mobile-health and human resource capacity strengthening.

Keywords: HIV/AIDS, care and treatment, antiretroviral, supply chain, Tanzania

Introduction

HIV/AIDS care and treatment centres (CTCs) were introduced in Tanzania through the National AIDS Control Programme (NACP) in 2003 (URT, 2003). The HIV/AIDS care and treatment is based at the primary, secondary and tertiary referral levels (district, region, referral hospitals) (URT, 2003). The Clinic for Chronic Diseases Ifakara (CDCI) in Kilombero district, was one of the first CTC to be established in Tanzania, and started providing ART services to Kilombero and Ulanga district in southern Tanzania since 2005 (Stoeckle et al., 2006). The CDCI is managed and supervised by the Ifakara Health Institute and Saint Francis Referral Hospital. Since its establishment, the CDCI has enrolled 6,500 HIV-positive clients, 3,600 of which initiated ART as of July 2012.

The Voluntary Counselling and Testing (VCT) unit of the CDCI and CTCs routinely offer sequential rapid diagnostic tests (Mossdorf et al., 2011) to establish HIV serostatus. As part of the efforts to decentralize HIV/AIDS care and treatment and to make antiretroviral therapy (ART) more accessible, several district level drug refilling sites were established in 2009 through the NACP (TACAIDS, 2008). These drug refilling stations were originally designed to provide antiretrovirals in the periphery and refer critical patients to the next CTC available for further management, but were not entitled to initiate or modify ART. After two years and without any

* Correspondence: E-mail: nyogea.daniel@gmail.com
specific performance and outcome evaluation, they were upgraded to full CTCs. The upgrade from refilling stations to CTCs aimed at improving services and access to HIV patients and thus providing comprehensive care for patients at peripheral settings. These include ART initiation, treatment change and handling of more complex issues in HIV patient’s management. These changes were expected to save patient’s time and resources while improving the quality of care and patients’ quality of life.

Thus, the original refilling stations are currently operating as peripheral CTCs linked to the large ART-cohort at the CDCI. The CDCI has been supervising the former drug refilling stations in Kilombero and Ulanga districts from the beginning of their activities based on the NACP guidelines. The present study was undertaken to evaluate the overall situation of ART service delivery in the two districts within the context of central CDCI and upgraded refilling stations. The specific objectives were to (i) assess the supply chain of the CTCs, (ii) evaluate key aspects of patient management such as functioning of laboratory services, ART management and resources used by patients to gain access ART (iii) describe the coping strategies of the CTCs and patients on ART in times of stock-outs of HIV test kits, cotrimoxazole and ART.

Materials and Methods

Study design, settings and participants
This explorative and cross-sectional study was undertaken in September 2011 and involved CDCI and all 11 peripheral CTCs in Kilombero and Ulanga districts. The peripheral CTCs were in Lupiro, Mahenge, Mwaya, Mtimbira, Lugala, Itete, Mngeta, Mlimba, Kibaoni, Mang’ula and Ilovo. Kilombero district is mainly a river plain with fertile alluvial soil while Ulanga is mountainous with some low-lying areas. The main economic activities of the population are subsistence farming and fishing (Masanja et al., 2006). The study targeted the person in charge of the facility (CTCs or CDCI) and adult ART patients attending the CTCs/CDCI on the date of study visit or who attended recently in the case that no ART patients attended the clinic on study visit date. We interviewed every second patient to reduce selection bias as family members tend to attend clinic at the same time. Critically ill patients as determined by the respective physicians were excluded from the study.

Data collection
Semi-structured questionnaires were designed and piloted in two CTCs (Kibaoni and Mang’ula) and at the CDCI. Field interviewers were recruited, specifically trained and supervised during the entire data collection period. Interviews with person in charge of CTC aimed at establishing (i) the overall functioning of the CTC; (ii) the occurrence of stock-outs of HIV rapid test kits; (iii) possible coping strategies of health staff and clients during stock-outs of HIV rapid test kits; (iv) timely delivery of medicines; (v) the frequency, determinants and dynamics of ART supplies and necessary drug changes and (vi) stock-outs experiences in the year preceding the study. In case of incomplete information, we visited respective sites up to three times to get the missing data. When ART patients were unavailable at the clinic, we had to visit them at their home with the help of a CTC staff.

The patient interview included the following variables: place of residence, facility where CD4 + T cell count was analysed for the last time before ART initiation, changes in ART regime and the treatment centre where the changes took place, reasons for the changes, duration under ART, whether they ever stopped medication and transport and accommodation costs associated with treatment (cost information was collected in Tanzania shillings (TShs) and later converted to US dollars at an exchange rate of TShs 1600 per US dollar.
Data analysis
Data were double-entered using EPI-DATA (EpiData Association, Odense, Denmark) and analysed using STATA 11.0 (STATA Corp., College Station, Texas, USA). The Shapiro-Wilk test was used to test for normality. Statistical tools for hypothesis testing were χ²-test for categorical variables and Mann-Whitney U test for continuous variables that followed a non-normal distribution.

Ethical considerations
The study received ethical and research clearance from the Ifakara Health Institute Institutional Review Board and the Medical Research Coordinating Committee of the National Institute for Medical Research. Research permit was granted by the Tanzania Commission for Science and Technology. All study participants provided oral informed consents.

Results
Participant’s characteristics
Eleven CTCs and the CDCI were involved in the interviews. The 11 CTCs in Kilombero and Ulanga districts were located between five and 150 km from the CDCI. At the time of the study, each CTC served between 48 and 700 HIV positive patients. A total of 89 ART patients (25 at CDCI and 64 at CTCs) were involved in the study (Table 1). In addition, 12 health care providers who were in charge of the CTCs and the CDCI were interviewed. At the CDCI the person in charge was a medical doctor and at the CTCs, five clinical officers and six nurses/midwives/assistant medical officers were included. All CTC staff, including those interviewed, had attended specific training on HIV care and treatment.

Supply chain management of HIV test kits, cotrimoxazole and ART
All respondents from the CTCs or CDCI reported to have experienced stock-outs of rapid tests to diagnose HIV in the year preceding the study. The CDCI and three CTCs experienced stock-outs of HIV test kits only once, five CTCs (42%) experienced stock-outs at least twice while three CTCs (25%) did not know how often stock-outs happened. The stock-outs lasted for an average of 5.6 weeks (range: 1 week - 3 months). At the time of the survey, CDCI had both HIV diagnostic tests in stock while 5 (42%) and 3 (25%) CTCs did not have Bioline or Determine, respectively. In addition, three CTCs (2 in Ulanga district) did not have any tests available at the time of the survey. The CDCI and 2 peripheral CTCs reported to get HIV test kits on time when ordered during stock-outs period, 7 of the CTCs reported that it took two or more weeks, 1 reported that it took 3 months to receive the HIV test kits once they were out of stock.

CDCI and 36% (4/11) of the CTCs reported to have never experienced stock-outs of cotrimoxazole in the year preceding the study. Six patients (9.3%) at peripheral CTCs reported to have not taken cotrimoxazole tablets because of stock-outs. Among the patients who reported stock-outs of cotrimoxazole in the peripheral CTCs, three of them experienced this once, two of them twice and one experienced stock-outs more than twice. Of these six, three of the patients reported that the stock-outs lasted for more than one month; one patient reported that it lasted for one month and 2 patients reported the stock-outs lasted for one day. In the year preceding the study, CDCI and 91% (10/11) of the peripheral CTCs reported to have experienced ARV stock-outs in the past year. The only site that had not experienced stock-out of supplies was the Kibaoni CTC at the administrative centre of the Kilombero district. Two of the 64 patients reported to miss their ARVs, one because of stock-outs at the nearest CTC and the other person ran out of pills.

The CDCI and 36% (4/11) of the peripheral CTCs reported not to receive drugs on time in the year preceding the study due to delays in delivering after an order was posted. The respondents at the peripheral CTCs mentioned that (i) there was no one responsible for ordering...
at the clinic (ii) they were late in ordering drugs (iii) there was a poor transport chain or (v) there were no drugs at the distributor’s site.

**Key aspects of patient’s management**

During the study period, CD4+ T cell count analysis was only processed at the CDCI and in two CTCs at Mahenge and Lugala. In the Kilombero district, patients from other CTCs had to travel to CDCI for CD4+counts. In contrast, blood samples of patients in Ulanga district were brought to Mahenge and Lugala CTCs or CDCI for the CD4 + T cell count analysis.

**Table 1: Participants characteristics attending CTCs and CDCI**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Response</th>
<th>CTCs N</th>
<th>%</th>
<th>CDCI N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of patients</td>
<td>-</td>
<td>64</td>
<td>72</td>
<td>25</td>
<td>28</td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>21</td>
<td>32</td>
<td>13</td>
<td>54</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>43</td>
<td>68</td>
<td>12</td>
<td>46</td>
</tr>
<tr>
<td>District</td>
<td>Kilombero</td>
<td>35</td>
<td>55</td>
<td>23</td>
<td>92</td>
</tr>
<tr>
<td></td>
<td>Ulanga</td>
<td>29</td>
<td>45</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Site for CD4 analysis before ART initiation</td>
<td>CDCI</td>
<td>31</td>
<td>48</td>
<td>21</td>
<td>84</td>
</tr>
<tr>
<td></td>
<td>Others</td>
<td>33</td>
<td>52</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>26</td>
<td>41</td>
<td>16</td>
<td>64</td>
</tr>
<tr>
<td>Incurred accommodation cost</td>
<td>No</td>
<td>38</td>
<td>59</td>
<td>9</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>1</td>
<td>2</td>
<td>20</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>63</td>
<td>98</td>
<td>5</td>
<td>20</td>
</tr>
<tr>
<td>Mean duration on ART in years</td>
<td>-</td>
<td>1.8 (1:3-3.2)</td>
<td>2.2 (1:1-3.3)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Among 20 patients interviewed at the CTCs who reported to have changed their ART regimen, 17 (85%) of them had their drug modified at the CDCI while drug modifications of the remaining 3 (15%) were done at the CTCs. All patients who were interviewed at the CDCI reported to have had that their drugs modified at the CDCI. Forty percent of peripheral CTCs patients whose drugs were modified came from three CTCs (Mahenge, Mlimba and Mngeta). Staff in charge of one of the CTCs reported to have stopped ARV medication in a patient with kidney and liver failures.

According to patients at the peripheral CTCs, the main reasons for modifying ARV regimens were side effects (70%), stock-outs (15%), clinical decisions (10%) and pregnancy (5%). The main reasons stated by the health worker in charge of the CTCs were side effects (82%), pregnancy and co-infection with tuberculosis and other diseases (63%), stock-outs (45%) and clinical decisions (18%) (multiple answers were common). Two patients at CTCs (3%) reported to have decided on their own to stop their medication in the past because of side effects. None of the patients interviewed at either CDCI or CTCs was ever recommended to stop the ART drugs for any reasons by an ART clinician. There were significant differences in costs incurred between seeking health care in CTCs and CDCI. Visiting a peripheral CTC costed US$ 8.7 less on transport and US$ 5.3 less on accommodation. It took three hours less to reach the CTC than the CDCI (Table 2).

**Coping strategies**

The CTCs, CDCI and patients had adopted several strategies to cope with stock-outs of HIV test kits and medicines. Apart from stopping HIV tests, they also changed the drug regimen while still maintaining triple therapy, temporarily closed the CTC and suspended taking medication. One and six patients stopped taking ARVs and cotrimoxazole, respectively after they were told of stock-outs during their clinical visits. The CDCI and 7 peripheral CTCs (64%) reported to have...
stopped HIV testing when they were out of stock of test kits. Two CTCs (17%) reported to post orders, while 1 (8%) reported the information to local authorities to inform them about the situation. Staff in charge of one CTC did not know what was done after the stock-outs.

Table 2: Resources used to get access to the CDCI and CTCs

<table>
<thead>
<tr>
<th>Variable</th>
<th>CTC</th>
<th>CDCI</th>
<th>P-Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transport cost (US $)</td>
<td>1.3, (0.6-1.9), 26</td>
<td>10, (6.3-12.5), 15</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Accommodation cost* (US $)</td>
<td>1</td>
<td>6.3, (1.9-6.9), 20</td>
<td>NA</td>
</tr>
<tr>
<td>Travel time (hours)</td>
<td>1 (0.5-2), 42</td>
<td>4, (3-5), 23</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*P-value for accommodation cost could not be calculated as there was no standard deviation because only one patient had incurred accommodation cost while attending peripheral CTC.

In case of stock-outs of ARV drugs at the CDCI, communication was made with the nearest CTC (Kibaoni) for possible local sharing. In the peripheral CTCs, patients were referred to another CTC (if on second line, the patients were referred to CDCI), or they were told to come back when drugs were available or changed to alternative regimens within the first line while maintaining the triple therapy. One CTC reported to shut down the CTC office during the period of stock-outs.

Discussion

This cross-sectional study has found stock-outs of HIV test kits and ARVs is common in Kilombero and Ulanga districts. There is also a limited access of second line and CD4 count services at point of care. Because knowledge of one’s HIV status is the entry point for all HIV care and treatment services, stock-outs of HIV testing kits have major impact on the effectiveness of the HIV control programme particularly with respect to access to and retention in care. All sites visited had experienced stock-outs of HIV test kits in the year preceding the study. An assessment of lower level health facilities in Tanzania preceding the introduction of HIV/AIDS care and treatment reported that more than 90% of facilities did not have adequate laboratory supply chains for laboratory materials (NACP, 2009). The main goals of programmes aiming at reducing HIV incidence may not be achieved as long as stock-outs of HIV test kits prevail. Stock-out of test kits and drugs has been reported to also affect other HIV programmes in Tanzania (Aavitsland et al., 2002; Gamell et al., 2013). Similarly, a recent report indicate that one in five health facilities in South Africa reported a stock-out of antiretroviral (ARV) putting the lives of many patients in danger (SSP Stock outs National Survey, 2013). Ensuring regular and uninterrupted supply of HIV diagnostic kits and antiretroviral medicines is critical for a successful HIV programme.

Stock-out of co-trimoxazole was common in the study area. The World Health Organization recommends provision of co-trimoxazole prophylaxis as long as CD4 cell count are less than 350cells/ml, during pregnancy and in children born to HIV positive mothers (WHO, 2014). Cotrimoxazole is a highly cost-effective approach to reduce mortality among patients who present with advanced HIV at ART initiation and it also yields benefits for people with opportunistic infection (Abimbola et al., 2012). Randomized trials that included ART-naive Africans found that cotrimoxazole improved survival while reducing the risk of malaria, pneumonia, sepsis, isosporiasis, toxoplasmosis encephalitis and wasting (Anglaret et al., 1999; Wiktor et al., 1999; Nunn et al., 2008). Stock-outs of the drug, resulting in a higher number of HIV patients developing opportunistic infections (Sethi et al., 2003), may further accelerate HIV disease progression (Nischal et al., 2005), increase hospital admissions (Mulenga et al., 2007) and increase both health care costs (McDonnell et al., 2002) and mortality rates among HIV patients (Wood et al., 2003).

All but one peripheral CTCs experienced stock-outs of ART drugs. In many low- and middle-income countries, the capacity of the procurement and supply management systems has
always been weak (Pasquet et al., 2010). A in 2009 revealed that 38% of countries had documented at least one stock-out of antiretroviral (ARV) drugs in health facilities (WHO, 2010). Stock-outs of ARVs directly affect adherence to antiretroviral therapy (Weidle et al., 2006) which in turn increases the risks of resistance development, disease progression (Oyugi et al., 2007) and mortality (Garcia de Olalla et al., 2002). A study in northern Tanzania revealed that stock-outs led to no or few drugs being dispensed to HIV patients (Lyimo et al., 2012). Stock-outs of ARVs for the PMTCT programme mirror the general health system inadequacies within which the programmes are implemented as reported by Nkonki et al., 2007). Interestingly, a report by the Tanzania National AIDS Control Programme indicates that only one third of the lower level health care facilities had a tracking system for ARVs in place and had sufficient storage space for a one month stock of ARVs (NACP, 2009).

Patients from the three sites (Mlimba Mngeta and Mahenge) had a higher proportion of drug changes which might have been attributed by the long distance from the supply site and thus have drug delays and shortages, hence are forced to send their patients to CDCI where changes are prescribed. A decrease in ART coverage has been associated with a proportional increase in HIV incidence among HIV uninfected adults (Hontelez et al., 2013). With the stock-outs of ART, fewer people will be under ART and we should expect a relatively higher HIV incidence among uninfected people.

Some coping mechanism adopted by the sites studied appeared to create additional problems. Closing temporarily the CTC might discourage clients from testing and thus increase the proportion of HIV positive people who are not aware of their status. Elsewhere in Tanzania, it has been reported that some clients give up testing after being turned away after stock-outs of HIV test kits (Layer et al., 2014). A study in Zimbabwe revealed priorities were focused on PMTCT during times of HIV stock-outs (Kranzer et al., 2014). In some settings to cope with stock-outs, health care staff dispense a few pills to their patients so that many of them could get at least some (Lyimo et al., 2011). This option should be discouraged as it is likely to lead to ART resistance and or treatment failure (Clavel et al., 2004; Tang et al., 2012).

CD4+ T-cell count analysis was done in very few sites in Kilombero and Ulanga districts. This is likely to be due to lack of skilled laboratory staff; the inability to maintain machines and/or assure reliable data; difficulties in managing the supply of reagents and a lack of adequate quality assurance schemes to ensure reliable results (Birx et al., 2009). The absence of point of care CD4 + T cell count may delay staging of HIV patients on site and thus increases the possibility of loss to follow-up (Jani et al., 2011).

Our study had several limitations. Firstly, the study had to rely on estimates of the staff in charge of the CTCs if the information required was not documented or unavailable. Secondly, the study had also a small number of ART patients and thirdly, and we did not ask follow-up questions such as on how many patients who were referred to another CTC for drugs actually went there. Nevertheless, our study has several strengths. The survey was unannounced, patients were randomly selected and staffs in charge of the CTCs in the region and the CDCI were included. Based on the fact that all CTCs in Tanzania have the same source of drug, we are confident that the study possessed internal validity and can be generalized to reflect situation in other peripheral CTCs in Tanzania and in other resource limited countries.

In conclusion, access to ART in Kilombero and Ulanga districts has some critical imbalances in the supply chain and management for HIV/AIDS care and treatment. Potential strategies to overcome these barriers and improve the functioning of CTCs in harmonization with the central CDCI should be considered by the NACP and the district health teams. Our study suggests the following: (i) Routine data collection on HIV test kits and drugs supplies to estimate the actual demand and early ordering of the items, (ii) Investments into mobile-health (m-health) by a targeted use of mobile phones for supervision and reducing stock-out problems; and (iii) more ART management training to be done for peripheral CTCs staff with special emphasis on how to handle second line drugs and complicated cases at their sites.
Acknowledgments

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Competing interests

The authors declare that they have no competing interest.

References


