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Vaccine handling practices and conformity to cold chain temperature requirements in selected regions of Tanzania: a descriptive cross-sectional study

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ABSTRACT

Background: Poor handling practices and infrastructures for vaccine management, especially in remote rural areas, pose a challenge to the accessibility of safe and efficacious vaccines. This study assessed vaccine handling practices and conformity to cold chain systems in Tanzania.

Methods: A cross-sectional study was conducted from March 2022 to October 2022 using temperature loggers, checklists and questionnaires adopted from the WHO Vaccine Management Assessment Tool. The study sites were 35 facilities in Dar es salaam, Kigoma and Mtwara regions in Tanzania. Data was analysed by R statistical software.

Results: A total of 89 vaccine handling personnel with 22 personnel of less than 30 years old were included in this study. Seventy vaccine-handling personnel out of a total of 89 had adequate knowledge and 63 participants had good vaccine-handling practices. Fifty-three participants had no prior training in vaccine handling. Most (80%) of the facilities visited complied with the WHO cold chain storage standard of 2°C to 8°C in one month of observation; however, 29 facilities did not have temperature alarms to alert in cases of temperature changes and 24 facilities had no voltage regulators.

Conclusion: In this study, most of the facilities studied were compliant with WHO vaccine storage temperature requirements over a 30-day period. However, significant gaps were identified, including inadequate infrastructure for emergency situations and a lack of prior training on vaccine handling among the majority of personnel.

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Background

Vaccination is one of the most successful and cost-effective healthcare interventions. Vaccines have proven to control childhood diseases such as measles, pertussis, and childhood tuberculosis. They have enabled the elimination of life-threatening diseases in some parts of the world and freed humankind from smallpox (WHO, 2018). Ensuring accessibility of quality, safe, and efficacious vaccines is therefore of paramount importance. For vaccines to remain safe and effective, they must be maintained under specific storage conditions. The WHO, through its prequalifiprogramme and working closely with national regulatory authorities, ensures the development and dissemination of global vaccine standards for the quality and safety of vaccines (WHO, 2015). Different factors can affect vaccine quality, including in-process manufacturing procedures, transportation and storage facilities, cold chain maintenance as well as handling of different types of vaccines accordingly (Rashid et al., 2009). Incorrect handling or storage of the vaccine, associated with poor temperature control, especially repeated freezing and thawing, has been reported to reduce vaccine effectiveness (Rashid et al., 2009).

Broadly there are two categories of vaccines; live vaccines, which require maintenance of the cold chain, and non-replicating vaccines, which require adjuvants to provide sufficient levels of protective immunity (Kartoglu & Milstien, 2014). The latter are generally more stable to heat. However, both vaccines can be freeze-sensitive, especially if the latter contains aluminium salts as adjuvants (Kartoglu & Milstien, 2014). Several approaches have been made to improve the heat stability of many vaccines, including measles and hepatitis; however, vaccine freezing threatens their quality (Jezek et al., 2009).

Cold chain maintenance and temperature monitoring are still major challenges in developing countries (Ateudjieu et al., 2013). Dedicated vaccine refrigerators, electronic refrigerator temperature loggers, and vaccine vial monitors (VVM) are important elements to ensure the viability of vaccines (Epile Akoh et al., 2016). Improper cold chain maintenance is assumed to be the highest factor affecting vaccine viability, especially in countries where power supply, transportation, and cold chain maintenance are underdeveloped (Feyisa, 2021). Facilities in developing countries face this problem due to the constraints of unsustainable electricity supply, inadequate and improperly set up storage facilities together with far travel distances in remote hard-to-reach areas (Epile Akoh et al., 2016). This raises concerns as facilities store vaccines such as Oral Polio Vaccine (OPV) and measles vaccines which require these freezing temperatures. Lack of proper storage facilities and power cut-offs especially in remote

areas exposes vaccines to temperatures above 8°C further affecting their effectiveness (Ringo et al., 2017).

One of the basic principles to ensure good vaccine storage and proper cold chain maintenance is the availability of trained staff who observe proper vaccine handling practices (Azira, Norhayati, & Norwati, n.d.). Trained personnel in charge of the vaccine cold chain are commonly available in developed countries; however, the situation is different in most developing countries (Azira et al., n.d.). To maintain the quality of medicines, all personnel along the supply chain must implement proper handling of temperature-sensitive products (WHO, 2019). Proper vaccine storage and handling practices play a very important role in protecting individuals and communities from vaccine-preventable diseases (CDC, 2021).

A study conducted in Mozambique, Niassa province documented that health workers in the peripheral health facilities were generally less educated, with little work experience and their knowledge of the cold chain was not as per required levels to support effective cold chain management (Mavimbe & Bjune, 2007). Like other developing countries, some studies conducted in Tanzania have reported inadequacy in the knowledge and practice of vaccine supply chain workers (Bulula et al., 2020).

Several measures have been taken to ensure the supply of good quality and efficacious vaccines including provision of training to vaccine supply chain personnel in countries like Mozambique (Prosser et al., 2017). However, poor infrastructures for vaccine management as well as inadequate knowledge and skills of vaccine handling personnel, still pose a challenge to the accessibility of safe and efficacious vaccines. Therefore, this study assessed the functionality of vaccine supply chain infrastructure and handling practices among healthcare facilities and personnel in selected regions of Tanzania, focusing on cold chain functionality, temperature monitoring, and adherence to vaccine handling practice guidelines.

Methods

Study design and settings

This was a descriptive cross-sectional study that was conducted from March to October among vaccine handling personnel and facilities including the Medical Stores Department, regional vaccine stores and 35 selected facilities of which 14 were Dar es salaam, 12 in Kigoma and 9 in Mtwara regions.

Dar es salaam is the major business city of Tanzania located along the Indian Coast with a population of 5,383,728 people. Kigoma is a region located in northwest Tanzania bordering Burundi and the Democratic Republic of Congo at 1241 km from Dar es Salaam with a population of 2,470,967. Mtwara is a coastal region located in southeastern Tanzania at

566 km from Dar es Salaam and has a population of 1,634,947 as per the 2022 Tanzania Census.

Sample size and sampling method

This study involved 35 vaccine handling facilities and 89 personnel responsible for vaccine management at the health facilities studied. We used a multi-stage sampling approach to ensure a representative selection of regions and facilities. Initially, we employed purposeful sampling to select regions in Tanzania based on specific criteria relevant to the study objectives. Subsequently, convenience sampling was utilised to choose districts within those regions, ensuring geographical accessibility and the presence of at least one health facility capable of storing vaccines in a cold chain.

In the selected districts, we compiled a list of vaccine handling facilities. From this list, we applied simple random sampling to select the final 35 facilities for the study. This selection was conducted using the random number generation function in Microsoft Excel, which assigned random numbers to each facility and allowed us to choose them in ascending order. The total of 35 facilities was determined based on the availability of data loggers within our budget constraints. Ultimately, all vaccine handling personnel present at the facilities on the day of our visit were included in the study.

Data collection tools and procedure

Checklists, questionnaires, and validated data loggers were used for data collection. We adopted the WHO Vaccine Management Assessment Tool to formulate a checklist and questionnaire for this study (21). The checklist was used to document the cold chain infrastructure available at the facility on the day of visit, whereas the questionnaire was used to document the knowledge and practices of vaccine handling personnel. Data loggers recorded temperature changes in vaccine storing units for 30 days. Trained data collectors visited the study facilities and filled in the checklist to document the available cold chain infrastructure, administered questionnaires to vaccine handling personnel present on the day of visit and they mounted calibrated data loggers in the vaccine storage units to record temperature data. After 30 days the data collectors went back to the facilities to remove the loggers for obtaining the collected data.

Study variables and measurement

The variables in this study were vaccine storage temperatures, knowledge and practices on vaccine handling. These were measured using validated data loggers and Likert scale respectively.

Data analysis

Descriptive statistics were summarised into frequencies and tables. Level of knowledge was ranked as adequate and inadequate for the score of 0-8, and above 8 (mean score) respectively using Bloom's cut-off point technique. Vaccine handling practice was ranked as poor and good for the score of 0-26, and above 26 (mean score) respectively using Bloom's cut-off point technique. The 30 days storage temperatures of the facilities were analysed by calculating the Mean Kinetic Temperature (MKT) (see formula below) and further ranked as compliant and non-compliant when the MKT fell beyond (2-8)C as per WHO requirements.

$$TK = \frac{\Delta H/R}{-ln\left(e\left(\frac{\Delta H}{RT1}\right) + e\left(-\frac{\Delta H}{RT2}\right) + \dots e\left(-\frac{\Delta H}{RTn}\right)/n\right)}$$

Where:

TK is the mean kinetic temperature in Kelvin.

 ΔH is the activation energy (83.144 kJ/mole)

R is the gas constant $(8.3144 \times 10-3 \text{ kJ/mole/degree})$

T1 to Tn are the temperatures at each of the sample points in Kelvin.

n is the total number of storage temperatures recorded during the period of 30 days.

e is the base of the natural logarithm.

t1 to tn are time intervals at each of the sample points.

Data was analysed by R software version 4.2.1 (20).

Results

Baseline characteristics of participants

A total of 89 vaccine handling personnel with 22 (25%) of less than 30 years old were included in this study. The majority of participants were female 65(73%) and a greater proportion 65(75%) were aged 30 and above. Most of the participants were nursing officers or midwives by profession 51 (57%) and the majority 55 (62%) had experience of 3-4 years or above in handling vaccines and cold chain medicines. 53 (60%) of the participants had never received any training on vaccine handling and storage, as summarised in Table 1 below.

Characteristics of health facilities included in the study

It was observed that 32 out of 35 of the visited facilities had electricity on the day of visit and only 25 of the facilities kept records of temperature as well as discarded vaccines, however, 14 facilities out of 25 had no working

Table 1. Participant Baseline Information (n = 89).

Characteristic	Raw count (%)
Sex	
Male	24 (27%)
Female	65 (73%)
Age Group	
< 30	22 (25%)
>= 30	65 (75%)
Profession	
Clinical officer	8 (9.0%)
Environmental health officer	2 (2.2%)
Medical doctor	2 (2.2%)
Nurse assistant	21 (24%)
Nursing officer/Nurse midwife	51 (57%)
Pharmacist	3 (3.4%)
Other	2 (2.2%)
Experience Group	
0–3 Years	34 (38%)
3–4 Years	55 (62%)
Received training on vaccine storage	
Yes	36 (40%)
No	53 (60%)

thermometer on the day of visit. The majority of the facilities or 29 out of 35 did not have temperature alarms to provide alert in cases of temperature changes and 24 facilities had no voltage regulators. It was also found that 28 facilities had insufficient ice pack freezing capacity; 21 facilities were without working generators and 24 facilities were without reserve fuel to cater for power cut offs. See Table 2 for more details.

Knowledge on vaccine handling and storage among healthcare providers

The study found that 70 vaccine handling personnel out of a total of 89 had an adequate knowledge of vaccine handling and storage as shown in Table 3 below. Most of them 85 (95.5%) had knowledge of the optimum temperature

Table 2. Characteristics of health facilities included in the study (N = 35).

Criteria	Yes Raw count (%)	No Raw count (%)	Total Raw count
Operational electricity on day of visit	32 (91.4%)	3 (8.6%)	35
Operational water on day of visit	30 (85.7%)	5 (14.3%)	35
Operational telephone on day of visit	30 (85.7%)	5 (14.3%)	35
Presence of temperature records	25 (71.4%)	10 (28.5%)	35
Presence of discarded vaccines records	25 (71.4%)	10 (28.5%)	35
Presence of working thermometer	21 (60%)	14 (40%)	35
Presence of temperature alarms	6 (17.2%)	29 (82.8%)	35
Presence of voltage regulators	11 (31.4%)	24 (68.6%)	35
Sufficient ice pack freezing capacity	7 (20%)	28 (80%)	35
Presence of working generator	14 (40%)	21 (60%)	35
Presence of reserve fuel	11 (31.4%)	24 (68.6%)	35



Table 3. Cross tabulation of participant characteristics and vaccine handling knowledge
(N = 89).

Characteristic	Raw count (%)		
	Adequate Knowledge 70 (79%)	Inadequate Knowledge 19 (21%)	Total count
Profession			
Clinical officer	6 (75%)	2 (25%)	8
Environmental health officer	2 (100%)	0 (0%)	2
Medical doctor	2 (100%)	0 (0%)	2
Nurse assistant	17 (81%)	4 (19%)	21
Nursing officer/Nurse midwife	39 (76%)	12 (24%)	51
Pharmacist	3 (100%)	0 (0%)	3
Other	1 (50%)	1 (50%)	2
Sex			
Female	49 (75)	16 (25)	65
Male	21 (88)	3 (12)	24
Age Group			
< 30	18 (82)	4 (18)	22
>= 30	50 (77)	15 (23)	65
Experience Group			
0–3 Years	29 (85)	4 (15)	33
4 and Above	41 (75)	2 (25)	43
Received Training			
No	43 (81)	10 (19)	53
Yes	27 (75)	9 (25)	36

for storing vaccines and cold chain medicines. However, only 56 out of 89 personnel reported that shifting of vaccine to another refrigerator is required if power failure occurs for more than 72 hours. Most of the vaccine handling personnel 87 (97.8%) mentioned that vaccines will be spoiled if exposed to heat, however, 82% understood that vaccines can be spoiled if exposed to frozen states.

Most of the participants 87 (97.8%) mentioned that a refrigerator should not be placed near sunlight, stove or microwave, whereas 64 out of 89 knew how to correctly place the thermometer in the refrigerator for temperature monitoring. However, only 57 participants understood that recording the monitored temperature in the chart is required, as shown in Table 4 below. However, analysis for the association between participants' characteristics and vaccine handling knowledge was not done due to the small sample size of the study.

Vaccine handling practices

Good vaccine handling practices were reported by only 63 of the vaccine handling personnel as shown in Table 5 below. Seventy three out of eight nine participants reported always record temperature changes in the vaccine storage units, however, 59 participants reported to never record the temperature of the room where the vaccines are stored. Eleven out of 89 participants reported to never discard vaccines once exposed to improper storage temperatures and 32 out of 89 participants always removed vaccines



Table 4. Knowledge on vaccine handling and storage (N = 89).

	Raw count (%)	
Knowledge question	Yes	No
a. 2–8°C is an optimal temperature for cold chain	85 (95.5%)	4 (4.5%)
b. Shifting of vaccine to another refrigerator is required if power failure occurs more than 72 h	56 (62.9%)	33 (37.1%)
c. Vaccines will be spoiled if exposed to frozen state	73 (82.0%)	16 (18.0%)
d. Vaccines will be spoiled if exposed to heat	87 (97.8%)	2 (2.2%)
e. Vaccines should not be placed with food and beverages	86 (96.6%)	3 (3.4%)
f. Vaccines should not be placed on the refrigerator door	85 (96.6%)	4 (4.5%)
g. Vaccines should not be placed in the lowest compartment of refrigerator	65 (73.0%)	24 (27.0%)
h. A refrigerator not be placed near sunlight, stove or microwave	87 (97.8%)	2 (2.2%)
i. Thermometer should be placed at the centre of the refrigerator compartment	64 (71.9%)	25 (28.1%)
j. Recording temperature in the chart is required	57 (64%)	32 (36.0%)

from their packaging to store more products in the refrigerator, as detailed in Figure 1 below. However, analysis for the association between participants' characteristics and having good or poor vaccine handling practices was not done due to the small sample size of the study.

Compliance to storage temperatures

In this study, 80% of the facilities visited complied with the WHO cold chain storage requirement of 2°C to 8°C with Kigoma region having the highest percentage of the facilities that complied (90.9%) as shown in Figure 2 below.

Table 5. Cross-tabulation of participant characteristics and vaccine handling practices (N = 89).

	Raw count (%)		
Characteristic	Good Practices 63 (71%)	Poor Practices 26 (29%)	Total count 89
Profession			
Clinical officer	6 (75%)	2 (25%)	8
Environmental health officer	2 (100%)	0 (0%)	2
Medical doctor	2 (100%)	0 (0%)	2
Nurse assistant	18 (86%)	3 (14%)	21
Nursing officer/Nurse midwife	31 (61%)	20 (39%)	51
Pharmacist	3 (100%)	0 (0%)	3
Other	1 (50%)	1 (50%)	2
Sex			
Female	46 (71)	19 (29)	65
Male	17 (71)	7 (29)	24
Age Group			
< 30	17 (77)	5 (23)	22
>= 30	45 (69)	20 (31)	65
Experience Group			
0-3 Years	26 (76)	8 (24)	34
4 Years and Above	12 (67)	18 (33)	30
Received Training			
No	40 (75)	13 (25)	53
Yes	23 (64)	13 (36)	36

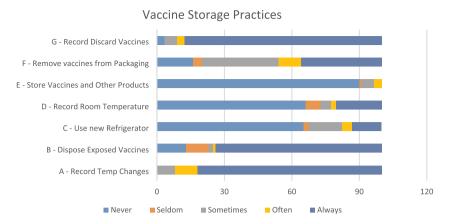


Figure 1. Stacked bar chart showing vaccine storage practices.

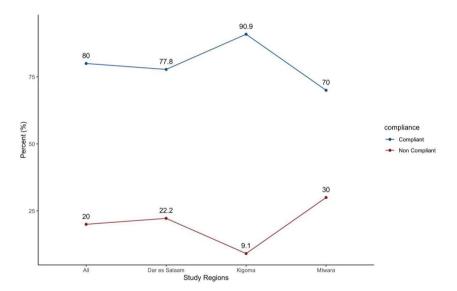


Figure 2. Summary of MKT Compliance of the study sites with respect to 2–8°C range.

Mtwara region had the highest number of facilities (30%) that failed to comply with the standard temperature range of 2°C to 8°C. The non-compliance observed in Kigoma and Mtwara was temperature values below whereas Dar es salaam had values above the recommended range of 2°C to 8°C as shown in Figure 3.

Discussion

This study described the vaccine handling practices and adherence to cold chain requirements in selected vaccine handling facilities across Dar es

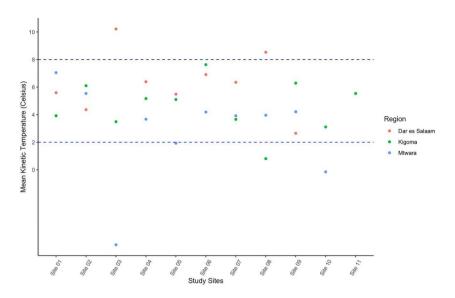


Figure 3. Mean Kinetic Temperature plots for the study sites.

Salaam, Kigoma, and Mtwara regions of Tanzania. The World Health Organization (WHO) emphasises the importance of proper handling of temperaturesensitive products to ensure the quality of vaccines (WHO, 2019).

Vaccine handling knowledge and practices

Our findings as demonstrated in Table 4 indicate that 70 participants out of 89 demonstrated adequate knowledge of vaccine handling and 19 participants with inadequate knowledge, while 63 participants exhibited effective practices. These results are similar to those from a study in Mozambique, which reported that 19% of health workers in peripheral facilities had inadequate knowledge of vaccine handling (Mavimbe & Bjune, 2007).

Interestingly, while 36 out of 89 of our participants had prior training in vaccine handling, it is in contrast with findings from Ethiopia, where only 24.4% of personnel received formal training (Mohammed et al., 2021). However, our results reflect a lower proportion of trained personnel than those reported in central Ethiopia (66.8%) (Yassin et al., 2019), Bale zone (78.1%) (Woldemichael et al., 2018), Nigeria (65.0%) (Dairo & Osizimete, 2016), and Brazil (91.3%) (Almeida et al., 2014). This gap may be attributed to limited health system budgets in the regions studied.

The analysis of knowledge by profession reveals that while 17 nurse assistants out of 21 and 39 nursing officers/midwives out of 51 demonstrated adequate knowledge; all medical doctors, environmental health officers, and pharmacists exhibited 100% adequate knowledge. This suggests a potential



variation in knowledge levels across different healthcare roles, which could influence vaccine handling practices.

Vaccine handling practices by professional role

The analysis of vaccine handling practices among various healthcare professional categories reveals significant differences in adherence to recommended practices. Among clinical officers, 6 exhibited good practices, while 2 demonstrated poor practices. This aligns with previous research indicating that clinical officers, while knowledgeable, often face challenges in consistently applying best practices (Ogboghodo et al., 2018).

Environmental health officers and medical doctors reported exemplary results, with all 4 of the participants in both categories demonstrating good practices. This suggests that their specialised training equips them well to handle vaccines, reinforcing the notion that higher education correlates with better adherence to vaccine handling standards (Mohammed et al., 2021).

Nurse assistants showed a strong performance as well, with 18 participants reporting good practices. However, nursing officers/midwives exhibited a more concerning trend, with only 31 participants adhering to good practices and 20 participants demonstrating poor practices. This variation may reflect differences in training depth or experience levels within these roles and a lot of responsibilities that they concurrently have together with managing vaccines. This was also evidenced by previous studies that have highlighted that nursing officers often juggle multiple responsibilities, which can detract from their focus on vaccine management (Almeida et al., 2014).

Interestingly, all three pharmacists reported a perfect score of 100% for good practices, indicating their specific training in medication management is effectively applied to vaccine handling. This reinforces the idea that pharmacological education directly supports safe and effective handling of vaccines (Dairo & Osizimete, 2016).

Impact of age and professional experience on healthcare workers' vaccine handling knowledge and practices

Our study further explored how demographic factors such as age and gender impact knowledge and efficiency in vaccine cold chain management. It was found that 18 out of 22 participants under 30 years of age demonstrated adequate knowledge, compared to 50 out of 65 participants aged 30 and above. This suggests that younger healthcare workers may be more attuned to current best practices in vaccine handling (Woldemichael et al., 2018). Additionally, gender analysis reveals that only 49 out of 65 of female participants had adequate knowledge, while 21 out 24 of male participants did,



raising questions about the equality in training quality and opportunities for female healthcare workers (Almeida et al., 2014).

Additionally, experience also played a role, with 29 out 33 of those with 0-3 years of experience showing adequate knowledge compared to 41 out 43 participants among those with 4 or more years of experience. This may suggest that newer employees are being trained in more contemporary practices, while longer-serving staff may rely on outdated methods (Dairo & Osizimete, 2016).

Temperature conformity and cold chain infrastructure

Various challenges to effective cold chain management were identified in this study, including the absence of temperature alarms, inadequate ice pack freezing capacity in 28 out of 35 facilities, and a lack of working generators in 21 facilities. Additionally, 69% of facilities did not have reserve fuel for power outages. These issues mirror findings from a study conducted in Ibadan, Nigeria, highlighting poor cold chain infrastructure as a significant barrier to proper vaccine storage (Ogboghodo et al., 2018).

While most facilities complied with the WHO's cold chain storage requirements of 2°C to 8°C, some facilities in Dar es Salaam exceeded this range. Contributing factors may include the region's consistently high temperatures and insufficient cold chain infrastructure. The infrequent and unreliable power supply exacerbates these challenges, leading to frequent exposure of vaccines to temperatures outside the recommended range. This aligns with observations from Cameroon, where vaccines were similarly exposed to extreme temperatures (Ateudijeu et al., 2013).

Conclusion

Most of the facilities visited were found to be compliant with WHO vaccine storage recommendations. The majority of the participants had adequate knowledge and good vaccine handling practices however, in this study most of the participants had no prior training on vaccine handling and it underscores significant challenges in cold chain management and notable knowledge differences among different professional roles.

Recommendations

Based on these findings, we recommend implementing regular training programmes for vaccine handling personnel to enhance their knowledge and practices. Additionally, it is crucial to upgrade the existing cold chain infrastructure by installing temperature-sensitive alarms, voltage regulators, and generators. These improvements will facilitate timely responses to



temperature excursions, ensuring the integrity of vaccine storage. Furthermore, we advocate for ongoing research to assess the functionality of cold chain systems, which is essential for effective vaccine management and to identify areas for continuous improvement.

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Disclosure statement

No potential conflict of interest was reported by the authors.

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Authors' contributions

WK: Conception, design of work, acquisition of data, analysis and interpretation of data and manuscript writing. CM: Acquisition of data, analysis and interpretation of data and manuscript writing. HN: Acquisition of data and manuscript writing. PN: Conception, design of work, analysis and interpretation of data and manuscript writing. DM: Interpretation of data and manuscript writing. EM: Design of work, interpretation of data and manuscript writing. RFM: Design of work, acquisition of data, analysis and interpretation of data and manuscript writing. EK: Conception, design of work, acquisition of data, analysis and interpretation of data and manuscript writing.

Ethical approval and consent to participate

All methods in this study were carried out in accordance with relevant guidelines and regulations or Declaration of Helsinki.

The ethical clearance was sought from the MUHAS institutional review board ethical committee under the director of research and publication (MUHAS-REC-10-2021-869). In addition to ethical clearance, permission to collect data was requested from the respective facility management. Informed consent was obtained from the participants prior to data collection. Confidentiality was observed using codes during data collection and analysis.

Availability of data and materials

The data sets used and/or analysed during the current study are available from the corresponding author on reasonable request.



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