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Prevalence and Trend of Oral and Maxillofacial Injuries among Patients Attended at Mbeya Zonal Referral Hospital, Tanzania: A four - years retrospective study

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Abstract

Background: Oral and maxillofacial injuries pose a significant public health burden, but data on their patterns and prevalence is lacking in many developing countries like Tanzania. This study aimed to establish baseline data on these injuries' prevalence, patterns, and associated factors among Mbeya Zonal Referral Hospital (MZRH) patients.
Methods: A retrospective assessment of electronic medical records was conducted for all patients presenting with oral and maxillofacial trauma at MZRH between January 2019 and December 2022. Data on demographics, injury types, and admission status were extracted. Descriptive statistics and logistic regression models were used for analysis.
Results: Of 608 patients, 82.9% were males, and the median age was 28. Fractures of the mandible (53%) were most common, followed by malar/maxillary fractures (34%) and soft tissue injuries (12%). Malar/maxillary fractures had the highest odds of admission. Males had 1.84 times higher odds of malar/maxillary fractures than females. The 0-17 age group had higher odds of soft tissue injuries than older ages. Patients aged 18-34 years had twice the odds of mandibular fractures versus the youngest group.
Conclusion: Oral and maxillofacial injuries predominantly affected young adult males in this region. Mandibular fractures were most common, but malar/maxillary fractures required more admission. Age and gender were associated with anatomical patterns of injuries. The findings highlight the need for preventive strategies and management protocols tailored to regional epidemiology.

Keywords: Oral and maxillofacial injuries, mandibular fractures, malar and maxillary fractures, soft tissue injuries, retrospective study, Tanzania

Introduction

Oral and maxillofacial trauma can be defined as any physical injuries of the orofacial soft tissues, underlying facial bones, and teeth within the oral and maxillofacial region. These injuries can lead to orofacial deformities and malfunctions, which may have economic, health, and emotional implications.

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(Mitchener & Canham-Chervak, 2010). According to WHO, oral and maxillofacial trauma poses a severe public health problem, and reliable data on its frequency and severity are still lacking in most countries, particularly in developing countries (Petersen, 2004). Due to its anatomical location and structure, the craniofacial region is more vulnerable to traumatic injury than other body parts (Obimakinde et al., 2012). Most of the studies that looked at the gender distribution found that males were more likely to sustain orofacial injuries compared to females. Two studies done in Tanzania had similar findings (Obimakinde et al., 2012)(Deogratius et al., 2006)(Majambo et al., 2013)(Owibingire & Sohal, 2018). Orofacial injuries have repeatedly been found to be more common among the younger population compared to the older ones. A study done in Rwanda found that the overall prevalence of oral and maxillofacial injuries was 16%, with most (53.8%) of the patients belonging to the 21-30 age group (Majambo et al., 2013). In another study done in Uganda, the same age group (21-30 years) was the most commonly affected. (Deogratius et al., 2006).

Mandibular fractures are more common than maxillary fractures when assessing the anatomical distribution of these injuries. A study in the United Arab Emirates revealed that mandibular fractures were four times more frequent than maxillary fractures (Ahmed et al., 2004). Also, the same study found that the distribution of maxillary fractures was mostly Le-Fort I (66.7 %), followed by Le Fort II (29.4%), Le Fort III (10.7%), and dentoalveolar fractures 49% (Ahmed et al., 2004). Another study done in Tanzania reported that mandibular fractures occurred more frequently (71%) than maxillary fractures (Owibingire & Sohal, 2018). Similarly, in Uganda, it was found that mandibular fractures were the most common injuries, which accounted for 66% of all maxillofacial fractures (Kamulegeya et al., 2009).

The most common causes of oral and maxillofacial injuries include motor traffic accidents, assaults (including gunshots), sports injuries, falls, chemical exposures, thermal burns or animal bites, and interpersonal violence. Studies done in developing countries have indicated that motor traffic accidents are the most common causes of oral and maxillofacial trauma (Alvi et al., 2003)(Majambo et al., 2013)(Ahmed et al., 2004). These etiological factors have been shown to vary in different countries or within the same country depending on factors such as socio-economic, cultural, and environmental conditions (Adeyemo et al., 2005). In a systematic review study, falling was found to be the most important cause of dental trauma in children and adolescents (Azami-Aghdash et al., 2015). This was similar to other studies done elsewhere (Gupta et al., 2011)(Ravishankar et al. N, n.d.)(Zhou et al., 2013). One study done in Tanzania found that the most (88%) victims involved in motorcycle accidents were the riders of motorcycles (Owibingire & Sohal, 2018). Also, another study done in the same country showed that the causes of maxillofacial fractures varied from assault (57.6%), falls (19.7%), motor traffic accidents (13.7%), and sports (8%) (Deogratius et al., 2006). The diverse variability in reported causes and prevalence of oral maxillofacial injuries is due to various contributing factors such as the sex, age, environment, and socio-economic status of the studied individuals.

In Tanzania, few studies have been conducted, mainly in Dar es Salaam, to determine the patterns of oral and maxillofacial injuries. So far, there is no established data on the prevalence and patterns of oral and maxillofacial injuries at Mbeya Zonal Referral Hospital (MZRH), which is a tertiary-level hospital that receives patients from more than seven regions of the Southern highlands zone and neighbouring countries. Recent observations at MZRH showed an increasing trend of oral and maxillofacial trauma related to motorcycle accidents, similar to reports from several studies done worldwide (Agbor et al., 2014)(Gabriella Pacheco da Silva et al., 2015)(Khanbhai & Lutomia, 2012)(Yamamoto et al., 2014). This study aimed to establish baseline data on the prevalence, patterns, and factors associated with oral and maxillofacial injuries among MZRH patients. This information will equip hospital management and healthcare providers with an understanding of the burden of these injuries and help them plan to manage these patients appropriately. These may subsequently translate into reduced morbidities and mortalities, improving the victim's quality of life.

Methods

Study design

We conducted a retrospective cross-sectional analysis of electronic records for patients who presented at the dental department of Mbeya Zonal Referral Hospital between January 1st, 2019, and December 31st, 2022.

Data source, definition, and variables

To estimate the burden of oral and maxillofacial injuries during the study period, we calculated the proportion of patients that presented with these injuries among all patients that presented for management of any conditions at the dental department. Details on the types of oral and maxillofacial injuries were extracted from electronic medical records (EMR) according to the ICD 10 diagnostic codes system. Demographic information collected included age, sex, admission status, and health care payment scheme. The patients' ages were stratified into one of the following subgroups: less or equal to 17 years, 18-34 years, 35-59 years, and more than 60 years old.

Data Analysis

Data was analyzed using STATA statistical software (StataCorp, College Station, TX). Descriptive statistics were calculated; for continuous data, we reported the mean, SD, median, and interquartile range, while for categorical data, we reported the frequency and percentages of all patients. Pearson's chi-squared tests were used to compare the association between categorical variables. Two binary logistic regression models were conducted to estimate the relationship and effect of different predictors of maxillofacial fractures and admission status. The odds ratio was reported at a 95% confidence interval, and a two-sided $P < 0.05$ was considered statistically significant.

Ethical consideration

The study was approved by the Mbeya Medical Research and Ethics Committee (Ref No: SZEC-2439/R.A/V.1/157a). Permission to conduct the study was obtained from the Mbeya Zonal Referral Hospital administration. Confidentiality and privacy of participants' information were observed. Names and other identifying information were not included.

Results

608 patients with all diagnoses of oral and maxillofacial injuries were attended at the Mbeya Zonal Referral Hospital in 4 years. These injuries comprised 3.8% of all diagnoses in the dental department. The majority 504 (82.9%) of the patients were males, and the median age was 28 years IQR (20-37.5). More than half (53.4%) of the patients were aged between 18 and 34. Most, 444 (73%) attended as outpatients, and about three-quarters (453) of all the patients paid out of their pockets rather than through insurance schemes.

Table 1: Demographic characteristics of the patients with oral and maxillofacial injuries attended at Mbeya zonal referral hospital (n=608)

Characteristic		Frequency (%)
Gender	Male	504 (82.9)
	Female	104 (17.1)
Age in years	Median (IQR)	28 (20 -37.5)
Age group	0 – 17	91 (15.0)
	18 – 34	325 (53.4)
	35 – 59	177 (29.1)
	≥ 60	15 (2.5)
Admission status	Admitted	164 (27.0)
	Outpatient	444 (73.0)
Payment scheme	Cash	453 (74.5)
	Health insurance	148 (24.3)
	Other	7 (1.2)

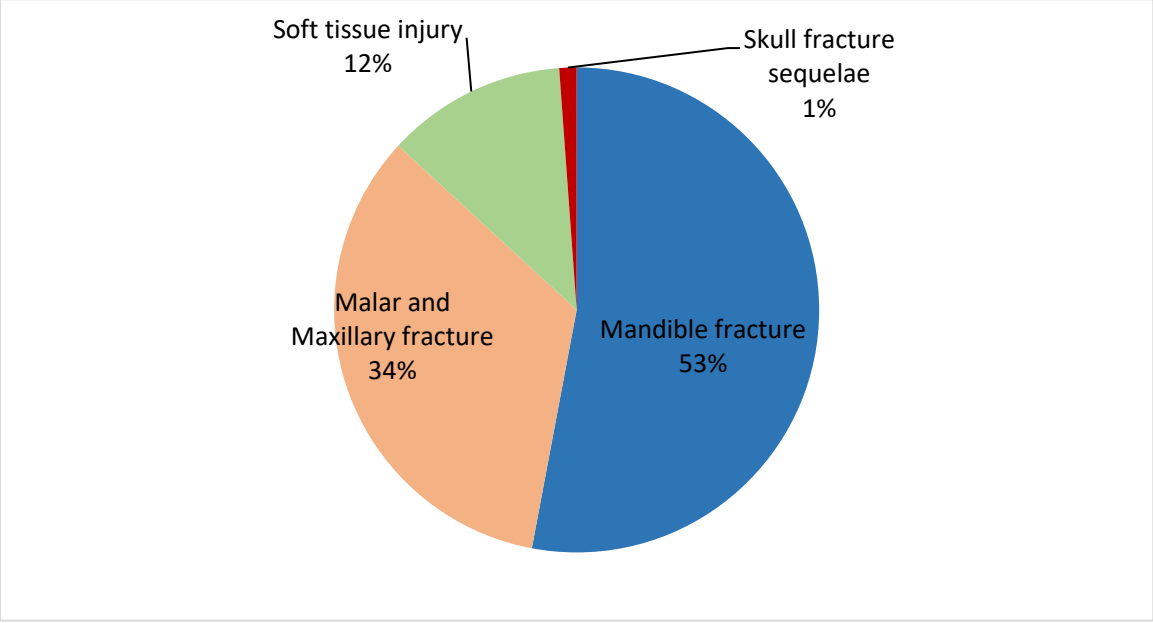

Figure 1: Distribution of the types of oral and maxillofacial injuries sustained by patients who sought treatment at MZRH between 2019 - 2022

The most commonly encountered oral and maxillofacial injuries were fractures of the mandible 322 (53%), followed by 207(34%) that had malar and maxillary bone fractures and twelve percent (73) that had a soft tissue injury (Figure 1).

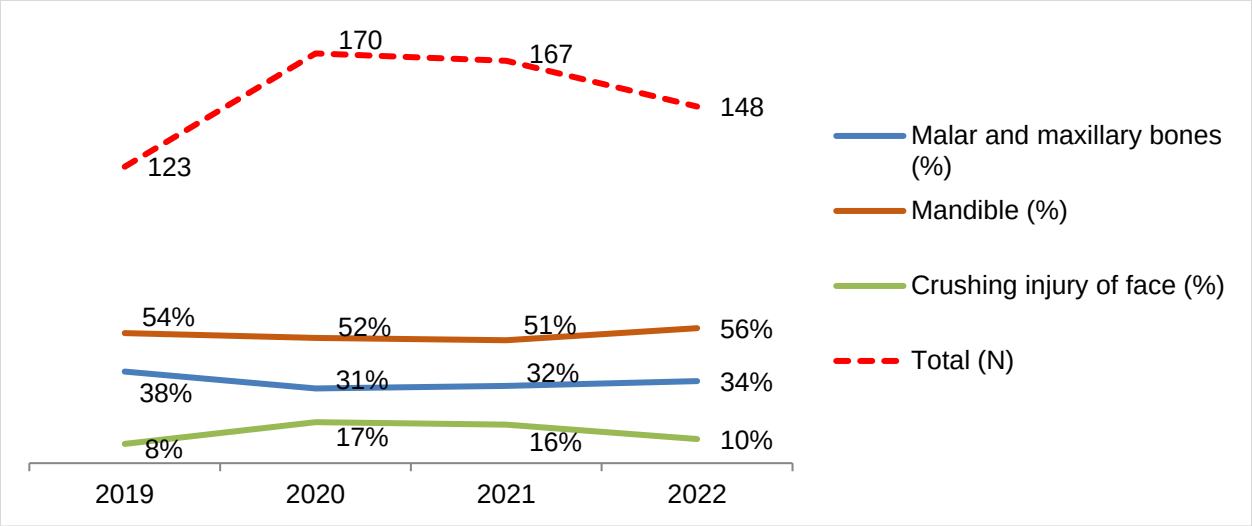

Figure 2: Trends of oral and maxillofacial injuries over the years at MZRH hospital

For the past four years, MZRH has attended more patients with mandibular fractures than other maxillofacial fractures. The majority of 337 (55.4%) patients with oral and maxillofacial injuries were attended at MZRH during the years 2020-2021, and almost an equal number of patients with oral and maxillofacial injuries were attended at this period (Figure 2). After adjusting for gender, age was associated with the odds of malar and maxillary fractures. Those aged 18-34, 35-59, and above 60 years had 2.12, 2.65, and 3.87 times the odds for malar and maxillary fractures compared to those aged 0-17. Males had 1.84 times the odds of malar and maxillary fractures compared to females CI (1.00-3.38). Those aged 18-34, 35-59, and above 60 years had 75%, 41%, and 85% lower odds for soft tissue injury, respectively. Male patients had 40% lower odds for soft tissue injuries than female patients (CI 0.38-0.95). Patients aged 18-34 years had twice the odds of mandibular fractures compared to those aged 0-17 years. There was no evidence of an association between gender and the odds of sustaining mandibular fractures.

Table 2: Multivariable logistic regression showing an association between demographic factors and anatomical types of maxillofacial fractures

Characteristics	Total N (%)	Type of fracture AOR (95% CI)		
		Malar and maxillary	Mandible	Soft tissue injury
Age group				
0-17	92(15.1)	Ref	Ref	Ref
18-34	326(53.6)	2.12(1.04 – 4.34)	2.24(1.38– 3.63)	0.25(0.15 – 0.42)
35-59	175(28.8)	2.65(1.26 – 5.58)	0.97(0.58 – 1.65)	0.59(0.35 – 0.99)
60 and above	15(2.5)	3.87(1.09 – 13.7)	1.84(0.61 – 5.53)	0.15(0.3 – 0.72)
Gender				
Female	104(17.1)	Ref	Ref	Ref
Male	504(82.9)	1.84(1.00 – 3.38)	1.08(0.70 – 1.68)	0.60(0.38 – 0.95)

After adjusting for the patient's health insurance status, age, and gender, there was strong evidence of an association between admission status and oral and maxillofacial injuries. Patients who sustained mandibular fractures and soft tissue injuries had 48% and 79% lower odds, respectively, of being admitted compared to those with malar and maxillary fractures.

Table 3: Multivariable logistic regression showing the association between oral and maxillofacial injuries and admission status

	Admission status			
	Admitted	Not Admitted	AOR (95% of CI)	P-value
Type of fracture				
Malar and maxillary bones fractures	51(38.4)	82(61.6)	*Ref*	
Fracture of mandible	74(24.7)	225(75.3)	0.52(0.33 – 0.82)	0.004
Soft tissue injury	21(11.9)	155(88.1)	0.21(0.12 – 0.39)	<0.001

Adjusted for health insurance status, age and sex

Discussion

Of all the dental diagnoses made at Mbeya Zonal Referral Hospital, oral and maxillofacial injuries accounted for 3.8%, higher than the (2%) national proportion. *Ministry of Health (MoH), 2023, Tanzania "District Health Information System (DHIS 2)" (Unpublished data).* This could be explained by the fact that Mbeya Zonal Referral Hospital is a zonal tertiary referral hospital where almost all oral and maxillofacial trauma patients are referred from all facilities in the Southern Highland regions. The fact that males (82.9%) were more affected than women in this study could be explained by the difference in socio-economic activities, which make men more mobile and thus vulnerable to such injuries since men use motorcycles and motor vehicles more commonly than women. Also, more men are involved in physical activities such as building, road works, and mining than women, which increases their exposure to accidents leading to physical injuries. Similar findings have been reported in other studies (Azami-Aghdash et al., 2015)(Kamulegeya et al., 2009)(Majambo et al., 2013)(Owibingire & Sohal, 2018)(Park et al., 2015). In line with this, the male patients in this study showed higher odds of malar and maxillary fractures than were females, which was similar to the study done in Romania (Juncar et al., 2021).

This study has shown that 325 (53.4%) individuals who presented with oral and maxillofacial injuries were aged 18 – 34 years. These results concurred with studies done in Rwanda (Kamulegeya et al., 2009) and Uganda (Deogratius et al., 2006), where individuals aged 21-30 were mainly affected, and also in Korea, where the 10 to 39 years age group was mostly affected (Park et al., 2015). Such findings may be explained by the more common involvement in physical and social activities in this age group, which increases their chances of being exposed to oral and maxillofacial trauma. The mandible (53%) was the most commonly affected anatomical part, which echoes findings from studies done elsewhere. A study done at Muhimbili National Hospital showed that mandibular fractures were four times more frequent than maxillary fractures (Owibingire & Sohal, 2018). Another study done in Uganda also showed the predominance of mandibular fractures compared to other parts of the oral and maxillofacial region (Deogratius et al., 2006). This could be explained by the anatomical protrusion of the mandible compared to other parts of the face. However, our findings differed from a study done

in Korea, which found that the malar and maxillary bones (41.9%) were the most commonly affected regions. In comparison, the mandible fractures accounted for 33% (Singaram et al., 2016).

Surprisingly, this study revealed a decreased occurrence of oral and maxillofacial trauma in 2022 compared to 2020 and 2021. Studies done elsewhere have shown increasing trends of oral and maxillofacial trauma over the years (Park et al., 2015)(Plawecki et al., 2017). This decreased trend in this study could be due to the government's decision to employ many dentists and equip most of the dental clinics in Regional Referral Hospitals in the country. This has probably enabled facilities to manage most trauma patients who would otherwise be referred to the Mbeya zonal referral hospital.

However less in number, patients with malar and maxillary fractures had the highest admission than those with mandibular fractures. This probably could be due to the anatomical structures and proximity of fractures to the vital aerodigestive organs. The current study also demonstrated that the youngest age group (0-17 years) and female patients had higher odds for soft tissue injury compared to older ones and males respectively, which was similar to what was observed in the studies done in Iraq (Awlla et al., 2013) and Nigeria (Osaghae IP, Eriamiator CO, 2019). This could be explained by the fact that females and young individuals are usually not exposed to outdoor environments much during their daily activities; hence, they are less likely to come across higher-impact accidents, which could lead them to sustain skeletal fractures. Most of the low-impact accidents result in soft tissue injuries. However, this finding (12%) by the current study differed from other studies done in Tanzania (Sohal et al., 2022) and Columbia (Contreras Ochoa et al., 2019).

This study involved a retrospective assessment of routine patient records related to oral and maxillofacial trauma, and thus, establishing the causal inferences, clinical characteristics, and management was complex. This calls for and necessitates conducting another prospective study to establish the common causes of oral and maxillofacial trauma in our locality. Also, the electronic medical record with the ICD 10 version could not classify the oral and maxillofacial fractures further according to the patterns of fractures. The information from this study portrays the snap-shot of oral and maxillofacial trauma among patients at MZRH and may thus be an excellent basis for improvement in both planning and management of oral and maxillofacial trauma patients

Conclusion

This retrospective study provides important insights into the epidemiological patterns and risk factors associated with oral and maxillofacial injuries among patients attending a major referral hospital in the Southern Highlands of Tanzania. The findings highlight that these injuries predominantly affect the younger population, with a striking male preponderance. Mandibular fractures emerged as the most common type of injury. However, malar and maxillary fractures were associated with higher odds of hospital admission, likely due to their proximity to vital anatomical structures and the complexity involved in their management. The observed associations between age, gender, and specific injury patterns underscore the role of demographic and behavioural risk factors in influencing trauma mechanisms and injury severity. Young adults, particularly males, may be more prone to high-risk activities or occupations that increase their vulnerability to maxillofacial trauma. Preventive strategies tailored to these at-risk populations could be crucial in mitigating the burden of such injuries. Furthermore, the insights gained from this study can inform the development of comprehensive management protocols and resource allocation for oral and maxillofacial trauma care within the region. Prospective studies are warranted to elucidate further the etiological factors and clinical characteristics of these injuries to optimize preventive and therapeutic interventions.

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Author contributions

MLB conceived the study. MLB, AFL, WO, and BK were involved in designing, analyzing, and interpreting the data and developing the first draft of the manuscript. ZM assisted in data analysis. All co-authors contributed to subsequent revisions. All authors read and approved the final manuscript.

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Conflict of interest

The authors declare that they have no competing financial and non-financial interests.

Availability of data and material

All data generated or analysed during this study is included in this published article.

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Education and Fertility preference among women in Uganda

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Abstract
Background: Women's education is pivotal in addressing elevated fertility rates, particularly in developing nations. Despite declining fertility rates, Uganda sustains a high fertility rate of 6.2, surpassing the sub-Saharan Africa regional average of 4.6. This heightened fertility poses a significant obstacle to Uganda's sustainable development goals. This study investigates the relationship between female education and fertility preference among Ugandan women in 2006, 2011 and 2016.
Methods: The study used data from the Uganda Demographic and Health Survey for 2006, 2011, and 2016, with a sample of 6,216, 5,205, and 10,741 women, respectively. A multivariable logistic model was utilized to establish the relationship between female education and fertility preference.
Results: Findings revealed the existence of an inverse relationship between female education and fertility preference over the years 2006, 2011 and 2016 (Primary OR=0.67, 95% CI 0.53-0.84; OR=0.58, 95% CI 0.45-0.74; OR=0.70, 95% CI 0.57-086) respectively. For secondary or more education, OR =0.43, 95% CI 0.22-0.87; OR=0.56, 95%CI 0.34-0.92, OR =0.80, 95% CI 0.56-1.14) respectively. Fertility preference is inversely related to the mother's income status, age and number of living children. Fertility preference is positively associated with the ideal number of children and contraceptive use.
Conclusion: This study has shown that female education helps to manage women's fertility preferences. Educated women can access information and get better employment to decide on the desired family size. The study advocates for the continued education of females to empower them in actively shaping their desired family size. It is recommended that government efforts to strengthen universal access to education at both primary and secondary levels. To cater for those outside the school setting, we recommend the strengthening of programmes on sexual reproductive health that should include an open discussion on the ideal family size.

Keywords: total fertility rate, female education, fertility preference, reproductive health

Introduction

Many development experts suggest enhancing female education is crucial in addressing elevated fertility rates, particularly in developing nations. Increased educational attainment equips women with empowerment and the ability to assert their rights (Bola, 2015). Multiple research studies have underscored a consistent inverse correlation between female education and fertility rates (Woldeamanuel et al., 2023; Monari et al., 2022; Muluneh & Habitu, 2022; Muluneh & Yikeber, 2021). The underlying mechanism linking female education and fertility operates in a manner that, as women attain higher educational levels, various factors influencing fertility experience adverse effects.

These factors encompass delaying the age of marriage, postponing the onset of first childbirth, and an increased adoption of contraceptive methods (United Nations Department of Economic and Social Affairs, 2020).

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In Sub-Saharan Africa, the fertility rate decreased marginally from 6.3 to 4.6 in 2019, while the global trend showed a reduction in fertility from 3.2 live births per woman in 1990 to 2.5 in 2019. In sub-Saharan Africa, Uganda has one of the highest fertility rates; it may take up to 34 years for the rate to decline from 6.0 (1995) to 4.0 (2029), from 3.1 (2050) to 2.1 live births per woman (2100). Uganda's estimated fertility rate is 6.2 (Kabagenyi et al., 2015). The likelihood of achieving the 2030 Agenda for Sustainable Development has been challenged by the expected high rates of female fertility in sub-Saharan Africa (United Nations Department of Economics and Social Affairs, 2020). In many sub-Saharan African nations, the implementation of universal primary education has increased the use of contraceptives by women who are of reproductive age and is assisting in lowering the region's high fertility rates.

The 2018 World Development Report offers significant insights into women's education, where less than two-thirds of girls in developing nations complete their primary education. Neglecting the girl child leads to their disempowerment, resulting in substantial losses to a country's human capital and, consequently, its national wealth. Failing to invest in girls' education represents a missed opportunity for countries seeking to harness the demographic dividend (Wodon, Montenegro, Nguyen, & Onagoruwa, 2018). The more empowered a woman is, the more likely she is to prefer using contraceptives (Sofia, Deborah Constant, Silvia Fraga, & Jane Harries, 2022).

In a study on the relationship between female education, labour force participation, and fertility in Uganda, Bbaale (2014) uncovered that female education, particularly at the secondary and post-secondary levels, leads to reduced fertility and increased female participation in formal employment. This view is echoed by (Kasarda, 1979). Numerous development economists link education to improvements in an individual's socio-economic status, which is closely associated with an enhanced quality of life and a preference for smaller family sizes (Muluneh & Habitu, 2022; Muluneh & Yikeber, 2021; Ariho & Nzabona, 2019). This study explores the relationship between individuals who do not progress to higher education levels or those who have completed a specific primary education level and their potential fertility preferences.

The literature identifies several factors that contribute to declining fertility rates. These factors include delayed marriage (Kabagenyi et al., 2015), increased education, improved access to family planning services (Abigail, 2020; Ariho & Nzabona, 2019; Kudesia, et al., 2018), and changing characteristics of women in the reproductive age (Ariho, Kabagenyi, & Nzabona, 2018). Pradhan (2016) argues that education empowers women to decide on the desired family size better. By pursuing more education, marriage is postponed, opportunities for higher earnings are reaped, and women are empowered to better decide on the desired family size (DeCicca & Krashinsky, 2016). Similar views are held by (Abigail, 2020; Kebede, 2019; Kim, 2016; Zuzanna, 2015). Open communication between husband and wife on the desired family is essential (Sarnak & Becker, 2022; Oni, David , & Oluwaseyi , 2021; Kasarda, 1979).

Factors contributing to women's empowerment, including education, employment status, freedom of movement, and decision-making power, were negatively associated with women's fertility (Shanjida et al. Haque, 2023). During periods of economic uncertainty, such as the COVID-19 pandemic, women are more likely to delay pregnancy, especially for their first birth (Ayşe et al. Karaşahin, 2023). Ayşe et al. (2023) observed that harsh living conditions positively affect women's decision to delay pregnancy.

The demographic structure of a country, particularly in terms of age distribution and residence patterns, positively impacts its Gross Domestic Product (GDP). In contrast, annual population growth and child mortality rates under five years harm per capita GDP (Kizza, Amonya, & Kigosa, 2020). A study conducted by Bola (2015) in Nigeria revealed that women who had their first child between the ages of 15 and 19 were less likely to have more children than those who had their first child at 14 or younger. Muluneh & Habitu (2022) found a strong inclination towards larger families among women with lower levels of education, those residing in rural areas, women without formal employment, and women from lower socioeconomic backgrounds. This is

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supported by (Agbaglo, et al., 2022; Kebede, 2019; Kasarda, 1979). Additionally, factors such as women's age, religious beliefs, their husband's occupation, age at first marriage, and contraceptive use were significantly linked to women's desire for children.

These findings are consistent with the work of Woldeamanuel et al. (2023), Monari, Orwa, and Agwanda (2022), and Muluneh and Yikeber (2021). The literature underscores those wealthier countries, such as the USA and countries in Europe, characterized by higher per capita GDP, tend to experience lower fertility rates. It is also evident from the literature that a country's education levels significantly influence its demographic structure. We find no literature explicitly focusing on the relationship between education and women's fertility preference with specific reference to Uganda.

Nations employ diverse strategies to address high fertility rates, especially when they risk exacerbating the country's dependency ratio. In numerous developing countries, such as Uganda, family planning is advocated as a pivotal measure to mitigate elevated fertility levels. Access to reliable information, facilitated by education, equips individuals to make informed decisions about family size (World Bank, 2021; Kasarda, 1979). We contend that acquiring at least primary education enables a broader understanding of family planning messages, subsequently increasing the utilization of family planning services and reducing a country's total fertility rates. It is posited that as a woman attains higher levels of education, her inclination to have more children diminishes (Woldeamanuel et al., 2023; Monari et al., 2022; Muluneh & Habitu, 2022).

While global fertility rates declined from 3.2 live births per woman in 1990 to 2.5 in 2019, Sub-Saharan Africa's fertility rate slightly decreased from 6.3 to 4.6 in 2019. The contributors to the high fertility rate in Uganda include residence in rural areas, lack of contraceptives and misconceptions about contraceptives, the patriarchal society where men make the decisions on children, the intention to have children, and low levels of schooling (Kwabaho et al., 2023; Nakkazi, 2022) and the values attached to childbearing. Other contributors include child marriage, with 34% of women reported to be married by the age of 15 (UNICEF, 2019) and the associated teenage pregnancy rate at 25% since 2016 (UDHS 2016).

Despite a gradual decline in fertility rates, Uganda maintains one of the region's highest rates at 6.2 (Kabagenyi et al., 2015). If left uncontrolled, this high fertility rate could significantly challenge Uganda's pursuit of sustainable development goals. This study investigated the relationship between female education and fertility preference among Ugandan women in 2006, 2011 and 2016. Specifically, our guiding research questions were: 1) What is the relationship between women's education and the desire for a child 2) What other factors have a significant effect on a woman’s desire for a child among women in Uganda?

Methods

Study setting and design

Uganda, situated in East Africa and intersecting the equator, is a landlocked nation bordered by Kenya to the east, Tanzania to the south, Rwanda to the southwest, the Democratic Republic of Congo to the west, and South Sudan to the north. Covering an expanse of 241,039 square kilometres, the country is subdivided into 112 districts. Uganda operates under a decentralized governance system, with various functions delegated to local governments. Despite decentralization, the central government remains responsible for policy formulation, setting and overseeing standards, and ensuring national security (UBOS and ICF, 2017). This study utilises three most recent Uganda Demographic and Health Surveys (UDHS) from 2006-2016.

Data Source and Study Population

The study combines secondary data from the 2006, 2011, and 2016 Uganda Demographic and Health Surveys (UDHS). The analysis reveals a consistent approach for data collection across the

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survey years. All surveys aimed at providing comprehensive estimates at the national level and for urban and rural areas, adhering to a two-stage sampling process. In all three surveys, the initial stage involved selecting clusters or enumeration areas (EAs) from previous national household surveys and linking samples for comparability.

The subsequent stage included a random selection of households from complete listings. While the number of households varied (9,864 households in 2006, 10,086 households in 2011 and 20,880 households in 2016), selecting a predetermined number from each cluster remained a common element. Interviews for each selected household consistently included men aged 15-54 and women aged 15-49. All women aged 15-49 who were permanent residents or visitors the night before the survey were eligible for the interview. About 8,531, 8,674 and 18506 women were successfully interviewed in 2006, 2011 and 2016, respectively (UBOS and Macro, 2007; UBOS and ICF, 2012 and 2017). After merging the data sets and generating the variables of interest, the study sample was 6,216, 5,205 and 10,741 women for the respective surveys.

Outcome variable: Our outcome variable is "fertility preference", which signifies the respondent's desire for more children. The response categories were "have another", "no more", "undecided", "sterilized" or "declared infecund". The Fertility preference variable was constructed as a binary outcome variable from two responses, with "have another" coded as 1 and "no more" coded as 0; the other responses were dropped to avoid a biased estimate of the outcome variable.

Exposure variable: Mothers' education is our study's primary variable of interest. The variable originally had four categories—mothers with no education, primary, secondary, and higher. We, however, keep only categories for no education, primary and secondary or higher. This is because the higher category had relatively fewer observations. To promote education, the government launched the Universal Primary Education (UPE) and Universal Secondary Education (USE) programmes (Nakkazi, 2022). The Uganda Vision 2040 and NDP III focus on girl child education. The Uganda Government is committed to the promotion of female education through programs and strategies that include the National Strategy for Girls' Education (MOES, 2013), establishing a secondary school in each sub-county, the Universal Primary Education Effective School Health (FRESH), the Education Plus and Promoting Equality in African Schools (PEAS). Other policies include The Second Chance Education Program, the policy to welcome previously pregnant mothers back into school and emphasis on "gender-sensitive educational infrastructure" in schools.

Confounding variables. The study uses other control variables in the estimation based on literature (Woldeamanuel et al., 2023; Monari et al., 2022; Muluneh & Habitu, 2022). These include the respondent's place of residence, contraceptive use, religion, occupation, age at first birth, wealth index, ideal number of children, number of living children, and the respondent's age. In Africa, the production of children is considered a blessing, and the production of a son is highly valued. Large families earn respect and prestige in society, and polygamous relationships are protected.

Most African women, on average, desire not to have less than five children, and in the process, end up producing more in search of a son, security for old age or the belief that one cannot stop producing twins (Kwabaho et al., 2023; Kabagenyi et al., 2016). Practices like bride wealth favour the production of more children as the decision on how many to produce is primarily a preserve of the men. The traditional gendered roles favour the education of the male child as opposed to the female child, who is often condemned to perform household chores (Kabagenyi et al.). In addition, religious values such as the command to produce and fill the world tend to make people apathetic to family planning. Yet other religions seem to favour child marriage, like the African traditional religion and Islam (Kabagenyi et al., 2016). This is despite the legal age of sexual consent, which is set at 18 years (Uganda Government, 2022). We employ a multivariate logistic model in the analysis and estimate the odds ratios with their respective confidence intervals.

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Model Specification

We apply a multiple logistic regression given that our outcome variable is binary, and the exposure and majority of the confounders are dummies. In this model, we estimate the odds that a woman desires more children, given as $P(y = 1)$ and $P(y = 0)$ for no more children. We associate the desire for more children with a high fertility preference; otherwise, it is low. We estimate the following results.

Results

In this section, we present the descriptive statistics in Table 1 for continuous variables, Table 2 for categorical variables, and Table 3 for the odds ratio.

Table 1: Descriptives for continuous variables

Dependent Variable	2006		2011		2016	
Fertility	**Frequency**	**Per cent**	**Frequency**	**Per cent**	**Frequency**	**Per cent**
Don't desire a child	2,757	44.4	2,180	41.9	4,140	38.5
Desire a child	3,459	55.6	3,025	58.1	6,601	61.5
Total	**6,216**		**5,205**		**10,741**	
Independent Variables						
	0	1	0	1	0	1
Current mother's age						
Obs	2,757	3,459	2,180	3,025	4,140	6,601
Mean	33	26	33	26	33	26
Std.Dev	6	5	6	5	6	5
Min	17	15	18	15	16	15
Max	49	49	49	49	49	49
Ideal No. of children						
Obs	2,757	3,459	2,180	3,025	4,140	6,601
Mean	5	5	5	5	5	5
Std.Dev	1	1	1	1	1	1
Min	0	0	0	0	0	0
Max	7	7	7	7	7	7
No. of living children						
Obs	2,757	3,459	2,180	3,025	4,140	6,601
Mean	6	3	5	3	5	3
Std.Dev	2	2	2	2	2	2
Min	1	1	1	1	1	1
Max	14	10	14	11	14	11

Table 1 shows that the percentage of women who desire a child has increased since 2006. The results indicate an increase from 55.6% in 2006 to 58.1% in 2011 and 61.5% in 2016. This trend seems to align with the literature that Uganda still has one of the highest fertility rates in SSA (United Nations Department of Economics and Social Affairs, 2020; Kabagenyi, Reid, Rutaremwa, Atuyambe, & Ntozi, 2015). The mean age for women who desire not to have a child has remained stable at 33 years over the period studied, while the mean age for women who desire to have a child has also remained stable at 26 years for the period under study. The ideal number of children is preferred for both those who desire a child and those who do not, and has remained stable at five children over the years. This supports earlier findings by (Kabagenyi et al., 2015) that despite

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the noticeable decline in the fertility rate in Uganda, the fertility rate remains. The findings suggest that most women in Uganda desire to have, on average, five children and a maximum of around seven children, which somehow falls back to the 6.2 fertility rate revealed in (Kabagenyi et al.,2015). The women who had a higher number of living children, from six in 2006 to five in both 2011 and 2016, expressed no desire for a child, while those with a smaller number of living children were revealed to be three (3) throughout the study period expressed the desire to have a child. This is logical for a person with fewer children to desire more than one with more children.

Table 2: Descriptives for categorical variables

Variable	2006		2011		2016	
	0	1	0	1	0	1
Education level						
No education	706	835(54%)	431	558(56%)	738	663(47%)
Primary Education	1,754	2178(55%)	1,388	1717(55%)	2,718	4120(60%)
Secondary Education and more	297	446(60%)	361	750(68%)	684	1818(73%)
Contraceptive use: Not using	2,200	2847(56%)	1,586	2268(58%)	2,683	4122(61%)
Using	557	612(52%)	594	757(56%)	1,457	2479(63%)
Birth Age						
Birth age-below 20	136	771(85%)	95	626(87%)	168	1507(90%)
Birth age-20-34	1,887	2534(57%)	1,504	2278(60%)	2,792	4870(64%)
Birth age-35-49	734	154(17%)	581	121(17%)	1,180	224(16%)
Wealth						
Poor	940	1454(61%)	889	1343(60%)	1648	2617(61%)
Middle Income	948	1162(55%)	695	848(55%)	1305	1983(60%)
Rich	869	843(49%)	596	834(58%)	1187	2001(63%)
Residence						
Rural	2,526	3217(56%)	1,783	2478(58%)	3,530	5493(61%)
Urban	231	242(51%)	397	547(58%)	610	1108(64%)
Religion						
Anglican	1,263	1654(57%)	934	1416(60%)	1,288	2036(61%)
Catholic	1,027	1131(52%)	735	844(53%)	1,705	2764(62%)
Muslims	267	377(59%)	245	376(61%)	467	817(64%)
SDA	144	230(61%)	234	354(60%)	64	95(60%)
Others	56	67(54%)	32	35(52%)	616	889(59%)
Occupation						
Profession/tech/managerial/skilled	198	262(60%)	92	168(65%)	878	1612(65%)
Clerical/sales/services	303	349(54)	551	835(60%)	559	1082(66%)
Agriculture/household/unskilled	2,256	2848(56%)	1537	2022(57%)	2703	3907(59%)
Total Sample	**6216**		**5205**		**10741**	

The desire to have a child among those not using contraceptives has been increasing over the years from 56% in 2006, 58% in 2011 and 61% in 2016. This is not very different from the desire among women who are currently using contraceptives. The only difference is in the magnitude where the desire to have a child among those not using contraceptives was slightly higher than those using contraceptives for the years 2006 and 2011. In 2016, the desire to have a child was higher among women using contraceptives (63%) compared to those not using contraceptives (61%). This may be explained by the value attached to the bearing of children in the African context.

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The desire for a child increases the higher the level of education one attains, and this is consistent over the study period. In 2006, the desire for a child of those with no education was 54%, those with primary education 55%, while for those with secondary or more education it was 60%. In 2011, the desire for a child of those without education was 56%; for those with primary education, 55%, and for those with secondary or more education, 68%. In 2016, the desire for a child of those without education was 47%; for those with primary education, 60%, and for those with secondary or more education was 73%. This may be explained from the fact that education tends to delay childbirth. So, when people finish schooling at a given level, their desire to have a child increases. She is ageing by the time one finishes secondary or higher education level. She feels more compelled to have a child before catching up with the complexities of childbearing at an ancient age.

The findings revealed that the desire to have a child is greater among those with a birth age below 20 years and very limited among those with a birth age of 35-49%. This result is consistent over the study period. Whereas the desire for a child for the birth age below has been increasing from 2006 at 85%, 2011 at 87% and 2016 at 90%, the desire for a child among those aged between 35 and 49 has remained relatively low at 17% in 2006/2011 and 16% in 2016. This may be explained in two ways: 1) the likelihood that by the age 35-49, one already has a child or 2) the health complications associated with childbearing at an old age. The analysis of the age cohorts in the descriptive statistics has thus revealed that the preference for a child reduces with age.

For 2006 and 2011, the findings revealed that the desire for a child reduces as the person gets richer. The period 2016 posted a slightly mixed picture where the desire for a child for the poor was 61%, fell to 60% for those with primary education and rose to 63% for the rich. This may be so given that as people's income status improves, they tend to feel more capable of raising children. It is also true that often, the rich delay childbirth through long periods of education, and when they complete their studies, they tend to have a higher desire for a child. Similarly, the income levels of society are recorded as improving. This means more people are entering the rich cohort, which explains the rising percentages among the rich desiring a child as the years go by, from 49% in 2006, 58% in 2011 and 63% in 2016.

The desire for a child has increased over the years, irrespective of residence. In rural areas, the desire for a child increased from 56% in 2006 to 58% in 2011 and 61% in 2016. The desire for a child in urban areas has increased from 51% in 2006 to 58% in 2011 and 64% in 2011. Whereas the desire for a child was higher in the rural areas at 56% in 2006 compared to urban areas at 51%, there was equal desire for a child at 58% for both types of residence in 2011. However, in 2016, the desire for a child for urban residents (64%) surpassed that of rural residents (61%). This may not be surprising as development studies indicate that as society grows, people tend to live in rural areas and settle in urban areas.

The desire for a child according to faith is mixed over the study period. In 2006, the desire for a child was highest among the SDA faith (61%), followed by the Muslim faith (59%). In 2011, the desire for a child was highest among Muslims (61%), followed by SDAs and Anglicans (60%). In 2011, the desire for a child was highest among Muslims at 64%, followed by Catholics at 62%. A close analysis shows the desire for a child to be highest among the Muslim faith compared to other faiths.

According to occupation, the desire for a child was highest among those engaged in agricultural services, household chores, and unskilled workers, from 60% in 2006 to 65% in 2011 and 2016. The desire for a child among professionals, though lower than those in agriculture, is steadily increasing, from 54% in 2006 to 60% in 2011 and 66% in 2016. The same trend is evident among those in clerical, sales, and services.

Results of the Odds Ratios

Table 3: Factors influencing the desire for a child among women in Uganda using UBOS data sets 2006,2011 and 2016

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Year	2006	2011	2016
Variable	**OR(95%CI)**	**OR(95%CI)**	**OR(95%CI)**
Current mother's age	0.91(0.89,0.93)**	0.88(0.86,0.90)**	0.88(0.87,0.90)**
The ideal number of children	2.22(0.48,0.54)**	2.07(1.93,2.22)**	2.18(2.07,2.300**
No. of living children	0.51(0.48,0.54)**	0.59(0.55,0.62)**	0.52(0.50,0.55)**
Contraceptive use	1.08(0.91,1.29)	1.39(1.18,1.65)**	1.22(1.10,1.36)**
Education level			
(Ref.No education)			
Primary level	0.67(0.53,0.84)**	0.58(0.45,0.74)***	0.70(0.57,0.86)**
Secondary and above	0.43(0.22,0.87)**	0.56(0.34,0.92)**	0.80(0.56,1.14)
Wealth (Reference poor)			
Middle income	0.67(0.49,0.91)**	0.64(0.41,0.99)*	0.49(0.35,0.70)**
Rich	0.49(0.31,0.78)**	0.63(0.32,1.22)	0.31(0.18,0.52)**
Wealth vs. education level			
(Ref. Poor with no education)			
Middle-income with primary	1.46(1.02,2.10)**	1.63(1.01,2.64)*	2.02(1.38,2.96)**
Middle income with secondary plus	4.13(1.79,9.55)**	2.23(1.10,4.52)**	2.53(1.50,4.27)**
Rich with primary	1.68(1.01,2.80)*	1.69(0.83,3.44)	3.23(1.50,4.27)**
Rich with secondary plus	2.47(1.06,5.75)**	2.99(1.30,6.85)**	3.77(2.03,7.03)**
Residence (Ref. rural)			
Urban	0.86(0.66,1.13)	0.65(0.52,0.82)**	0.94(0.80,1.09)
Birth age			
(Ref.Birth age 35 to 49			
Birth age before 20 years	0.79(0.51,1.23)	0.70(0.43,1.13)	0.75(0.53,1.05)*
Birth age 20 to 34	0.91(0.68,1.22)	0.80(1.06,1.48)	0.87(0.70,1.09)
Religion (Ref. Catholics)			
Anglicans	1.14(0.98,1.32)*	1.25(1.06,1.48)**	1.11(0.98,1.25)
Muslims	1.60(1.27,2.02)**	1.16(0.91,1.47)	1.22(1.02,1.45)**
SDA	1.47(1.10,1.95)**	1.28(1.00,1.64)*	1.05(0.67,1.63)
Others	1.81(1.09,3.00)**	1.09(0.58,2.05)	1.04(0.89,1.22)
Ocupation			
(Ref.Agriculture/household/unskilled)			
Profession/technical/managerial/skilled	1.19(0.91,1.55)	1.02(0.70,1.47)	1.11(0.97,1.26)
Clerical/sales/services	0.91(0.72,1.14)	0.88(0.74,1.05)	1.11(0.95,1.30)
_cons	9.04(4.07,20.08)**	25.52(10.75,60.54)**	26.83(14.26,50.51)**

Standard errors in parentheses ** p<0.05, * p<0.1

The odds of desire for a child reduce as one grows older. In 2006, the desire for the child as one grows older was (OR =0.91, 95% CI 0.89-0.93). In 2011, the OR was (OR =0.86, 95% CI 0.86-0.90), while in 2016, it was (OR=0.88, 95% CI 0.87-090). These results indicate that as a person ages, the odds of desiring a child reduce compared to women slightly in a lower age bracket.

The odds of desiring a child increase with the ideal number of children. The women who prefer a high ideal number of children are more likely to desire a child than those who prefer a lower ideal number. In 2006, women desiring more children were 2.22 (95%CI 0.48-0.54) times more likely to desire a child than those who prefer a lower ideal number of children.

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Women with a higher number of living children have lower odds of desiring a child than women with fewer living children. In 2006, women with more living children were 0.51 times (95%CI 0.48-0.54) less likely to desire a child. In 2011, they were 0.59 times (95%CI 0.55-0.62) less likely to desire a child, and in 2016, they were 0.52 times (95%CI 0.50-0.55) less likely to desire a child than women with fewer living children.

The odds of the desire for a child among women who use contraceptives are higher compared to women who do not use contraceptives. In 2006, the women who use contraceptives were 1.08 times (95%CI 0.91-1.29) more likely to desire a child; in 2011 (OR=1.39, 95%CI 1.18-1.65) and in 2016 (OR=1.22, 95%CI 1.10, 1.36) than women who do not use contraceptives.

The odds of desiring a child reduce the more education one attains. In 2006, those with primary education were 0.67 times less likely to desire a child than those with no education, while those with secondary or more education was even less likely to desire a child compared with those with no education (OR=0.43,95%CI 0.22-0.87). In 2011, those with primary education had a 0.58 lower likelihood of desiring a child than those without education. The rich were 0.56 times less likely to desire a child than the poor. In 2016, the odds of desire for a child among those with primary education was (OR=0.70, 95%CI 0.57-0.86) lower than those with no education, while the odds of those with secondary or more education to desire a child was (OR=0.80, 95%CI 0.56-1.14) lower compared to those with no education. The findings generally reveal that the more education one attains, the lower the likelihood of desiring a child. The gap in desire seems to be lower in 2016 than in 2016 and 2011.

The odds of desiring a child are lower with improvements in one's income status, and this is consistent over the study period. In 2006, those in middle income were (OR=0.67, 95%CI 0.49-0.91) less likely to desire a child compared to the poor, while the rich even had lower odds (OR=0.49, 95% CI 0.31- 0.78) than the middle income. In 2016, it became even more clear that as one's income increases, the likelihood to desire a child lowers (OR=0.49, 95% CI 0.35-0.70) for the middle income and (OR=0.31, 95% CI 0.18-0.52) for the rich compared to the poor.

The interaction between education and wealth over the study period reveals that the odds of the desire for a child are more likely for both women with middle income or rich with some level of education compared to those who are poor with no education. This may be because educated women, who at the same time are well off, tend to feel more capable of taking on motherhood responsibilities.

Apart from 2011, the results revealed no significant difference in the desire for a child according to residence. However, in 2011, the results revealed that the odds of desiring a child for an urban resident were 0.56 times (OR=0.65, 95%CI 0.52, 0.82) lower than for rural residents. In 2016, the results revealed that birth age before 20 years was 0.75 times (95%CI 0.53-1.05) less likely to desire a child than those aged 35 -49.

Fertility preference decreases as the age at first birth increases, with significance observed in 2011. In general, women from faiths other than Catholicism exhibit a higher fertility preference. Between 2006 and 2011, women from the Anglican faith were, on average, 2.7% more likely to express a higher fertility preference than Catholic women. Muslim women had a 6.7% higher preference for fertility in 2006 compared to Catholic women. This trend persisted in 2011 and 2016. Other faiths, such as Pentecostals, Baptists, and Mammon, showed a 9.5% higher preference for fertility in 2006, with varied trends in 2011 and 2016, although these were not statistically significant.

Discussion

This study sought to investigate the factors contributing to the desire for a child among Ugandan women in 2006, 2011 and 2016. A sample of 6216, 5205, and 10,741 women were used as derived from the data sets for the period under study. Two research questions were formulated to guide this investigation. 1) What is the relationship between women's education and the desire for a child

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2) What other factors have a significant effect on a woman's desire for a child among women in Uganda?

What is the relationship between women's education and the desire for a child among women in Uganda? The results indicated that the desire for a child among women over the study period does reduce with one's education level. This means that education is inversely related to the desire for a child. As a woman attains higher levels of education, her desire for a child lowers. The finding aligns with several authors (Woldeamanuel et al., 2023; Monari et al., 2022; Muluneh & Habitu, 2022; United Nations Department of Economics and Social Affairs, 2020). Education is associated with delaying the age at first birth (United Nations Department of Economics and Social Affairs, 2020; DeCicca & Krashinsky, 2016). This implies that when one is still pursuing her education career, the likelihood of desiring a child is generally lower than that of someone not in school. Education also empowers women to decide on when to have a child and to have a child that one is better able to look after (Pradhan, 2016). Women's empowerment through education improves their decision-making power to the desired family size (Shanjida et al., 2023)

Education plays a significant role in raising awareness about contraceptive methods, and a positive relationship between education and contraceptives has been established in various studies (Sofia et al., 2022; Bbaale, 2014). Education raises awareness about reproductive health and lessens the high infant mortality rate associated with poor child-rearing habits. The higher the expected survival rate of children, the less likely the desire for more children will be. Our results have indicated that a woman's number of living children is inversely related to her preference for more children. Education increases the woman's opportunity to access paid employment. Our findings have revealed that the desire for a child reduces as one's income status rises. Contrary to where people in African tradition associated more children with wealth, in modern society, people rarely use children to hedge against poverty. Through education, women access information that enables them to plan for their desired family size (WorldBank, 2021).

What other factors significantly affect a woman's desire for a child among women in Uganda? Several factors, as informed by the literature, were considered, and only those found significant are discussed here. The current age of the woman was found to be significantly related to the desire for a child. The desire for a child lowers with the increase in the mother's age. This result is consistent with research from the United Nations Department of Economics and Social Affairs (2020) and the work of DeCicca and Krashinsky (2016). As women age, they tend to be less inclined to take on the added responsibilities of childcare and support.

The desire for a child increases when the desired number of children is not yet attained. Reducing the desired family size is a prerequisite for fertility decline, as Kebede echoed in 2019. Women with a reasonable number of living children are less likely to desire a child. This is because such women may find it more reasonable to look after the children properly as they already have rather than take on additional responsibilities that come with a new birth.

There is a higher desire for a child among women who use contraceptives. Much as the rationale for contraceptives is to limit childbirth, the intention is more on planning for a desired family as opposed to limiting production. This means that the time must come when one has to produce. This explains why our results indicate the existence of a significant relationship between contraceptive use and the desire for a child. The desire for a child among contraceptive users is more likely to increase until the desired family size is attained.

As the income status of the woman improves, her desire for a child lowers. This is consistent with research indicating a negative relationship between women's wealth and fertility (Agbaglo, et al., 2022; Muluneh E. K. & Habitu , 2022). Researchers like (Ayşe et al., 2023) have reported a positive association between harsh living conditions and the women's decision to delay pregnancy.

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Much as the results revealed that women residing in urban areas have a lower desire for a child than their counterparts in rural areas, this result is only significant for 2011. Though the desire to have a child increases with age, this is only significant for the year 2016 among the birth age before 20 and is in line with (Bola, 2015).

Whereas the faiths studied had a higher desire for a child compared to the Catholic faith in 2006, this was only significant for Anglicans and SDAs in 2011 and only significant for Muslims in 2016. This differs somewhat from the findings of Muluneh M. W. & Yikeber (2021), who found that Catholics and Muslims had a higher preference for more children compared to women from other faiths in Ethiopia.

Our study did not find significant results regarding the connection between a woman's occupation and the desire for a child. This is contrary to earlier research, as seen in the study by Shanjida and colleagues (2023).

Conclusion and Policy Recommendations:

This study explored the relationship between female education and fertility preference among Ugandan women in 2006, 2011 and 2016. The study findings have revealed that the desire for a child, the ideal number of children and religion have a positive influence on women's fertility preference in Uganda. On the other hand, the mother's age, education, income and urban residence negatively influence women's fertility preference. The study findings have revealed that female education is inversely related to women's fertility preferences throughout the study period. The other significant factors that moderate this relationship include the mother's current age, the number of living children, wealth, and religion. Factors such as the ideal number of children and contraceptives showed a significant positive relationship with education. Though depicting a negative relationship, factors like residence and birth age showed mixed results of significance.

The study concludes that female education is negatively associated with women's fertility preference. Women's education empowers them to make better-informed decisions regarding the desired family size. Therefore, we recommend that government efforts to strengthen universal access to education at both primary and secondary levels. This may involve the government taking care of the hidden costs of schools, especially the uniform and feeding costs that often tempt schools to charge fees; in line with this, programmes on sexual reproductive health need to be strengthened to enrich outreach, especially for women out of school. These programmes should focus on the available sexual reproductive health services and should include a discussion on the ideal family size. We also recommend the inclusion of men in the sexual reproductive health programmes, given that most of the critical decisions regarding the production of children are made by men.

Women who are educated and have money tend to have a low fertility preference. The implication to policymakers is to develop strategies that economically empower women. The school matrons and senior women are crucial in helping the girl child stay in school. These should be supported and equipped with the relevant counselling skills. Whereas the policy to have a secondary school in each sub-county is a move in the right direction, the issue of distance to the schools needs to be considered. We recommend that the ideal of a secondary school per 5 kilometres be implemented to limit the number of girls that drop out due to long distances.

The implication to the community is the need to sensitize their members to embrace government programmes like UPE and USE. The community leaders should spearhead the sensitization of the communities on harmful cultural practices such as those that tie the girl child to performing household chores. The local leaders should lead the mobilization campaigns in support of sexual reproductive health programmes. The government should engage religious leaders to develop a common ground for positive family planning practices. This study has limitations, particularly in establishing causal relationships between education, the moderating variables, and the outcome variables, given that the data used is cross-sectional.

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Implementation and challenges towards hospital information system deployment for improving the quality of care for women and people with disabilities

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Abstract
This study explored the use of hospital information systems (HIS) to improve care for underprivileged groups, especially women and people with impairments. It thoroughly investigated HIS dynamics and issues in healthcare through focus groups, questionnaires and interviews. The study was carried out at Comprehensive Community Based Rehabilitation in Tanzania (CCBRT), a Tanzanian healthcare institution focused on enhancing the health of mothers and newborns and providing care for those with impairments. The study shows significant advancements in HIS deployment and enhanced data accessibility. Still, it also points out challenges like a lack of ICT skills, excessive reliance on technology, data problems, inadequate connectivity, and financial limitations. Optimizing the use of HIS in healthcare requires addressing these issues.

Keywords: Data accessibility, underserved populations, healthcare technology, healthcare improvement, healthcare quality improvement

Introduction

Improvements to healthcare systems are now widely acknowledged as necessary to meet the unique needs of vulnerable groups, including women and individuals with disabilities (Lwoga, Sangeda, & Mushi, 2021). As healthcare organizations strive to provide equitable and inclusive care, the implementation of Hospital Information Systems (HIS) has emerged as a promising solution to bridge existing gaps and improve the quality of care (Khubone, Tlou, & Mashamba-Thompson, 2020). A Hospital Information System is broadly defined as a system that integrates data collection, processing, reporting, and use of the information necessary for improving health service effectiveness and efficiency through better management at all levels of health services (Torab-Miandoab, Samad-Soltani, Jodati, & Rezaei-Hachesu, 2023). According to Lwoga, Sangeda, and Mushi (2021), HIS helps healthcare organizations collect, process, and disseminate information inside and outside the organization.

Patient information systems, administrative systems, radiology and pharmacy information systems, telemedicine, and hospital information systems, such as computerized physician entry systems, are just a few of the systems incorporated into HIS. By leveraging advanced technologies and digital platforms, HIS implementation aims to improve the efficiency, accuracy, and accessibility of healthcare services while promoting patient-centred care.

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Effective technology can reduce clinical errors, support clinicians, improve information management, and increase patient access to health services, remote care, and the continuity of services. HISs are expected to have social and economic benefits for patients, families, and healthcare providers (Sligo, Gauld, Roberts, & Villa, 2017). Moreover, the HIS can enhance data management throughout the hospital, improve the treatment of patients with disabilities, and help gather crucial maternal and disability health data.(Lwoga *et al*., 2021).

Despite the enormous potential and opportunities of HIS to fundamentally change the healthcare industry, there are several apparent and impending difficulties. The adoption of healthcare IT is slow and lagging. These difficulties include a variety of topics, including those about the technology itself, the healthcare setting, system users, and the regulatory environment (Azevedo, 2017; LeBlanc, 1996). A key challenge in developing countries is the lack of sufficient awareness and use of ICTs and the lack of well-trained ICT professionals (Kimaro, 2006). Studies in Sub-Saharan Africa (SSA) have noted challenges with data quality, such as completeness and timeliness, correctness, consistency, and inadequate use of HIS tools (Teklegiorgis, Tadesse, Mirutse, & Terefe, 2016; Xiao & Watson, 2017).

According to Donald and Lwoga (2022), The benefits of HIS are unclear to most users for several reasons. First, some health facilities did not implement all the HIS modules. The second reason is user demographic components or characteristics, such as age, professional cadre or occupation, sex, and experience. Chang and Hsu (2012) highlighted that the age and gender (specifically male) of a user negatively affect his/her intention to use the system, while years of work experience and professional cadre (specifically a nurse) of a user positively affect his/her intention to use the system.

Increasing the efficiency and quality of care, supporting healthcare delivery, reducing costs, and attaining better health outcomes depend on effective data management through health information systems. Tanzania has made little effort to collect and manage health data on its most vulnerable citizens, such as people with disabilities (PWDs), women who are pregnant at high risk, women who have had obstetric fistulas, young pregnant teenagers, and teenagers who are at risk of teenage pregnancies. Innovative technologies must be adopted to handle these groupings of underprivileged minorities. Electronic hospital management information systems (eHMIS) have recently been embraced by the majority of hospitals as projects to raise the standard of patient care, particularly for vulnerable populations (Lwoga *et al*., 2021).

Comprehensive community-based rehabilitation (CCBRT) is a prominent healthcare organization in Tanzania. Their primary objective is to prevent disabilities and ensure accessible healthcare and rehabilitation services while empowering individuals with disabilities and their families. To achieve early detection and prevention of impairments, CCBRT aims to enhance the maternal and newborn health systems. Although CCBRT maintains a satellite facility in Moshi, its main offices are in Dar es Salaam. In Dar es Salaam, CCBRT offers various healthcare services, including maternity and newborn care, childcare, plastic and reconstructive surgery, orthopedics, and physical rehabilitation. The Moshi CCBRT centre is a crucial provider of essential healthcare and support services for individuals with disabilities who lack other accessible options. In 2015, CCBRT initiated the transition from a paper-based system to an electronic health administration Information System (eHMIS) to enhance overall data management, improve care for vulnerable patients, and facilitate collection of vital disability and maternity health data (Lwoga *et al*., 2021).

This study examines the implementation and challenges of hospital information system deployment to improve care quality for women and people with disabilities. It aims to advance inclusive healthcare systems, ensuring equitable access to high-quality care for all individuals.

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Methods

This study employed a mixed-methods approach, using qualitative and quantitative data collection methods. It was conducted in three phases at the CCBRT headquarters in Dar es Salaam, as outlined below.

a) A Baseline survey aimed to assess the implementation status of HIS and the challenges faced by health workers when using it. Semi-structured interviews were conducted with an ICT technical expert to determine the implementation status. Two separate FGDs were conducted with four clinical and five non-clinical staff members between March and April 2019 to assess the challenges faced by health workers when using HIS.
b) Mid-review aimed to assess the use of HIS among health workers. About 96 employees were approached to respond to the developed questionnaire. An interviewer used a tablet (69) with pre-designed questions, and for another 28 participants, an online survey link was forwarded by email. 69 (71.9%) participants responded to the questionnaire (66 tablets and 3 online surveys).
c) The final evaluation aimed to explore any changes in the implementation and usage of HIS and the challenges health workers face in using HIS. The study was conducted between October and November 2019 using a questionnaire survey of 70 employees who responded to the study out of 96 employees.

In the data analysis, we conducted a descriptive study to explore if there were any changes in the usage of HIS and challenges faced in deploying HIS by using frequencies, percentages and means. Qualitative data from interviews with ICT staff and FGDs with healthcare workers were transcribed verbatim. We used a thematic analysis approach to analyze the findings. The data were analysed through examination and categorization of the respondents' opinions. The analysis was carried out in three stages: first, line-by-line coding of field notes and transcripts (unpacking of text into discrete elements to expose underlying thoughts and meanings); second, in-depth examination and interpretation of the resultant codes into descriptive themes; and third, interpretation of the descriptive themes into more abstract analytical themes.

Results

Profile of the respondents

There was no gender inequality among participants in either survey. The mean age was similar between the two groups. More health workers with bachelor's degrees participated in the mid-survey, whereas most diploma holders agreed to participate in the final evaluation.

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Table 1: demographic characteristics

	Mid-survey	Final survey
The sample size for the evaluation	69	70
Demographic characteristics		
Gender		
• Male	52.2% (n=36)	52.9% (n=37)
• Female	47.8% (n=33)	47.1% (n=33)
Age	Mean = 39.5	Mean = 39.11
Education		
• Certificate	(17.4%, n=12)	(22.9%, n=16)
• Diploma	(27.4%, n=19)	(38.6%, n=27)
• Bachelor	(29%, n=20)	(28.6%, n=20)
• Postgraduate Diploma	(5.8%, n=4)	(7.1%, n=5)
• Masters	(18.8%, n=13)	(2.9%, n=2)
• PhD	(1.4%, n=1)	None
Professional cadre type		
• Clinical	37.7% (n=26)	50% (n=35)
• Non-clinical	62.3% (n=43)	50% (n=35)

Implementation status of HIS

The findings from interviews with ICT staff at the baseline study revealed that the hospital has four clinical services: Orthopedic and physical rehabilitation clinical services; Ophthalmology; Maternal, Newborn, and Child Health; and Plastic and Reconstructive Surgery. In 2015, the hospital partnered with the Vrije Universiteit Brussel (VUB) to adapt OpenClinic, an open-source HIS software, to fit CCBRT's data management needs**.** OpenClinic implementation began in October 2015. By the end of 2018, the HIS was used in Orthopaedic and physical rehabilitation clinical services to register patients and book surgeries, as well as to digitize forms, bill patients, and index medical supplies. Hospitals have information systems for finance and human resources.

The interviews at the baseline and the final study revealed that HIS was covered in two clinical services (Orthopaedic and physical rehabilitation and ophthalmology) by the end of the final survey in 2019 from one clinical service (orthopaedic and physical rehabilitation) during the baseline survey. Hence, the HIS did not cover the following clinical services: Maternal, Newborn and Child Health, and Plastic and Reconstructive Surgery. Furthermore, the number of modules implemented in the HIS by the end of 2019 had increased from 12 to 16 (See Table 2). The hospital had not implemented systems other than the same ones (ie., human resource management and accounting information systems).

The HIS was also integrated with the health insurance claim management system (e.g., the National Health Insurance Fund (NHIF) and SMS reminder system for surgery and club foot patients, appointment booking via phone calls, and mobile payment services). The HIS reports are only submitted monthly via email and paper printouts to higher authorities (e.g., the District Health Information System (DHIS2) at the Ministry of Health).

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Table 2: Implementation status of HIS

	Baseline survey	Final survey
Analysis of the implemented HIS business processes	Implemented 12 out of 26 business processes, which included: outpatient registration, patient billing and payment, diagnostic services (laboratory, radiology, and imaging), store/inventory management, picture archival and communication system (PACS), user management module, and security features	Implemented 16 out of 26 business processes. Additional modules from the baseline study were pharmaceutical management, inpatient, Electronic Medical Records, and surgery.
Clinical services covered by HIS	One clinical service was covered by HIS: orthopaedic and physical rehabilitation clinical services	Two clinical services were covered by HIS: Orthopaedic and physical rehabilitation clinical services and Ophthalmology
Integration with other systems at the National level	The HIS was only integrated with the NHIF	The HIS was only integrated with the NHIF
Other implemented information systems in the hospital	Human Resources Management Information System, SMS reminder system, and Accounting Information system	Human Resources Management Information System, SMS reminder system, and Accounting Information system

Usage of HIS by health workers

The findings from FGDs with clinical and non-clinical staff in the baseline study revealed that they used the HIS daily, especially for entering patient data, medical tests/supplies, and financial data. Generally, clinicians and non-clinicians acknowledge that accessing data from the HMIS is easy. One participant commented,

> *' Before 2018, it was difficult to access data. One needs to access data from a specific link. However, currently, I can easily retrieve data when I log in to the system*" (Participant 1, FGD 2).
>
> Both clinical and non-clinical studies acknowledged that it was straightforward for them to retrieve medical reports from the HIS. A typical comment was that "*it is straightforward to retrieve a report because the template of the report is already set according to what you have requested*' (Participant 2, FGD 1). Another participant added, "*You can produce reports in different formats you want, e.g. power, point, excel, word, etc*".

Both clinical and non-clinical studies have acknowledged that some modules can be Integrated into the HIS. For example, the patient registration, store, and pharmacy modules were all linked to the payment system. Therefore, it is easy for medical staff to prescribe medications to patients.

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Typical responses were that:

> *"When we refer the patient, the prescription is linked to the optics department. The patient can go to the optics department and access the prescription there. The optics department can automatically request the material from the main warehouse to go to the workshop where the spectacles are made. They can go to the delivery desk, which indicates integration in the whole department, I would say. The system is also integrated with the finance… is integrated"* (Participant 2, FGD1).

> *"Clinicians at the departments like orthopaedics, eyes, and gynaecology can prescribe anything from their department. In the laboratory section, I can see the prescription and enter the results so the same doctor can see it. This is how the data is integrated into different departments also to the warehouse where we request materials"* (Participant 2, FGD 1).

> "*A doctor can retrieve patients' data and enter prescription data into patient's history, and thereafter, the patient can go to the finance to receive an invoice for payment*" (Participant 5, FGD 2).

Similar findings were revealed in the mid-survey and final survey, and clinical and non-clinical studies were frequently acknowledged using HIS. The results indicated an increase in the frequency of HIS use among health workers from 81.2% of staff at the baseline to 87.1% at the final evaluation (See Table 3). The results indicate an increase in how health workers spent time on the system, from 58% of the staff during the baseline survey to 77.1% during the final evaluation (See Table 3). The findings showed that all staff members supported the deployment of the HIS at CCBRT during both surveys.

Table 3: Use of HIS among health workers

	Mid-survey	Final survey
1. Analysis of how frequently HIS is used (*Several times a day*)	(81.2%, n=56)	(87.1%, n=61)
2. Analysis of how much time is spent on HIS per day (*four hours or more*)	(58%, n=40)	(77.1%, n=54)
3. Support the deployment and implementation of the HIS	(98.6%, n=68)	(100%, n=70)

Challenges of Using HIS

Data from interviews with ICT teams and FGDs with clinical and non-clinical staff during the baseline study revealed the following challenges regarding the implementation of the HIS: inadequate ICT skills, incomplete data due to errors made during data entry, difficulties in data entry and retrieval, the inefficiency of the HIS because some modules are not integrated or they are missing in the HIS, poor internet connectivity, difficulties in confirming patient histories, and inadequate budget. These challenges are explained in detail below:

Inadequate ICT skills: The findings from FGDs revealed inadequate skills in entering data into the system despite having received training on using the HIS from clinical and non-clinical staff. The typical narratives are as follows:

> *"It is easy to add or customize some of the tests or other information in the system. About half of the staff in my department have been able to add and/or create data and use this system comfortably. However, some are still facing difficulties operating the system or customising data we need to add to the system"* (Participant 1, FGD 1).

> *"I'm not skilled enough because there are still a lot more things I need to know about using the HIS"* (Participant 3, FGD 1).

> *"I'm not skilled; I still need more training and skills to be more competent in using the system, as some fellows say"* (Participant 4, FGD 1).

> *"If you want to add some of the tests that were not there, it is easy to do so, but for some colleagues, it is not quite easy"* (Participant 1, FGD 1).

> *"I need to have more training, especially on how to use HIS"* (Participant 5, FGD 2)

Similarly, the interviews with ICT technical staff revealed that the key challenges that might hinder the implementation of HIS were related to digital illiteracy among staff and a lack of ownership from the clinical team. A typical observation was that "once you put a computer in front of a medical doctor or a clinician, it stops being their job."

Despite this challenge, clinical and non-clinical staff acknowledged that ICT teams were always available to assist when they faced difficulties using the system. They usually reported issues via email or telephone calls.

> *"I can say that as days go by, this system comes so easily because as we get the difficulty, we consult our IT department and make it easy according to our request"* (Participant 3, FGD 1). Another participant added that *"ICT technical staff either come physically or they can instruct you how to solve the problem depending on the nature of the problem. However, they are always there to help us if the reported problem is so complicated. It might take time, but it depends on the nature of the problem. Generally, they help us"* (Participant 3, FGD 2).

> Some non-clinical staff recommended continuous training on HIS use because of the challenges they experienced. One respondent said, ' A fresher course on HIS should be provided during job orientation or at least once in the year' (Participant 1, FGD 2).

Over-dependency on ICT: Another challenge was related to over-dependency on computers, as revealed in both FGDs. One participant said,

> *'When you do automation, you create dependency on your system' (Participant 2, FGD 2). The interviewee with ICT staff revealed that approximately 47% of the staff (i.e., clinical and non-clinical staff) had been trained in using HIS. Thus, there is a need to work on staff capacity building and changing* mindset towards ICT utilization.

Difficulties in data entry and retrieval: Lack of ICT skills led to difficulty accessing some data, as reported in one FGD. Some non-clinical staff members noted that accessing the required data in the ophthalmology department was difficult. One respondent said,

> *"...until you dig deep in the system, that when you able to access some data in HIS. Therefore, the system must be improved"* (Participant 4, FGD 2). The clinical staff also reported that

entering data that was not defined in the system was difficult. One participant observed, *"Although I have received training, it is not easy to trace medicine which was not previously in our HIS"* (Participant 3, FGD 1).

Incomplete data due to errors made during data entry: Some data were incorrectly entered into the HIS, which led to incomplete and incomprehensive data, as reported by clinical staff. A typical comment from the clinical staff was,

"Sometimes if the result is 2.45, you can just find it to 24.5; these errors can be reduced by automatically capturing *data rather than manual data entry"* (Participant 1, FGD 1).

In parallel, the data from the interviews with ICT technical staff revealed that it was challenging to confirm patient histories and patient information, and hospital data were still incomplete. None of the medical records were digitized during the baseline study because Electronic Medical Records were not established.

Some modules are not integrated or missing in HIS: some features were not incorporated into the HIS, as reported by clinical and non-clinical staff. For instance, one respondent commented,

"*There is a need to improve the pharmacy module, such as bill the patient and dispense medicines simultaneously"* (Participant 3, FGD 1). Another participant also echoed this finding. *"We expect the HIMS to link with those machines which we have in my department so that once we are done with the test, they can just pick the results, rather than putting it manually, so these are the improvements we expect particularly this 2019 to 2020 we expect those features to be added. We also expect that some of the tests we are not doing now but expect to be doing may be incorporated into the HIMS … for improvement"* (Participant 1, FGD 1).

Typical observations were:

"The HIS needs to be customized per departments' requirements. Some of the features are not present, so this is the challenge I have been facing" (Participant 1, FGD 1).
"I always contact the ICT team to request them to add some features when I find those items are not integrated into the system" (Participant 4, FGD 1).

"I wish the ICT team to add the feature that I wish to use: … when preparing patient operation procedure, it is difficult to capture a patient who is scheduled to undergo two surgeries at a time. The system allows capturing only one surgery, such that the other must be put in the remark section rather than automatically capturing it because it does not allow that" (Participant 4, FGD1).

"if you have a patient who needs to be transfused and you send blood units to that particular patient, you do not find an appropriate tool to feed the information; for example, you have to identify the client blood group which is there in the systems, again, you want to identify the units that are available, you also want to ascertain if the type of blood group wants to transfuse is available, we wish that this kind of information need to be captured and integrated in the current year 2019 having them in the system, would be very helpful to our department" (Participant 1, FGD1).

"I wish the HIS to have bar codes, having much more control in the system, and I'm looking forward to having a digital signature attached to the invoices to acknowledge the customer" (Participant 2, FGD1).

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"I wish we could improve how we capture and generate reports on clinical data. The system is more focused on generating financial data" (Participant 1, FGD2).

"At the pharmacy module, there are features which we are using to capture those data. However, there is a need for some improvement, such as how to clean up data and put it in a grouped way so that it can be easily interpreted by users" (Participant 3, FGD 2).

"There is a need to improve how we generate reports" (Participant 2, FGD 2).

System workflow: Issues with the system workflow pose a challenge in confirming patient histories, as reported by non-clinical staff. Participants reported that the system allowed the patient to attend one clinical service and complete it before commencing another service. However, they felt that this was a problem for the patients. One participant said,

"Maybe some patients have two problems (i.e. eye and orthopaedic). The system will only allow the patient to complete one clinical service and thereafter go for another service' (Participant 5, FGD2).

Poor Internet connectivity: The clinical staff reported other challenges related to poor Internet connectivity. Participants acknowledged that the Internet was so slow that it inhibited the use of the HIS more effectively.

Inadequate budget: ICT teams reported inadequate budgets as another challenge. Hospitals must improve their networks, hardware, software, and technical ICT staff. On the other hand, the final survey questionnaire revealed that lack of training and skills in using HIS were significant limitations in the effective implementation of HIS among health workers.

Table 4: Challenges of implementing HIS

	N (Percent)
Lack of training	39(58.2%)
Lack of skills on how to access and use HIS	32(47.8%)
Lack of electrical power	17(25.4%)
Workload pressure	16(23.9%)
The process of health data in the current HIS was long and difficult	14(20.9%)
Lack of feedback from a high level to a low level	13(19.4%)
Limited ability to exchange information between systems	12(17.9%)
Poor quality of data	10(14.9%)
Lack of access to a computer in my department	10(14.9%)
Poor managerial skills	9(13.4%)
Lack of skilled ICT experts	9(13.4%)
Limited feedback of data in systems for patient care	8(11.9%)
A negative attitude about HIS	6(9.0%)

Multiple responses were allowed.

Overall, a lack of training and skills in using HIS was a significant limitation in the effective implementation of HIS in both interviews and FGDs during baseline and questionnaire surveys in the final study. Other challenges that emanated in both interviews and questionnaires were related to the process of health data in the current HIS, which was long and arduous; lack of feedback from a high level to a low level; poor quality of data; limited ability to exchange information between systems; lack of access to some data because the system is not integrated; negative attitude about HIS; some modules are not integrated or they are missing in HIS, leading to lack of access to some data; and poor response time on HIS, for example, sometimes the system is slow or hangs.

Discussion

Implementation status of HIS

The HIS was deployed in orthopaedic and physical rehabilitation clinical services during the baseline study at CCBRT. Other nations, such as Kenya, Peru, Haiti, Uganda, Malawi, and Brazil, have demonstrated a consistent tendency to initially deploy HIS in specific departments or services within healthcare institutions (Fraser *et al*., 2005). This approach allows for targeted implementation and gradual expansion of other clinical services.

Orthopaedic physical therapy and ophthalmology were added to the HIS coverage when the final research was completed in 2019. This shows the development of CCBRT's HIS implementation. However, HIS has not yet covered the costs of plastic and reconstructive surgery and maternal, newborn, and child health services. This result is consistent with those of some studies (Alsalman *et al*., 2021; Mekonnen, Chanyalew, & Tilahun, 2022) that showed variances in the degree of HIS deployment across various clinical services within healthcare institutions. It often takes longer to administer all healthcare services because it may be difficult and time-consuming (Mekonnen *et al*., 2022).

By the end of 2019, 16 modules were integrated into the HIS, an increase from the previous 12 modules, indicating that attempts to improve the system's usability are still being made. This finding is in line with those of other studies that have stressed the significance of broadening the scope of HIS modules to support many facets of healthcare delivery, including patient management, billing, and inventory control (Kagiri, Waiganjo, & Ngechu, 2015; Lwoga *et al*., 2021).

The HIS has been integrated into the health insurance claim management system, SMS reminder system, appointment booking, and mobile payment services to improve patient care and administrative procedures. Similar integrations have been observed in other studies, which suggests that there is a growing understanding of the benefits of integrating various systems and services to improve patient experience and streamline healthcare operations (Asangansi *et al*., 2013; Kagiri *et al*., 2015).

The reporting of HIS data is one area where implementation at the CCBRT might be even better. The reliance on higher authorities' monthly emails and paper printouts raises the possibility of a delay in data availability for analysis and decision-making. Other studies (Csonka & Korppi, 2022; Kohane *et al*., 2021) have stressed the significance of real-time or almost real-time reporting using electronic platforms, enabling timely monitoring and reaction to health trends and concerns.

Usage of HIS by health workers

The study found that clinical and non-clinical workers at CCBRT regularly entered patients, medical tests, and financial data into the HIS. Participants indicating that retrieving data from the HIS was more straightforward than in the past noted the simplicity of the process. This optimistic view of data accessibility is consistent with research results from other studies, which have suggested that it may enhance data availability and retrieval for healthcare professionals (Girardi, De Gennaro, Colizzi,

& Converting). The participants at CCBRT acknowledged that it was easy for them to retrieve medical reports from the HIS, as the system had pre-defined report templates that matched their specific needs.

This feature facilitates the generation of reports in different formats, such as PowerPoint, Excel, or Word. Similar results have been observed in other research, showing that having adaptable report templates available can improve the HIS's use and efficiency for health workers (Khalifa & Alswailem, 2015; Lau, Price, & Keshavjee, 2011; Lwoga *et al*., 2021).

The clinical and non-clinical staff at the CCBRT acknowledged the integration of several modules within the HIS. For instance, there was connectivity between the patient registration, retail, pharmacy, and payment system modules. Through this connectivity, procedures might be expedited, including the automatic ordering of supplies from the central warehouse and the direct prescription of medication from the HIS. Such an integration can increase the overall coordination of healthcare services, increase workflow efficiency, and reduce errors. The relevance of integrating various HIS components to improve healthcare delivery has been highlighted by comparable findings of module integration that have been published in related contexts (Aguirre, Suarez, Fuentes, & Sanchez-Gonzalez, 2019; Lwoga *et al*., 2021).

The study also showed that health professionals used HIS more frequently over time. The percentage of workers using the HIS increased from the baseline to the final evaluation, demonstrating a rising acceptance and reliance on the system. The amount of time spent on the system also increased, indicating the increased integration of the HIS into the daily workflow of health workers. These results are consistent with those of other studies (Donald & Lwoga, 2022; Rouibah, Hamdy, & Al-Enezi, 2009). The acceptance and engagement of health workers are critical for successfully adopting and utilising the system.

Challenges of using HIS

Insufficient ICT skills have been a significant problem for health professionals at CCBRT. Some staff members complained of data entry and modification challenges despite HIS training, indicating the need for ongoing training and skill development. Other studies have highlighted the significance of continuing training programs to improve the ability of health workers to use HIS efficiently by reporting similar ICT skills issues (Gesulga, Berjame, Moquiala, & Galido, 2017; Lwoga *et al*., 2021) .

Difficulties in data entry and retrieval were reported in the CCBRT, with some staff members finding it challenging to access the required data or enter data that were not predefined in the system. These challenges can be attributed to a lack of ICT skills, incomplete system integration, or limited customization options. Similar results have been observed in other studies, indicating the necessity for intuitive user interfaces, extensive data entry options, and increased system integration to support effective data management in HIS (Donald & Lwoga, 2022; Jahanbakhsh, Tavakoli, & Mokhtari, 2011).

Another issue with CCBRT is incomplete data owing to errors during data entry. Employees mentioned occasions when mistakes in data entry resulted in erroneous or incomplete data. This study emphasizes the significance of data quality control procedures, such as automated data collection and validation checks, in reducing data entry errors. Similar issues with data correctness and completeness have been noted in other studies, highlighting the necessity of user-friendly interfaces and data validation methods to reduce manual data entry errors (Endriyas *et al*., 2019; Rumisha *et al*., 2020) .

The lack of integration or missing modules within the HIS was also identified as a challenge at CCBRT. Staff members reported needing more features and better integration to improve system performance. The significance of customization options and ongoing system improvements to meet

particular clinical requirements and workflow needs is demonstrated by this finding, which is consistent with studies conducted in related contexts (Aguirre *et al*., 2019; Kawila & W., 2017; Lwoga *et al*., 2021; Mekonnen *et al*., 2022).

For health professionals at CCBRT, poor internet access presented a hurdle that reduced the efficacy and efficiency of using the HIS. This study emphasizes how infrastructure constraints can make it difficult for electronic systems to function correctly when resources are scarce. Other studies have noted similar issues with internet connectivity, highlighting the requirement for robust IT infrastructure and dependable connectivity to guarantee continuous access to the HIS (Gesulga *et al*., 2017; Lwoga & Musheiguza, 2023).

Inadequate budgets have also been identified as a challenge. The development, extension, and maintenance of an HIS can be hampered by a lack of funding, which affects the efficiency and usefulness of the system. Similar financial restrictions have been reported in other studies, highlighting the significance of long-term investment and financial planning to support the effective implementation and ongoing operation of HIS in healthcare facilities (Kruse, Stein, Thomas, & Kaur, 2018; Mekonnen *et al*., 2022; Ngafeeson, 2014).

Implication of study findings

The study's results have important implications for implementing Hospital Information Systems (HIS) to improve the quality of care for women and people with disabilities. Expanding HIS coverage to multiple clinical services has led to progress in implementing the system at CBRT. This result suggests that targeted implementation in specialized departments or services can be an effective strategy for continuously expanding HIS within healthcare facilities.

Integrating various modules within an HIS, such as patient registration, storage, pharmacy, and payment systems, has improved workflow efficiency. This integration allows healthcare providers to perform tasks more effectively, such as prescribing medications directly from the HIS and automatically requesting materials from the central warehouse. The ease of accessing data and retrieving medical reports from HIS has enhanced data availability and retrieval for healthcare providers. Customizable report templates facilitate the generation of reports in different formats, catering to users' specific needs. These findings highlight the importance of user-friendly interfaces and customizable features for enhancing the usability and effectiveness of HIS.

The study also revealed several challenges that need to be addressed to enhance the utilization of HIS. Inadequate ICT skills among healthcare workers pose a common challenge, emphasizing the need for continuous training and skill development programs. Challenges such as difficulty in data entry and retrieval, incomplete data, and lack of integration or missing modules within the HIS hinder efficient data management. To overcome these challenges, user-friendly interfaces, comprehensive data entry options, improved system integration, and data quality control measures such as validation checks and automated data capture are essential. Another significant challenge is poor internet connectivity, mainly in resource-constrained settings. This study highlights the importance of robust IT infrastructure and reliable connectivity to ensure uninterrupted access to HIS.

Conclusions

The use of Hospital Information Systems (HIS) has the potential to significantly raise the standard of care provided to both women and individuals with disabilities. The results of this study include information on the development of the HIS at the Comprehensive Community-Based Rehabilitation in Tanzania (CCBRT) as well as the difficulties health professionals face when using the system.

According to the study, HIS deployment at CCBRT has advanced, with the system initially being put in place in specialized departments before eventually being extended to other clinical

areas. The HIS integration of several modules reduces the number of procedures and increases workflow effectiveness. The results also highlight healthcare professionals' positive comments and rising system usage over time, demonstrating a growing acceptance and reliance on HIS. The system's improved data accessibility and the accessibility of customized report templates have made it simple for healthcare professionals to use.

Several issues need to be resolved to use HIS best. The dilemma faced by health personnel with inadequate ICT skills highlights the need for ongoing training and skill development programs. Effective data management is hampered by challenges such as data entry and retrieval, insufficient data, and lack of integration or missing modules within the HIS. Ineffective budgeting and poor Internet connectivity also challenge using an HIS to its full potential.

Investment in regular training programs to improve the ICT abilities of health personnel is essential to overcome these obstacles. To enable effective data management inside an HIS, user-friendly interfaces, thorough data entry choices, and better system interactions should be prioritized. Implementing automated data collection and validation checks will ensure data quality control. A solid IT foundation and dependable internet connectivity are crucial for continuous access to an HIS. Sustained financial investment and planning are required to enable the successful deployment and operation of the HIS.

Healthcare organizations may have the potential to raise the standards of care for women and persons with disabilities by addressing these issues. The results of this study will contribute to the development of inclusive healthcare systems and ensure that all people, regardless of their vulnerability, have fair access to high-quality care. They also offer important insights and lessons for healthcare facilities in implementing HIS.

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Incidence, predictors and early outcomes of acute kidney injury among patients undergoing abdominal surgery at Bugando Medical Centre, Mwanza, Tanzania

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Abstract

Background: Acute kidney injury (AKI) is a frequent occurrence following major surgery and is independently associated with high morbidity and mortality. Data regarding AKI following abdominal surgery is limited in sub-Saharan Africa and Tanzania in particular. This study aimed to determine the incidence, predictors and early outcome of AKI among patients undergoing abdominal surgery at Bugando Medical Centre (BMC).

Methods: This was a longitudinal study to determine the incidence, predictors and early outcome of acute kidney injury among patients undergoing abdominal surgery at BMC between March 2022 and July 2022.

Results: 172 patients were studied (M: F= 1.1: 1). The overall median age of patients at presentation was 34 years. Forty-six (26.7%) patients developed AKI postoperatively. Among the patients who had AKI, 30(65.2%) were classified as KDIGO stage 1, 12 (20.1%) as stage 2 and 4 (8.7%) as stage 3. On multivariate analysis, the age ≥45 years (p=0.036), pre-existing medical illness (p=0.015), pre-existing renal dysfunction (p= 0.007), duration of surgery (p=0.007) and emergency surgery (p= 0.001) were the main predictors of postoperative AKI. The overall median length of the hospital was 8.7 days, and the overall mortality rate was 5.8%. The mortality rate among patients with AKI was significantly high compared to patients without AKI (15.2% v/s 2.4%; p= 0.020). Postoperative AKI was independently considerably associated with prolonged length of hospital stay (p= 0.001) and mortality (p=0.020). Recovery was observed in 63% of patients who developed postoperative AKI.

Conclusion: AKI incidence is high among patients undergoing abdominal surgery at BMC and is associated with high mortality and increased LOS. Prompt identification and aggressive treatment of postoperative AKI risk factors offer the potential to reduce the burden of AKI in this group of patients.

Keywords: Acute kidney injury incidence, predictors, early outcome, abdominal surgery, Tanzania

Introduction

Acute kidney injury (AKI) is a clinical syndrome that primarily presents as a rapid decline in kidney filtration function that results in the retention of urea and other nitrogenous waste products, deregulation of extracellular volume and electrolytes (Mehta *et al*., 2007; Lewington *et al*., 2013). AKI is a significant cause of morbidity and mortality among patients undergoing major surgical interventions worldwide and contributes to prolonged hospital stays and increased cost of treatment

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(Bellomo *et al.,* 2012). The epidemiology of AKI appears different between high-income countries (HICs) and low- and middle-income countries (LMICs) (Priyamvada *et al*.,2018). Whereas it is often seen following major cardiac surgery in the former, this is not the case in LMICs) Priyamvada *et al*.,2018; Melfd *et al*., 2020) .

Globally, surgery remains a leading cause of AKI in hospitalized patients, accounting for up to 40% of in-hospital AKI cases. The rate of AKI in this group of patients is variable, depending on the surgical setting and the AKI definition used) Uchino., 2005). The highest rates are found after cardiac surgery, followed by general and thoracic surgeries (Thakar.,2013; Grams *et al*., 2016). In Sub-Saharan Africa (SSA), the outcome of patients with AKI is very poor, with an overall mortality of 32% in adults. This is extremely high compared to the pooled world mortality of 23.9%. This mortality increases with the severity of AKI, which is estimated at 50–60% amongst patients requiring renal replacement therapy (RRT) and 82% in those in need of dialysis who could not receive it) Jha & Parameswaran., 2013). This high mortality in SSA is due to the late presentation of patients with severe disease in the hospital, the non-availability of RRT and the inability to afford treatment as health care costs are covered by out-of-pocket payment in most SSA countries) Jha & Parameswaran., 2013; Olowu *et a*l., 2016). Most of the reports from the SSA region are on community-acquired AKI, while reports on the epidemiology of AKI among individuals undergoing surgery are limited. With the increase in the volume of surgical procedures performed in SSA) Jha & Parameswaran., 2013; Olowu *et a*l., 2016 Cerdá *et al.,* 2017), it has been hypothesized that most cases of surgery-related AKI are under-detected. The impact of delayed or undetected AKI is enormous in patients undergoing surgical interventions, and it is associated with increased morbidity and mortality, prolonged hospital stays and higher cost of treatment) Cerdá *et al.,* 2017).

Although numerous strategies have been reported to prevent and treat AKI, the incidence of AKI is still increasing (Jha & Parameswaran., 2013; Cerdá *et al.,* 2017). Current literature on AKI is mainly from developed countries with well-established early AKI detection and management programs (Olowu *et a*l., 2016). In contrast, there is limited data on AKI from developing countries, representing over 85% of the world's population (Olowu *et a*l., 2016; Cerdá *et al.,* 2017). Despite perioperative AKI being a preventable disease with enormous benefits of early detection and intervention, which is feasible through the identification of risk factors and prompt institution of appropriate treatment during the peri-operative period, very limited data are available on the magnitude of AKI and its risk factors among patients undergoing surgery in the SSA and Tanzania in particular. This study aims to determine the incidence, predictors and early outcomes of AKI among patients undergoing abdominal surgery at Bugando Medical Centre

Methods

Study design and setting

This longitudinal study determined the incidence, predictors, and early outcomes of acute kidney injury among patients undergoing abdominal surgery at BMC between February 2022 and June 2022. BMC is a consultant, tertiary care, and teaching hospital for the Catholic University of Health and Allied Sciences (CUHAS) with 960 beds. The hospital is located in Mwanza City, in northwestern Tanzania. It serves as a referral centre for tertiary specialist care for a catchment population of approximately 17 million people from neighbouring regions.

Study population, sample size estimation, sampling procedure and study variables

The study population included all patients aged 18 and above undergoing abdominal surgery at BMC during the study period. All patients aged 18 years and above who underwent abdominal surgery at BMC during this study and were willing to participate after signing an informed consent form were

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included. Patients with pre-existing end-stage renal disease and those on dialysis or living with a functioning transplanted kidney were excluded from the study. Patients who experienced polytrauma, or abdominal trauma where the kidney was involved in the trauma, were also excluded from the study. The minimum sample size of this study was calculated using Daniel's formula for proportion as follows: $n = Z^2 \times p(1-p)/e^2$. Where n = the sample size; Z = standard error associated with the chosen level of precision (1.96); e = the level of precision = 0.5; p is the proportion of patients developed post-operative AKI in the study by Lugazia *et al* (2022) in Tanzania, which was 12.8%; Hence, $n = 1.96^2 x 0.128 x (1-0.128)/0.05^2 = 171$.

The estimated minimum sample size was 171 patients 10% (loss to follow-up) = 188 patients. Convenience sampling was performed to include all patients who met the inclusion criteria within the study period. All patients enrolled in the study were assessed preoperatively, intraoperatively, and postoperatively. Preoperative assessments were done on all patients, including a detailed history, physical examination, and relevant investigations. Blood samples were taken for serum creatinine, measured at the BMC laboratory. Creatinine was measured using the Jaffe kinetic method with a spectrophotometer (BIOMERIEUXVR, FRANCE). The initial serum creatinine was taken upon enrollment to determine the baseline upon admission.

Creatinine measurement was subsequently repeated for study purposes within 48 hours (day 2) after surgery and within 7 days of surgery to diagnose AKI. For patients with AKI, serum creatinine assay was repeated on discharge and day 30. Other routine preoperative investigations were done according to BMC protocol, including haemoglobin levels, packed cell volume, serum electrolytes, blood grouping and cross-matching. In addition, all patients were requested to test for HIV infection according to the National AIDS Control Program. Radiological investigations, including chest X-ray, abdominal X-ray, abdominal Ultrasonography, and abdominal CT scan, were done following the hospital routine if required to reach the correct diagnosis. AKI was diagnosed and staged according to the Kidney Disease Improving Global Outcomes (KDIGO) criteria (KDIGO., 2012). In brief, AKI is defined by an absolute increase in serum creatinine (SCr) by 0.3 mg/dL (26.4µmol/L) within 48 h of admission or an increase in SCr ≥ 1.5 times from baseline within 7 days. KDIGO definition will also be used to classify AKI into 3 stages based on serum creatinine (SCr) as follows: -

- Stage 1: SCr 1.5–1.9 times baseline;
- Stage 2: SCr 2.0–2.9 times baseline;
- Stage 3: SCr 3 times baseline, increases in SCr >4md/dl or (353.6umol/l), or initiation of haemodialysis.

Patients scheduled for emergency surgery were admitted through the emergency department after thorough resuscitation, and patients scheduled for elective surgery were admitted a day before surgery through the surgical outpatient clinic. All patients scheduled for surgery were assessed for fitness for surgery and anaesthesia. Haemodialysis was done when indicated. Postoperatively, all patients were followed until they were discharged from the hospital.

Independent (predictor) variables recorded in this study included patient-related (age, sex), associated medical illness, pre-existing sepsis, use of nephrotoxic drugs, use of IV contrast); laboratory characteristics (serum creatinine levels, haemoglobin levels, HIV status); operative characteristics (type of surgical procedure performed, the rank of the operator/surgeon, duration of surgery, hemodynamic instability, requirement of blood transfusion) and procedure-related complications: (E.C.F, sepsis). Dependent (outcome) variables were recorded as complete recovery from AKI, in-patient mortality, renal recovery, need for haemodialysis therapy and length of hospital stay. Complete (full) recovery from ARF was declared when renal function returned to normal range.

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Data management

Data collection

Data were collected using a standardized, pre-tested, and coded questionnaire. The collected data were entered into a computer using Epi-data version 3.1 (CDC, Atlanta, USA) and analysed using STATA version 15 (College Station, Texas, USA).

Statistical data analysis

Data were summarized in proportions and frequent tables for categorical variables. For continuous variables, data were reported as mean ± standard deviation (SD) or median ± inter-quartile range (IQR) depending on their distribution. Odds ratio (OR) with a 95% confidence interval (CI) was calculated to test for the strength of association between predictor and outcome variables using univariate analysis followed by multivariate logistic regression analyses for all predictors found to be significant on the univariate analysis. Significant association was defined as a p-value of less than 0.05.

Data quality control

To ensure the internal validity of the study, the following precautions were taken into consideration: -

- The data-collecting tool was pre-tested.
- Research assistants were trained to administer the questionnaire and collect data.
- the principal investigator ensured completeness and consistency and edited the data collected.

Results

Number of patients recruited in the study

During the study period, a total of 178 patients underwent abdominal surgeries at BMC due to different indications. Among these, 175 patients were recruited for enrolment in the study. Three patients were excluded from the study due to failure to meet the inclusion criteria. Thus, 172 patients were available for the final analysis, as shown in Figure 1 below

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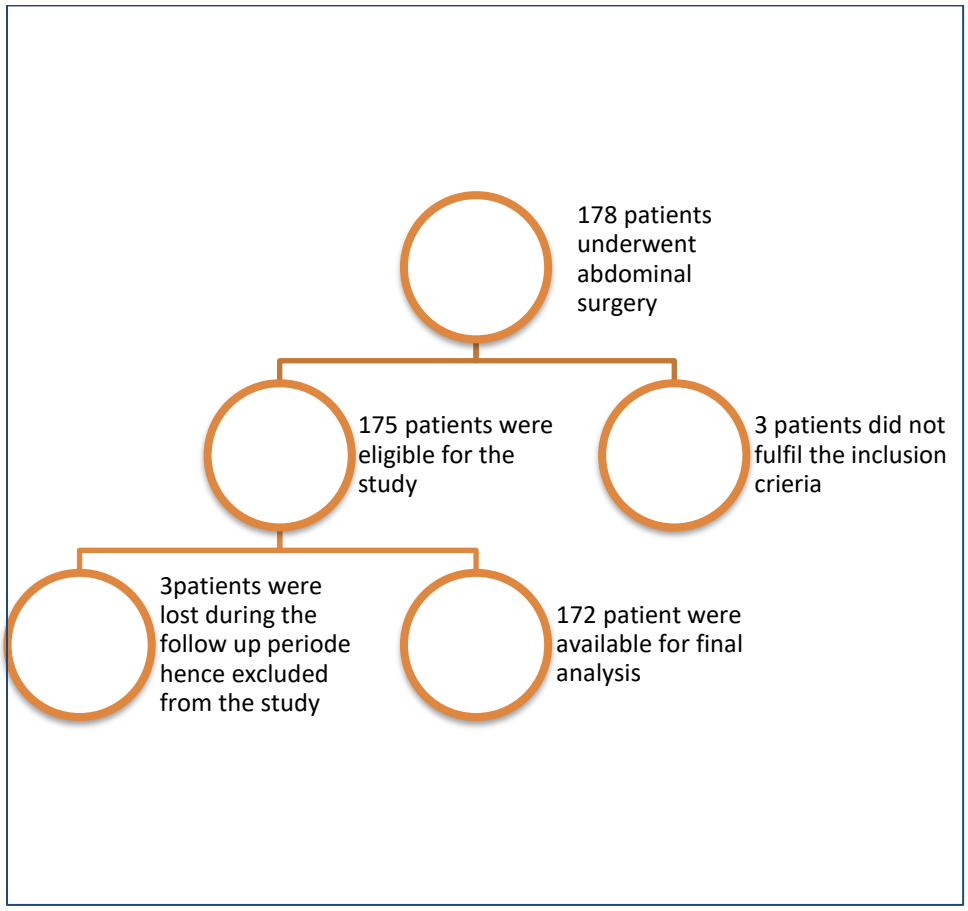

Figure 1: Flow diagram of patients recruited in the study

Socio-demographic and clinical characteristics of patients

The youngest patient was 18 years old, and the oldest was 76 years old. The overall median age of patients at presentation was 34 [IQR: 12-38] years. The modal age group at presentation was 31–40 years, accounting for 32.6% of cases (Figure 2). One hundred and twenty-six (73.3%) patients were aged 45 years and below. Of 172 patients, 91 (52.9%) were males, and 81 (47.1%) were females, giving a male-to-female ratio of 1.1: 1. More than half of the patients came from rural areas. Associated pre-existing medical illnesses were reported in 20(11.6%) cases (Figure 3).

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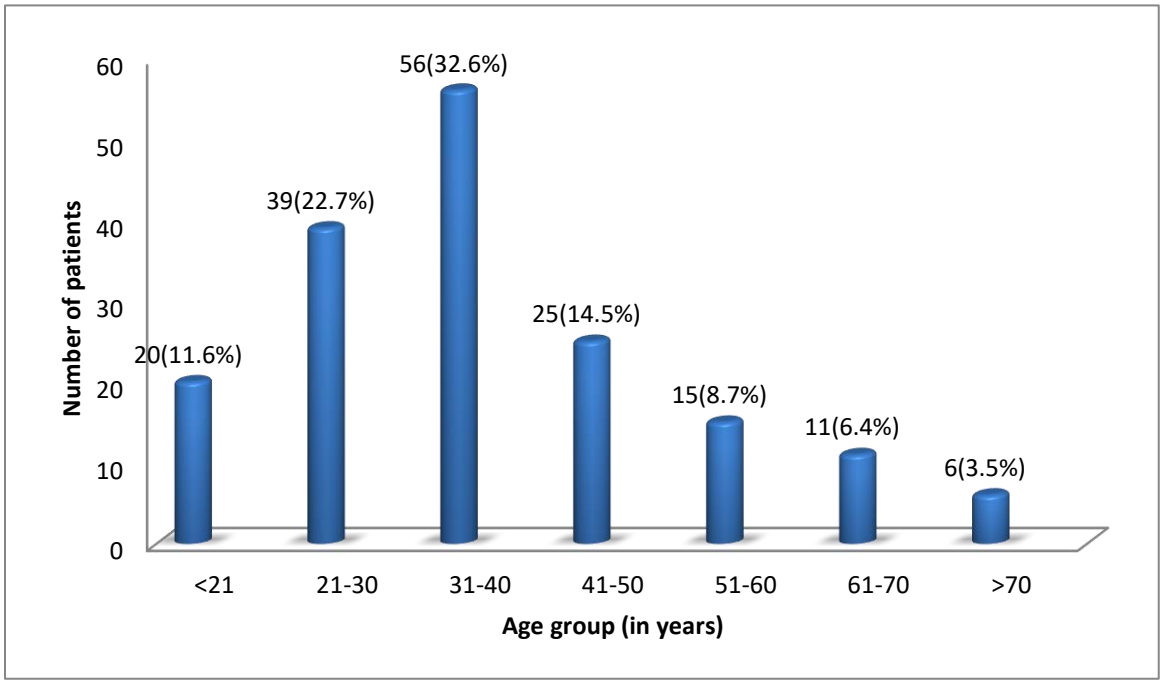

Figure 2: Age group distribution among patients who underwent abdominal surgeries at BMC

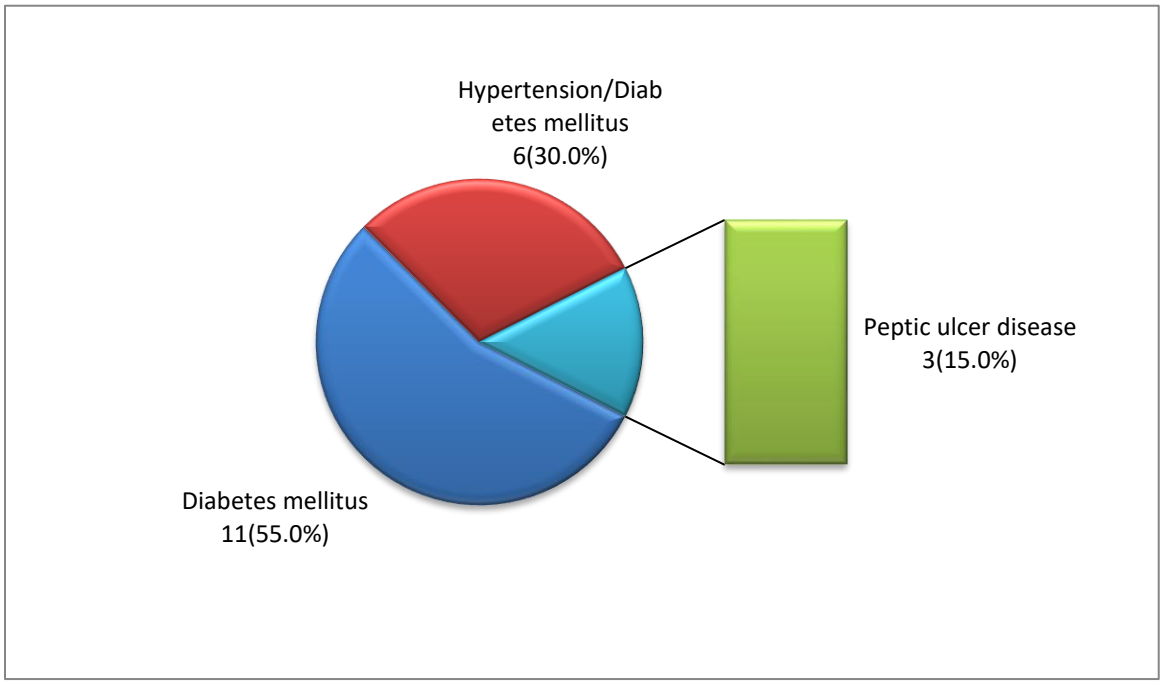

Figure 3: Distribution of patients according to pre-existing medical illness

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Table 1: Sociodemographic and clinical characteristics of patients

Patient characteristics	Number (n= 172)	Percent (%)
Gender		
Male	91	52.9
Female	81	47.1
Residence		
Urban	85	49.4
Rural	87	50.6
Employment		
Employed	79	45.9
Unemployed	93	54.1
Pre-existing medical illness		
Present	20	11.6
Not present	152	160.4
HIV infection		
Infected	12	7.0
Not infected Unknown	157 3	91.3 1.7

Preoperative and intra-operative characteristics

Out of 172 patients who underwent abdominal surgery, 93 (54.1%) underwent elective surgery, while 79(45.9%) had emergency surgery (Table 2) for intestinal perforation with peritonitis in 40(23.3%) patients and intestinal obstruction in 27(15.7%) (Figure 4). Bowel resection and stoma formation were the most common surgical procedures, accounting for 22.0% of cases (Figure 5). Table 3 below shows pre-operative creatinine, haemoglobin, and WBC. Most patients, 95(55.2%), had the surgery duration lasting more than 2 hours (Table 5).

Table 2: Preoperative characteristics of patients undergoing abdominal surgery

Variables	Number of patients (N 172)	Percentage (%)
Nature of surgery		
Emergency	79	45.9
Elective	93	54.1
Duration of illness		
Less than 48hrs	84	48.8
More than 48hrs	88	51.2
Use of nephrotoxic drug		
No	147	85.5
Yes	25	14.5
Preexisting sepsis		
No	152	88.4
Yes	20	11.6

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Table 3: Pre-operative serum creatinine, haemoglobin and WBC

Variable	Number (n =172)	Percent (%)
Serum Creatinine (µmol/l)		
Normal (62-106)	135	78.4
High>106	37	21.5
Haemoglobin (g/dl)		
Normal (10 and above)	124	72.0
Low (<10)	48	27.9
WBC		
Normal (<12)	96	55.2
high (>12)	76	44.7

Table 4: Intra-operative characteristics of patients undergoing abdominal surgery

Variables	Number of patients (N= 172)	Percentage (%)
Duration of surgery		
Less than 2hrs	77	44.8
More than 2hrs	95	55.2
Rank of Operator		
Senior (Surgeon)	147	85.5
Junior (registrar / Resident)	25	14.5
Type of anaesthesia		
GA	153	88.9
SAB	19	11.1
Blood transfusion		
No	145	84.3
Yes	27	15.7

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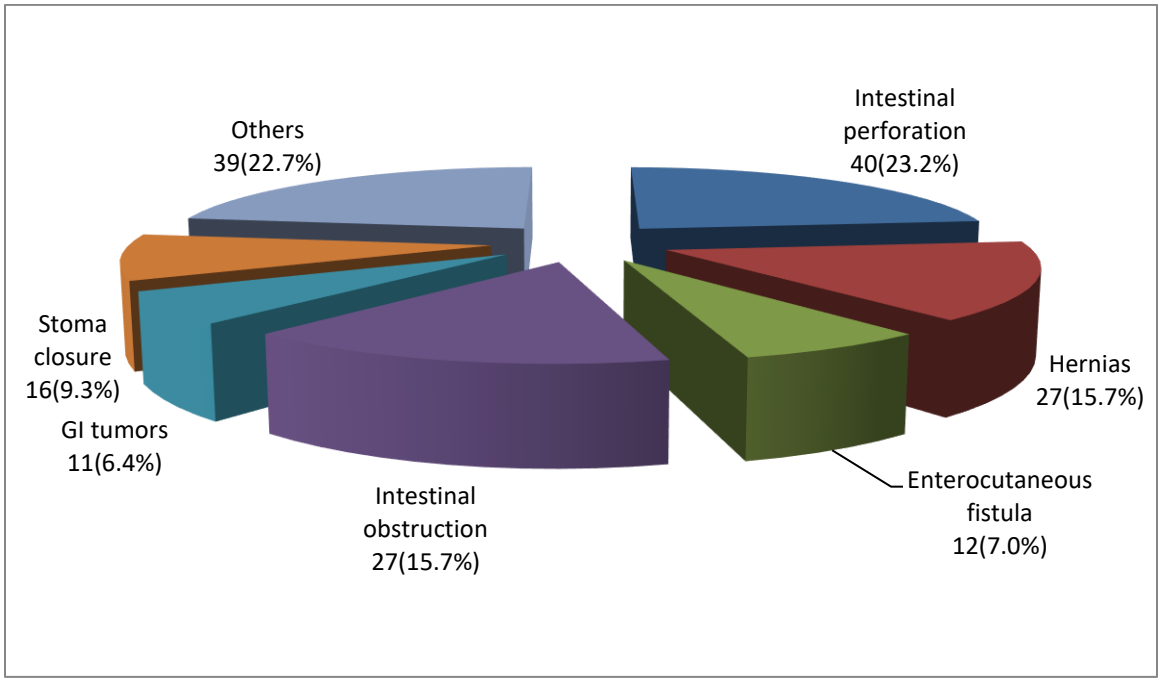

Figure 4: Distribution of patients according to indications for surgery

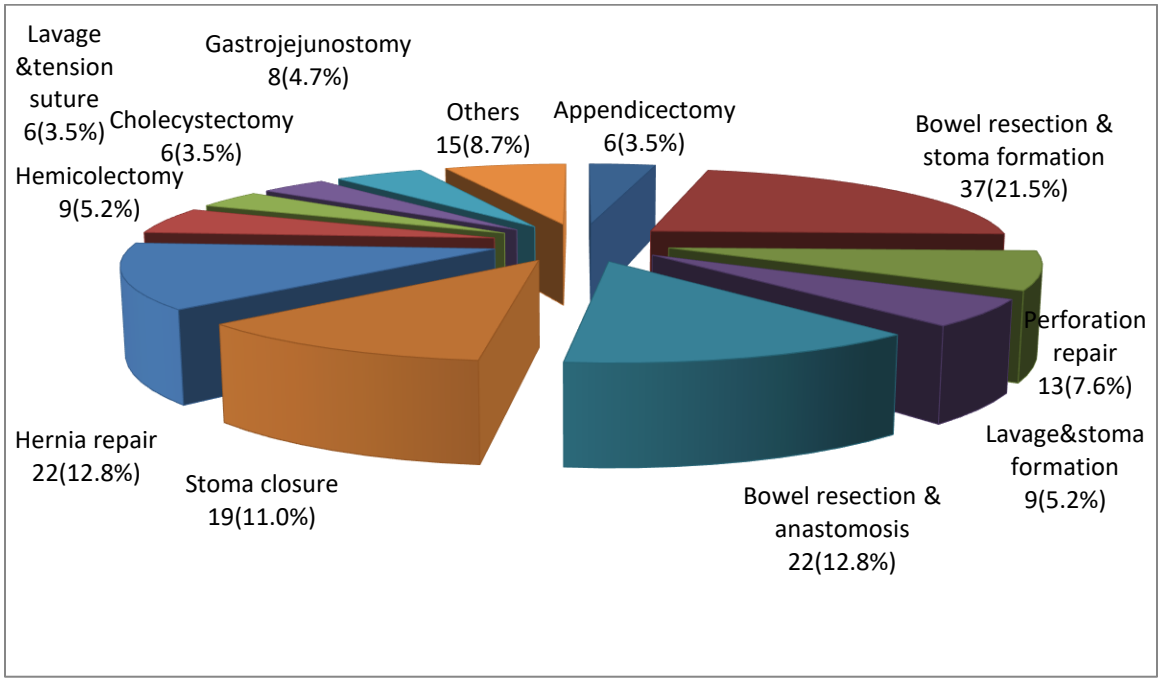

Figure 5: Distribution of patients according to the type of surgery performed

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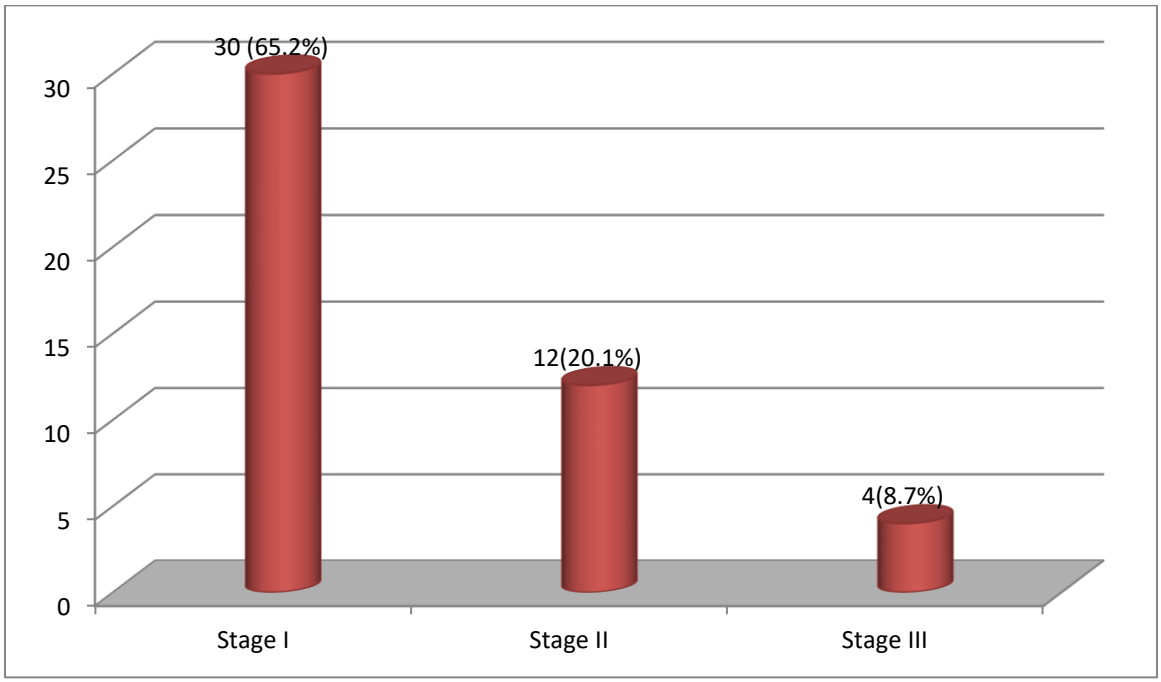

Figure 6: KDIGO grading among patients with AKI

Incidence and predictors of AKI

Out of 172 recruited patients, 46(26.7%) developed AKI postoperatively. The severity of AKI using KDIGO grading shows that the majority of patients had stage I, accounting for 65.2% of cases (Figure 6). Table 6 below shows predictors of postoperative AKI according to univariate analysis. On multivariate analysis, the age ≥45 years (p=0.036), pre-existing medical illness (p=0.015), pre-existing renal dysfunction (p= 0.007), duration of surgery (p=0.007) and emergency surgery (p= 0.001) were the main predictors of postoperative AKI (Table 7).

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Table 5: Predictors of postoperative AKI according to univariate analysis

Variables	No of pts with AKI	No of pts without AKI	Odds ratio (95% CI)	p-value
Gender				
Female	21(25.9)	60(74.1)	1	
Male	25(27.5)	66(72.5)	1.08(0.54- 2.13)	0.819
Age				
<45	27 (21.4)	99(78.6)	1	
≥ 45	19(41.3)	27(58.7)	2.79(1.30-5.60)	0.007
Pre-existing illness				
Absent	33(21.7)	119(78.3)	1	
Present	13(65.0)	7(35.0)	6.69(2.41-18.1)	<0.001
HIV status				
Positive	2(16.7)	10(83.3)	1	
Negative	44(27.5)	116(72.5)	1.89(0.39- 9.00)	0.421
Duration of illness				
<48hrs	9(10.7)	75(89.3)	1	
>48hrs	37(42.1)	51(57.9)	6.04(2.68- 13.5)	<0.001
Use of nephrotoxic drug				
Yes	5(26.3)	14(73.7)		
No	41(26.8)	112(73.2)	1.02(0.34- 3.02)	0.964
Pre-existing sepsis				
No	17(17.0)	83(83.0)	1	
Yes	29(40.3)	43(59.7)	3.29(1.63-6.64)	0.001
Preoperative creatinine				
Normal	26(19.3)	109(80.7)	1	
Elevated	20(54.1)	17(45.9)	4.93(2.27- 10.70)	<0.001
Hb level				
<10	22(45.8)	26(54.2)	1	
>10	24(19.3)	100(80.7)	0.28(0.14-0.58)	0.001
Rank of operator				
Senior	45(30.6)	102(69.4)	1	
Junior	1(4.0)	24(96.0)	0.09(0.01-0.72)	0.023
Timing of surgery				
Emergency	35(44.3)	44(55.7)	1	
Elective	11(11.8)	82(88.2)	0.17(0.07-0.36)	<0.001
Duration of surgery				
<2hrs	12(15.6)	65(84.4)	1	
>2hrs	34(35.8)	61(64.2)	3.01(1.43- 6.36)	0.004
Intra-operative BT				
No	33(22.8)	112(77.2)	1	
Yes	13(48.2)	14(51.8)	3.15(1.34- 7.36)	0.008

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Table 6: Predictors of postoperative AKI according to Multivariate logistic regression analysis

Variables	Odds Ratio	95% Confidence interval	p-value
Age ≥45 years	2.37	1.78-20.14	**0.036**
Pre-existing medical illness	5.90	1.41-24.61	**0.015**
Pre-existing sepsis	1.02	0.34-3.05	0.960
Duration of illness	1.67	0.60-4.57	0.318
Preoperative haemoglobin levels	0.47	0.15-1.46	0.196
Pre-existing renal dysfunction	3.82	1.44-10.17	**0.007**
Intraoperative blood transfusion	1.77	0.51-6.11	0.363
Duration of surgery Rank of operator	4.49 0.18	1.50-13.43 0.18- 1.86	**0.007** 0.153
Emergency surgery	0.13	0.04-0.46	**0.001**

Outcomes of patients

The overall LOS ranged from 1 day to 50 days with a median duration of 8.7[IQR, 2.8 -11.7] days. In this study, ten patients died, giving a cumulative mortality rate of 5.8%. The mortality rate among patients with AKI was high compared to patients without AKI (15.2% [i.e. 7/46] versus 2.4% [i.e. 3/126]). This difference was statistically significant (p= 0.011). Postoperative AKI was independently significantly associated with LOS (p= 0.001) and mortality (p=0.016) (Table 8). Among the 46 patients who developed postoperative AKI, 29(63.0%) were found to have recovered from AKI. Renal replacement therapy (RRT) was required in 4(8.7%) patients who had KDIGO grade III AKI. However, none of these patients received this form of treatment because they couldn't afford it.

Table 7: Association between postoperative AKI and outcomes (LOS & mortality)-results of univariate and multivariate analyses

Outcome variables	Postoperative AKI		Univariate analysis	Multivariate analysis
	AKI(n=46)	No AKI(n=126)	OR[95 CI];p-value	OR[95 CI];p-value
LOS				
<14	20(14.9)	114(85.1)	1	
≥14	26(68.4)	12(31.6)	12.3[5.3-28.4];<0.001	5.84[2.12-16.06]; 0.001
Survival				
Alive	39(24.1)	123(75.9)	1	
Dead	7(70.0)	3(30.0)	7.35[1.11-6.13];0.005	5.67[0.22-0.98];0.02

Discussion

Acute kidney injury (AKI) is a common postoperative complication, with incidence accounting for up to 40% of in-hospital AKI cases (Uchino., 2005). The incidence of AKI in this group of patients is variable, depending on the surgical setting and the AKI definition used, with the highest rates found after cardiac, general, and thoracic surgeries (Thakar.,2013; Grams *et al*., 2016). Studies have shown that the

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incidence of AKI following major abdominal surgery varied between 3.1 and 35.3% and showed considerable heterogeneity (Bellomo *et al*., 2004; Bellomo *et al*., 2012). In this study, the incidence of AKI was found to be 26.7%, which is low compared to a high AKI incidence of 39.3% reported by Bihorac *et al.* (2013) following major abdominal surgery. In comparison, Kim *et al.* (2013) examined AKI after abdominal surgery in a large multicenter study, reporting a rate of 1.1%. Patients who underwent explorative laparotomy had the highest AKI incidence, which is in line with our findings. Similarly, a study by Kheterpal *et al.* (2007) revealed an AKI rate of 1.0%. Interestingly, Teixeira *et al*. (2014) examined postoperative AKI after abdominal surgery using the KDIGO criteria and found an incidence of 22.4%, which is almost similar to the overall incidence in our study. This wide variability in the incidence of AKI in these studies may be related to the differences in case mix between studies and diagnostic criteria used to define AKI. For example, in our study, we used the KIDGO definition of AKI and only serum creatinine was used. In contrast, other components like eGFR and cystatin-C were used in other studies. Others evaluated simultaneously serum creatinine and urine output to define and categorize AKI, as recommended (Bellomo *et al*., 2004).

Recent studies have documented that detecting AKI using serum creatinine levels is problematic because serum creatinine levels are elevated after renal function has declined and does not reflect injury (Macedo., 2011; Macedo *et al*., 2015). Therefore, recent investigations have focused on finding practical serum and urine biomarkers to reveal early injury before profound functional damage occurs (Koyner *et al.,* 2013). The most promising marker includes plasma and urinary neutrophil gelatinase-associated lipocalin NGAL) (Koyner *et al.,* 2013). Also, the combination of urinary Kidney Injury Molecule-1 (KIM-1), *N*-acetyl-beta-d-glucosaminidase, and NGAL improved the sensitivity of early recognition of postoperative AKI when compared with individual biomarkers (Han et *al.,* 2009). Recently, tissue inhibitors of metalloproteinases-2 (TIMP-2) and insulin-like growth factor binding protein 7 (IGFBP7) have been validated as risk predictors for AKI (Meersch *et al*., 2014). Recently, some researchers have assessed combinations of two or more biomarkers to improve the diagnostic power for AKI. This approach is promising because different biomarkers indicate different aspects of renal injury (Meersch *et al*., 2014). The development of novel biomarkers may provide a more accurate and faster way of detecting postoperative AKI, which could eventually lead to earlier intervention. However, these biomarkers are limited in resource-limited settings due to unavailability and high costs. The high incidence of AKI in our study indicates a vast and as yet unrecognized burden of AKI among postoperative patients following major abdominal surgery in our local setting.

Some studies have investigated and identified several factors associated with the development of postoperative AKI (Bihorac *et al.,* 2013; Grams *et al*., 2016). As reported by Lugazia *et al.* (2022) in Dar es Salaam, Tanzania, this study found that AKI was 2.7 times more likely to occur in patients over 45 years than patients less than or equal to 45 years. This has been the trend in other parts of the world as well, with higher renal insults from trauma in the elderly of up to 3 to 6-fold (Coca., 2010; Rosner *et al*., 2013). Age-related changes, including structural and physiological changes, are greatly responsible for this. Changes which occur in the kidneys include a decrease in renal mass with ageing (Lindeman., 1990), loss of cortico-glumeruli due to ischemic changes, subclinical injury to the kidney from co-morbid conditions, reduction in the number and size of tubules, increasing tubulo-interstitial fibrosis and a decrease in glomerular filtering surface (Kaplan., 1975; Frocht & Fillit., 1984). Additionally, older patients are more often exposed to medications that can affect renal function, such as diuretics and contrast media (YIlmaz & Erdem., 2010). Pre-existing medical conditions, such as chronic kidney disease, diabetes mellitus, hypertension, cardiovascular disease, liver disease, and chronic obstructive pulmonary disease, are well-documented risk factors predisposing a patient to postoperative AKI (Raji *et al*., 2018). In this study, pre-existing medical illnesses, including diabetes mellitus, hypertension and peptic ulcer diseases, were observed to be associated with an increased risk of postoperative AKI by

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5.9-fold. This agrees with the observations by Raji *et al. (2018) in Nigeria,* who reported pre-existing medical illness as an independent risk factor for developing postoperative AKI. Biteker *et al.* (2011) reported a prevalence of 49% among patients who had hypertension and 30% in those having diabetes mellitus. Patients with more than one preexisting medical condition had more risk (Biteker *et al.,* 2011). There is a need to do a thorough preoperative evaluation of those patients to know their renal function status and optimize them before scheduling them for surgery. It is also imperative to weigh the risk a particular surgery carries, the type of pre-existing medical illness a patient has, and having a perioperative renal care plan. Also, further studies are needed to evaluate the exact risk of each particular disease in our settings

In this study, pre-existing kidney dysfunction (pre-existing elevated SCr) was identified as a predictor of AKI among our patients. However, we couldn't establish whether the pre-existing kidney dysfunction was chronic kidney disease (CKD) or AKI. This is because most patients had no baseline SCr records at least 3 months before admission for the surgical procedures. The existence of pre-existing kidney dysfunction in our study increased the risk of developing postoperative AKI by 3.8-fold. This finding is in keeping with previous reports that classified CKD as a risk factor for AKI (Singh *et al*., 2010). Although CKD may not be reversible, prompt identification of modifiable postoperative risk factors for AKI and instituting preventive measures may safeguard against the development of AKI, which is a known risk factor for CKD progression. Also, the early involvement of nephrologists in the optimal care of at-risk patients prior to surgery will go a long way in reducing the burden of AKI among individuals undergoing surgical interventions.

The timing of surgery has been reported to have a significant effect on the risk of postoperative AKI occurrence (Biteker *et al.,* 2011; Raji *et al*., 2018). The risk of postoperative AKI is increased in emergency surgery versus elective operations (Raji *et al*., 2018). In the present study, patients who underwent emergency surgery were more likely to develop AKI compared to those who underwent elective surgery. This finding is in keeping with a Nigerian study by Raji *et al. (2018), who reported similar observations but contrary to Lugazia et al. (2018) in Tanzania, who found no statistically significant association between emergency surgery and the* development of AKI. This association between emergency surgery and post-operative AKI reflects that most emergency surgeries are done to restore physiological function or save lives. Thus, there is little time to evaluate or optimize the patients before surgery.

In the current study, the duration of surgery > 2 hours was found to be associated with an increased risk of postoperative AKI. This agrees with other studies by Raji *et al. (2018) in Nigeria and Deng et al.* (2017) in China. Raji *et al. (2018) found that among those surgeries that* took more than 2 hours, the incidence of peri-operative AKI was 65.3%. Therefore, good patient preparation for those surgeries that take extended time or are presumed to be prolonged, together with close intra-operative monitoring and surveillance, is vital to minimize the risk. For surgery lasting >120 min, adequate fluid balance both prior to and during surgery must be ensured, in addition to optimal BP control to prevent episodes of intra-op hypotension and hypertension. These steps will reduce the risk of AKI in patients undergoing abdominal surgery.

Various studies have documented the deleterious impact of AKI on the early outcomes of patients (Bihorac *et al.,* 2013; Grams *et al*., 2016). Postoperative AKI remains a leading cause of morbidity, mortality, prolonged hospital stays, and increased hospital costs (Chertow *et al*., 2005; Neves *et al*., 2015). The influence of postoperative AKI on prolonged length of hospital stay has been demonstrated after abdominal surgery (Chertow *et al*., 2005). In the present study, postoperative AKI was statistically significantly associated with a more extended hospital stay. This is in keeping with reports from other studies (Chertow *et al*., 2005; Neves *et al*., 2015). In a retrospective study of 595 patients by Lee *et al.* (2014), it was found that the extent of hospital stay following abdominal surgery was significantly

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longer in patients with AKI. Similarly, Tomozawa *et al*. (2015) reported that AKI after liver resection surgery was correlated with prolonged length of stay, increased rates of artificial ventilation, need for re-intubation, and requirement for renal replacement therapy. In a retrospective study by Kim *et al*. (2013), gastric surgery patients with AKI had significantly more extended hospital stays and a higher prevalence of intensive care unit admission after the operation.

In this study, the mortality rate among patients with AKI was 15.2%, a figure which is comparable to the 10% that was reported by Lugazia et al. (2022) in Dar Es Salaam, Tanzania. Several studies have demonstrated a mortality rate in patients with AKI ranging between 10-20% (Olowu *et al.,* 2016), which is comparable to a figure which was observed in our patients who developed AKI. The finding that post-operative AKI is a strong predictor of in-hospital mortality following abdominal surgery is well documented in the literature (Kim *et al*. (2013; Tomozawa *et al*., 2015) as well as in the current study. In a retrospective study of 4718 gastric surgery patients, Kim *et al. (2013) found that the in-hospital mortality for patients with AKI was* significantly higher than that for patients without AKI. In another retrospective analysis of 642 liver resection patients by Tomozawa *et al*. (2015), AKI was associated with increased mortality. In a study by Teixeira *et al.* (2014), 450 primary abdominal surgery patients were retrospectively studied, and postoperative AKI was independently associated with increased in-hospital mortality.

Renal recovery after AKI is essential for patients, families, and stakeholders. Several studies have reported renal recovery rates between 17 and 84% (Kim *et al., 2013*; Lugazia *et al*., 2022). Our study shows a 63.0% recovery rate at hospital discharge and during follow-up based on serum creatinine results. This is comparable to the renal recovery of 60% that was reported by Lugazia et al. (2022) in Dar es Salaam, Tanzania. Despite a good proportion of the subjects recovering from AKI, those with severe AKI usually require temporary Renal Replacement Therapy. None of our patients who developed post-operative AKI underwent temporary RRT. Those who do not recover may end up with chronic renal failure and require long-term RRT or death in the event of complications or lack of access to this life-sustaining therapy due to economic hardships (Injury *et al.,* 2014). These observed outcomes and anticipated social, economic, and health impact of post-operative AKI on quality of life call for deliberate efforts to prevent and aggressively treat peri-operative AKI.

The strengths of this study are the relatively large sample size and the use of recent and validated AKI definitions for assessing clinical outcomes. However, this study has several limitations. First, findings from this study cannot be generalized to the rest of the population as it is single-centred and time-limited. Second, only serum creatinine was used to define AKI, which may not detect early renal dysfunction, and this may have resulted in an underestimation of the incidence of AKI. Third, due to the nature and reality of patients, there was missing information from some subjects that caused a dropout from this study despite initial enrolment.

In conclusion, this study demonstrated a high incidence of predicting factors for AKI among patients undergoing major abdominal surgery at BMC. The cumulative incidence of AKI was high and independently associated with the patient's age, pre-existing medical illness, pre-existing renal dysfunction, duration of surgery and emergency surgery. Most of these factors are preventable/modifiable; thus, a strong follow-up and adherence to standard operating procedures and multidisciplinary care of patients can help reduce the incidence and provide good care for the affected individuals. The presence of AKI increased the mortality rate and length of hospital stay among patients undergoing major abdominal surgery. Renal recovery was observed in approximately two-thirds of those who developed postoperative AKI. None of our grade 3 AKI patients who required temporary renal replacement therapy (RRT) received such a modality of treatment. It is therefore recommended that: -

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- Prompt identification and aggressive treatment of AKI risk factors following abdominal surgery in order to reduce the burden of AKI in this group of patients.
- Temporary RRT should be made available to all patients in acute status
- A similar study should be conducted to involve all general surgical patients undergoing major surgery at BMC for a more extended follow-up and a larger sample size

Ethical considerations

This study adhered to the Joint CUHAS-Bugando/BMC Research Ethics and Review Committee (CREC) requirements, and ethical approval to conduct the study was sought from the committee **(ethical clearance number CREC/537/2022)** before the commencement of the study. Permission to conduct the study was obtained from the hospital authority (BMC) where the study was conducted. Enrolled patients were required to sign a written informed consent for the study and HIV testing. Patients were assured that the information collected would be maintained under strict confidentiality. The study did not interfere with the attending doctors' decision, and the patient's refusal to consent or withdraw from the study did not alter or jeopardize their access to medical services.

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Traditional medicines that are used to treat witchcraft-related diarrhoea among under-five children in northern Tanzania

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Abstract

Introduction: Diarrhoea continues to be a severe public health concern, particularly in developing nations. The illness is caused by various bacterial, viral, and other physiological changes. Interestingly, it has also been perceived by the community that diarrhoea among under-five children could be due to witchcraft. In principle, all forms of diarrhoea can be managed with well-established contemporary therapies; nonetheless, it has been suggested that perceived witchcraft-related diarrhoea among under-five children can only be managed by traditional medicines. In northern Tanzania, the use of traditional medicines in the management of perceived witchcraft-related diarrhoea among under-five children is substantial. Yet, there are limited studies on this subject. The present study explored traditional medicines that are used to treat perceived witchcraft-related diarrhoea among under-five children.

Methods: A cross-sectional study using a qualitative research approach was carried out in Korogwe and Handeni districts in northern Tanzania. The study population included paediatric health workers, caretakers of under-five children, and traditional healers. In-depth interviews and focus group discussions served as the data collection methods. Thematic analysis was employed for data analysis.

Results: A total of 247 participants were enrolled, which included 127 males and 120 females. Most participants, especially caretakers and traditional healers, preferred the use of traditional medicines in treating diarrhoea among under-five children and held the belief that a specific form of diarrhoea among under-five children is caused by witchcraft. It was also revealed that traditional medicines are the only types of medication that can treat this form of diarrhoea among under-five children. Plants were the primary source of many traditional remedies that were purported to be capable of treating perceived witchcraft-related diarrhoea among under-five children.

Conclusion: Most participants believed that there is a specific form of diarrhoea among children that is caused by witchcraft, and they boldly stated that traditional medicines are the only treatment option for this form of diarrhoea. Thorough research on this topic is essential. If additional research confirms that traditional remedies effectively treat the illness, these treatment regimens should be extended to other serious illnesses the community suffers from.

Key Words: Traditional medicines, witchcraft-related diarrhoea, under-five children, northern Tanzania

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Introduction

Public health is ruthlessly troubled by diarrhoeal ailments (Collaborators 2018). Around the world, 2.5 billion people lack adequate sanitation, which is believed to be the major determinant of diarrhoeal ailments, and 780 million people lack access to safe and clean drinking water (WHO 2017). It has been documented that diarrhoea kills more under-five children in certain places than all other illnesses combined, especially in poverty-stricken communities (Petri et al., 2008; Ugboko et al., 2020).

In low and middle-income nations, diarrhoea is the second leading cause of illness and death among under-five children (Mosisa et al., 2021). Consuming contaminated food, drinking contaminated water, and living in an unsanitary environment have all been found to be major contributing factors to the persistence of diarrhoeal diseases among under-five children (Mosisa et al., 2021). Moreover, the caretaker's age, the size of the household, the caretaker's state of employment and the household's proportion of under-five children have also been linked to contributing to the persistence of diarrhoeal ailments among under-five children (Agegnehu et al., 2019; Moon et al., 2019; Atnafu et al., 2020).

In a research that included most of the sub-Saharan countries (Demissie et al., 2021), it was found that the prevalence of childhood diarrhoeal morbidity during two weeks was 15.3%, much higher than the results of comparable research conducted in Vietnam (11%) and India (5%) (Gupta 2014; Lee et al., 2016). The potential grounds for these variations were believed to be the disparities in the availability of water, the presence and use of latrines, the presence of hand washing etiquette, , and the waste disposal methods (Alebel et al., 2018).

Tanzania has a 12% overall prevalence of diarrhoea among under-five children (Edwin and Azage 2019). The study found that mother's age was allegedly one of the factors associated with the diarrhoeal illness experienced by the child or children of the mother in question. It has been demonstrated that as a mother gets older, her attentiveness rises, and her child or children have a reduced risk of succumbing to diarrhoea compared to a younger mother (Edwin and Azage 2019).

Even though children are more at risk of suffering from diarrhoea, there are established measures worldwide to treat or prevent the disease. These standardized measures include the right to use hygienic and risk-free water, exclusive breastfeeding for the first six months of life, enhanced sanitation practices, recommended diet, and vaccines for diarrhoea (rotavirus and cholera) (WHO 2017).

On the other hand, traditional medicines have also been used for a long time to treat diarrhoea. Traditional medicines can be defined as the "entirety of all the knowledge, abilities, and procedures derived from theories, convictions, and life experiences that are used to safeguard health as well as the prevention, diagnosis, and enhancement of physical and mental disorders" (WHO 2023). Despite the lack of comprehensive research to determine their safety and effectiveness, traditional medicines are nevertheless frequently used to treat diarrhoea among under-five children (Olisa and Oyelola 2009; Mwambete and Joseph 2010; Farag et al., 2013; Woldeab et al., 2018; El-Dahiyat et al., 2020).

It is believed that the increasing usage of traditional medicines that are useful for treating childhood diarrhoea is a vital part of the long-standing culture that communities have inherited from earlier generations (Uddin et al., 2015). Cultural connectivity, efficacy, safety, ambitions for self-care, accessibility, affordability, influence from senior family members and barrier-free use of the traditional medicines have been reported as the grounds that motivate their use (Ansari et al., 2012; Al Akeel et al., 2018; El-Dahiyat et al., 2020).

According to projections, up to 80% of people in non-industrialized nations rely on traditional medicines for their main healthcare (WHO 2019). In Tanzania, the use of traditional medicines is a practice well attached within the traditions and customs of varied communities (Maregesi et al., 2007; Smith 2019; Mujinja and Saronga 2022). As previously explained, living in an unhygienic environment, consuming contaminated food, and drinking polluted water can all contribute to diarrhoea; however, it has been documented that witchcraft can as well cause diarrhoea among under-five children (Ansari et al., 2012; Budhathoki et al., 2016). Studies have

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been able to thoroughly describe and document the medications used to treat children's normal diarrhoea, but not the medications used to treat children's diarrhoea believed to be caused by witchcraft (Mwambete and Joseph 2010; Sibandze et al., 2010; WHO 2017; Liheluka et al., 2023b).

The present study was carried out in the northern Tanzanian districts of Korogwe and Handeni because the locals largely believe that witchcraft is the primary cause of diarrhoea among under-five children (Liheluka et al., 2023a). Furthermore, in these two districts, diarrhoea is a prevalent illness among under-five children. For example, according to data from the Korogwe District Health Information System (DHIS) books, the prevalence of diarrhoea among under-five children was 59%, 61%, and 65% in 2018, 2019, and 2020, respectively. In the Handeni District, the prevalence of diarrhoea among under-five children was 59% in 2018, 70% in 2019, and 70% in 2020 (Ministry of Health Community Development Gender Elderly and Children 2021).

Despite the widespread belief in the study setting that childhood diarrhoea can be due to witchcraft and that there are specific traditional medicines and methods to treat this form of diarrhoea, to the best of the authors' knowledge, there has been limited research conducted on this subject in Tanzania and other countries. Thus, the present study was conducted to explore traditional medicines that are used to treat the perceived witchcraft-related diarrhoea among under-five children in northern Tanzania. Having this data is vital when planning to establish effective diarrhoeal-related health interventions and policies that align with the widely accepted social and cultural norms of the relevant communities. Furthermore, the study findings may serve as baseline data for relevant, in-depth future investigations.

Methods

Study area

The present study was carried out from February 2023 to October 2023 in the northern Tanzanian districts of Korogwe and Handeni, Tanga Region (Figure 1). Korogwe District has an area of 3,544 square kilometers (PO-RALG 2024b), which is equal to 12.9% of the entire area of Tanga Region. Korogwe District has a population of 359,421 (NBS 2022). Handeni District has an area of 6,453 square kilometers, which is equal to 23.59% of the entire area of Tanga Region (PO-RALG 2024a). Handeni District has a population of 493,321 (NBS 2022). The districts of Korogwe and Handeni are divided into eleven divisions' altogether. The four divisions in Korogwe District are Mombo, Bungu, Magoma, and Korogwe; the six divisions in Handeni District are Chanika, Sindeni, Mkumburu, Magamba, Kwamsisi, and Mazingara (PO-RALG 2024b).

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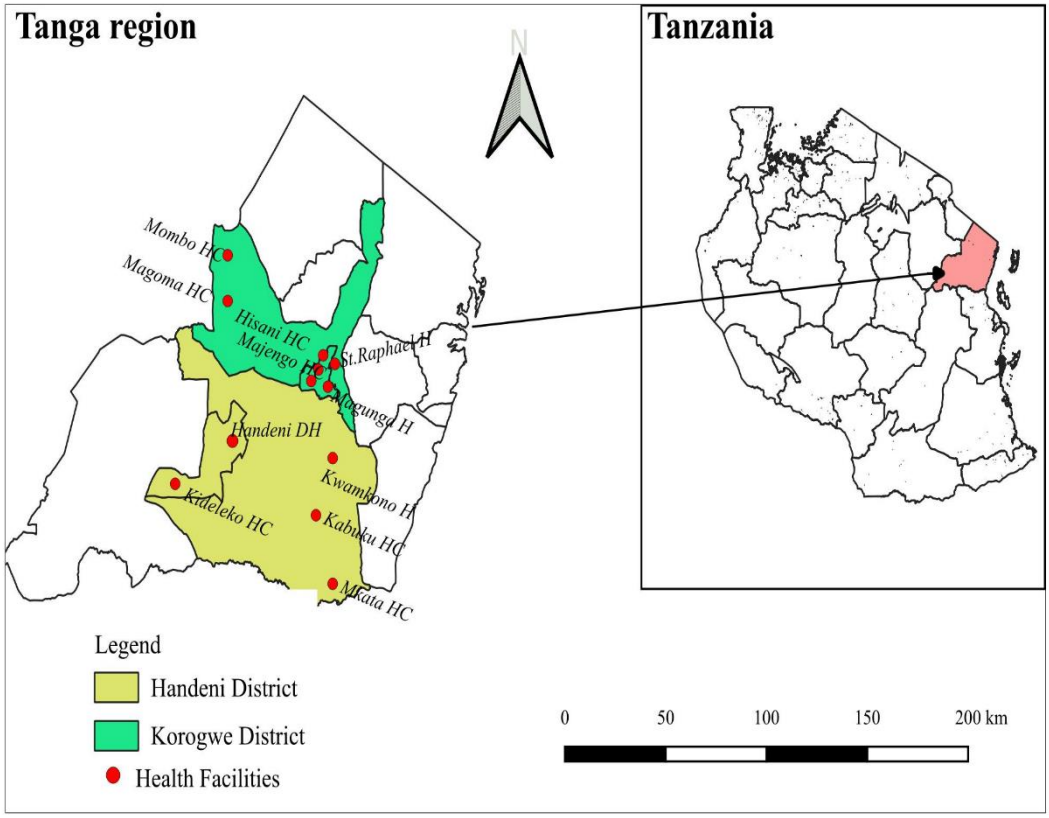

Figure 1: A map showing the study area and health facilities involved in the present study

Study design and approach

A hospital and community based qualitative cross-sectional study design was used.

Study population, inclusion and exclusion criteria

The target population included caretakers of under-five children who reside in the districts of Korogwe and Handeni who were visiting the 12 main healthcare facilities in each of the two districts. Others included paediatric healthcare providers working at the main healthcare facilities designated for this study and traditional healers who treat under-five children. Respondents who consented to participate in the study were included. The study excluded respondents who were unable to participate due to illness and those who failed to show up on the day of data collection.

Data collection methods and tools

To facilitate data gathering, focus group discussions (FGDs) and in-depth interviews (IDIs) with semi structured open-ended questions from interview guides were used. The rationale behind the selection of FGD and IDI methodologies was their acknowledgment as sources of qualitative data in the field of health care (Green and Thorogood 2018).

Selection of IDI participants

As previously stated, there are 10 divisions in the districts of Korogwe and Handeni. The two districts have a total of 12 main healthcare facilities. For the present study, participants were recruited in 10 divisions and 12 healthcare facilities in each of the two districts. The objective was to collect a diverse array of viewpoints from different stakeholders, including paediatric health workers, caretakers and traditional healers.

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Selection of paediatric health workers for IDI

A total of 24 paediatric health workers participated in this study, with one paediatric clinician and one paediatric nurse purposively chosen from each of the 12 health facilities. Following their selection, the study team tracked down the health workers and informed them of their inclusion in the study, two weeks prior to the scheduled interview date. After giving them a thorough explanation of the project, the research team set up a time for the health workers to be interviewed.

Selection of caretakers for IDI

Out of the 12 health facilities, two caretakers (one male and one female) were purposively chosen, bringing the total to 24. The DHIS books were used to choose study participants. The participants were caretakers whose under-five children had visited one of the 12 health facilities for treatment of diarrhoeal illness within six months prior to the interview day of the present study. Numerous patient details are included in the DHIS books, including the patient's name, residence, gender, age, and the ailment that led to their visit to the health facility. The study team located the participants at their place of residence two weeks before the interview date and notified them that they had been selected to participate in the research. The research team scheduled an interview with the participant and provided a thorough explanation of the study.

Selection of traditional healers for IDI

A minimum of five and a maximum of six traditional healers from each of the 10 divisions in the districts of Korogwe and Handeni were purposively chosen as IDI participants. At least five traditional healers from each division were chosen after consultation with the traditional healer coordinators of the Korogwe and Handeni districts, bringing the total to 52. Two weeks prior to the scheduled interview, the study team located the traditional healers and informed them that they had been chosen to take part in the research. After spending some time explaining the project goals in detail, the study team set up a time for interviews with the traditional healers.

Selection of FGD's participants

Purposively, a minimum of six and a maximum of 10 caretakers (male and female) who brought their under-five children to the 12 health facilities were selected for this study, specifically those who brought children for treatment of diarrhoea within the previous six months as extracted from the DHIS books. The ultimate sample size for FGD participants was made up of 147 individuals. Two weeks before the interview date, the study team located the FGD participants in their neighbourhoods and let them know they had been chosen to participate in the research. The research team scheduled an interview and thoroughly explained the study's purpose to each participant.

Conducting IDI and FGD interviews

After a study participant consented to take part and duly signed and dated the Informed Consent Form (ICF), the interview process started. An impartial witness was consulted before signing the ICF in cases where the study participant lacked literacy. When a participant gave permission, a digital audio recorder was used to capture data in addition to taking notes. Saturation points during interviews have been reported to occur, at least in the first 12 interviews (Guest et al., 2006). In light of this guideline, the IDI interviews comprised, as previously mentioned, a minimum of 24 paediatric health workers, 24 caretakers, and 52 traditional healers. According to the FGD literature, most qualitative studies can satisfactorily address their research objectives with a minimum of six FGDs (Guest et al., 2016). Based on the aforementioned knowledge, this study carried out 24 FGDs; 12 groups consisted of male caretakers and 12 groups consisted of female caretakers. Every interview was conducted in a location that was convenient for the study subject.

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Data management and analysis

Data were analyzed using thematic analysis, which is a widely used method for identifying themes in the qualitative research dataset. Initially, the data were collected in Kiswahili and later transcribed verbatim. Listening to audio recorded data and reading the transcripts, were done as part of data quality check to correct transcription errors. After that, the transcripts were translated into English. The data were scanned repeatedly by the principal investigator (PI) and the research team with the aim of understanding them. Codes were grouped into categories and during coding process, one researcher performed the initial coding, and then two researchers met to compare the codes versus the transcripts and reached a consensus on the final codes. Codes were categorized based on the study specific objectives. An inductive approach (concepts derived from the data) was used for data analysis by following the six phases of thematic analysis suggested by Braun and Clarke (2006): familiarization with the data, generating first-round codes, searching prospective themes, reviewing themes, defining and naming themes, and ultimately generating the report (Braun and Clarke 2006).

Ethical approvals

The present study was submitted to the University of Dodoma Institutional Research Review Committee (UDOM IRRC) and received ethical approval (Reference number MA.84/261/02/, dated May 24, 2022). Prior to starting the research, the study team visited the village, district, and regional authorities where the study was conducted. These visits had the dual purposes of raising awareness and providing the officials with comprehensive information about the study. As previously mentioned, eligible study participants also received comprehensive study information prior to enrolment. Participants were made aware that participation in the study was entirely voluntary and that they could choose not to participate.

Results

Participants' socio-demographic characteristics: Table 1 presents the socio-demographic characteristics of the study participants. A total of 247 participants were recruited, which included 127 males and 120 females. More than half (57%) of the study population were aged 18–40 years. One hundred participants took part in the IDI interviews, while 147 participants took part in the FGD interviews. Most caretakers and TH participants had primary education. The health professionals who took part in this study were nurses and clinicians. All of them had completed tertiary or higher education, and their ages ranged from 25 to 67. Of them, 29 (29%) were male.

Participants socio-demographic characteristics

Characteristics	Caretakers	Health workers	Traditional healers
	N= 171 (69%)	N= 24 (10%)	N= 52 (21 %)
District			
Korogwe	102 (59.6%)	14 (58.3%)	21 (40.4%)
Handeni	69 (40.4%)	10 (41.7%)	31 (59.6%)
Sex			
Male	88 (51.5%)	7 (29.2%)	32 (61.5%)
Female	83 (48.5%)	17 (70.8%)	20 (38.5%)
Age (In years)			
18-40	114 (66.7%)	16 (66.7%)	10 (19.2%)
41 >	57 (33.3%)	8 (33.3)	42 (80.8%)
Data collection methods			
IDIs	24 (14%)	24 (100%)	52 (100%)

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FGDs	147 (86%)	0 (0%)	0 (0%)
Level of education			
No formal education	11 (6%)	0 (0%)	7 (13%)
Primary education	116 (68%)	0 (0%)	41(79%)
Secondary education	37 (22%)	0 (0%)	4 (8%)
Tertiary and higher education	7 (4%)	24 (100%)	0 (0%)

Upon data analysis, the following three key themes emerged: Participants understanding of the causes of diarrhoea among under-five children, traditional medicines and other methods for treating perceived witchcraft-related diarrhoea among under-five children, and the efficacy of traditional medicines in treating perceived witchcraft-related diarrhoea among under-five children.

Participants understanding of the causes of diarrhoea among under-five children

The participants had different opinions when asked about the causes of diarrhoea among under-five children. Most caretakers and all traditional healers reported that, in addition to the known scientific causes of diarrhoea, the illness is largely caused by witchcraft. This is in contrast to health workers who explained the known scientific causes of diarrhoea, which include eating contaminated food or drinking contaminated water, although they did acknowledge that a significant portion of society still believes that superstitions are the primary cause of diarrhoea among under-five children.

Traditional healers had these to say:

> *"Many individuals in our community think that diarrhoea among under-five children is the result of witchcraft" (Traditional healer, Male, 51 years).*
>
> *"It is possible for the child to get diarrhoea due to bewitchment or from his/her mother's devils" (Traditional healer, Female, 70 years old).*

One caretaker had this opinion:

> *"It is true that there are witches; a child who is suffering from diarrhoea may have been bewitched" (Caretaker, Female, 35 years).*

Health workers had these explanations:

> *"A lot of caretaker's cure diarrhoea with traditional medicines because they think it is caused by witchcraft. Their children end up in the hospital when such medications don't work" (Medical Doctor, Male 43 years old).*

One nurse said:

> *"People in this community have a belief that witchcraft is the cause of a certain type of diarrhoea among children. They also think that traditional medicine is the sole way to treat this form of diarrhoea, and some individuals have recovered from it without even visiting the hospital" (Nurse, Female, 39 years old).*

Traditional medicines and other methods for treating the perceived witchcraft-related diarrhoea among under-five children

In this theme, all sorts of participants shared their opinions, but compared to caretakers and healthcare professionals, traditional healers appeared to know more about treating children's

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diarrhoea, which is thought to be caused by witchcraft. Although some traditional healers share some modest similarities, the traditional medications and treatments used to cure diarrhoea in under-five children vary from one traditional healer to another.

Traditional healers had the following to talk about:

> *There is a medicine that is prepared by taking the fresh leaves of the "Mhasu"* (a local language name) (*Mahasu-microglossa* – Family Acanthaceae) *and mixing them with the leaves of the "Mlama mweusi"* (a local language name) (*Combretum molle* – Family Combretaceae). *You put them on fire until they are completely dry, and then you grind them. After that, you take a teaspoon of the powder, mix it with half a cup of warm water, and give it to the child only once a day. The child should only take half a cup a day until s/he recovers (*Traditional healer, Male, 42 years old).
>
> *To make a remedy for diarrhoea in children caused by witchcraft, take the roots of the "Masuchemengi"* (a local language name), (*Strophanthus eminii* - Family Apocynaceae), *peel the barks, let them dry in the sun, and then grind them until they become powdery. A teaspoon of the powder must be taken and added to the porridge. For seven days, the child drinks it three times a day (Traditional healer, Female, 54 years old).*

Another traditional healer stated:

> *"Another method that you can use to treat a child's diarrhoea caused by witchcraft is to take a broom made from the leaves of "Ukindu"* (a local language name), (*Phoenix reclinata* - Family Arecaceae) *and then use it to sweep the child's body from the chest down to the feet. You must sweep the child's body three times, from the chest to the feet, and then you repeat it three times in just one day. Then, when you finish sweeping the child, you quickly throw the broom down. This is the most common method that we employ. Following that, the child fully recovers" (Traditional healer, Male, 64 years old).*

Another traditional healer had this to elucidate:

> *"To cure a child's diarrhoea caused by magical beliefs, you take seven leaves of "Ndulele"* (a local language name) (*Solanum incanum* – Family Solanaceae) *and mix them with the leaves of "Mzumbasha"* (a local language name) (*Ocimum suave* – Family Lamiaceae),*"and leaves of the "Kongo"* (a local language name), (*Polyscias stuhlmannii* - Family Araliaceae) *dry them in the sun, and grind them. After that, you take a small amount, mix it with warm water, and then give it to the child only once. If the child was crying and had diarrhoea, s/he recovers immediately" (Traditional healer, Male, 32 years old).*

The majority of caretakers stated that they seek the advice of traditional healers if they suspect a child is experiencing diarrhoea related to witchcraft because they believe traditional healers have skills to treat such cases of diarrhoea. Although a small segment of caretakers was aware of how to treat diarrhoea caused by witchcraft, their levels of skills were inferior to those of the traditional healers. Some caretakers mentioned that the grandmothers of their children consistently prepare and administer the children's medications.

For example, one caretaker had this to say:

> *"The caretaker has to take a normal broom used for sweeping and spit three times on the ground. After that s/he must sweep the child twice on the right side and twice on the left side of his body, starting from the head to the feet. Then the caretaker must throw the broom on the ground. Following that, the child's magical belief-related diarrhoea subsides" (Caretaker, Male, 33 years old).*

Another caretaker explained:

> *"When my child has witchcraft-related diarrhoea, his/her grandmother makes medicine for him/her, which the child swallows and helps him/her to recover"* (Caretaker, Female, 23 years old).

Most health professionals did not know about the traditional remedies for treating diarrhoea among under-five children, which is thought to be caused by magical beliefs. One health worker did, however, briefly mention that his/her clients regularly tell him that they use a medication called "Makata" *(a mixture of sodium carbonate and other traditional medicines)* to treat a child's diarrhoea that is brought on by witchcraft.

Health workers had this to explain:

> *"I always inquire about the medications given to children by caretakers prior to their arrival at the hospital when they bring them here for diarrhoeal treatment. Most of them used to tell me that they gave their children a traditional medicine called "Makata,"* (a mixture of sodium carbonate and other traditional medicines) *because they believed children were bewitched" (Medical Doctor, Male, 35 years old).*

The efficacy of traditional medicines in treating the perceived witchcraft-related diarrhoea among under-five children

Diarrhoea resulting from witchcraft is incurable with modern treatment; only traditional medicines can treat this form of diarrhoea, according to all traditional healers and most caretakers. Traditional healers and most caretakers believed that there are people in the community who are bewitching children to make them sick with diarrhoea just out of hatred or jealousy. It was clarified by traditional healers and caretakers that, children, not adults, are commonly bewitched to contract diarrhoea. The participants thought that children are more vulnerable to this form of diarrhoea because their bodies have not yet fully matured. Health professionals did not think that diarrhoea could be classified as either treating with contemporary medicines or using traditional medicines. In their opinion, the standard treatment guidelines ought to be followed for any diarrhoeal illness.

Traditional healers said:

> *"Hospital medications, in my opinion, cannot treat a child's witchcraft-related diarrhoea, although they can treat other forms of diarrhoea. Children are especially susceptible to this form of diarrhoea since they are not fully mature" (Traditional healer, Male, 56 years old).*

Caretakers had this to narrate:

> *"Many people believe that a child with diarrhoea must have been bewitched, so they prefer to start with traditional medicines" (Caretaker, Male, 31 years old).*

> *"Many times, people turn to traditional medicines since hospital medications are unable to heal a child who might have been bewitched" (Caretaker, Male, 37 years old).*

Health workers reported:

> *"They don't seem to heal diarrhoea in any way, in my opinion. Before a child is given medication for diarrhoea, s/he has to be tested to determine the exact cause of the illness" (Nurse, Female, 49 years old).*

> *"Traditional medicines, in my opinion, are ineffective in treating any form of diarrhoea among under-five children even adults" (Medical Doctor, Female, 34 years old).*

A different health worker clarified:

> *"From a medical perspective, several individuals get diarrhoea due to contaminated environments, resulting from consuming unclean food or drinking contaminated water. However, it is noteworthy that hospital medications play a crucial role in treating patients who are suffering from diarrhoea" (Medical Doctor, Male, 51 years old).*

In response to the question, "How do you know that a certain type of diarrhoea is caused by witchcraft and a certain type of diarrhoea is just normal diarrhoea?" the participants, particularly the traditional healers, clarified that the two key signs that a child's diarrhoea is specifically caused by witchcraft are persistent diarrhoea and foul-smelling stools.

Traditional healers had this to explain:

> *"Normal diarrhoeal stools don't have a strong odour. You will know if the diarrhoea is caused by witchcraft if the child's stool smells very bad and the child has continuous diarrhoea" (Traditional Healer, Male, 64 years old).*

> *"A pungent smell coming from the child's faeces is one of the signs of witchcraft-induced diarrhoea. The stool has a very strong smell that is unbearable; you can compare it to a rotten egg or carcass. Even if a child farts, the smell is awfully bad" (Traditional Healer, Male, 54 years old).*

Discussion

The present study explored traditional medicines and other methods that are employed to treat the perceived witchcraft-related diarrhoea among under-five children in Korogwe and Handeni districts, northern Tanzania.

Overall, the participants had differing views and opinions regarding the causes and management of diarrhoeal illnesses among under-five children. While most caretakers and traditional healers thought that witchcraft was mostly to blame for children's diarrhoea, health professionals had a more scientific belief that children can contract diarrhoea, particularly if they consume contaminated food or drink contaminated water. Although they did acknowledge that a significant portion of the study area's population thinks that diarrhoea among under-five children is largely due to witchcraft.

In particular, most caretakers and traditional healers believed that children are more susceptible to witchcraft-related diarrhoea than adults. The participants believed that due to naïve immunity, children are more susceptible to this form of diarrhoea. On the other hand, medical professionals thought that if a person has consumed contaminated food or water, s/he can acquire diarrhoea, regardless of his/her age. This finding is not new; other studies have also shown that there are situations in which a child can contract diarrhoea due to witchcraft (Ansari et al., 2012; Budhathoki et al., 2016). People can better understand the causes of diarrhoea and the appropriate treatment for the illness by receiving sustainable health education (Gever and Ezeah 2020; Stellefson et al., 2020). The key authorities should develop sustainable plans to reach out to these groups and educate them about health matters in order to lessen the potential harm to the children as a result of the negligence from their caretakers, who still believe that diarrhoea can be caused by witchcraft and that the only management is the use of traditional medicines. Similarly, a more thorough investigation is required to determine the science that is unwittingly performed by "black magic practices" to infect a child with diarrhoea. If the science behind this claim is confirmed by research, it ought to be applied to enhance rather than worsen children's health, as it is currently being done. According to study findings, some members of the community are intentionally inflicting diarrhoea on children by bewitching them out of jealousy or anger. It is wrong and should not be supported to intentionally injure someone out of envy or hatred.

Plants were the main source of many traditional medicines that were supposed to be able to treat perceived witchcraft-related diarrhoea among under-five children. The steps to prepare plant-based traditional medicines differ from one traditional healer to another, although some are similar. Such a discrepancy in preparation is possibly due to the lessons that the corresponding traditional healer's elder relatives or ancestors had given him/her and could have a significant effect on the efficacies based on the mode of preparation. Often, the relevant plant is picked and dried in the sun or by using fire, and after that, it is ground to get the powder that is used by the child either by mixing it in warm water or porridge. These methods of herbs preparation have also been documented in other studies conducted elsewhere (Mwambete and Joseph 2010; Semenya and Maroyi 2012; Jaradat et al., 2016; Woldeab et al., 2018).

The diarrhoeal diseases that are thought to be caused by witchcraft can be easily diagnosed, notably by traditional healers and experienced caretakers, based on the child's constant diarrhoea and the foul-smelling stool. Thus, the study's findings indicated that there are specific traditional medicines that are used to treat this form of diarrhoea. Health professionals generally clarified that they were unaware of the medications needed to treat the diarrhoeal illness, which is said to be caused by witchcraft. However, they acknowledged that they used to hear about traditional medicines being talked about in the community, and sometimes caretakers used to mention them when they came to the hospital to bring children for treatment. The formal knowledge that health workers received regarding health matters may have an impact on their attitude towards traditional medicines. Providing continuous education on a variety of health topics to community members, particularly those who look after under-five children can help them develop a comprehensive understanding of health issues and make informed decisions about the best course of action when it comes to treating their sick children (Gever and Ezeah 2020; Stellefson et al., 2020). Although research on issues related to superstition can be challenging, it is beneficial if the key authorities will do more research to find out the truth about whether these traditional medicines can cure perceived witchcraft diarrhoea diseases among under-five children. If the results of the same research support the traditional remedies' ability to treat the disease, these treatments and methods should be extended to other serious illnesses that afflict individuals in the community.

In reference to the curative potential of traditional medicines in treating diarrhoea which is thought to be caused by witchcraft among under-five children, the majority of caretakers and all traditional healers believed that traditional medicines are the only remedies capable of curing this particular form of diarrhoea. They also insisted that modern medications are unable to do so. Since this knowledge is not taught in any Tanzanian school or college, it was most likely passed down to them from their ancestors in the past. Therefore, it will be useful if this knowledge is further researched and documented for the benefit of future generations. In a study conducted in Nepal, participants reported using traditional remedies and other methods to treat diarrhoea that a child had contracted through evil spirits (Budhathoki et al., 2016).

In the present study, even though they were aware that the community considers traditional medicines to be the sole treatment capable of curing witchcraft-related diarrhoea among under-five children, the medical staff persisted in emphasizing that children with diarrhoea should only be treated in hospitals. They were of the view that at the health facility, patients will undergo the appropriate diagnostic testing and, in the end, be prescribed appropriate medication based on their specific medical conditions. This attitude of healthcare providers might be attributed to the formal training they underwent regarding the management of a patient with diarrhoea upon admission to the hospital.

The significance of bringing children to the hospital when they contract diarrhoea or other illnesses is emphasized in Tanzania's health policy (Ministry of Health Community Development Gender Elderly and Children 2017). As per Tanzania's health policy, in all government health facilities, health care for under-five children is provided free of charge (Ministry of Health Community Development Gender Elderly and Children 2017). In response to this call, the community should make use of the free medical services offered in government hospitals to

under-five children and abstain from the myth that diarrhoea is caused by witchcraft. Numerous studies have been able to describe the kinds of medications and immunizations that are efficient in treating and preventing any form of diarrhoea (Jani et al., 2018; Masanja et al., 2019). Consequently, communities should not have any worries or uncertainties regarding the hospital's therapies because they have been validated to be effective in curing all diarrhoeal illnesses among under-five children.

Strengths and Limitations of the study

The main strength of this study is the use of both male and female participants with different backgrounds as data sources and both FGDs and IDIs as methods to collect the data. This allowed for the two data sources and methods to cross-validate each other, and, more importantly, it allowed for a deeper and more holistic understanding of the topic by providing different perspectives on it. Despite its strength, this research has certain drawbacks. First, since all assessments relied on participants' personal experiences, there may probably be biases in some of the data. Secondly, given that the present study was limited to two districts in the Tanga Region; it is likely that participants' perceptions cannot be generalized as may differ from those of other Tanzanian districts.

Conclusion

In the districts of Korogwe and Handeni, northern Tanzania, the present study has revealed that most people, especially caretakers and traditional healers, preferred the use of traditional medicines and held the belief that a certain form of diarrhoea among under-five children is caused by witchcraft. The participants also reported that traditional medicines and other specialized traditional approaches are the only types of medication that can treat witchcraft-related diarrhoea among under-five children. Plants were the main source of many traditional medicines that were purported to be capable of treating perceived witchcraft-related diarrhoea. The herbs that were reported to be commonly exploited to treat witchcraft-related diarrhoea come from the families of *Rubiaceae, Solanaceae, Arecaceae, Asparagaceae, Acanthaceae, Loganiaceae, Vitaceae, Araliaceae, Combretaceae, Apocynaceae, Lamiaceae,* and *Amaryllidaceae*. Although research on issues related to superstition can be challenging, it is beneficial if the key authorities will do more research to find out the truth about whether these traditional medicines can cure diarrhoeal diseases that are thought to be caused by witchcraft. If the results of the same research support the traditional remedies' ability to treat the disease, these treatments should be extended to other serious illnesses that afflict lots of individuals in the community.

Recommendations

The key government agencies should implement additional strategies to raise public awareness of the dangers of diarrhoeal illnesses among under-five children and the risks associated with utilizing traditional medicines in an effort to encourage more people to seek healthcare from health facilities. Caretakers should always consider taking their children to health facilities in case they exhibit signs of diarrhoea. They should also refrain from presuming that specific forms of diarrhoea can be caused by witchcraft. In addition to providing patient care, health professionals must educate their patients about the value of visiting a facility for testing and treatment and should dissuade them from taking traditional medications. Furthermore, it is not advisable for traditional healers to have excessive confidence in the effectiveness of traditional medicines in curing diarrhoea among under-five children. It is vital that traditional healers consistently counsel their patients to get treatment at a medical facility.

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Understanding Knowledge Levels and Influencing Factors among Implementers of the Prime Vendor System: A Case Study of Tanzania Mainland

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Abstract

Background: The United Republic of Tanzania's government has implemented various significant health commodities supply chain management reforms, including introducing and national rollout of the Prime Vendor System in October 2018. This initiative aimed to address and complement the 40% health commodities supply chain gap observed at the Medical Stores Department (HRSC-2017). Over the five years since its implementation, the Prime Vendor System has shown high acceptability by the Government, implementers, and the beneficiaries of the intervention; it resulted in increased availability of health commodities at health facilities, improved order fulfilment rates, and timely delivery of commodities, it made contributions to Tanzania's public health sector. However, despite the Government's strong commitment to the health sector, administrative reports indicate regional disparities in the Prime Vendor System bridging the health commodities supply chain gap.

Little has been done to explore the knowledge level and influencing factors among Prime Vendor System implementers in addressing health commodities supply chain challenges. Therefore, this study aimed to understand the level of knowledge and its influencing factors among implementers regarding the Prime Vendor System Implementation in Tanzania Mainland.

Methods: A quantitative cross-sectional study was conducted between June and September 2023, collecting data via the ODK application from 356 respondents across the Dodoma, Morogoro, Mtwara, and Mwanza regions. Statistical analysis was performed using SAS version 9.4, with significance set at a 95% confidence level.

Results: All respondents (100%) were aware of the Prime Vendor System, with only 30.9% receiving formal orientation training. Most respondents (78.93%) reported having no prime vendor contracts in their health facilities yet recognized and acknowledged the PVS as complementary to the Medical Stores Department (MSD). However, only 60.76% knew of changes made since the PVS's introduction. Factors such as age and position within the healthcare organization influenced PVS knowledge.

Conclusion: Respondents have a high level of knowledge and awareness of the prime vendor system's basic structure and transitional phases. However, there is a need for more sensitization and training in prime vendor contracts and continuous refresher training of the prime vendor system, especially for lower-level health facilities.

Keywords: Prime Vendor System, Supply Chain Management, Medical Stores Department, Knowledge levels, Influencing factors and Health Commodities

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Introduction.

Supply Chain Management in healthcare aims to ensure complete end-to-end visibility of information among stakeholders. The involvement of governmental institutions, regulatory agencies, and insurance companies adds further complexity to the system.

The healthcare logistics landscape has evolved significantly since 1999. Initially, it focused primarily on purchasing with little emphasis on inventory management or internal distribution. As healthcare supply chains developed, the Directorate of Purchasing integrated with the Directorate of Finance (Riverd-Royer et al., 2002).

Many countries have implemented Public-Private Partnership policies, recognizing the role of the private sector in enhancing the public supply chain system. Governments have realized the ability of the private sector to complement the general supply chain. Public-Private Partnerships (PPPs) improve essential health commodities availability in public health facilities by improving order fulfilment rates, controlling cost, and increasing client/patient satisfaction (Kuwawenaruwa et al., 2020), (MoHCDGEC, 2021), (Tanzania. Technical Assistance, 2018) and (Arney et al., 2014).

Therefore, it is evident that the pharmaceutical supply chain in these countries has attracted substantial attention, focusing on health system strengthening, specifically targeting options for redesigning and optimizing the performance of the supply chain (Lamphere et al., 2019) (MoHCDGEC, 2013). Such interventions include expanding funding sources, staff training and re-training, improving supply chain procurement and distribution processes, promoting the responsible use of commodities, and improving data visibility and utilization to make well-informed decisions.

In Tanzania, the Public Supply Chain System for Health Commodities has evolved from a push system to a pull system. The introduction of the prime vendor system contributed a lot in complementing all health commodities out of stock and reduced the burden from MSD. Continuous monitoring in the prime vendor system pilot regions shows that the complementary prime vendor system has effectively increased the availability of essential medicines in public health facilities; improved commodities availability was the main criterion that, in 2018, pushed the Government decision to roll out the prime vendor system to all 26 regions of Tanzania's mainland.

The Medical Stores Department (MSD), an autonomous public organization under the Ministry of Health (MOH), is responsible for procuring, storing, and distributing essential health commodities to all public and approved non-public and non-profit health facilities in the country. However, in recent years, MSD has encountered difficulties that have hindered its efficiency in supplying 100% of all facilities' needs.

Pharmaceutical supply chain systems face multiple challenges in most low- and middle-income countries, including insufficient funding, poor drug quality, low acceptability and affordability, transparent procurement procedures, weak accountability mechanisms, inefficient management systems, and a lack of well-equipped and knowledgeable personnel with experience in pharmaceutical supply chain management.

Despite significant reforms, including introducing the Prime Vendor System in 2018, challenges persist, leading to regional disparities in commodity availability. Various initiatives have been introduced to improve supply chain efficiency, yet gaps remain, highlighting the need for further exploration.

However, successfully establishing an intervention based on PPPs within the public sector supply chain system requires high acceptability by the Government, implementers, and the intervention's beneficiaries (Chandani et al., 2017) (Kuwawenaruwa et al., 2021). However, most research does not report on implementers' knowledge, awareness, and influencing factors regarding prime vendors. The study aims to understand the level of knowledge of prime vendor system

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implementers and to identify factors influencing the fidelity of implementation of the prime vendor system in Tanzania.

Methodology

Study Design

The research adopts a quantitative cross-sectional design, focusing on four regions in Tanzania's Mainland: Dodoma, Morogoro, Mtwara, and Mwanza. Within these regions, the study encompasses thirteen diverse local government authorities, including Dodoma (Dodoma City Council, Kondoa District Council, Kongwa District Council), Morogoro (Morogoro Municipal Council, Mvomero District Council, Kilosa District Council), Mtwara (Mtwara District Council, Mtwara Municipal Council, Newala Town Council, Masasi District Council), and Mwanza (Magu District Council, Nyamagana District Council, Ukerewe District Council).

Study Population

The study population consisted of purposively selected members from various levels of the health facilities who were directly involved in the health commodities supply chain, including their crucial role in the fidelity implementation of the Prime Vendor system in Tanzania. This includes health facilities in charge, storekeepers/pharmaceutical personnel, and laboratory personnel at the health facility level.

Sample Size and Sampling

The sample size for this study was determined using Yamane's formula (1967), which considers the study population, marginal error, and confidence level. With a total study population (N) of 3,203 individuals and a chosen marginal error (e) of 0.05, the calculated sample size (n) is 356. Regarding the sampling strategy, regions were purposively selected based on their relevance to the research objectives, including regions with and without medical store department zonal offices and regions with facilities with high health commodity consumption rates. From these regions, councils were chosen randomly, ensuring the representation of rural and urban settings to capture diverse perspectives. This random selection of councils enhances the study's representativeness. Within these councils, facilities and individuals were also randomly chosen, contributing to the inclusivity and generalizability of the study findings. This comprehensive approach ensures that a wide range of experiences and characteristics are represented within the selected regions and councils, thereby improving the validity and reliability of the research outcomes.

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 the University of Dodoma's Institutional Review Board.

Data collection and data processing

A face-to-face interview was conducted with all purposefully selected respondents, and a guided and constructive structured questionnaire containing both open- and closed-ended questions was utilized to gather information from the selected participants. All quantitative data was 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, and the data collection was done from June up to September 2023.

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Dependent variable

The study's dependent variable, the "Level of knowledge," was derived from twenty questions designed to assess respondents' understanding. Each question had a correct and incorrect answer. A score of 1 was assigned for a correct response, while a wrong answer received a score of 0. These questions were categorized into Basic Knowledge of Prime Vendor, Transition Period, Prime Vendor Structure, and Contract Management. The total score was calculated by summing the scores from all questions.

Independent Variables

The independent variables in this study encompass various factors: demographic indicators such as sex, age, and education level; professional attributes such as position within the health facility and years of experience; and contextual elements including the type of health facility, region, and mobility-related factors. The objective is to investigate the multitude of factors that may impact the knowledge levels of individuals involved in implementing the Prime Vendor System.

Data Analysis

Basic descriptive statistics were computed to elucidate the respondents' baseline characteristics, including frequency and percentage for categorical variables and mean and standard deviation for non-categorical variables. Since the outcome variable, the knowledge score demonstrated an approximately normal distribution and is non-categorical. A multiple linear regression model was utilized to identify factors associated with the knowledge level among Prime Vendor System implementers. The analysis was performed using SAS version 9.4, with statistical significance set at a 5% level.

Ethical Considerations

The University of Dodoma Ethics Committee granted ethical approval and registration for the study. In addition, the Office of the President of the Local Government Regional Administration and the Ministry of Health in Tanzania granted permission for access to all facilities supporting/implementing the Prime Vendor System within the Regional Secretariat and Local Government Authorities as well as four regional referral hospitals (Mwanza, Dodoma, Morogoro and Mtwara). Finally, informed consent was obtained from respondents during data collection, and confidentiality was maintained throughout the study.

Results

The study was conducted in all four regions: Dodoma, Morogoro, Mtwara, and Mwanza. A total of 356 respondents were interviewed from health facilities visited; vast numbers of respondents are from Mwanza (27.81%) and Morogoro (27.81%), followed by Mtwara (26.40%) and with a few participants from Dodoma (17.98%).

In Tanzania, there is a decline in health facilities when transitioning from lower to upper levels. This trend was particularly evident in my study, where a significant portion of the visited health facilities were dispensaries, in contrast to the Regional Referral Health facilities. Figure 1 This pattern is also mirrored in the distribution of respondents from our results, with the majority coming from dispensaries (45.79%) and health centres (39.89%). A smaller percentage of participants were

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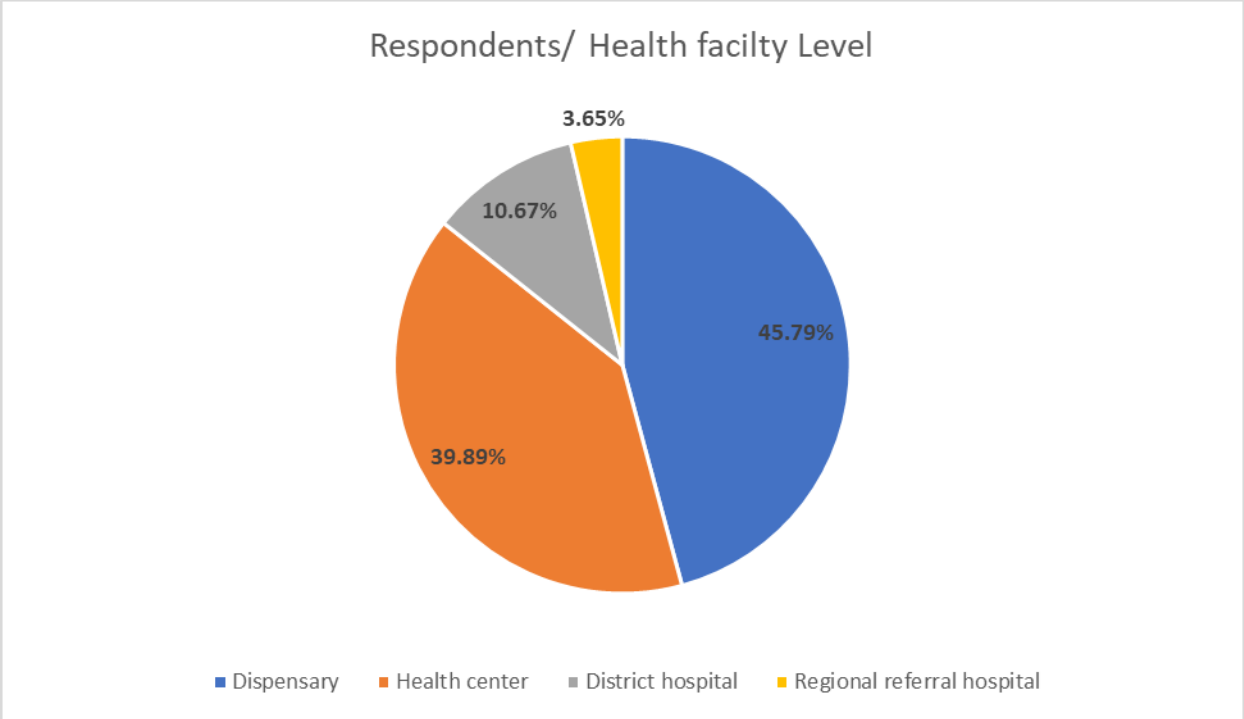
associated with District hospitals (10.67%), and the least were from Regional Referral Hospitals (3.65%).

Figure 1: Respondents Interviewed per Health Facility Level



Demographic Results of Respondents

All 356 intended respondents (100% of the sample) participated throughout the data collection process. Notably, a substantial proportion of the participants were females, accounting for 181 (50.84%), while males constituted 175 (49.16%) in the study.

Most respondents fell within the 30-34 age range, comprising 33.71% of the total. Subsequently, individuals aged 35-39 constituted 20.79%, and those above 45 accounted for 19.10%. In contrast, a smaller % of participants, 8.71%, belonged to the 40-44 age group.

During data collection, we aimed to interview the Health Facility in charge, the storekeeper, and Laboratory personnel at each health facility. The findings across all visited health facilities revealed that 41.85% were Health Facility In charge, followed by Storekeepers at 32.58%. A smaller percentage, 25.56%, represented Laboratory personnel, as many of the observed dispensaries lacked standard laboratories.

The results showed that most respondents had no upper level of education; only 3.37% had a master's degree, and 14.61% had a first degree. Meanwhile, most % had a diploma, 55.06%, and 26.97% had a certificate. (See Table 1)

Table 1: Demographic results

Demographic Results			
Variable	**Frequency**	**Percentage (%)**	**Mean ±SD**
Sex			
Male	181	50.84	
Female	175	49.16	

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Total	**356**	**100.00**	
Age category			36.74±8.33
<30	63	17.70	
30-34	120	33.71	
35-39	74	20.79	
40-44	31	8.71	
45+	68	19.10	
Education level			
Certificate	96	26.97	
Diploma	196	55.06	
Degree	52	14.61	
Master	12	3.37	
Position in this health facility			
The Health Facility In charge	149	41.85	
Storekeeper/ Store In – Charge	116	32.58	
Laboratory Personnel	91	25.56	

General Information of respondents

Table 2 shows that among the interviewed respondents, the majority had 5 – 9 years (40.17%) of experience as government officials working as healthcare workers. During their working period, half of the interviewed respondents (59.27%) had transferred from one working station to another, the majority of them transferred once (56.40%) or twice (22.27%), while 40.73% had never transferred to any station since their employment.

Table 2: General Information of Respondents Interviewed

General Information of Respondents			
Variable	**Frequency**	**Percentage (%)**	**Mean ±SD**
Experience			9.72±7.30
<5	66	18.54	
5-9	143	40.17	
10-14	85	23.88	
15+	62	17.42	
Ever transferred from one working station			
No	145	40.73	
Yes	211	59.27	
How many Times? (n=211)			
1	119	56.40	
2	47	22.27	
3	17	8.06	
4	28	13.27	

Throughout the data collection process, we aim to assess healthcare workers' understanding of fundamental aspects such as the Prime Vendor, the Transition of the Prime Vendor, the structure of the Prime Vendor, and contract management of their respective prime vendor. In the questionnaire, we mixed false statements to measure their knowledge through understanding and checking their awareness of respondents on the prime vendor system.

Results regarding Basic Knowledge of Prime Vendor

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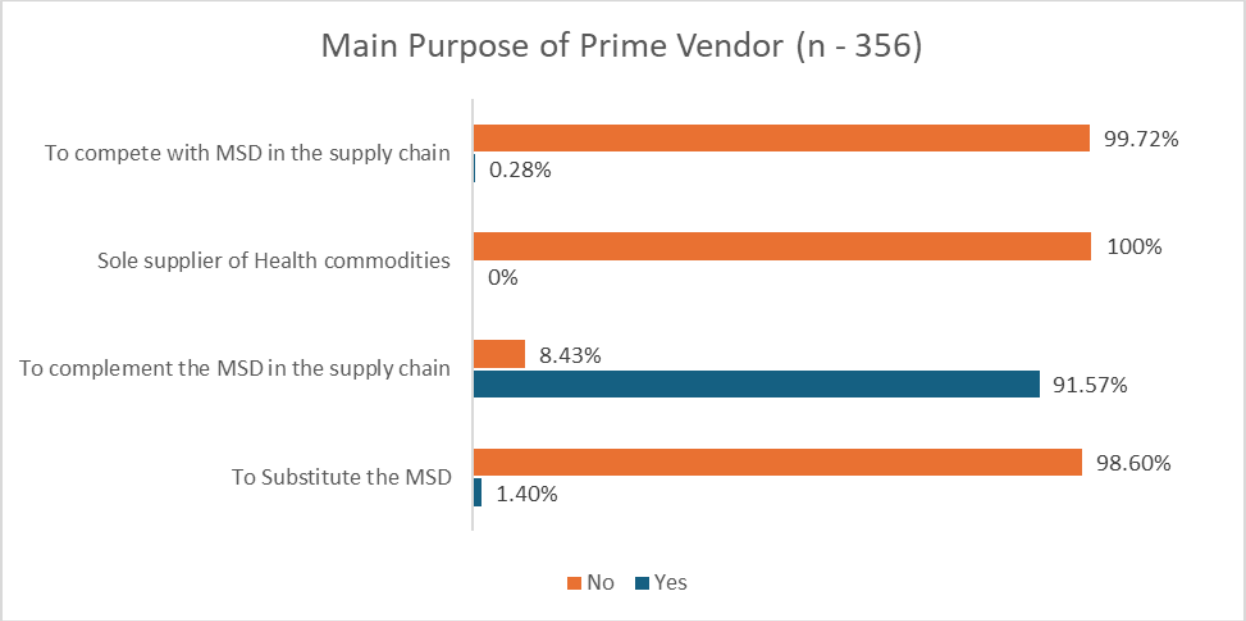
A total of 316 (88.76%) respondents heard about Prime Vendor, while 40 (11.24%) respondents never heard about Prime Vendor at all; this is due to a few of the respondents being new employees at the station. When the respondents were asked about whether the national rollout of the prime vendor system in Tanzania was in 2017, half of the respondents did not agree, 197(55.34%) that it is true, while the remaining 159 (44.66%) agreed on the statement the claim is not valid.

Furthermore, when participants were prompted to elucidate the purpose of the prime vendor system in Tanzania, the data revealed that the majority understood its purpose. Specifically, 326 (91.57%) respondents acknowledged that the prime vendor system complements the Medical Stores Department (MSD) in the Health Commodities Supply Chain System. Moreover, a significant majority, 351 (98.60%), disagreed with the notion that the prime vendor is intended to substitute the MSD, and 356 (100%) respondents disagreed that the prime vendor is the sole supplier of health commodities. Additionally, 355 (99.72%) respondents also disagreed that the prime vendor system is there to compete with the MSD in country health commodities supply chain system. See figure 2.

This indicates that while most respondents possess a basic knowledge about the Prime vendor System, still they lack updated information regarding the implementation dates of the Prime vendor system in Tanzania.

Figure 2: Main purpose of Prime vendor system



Knowledge of the transition period of the Prime vendor system

The nationwide implementation of the prime vendor system has significantly enhanced Tanzania's Health Commodities Supply Chain System. However, throughout the entire rollout period, adjustments and transitions have been made to enhance the overall efficiency of the health commodities supply chain system.

During the data collection, we wanted to know if the respondents were aware of the prime vendor system's transition period, what has changed or improved in it, and when the circular for changes issued by PORALG was.

According to the respondents' results, more than half were aware of amendments to the prime vendor system 192(60.76%). In comparison, the remaining respondents were not aware of the amendments 88 (27.85%), and 36 (11.39%) did not agree if there were any amendments in the prime vendor system. Regardless, few of them were unaware of the amendments made to the prime

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vendor system. Surprisingly, 255 (80.70%) correctly identified when the circular for changes was issued by PORALG (July 2021).

Moreover, when asked if the transition in prime vendor enables a region to procure from a single LOT system to a four LOT system, half of the respondents 171 (54.11%), agreed, while 127 (40.19%) were unaware of it. Additionally, this was seen when 126 (39.87%) of respondents stated that the transition enabled more than four LOT systems in the region, which is wrong. (See Table 3) This indicates a disparity in information among healthcare workers, with some respondents being aware of the transition in the prime vendor while a few are not, and others do not agree, likely due to lack of prior knowledge.

Table 3: Transition period

Transition Period		
Variable	**Frequency**	**Percent (%)**
Awareness of any amendments made to the Prime Vendor System		
No	36	11.39
Yes	192	60.76
I don't know.	88	27.85
When was the circular for changes issued by PORALG?		
Oct-20	4	1.27
Jul-21	255	80.70
Jan-22	57	18.04
The transition in the Prime Vendor System enables a region to Procure from a single LOT system to Four LOT system		
No	18	5.70
Yes	171	54.11
I don't know.	127	40.19
Changes made in the Prime Vendor system		
The transition from single LOT to 4 LOT system	190	60.13
Having more than four LOT systems in the region	126	39.87

Knowledge of prime vendor structure

We included questions to verify respondents' comprehension of the prime vendor structure. Most responses were accurate, indicating respondents were aware of the prime vendor system.

A considerable number of respondents, 299 (94.62%), acknowledged the prime vendor role as complementary to the MSD. Additionally, more than half of the respondents, 219 (69.30%), recognized the Prime Vendor System as an integral part of the Government Structure. Furthermore, 207 respondents (65.51%) noted that only designated healthcare workers were authorized to communicate with the Regional Prime Vendor, which most respondents heard, stating only the District Pharmacist was allowed to do so. Additionally, most respondents, 224(70.89%), agreed that currently, the region can contract more than one prime vendor.

Nevertheless, several aspects remained relatively unfamiliar to most respondents. For instance, 178 (56.33%) respondents acknowledged a lack of awareness regarding the allowance for a Regional Prime Vendor to serve multiple regions, and 146 (46.20%) were unaware of the Ministry of Health's responsibility for contracting a Regional Prime Vendor, as depicted in Table 4

Table 4: Prime vendor structure

Prime Vendor Structure			
Variable	**No (%)**	**Yes (%)**	**I don't know (%)**
Acts as a complementary system to MSD	4(1.27)	299(94.62)	13(4.11)

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Anchored within the Government Structure	41(12.97)	219(69.30)	56(17.72)
Any healthcare worker is allowed to communicate with the Regional RPV at any time when the facility receives a stock-out from MSD	207(65.51)	62(19.62)	47(14.87)
The Region is allowed to have more than one Prime Vendors	17(5.38)	224(70.89)	75(23.73)
The regional prime vendor is supposed to be registered by TMDA	5(1.58)	242(76.58)	69(21.84)
Regional Prime Vendor is allowed to serve more than one region	25(7.91)	113(35.76)	178(56.33)
The Ministry of Health is responsible for contracting a Regional Prime Vendor	109(34.49)	61(19.30)	146(46.20)

Contractual Understanding of Prime Vendor System

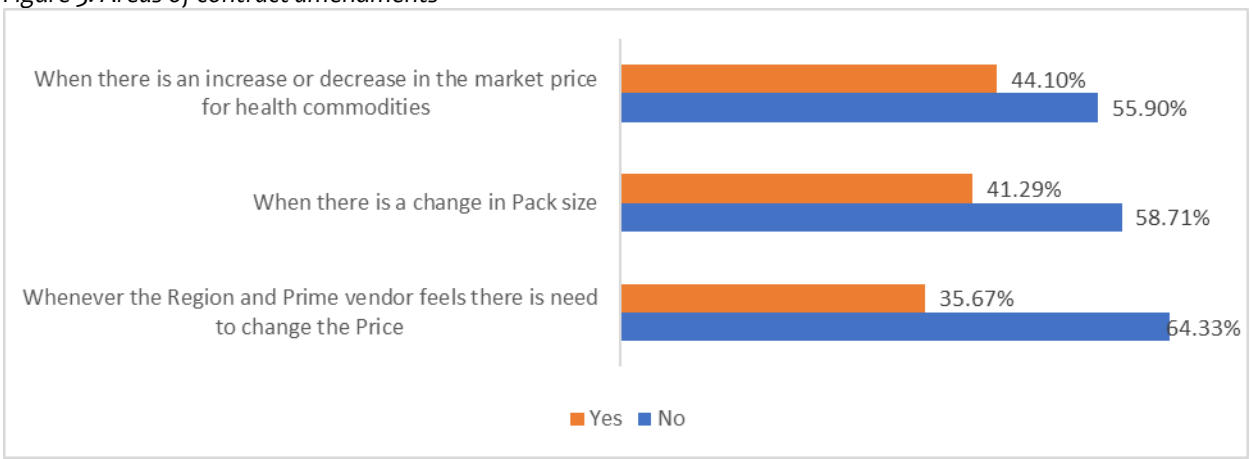
We also wanted to assess respondents' awareness of Contractual management, including whether they know all the procedures for finding a new prime vendor, Contractual agreement time with a prime vendor, contractual review, and termination terms.

Most respondents were not aware of most of the contract terms the region enters with their respective regional prime vendor, and this was confirmed when 283 (79.49%) of the respondents stated that they were not aware of any process of contracting a new prime vendor, while the remaining 73(20.51%) of the respondents stated that they were aware of all processes.

Surprisingly, most respondents knew the contractual agreement time with a prime vendor. This was confirmed when 348 (97.75%) did not agree when asked if the agreed contractual period is 2 years between the region and their respective regional prime vendor. Additionally, 313 (87.92%) disagreed that the regional commissioner signs the contract on behalf of their region.

Regarding the contract review process, more than half of the respondents 209 (58.71%) were unaware that the contract between the region and their regional prime vendor could be reviewed/amended after signing the contract. In comparison, 147 (41.29%) knew the contract could be amended. From Figure 3, Amendments were reported to occur under various circumstances: Whenever the Region and Prime vendor needs to change the Price 229 (64.33%). When there is a change in Pack size, 209 (58.71%), and when there is an increase or decrease in the market price for health commodities, 199 (55.90%).

Figure 3: Areas of contract amendments



Distribution of Knowledge among variables with correlation test

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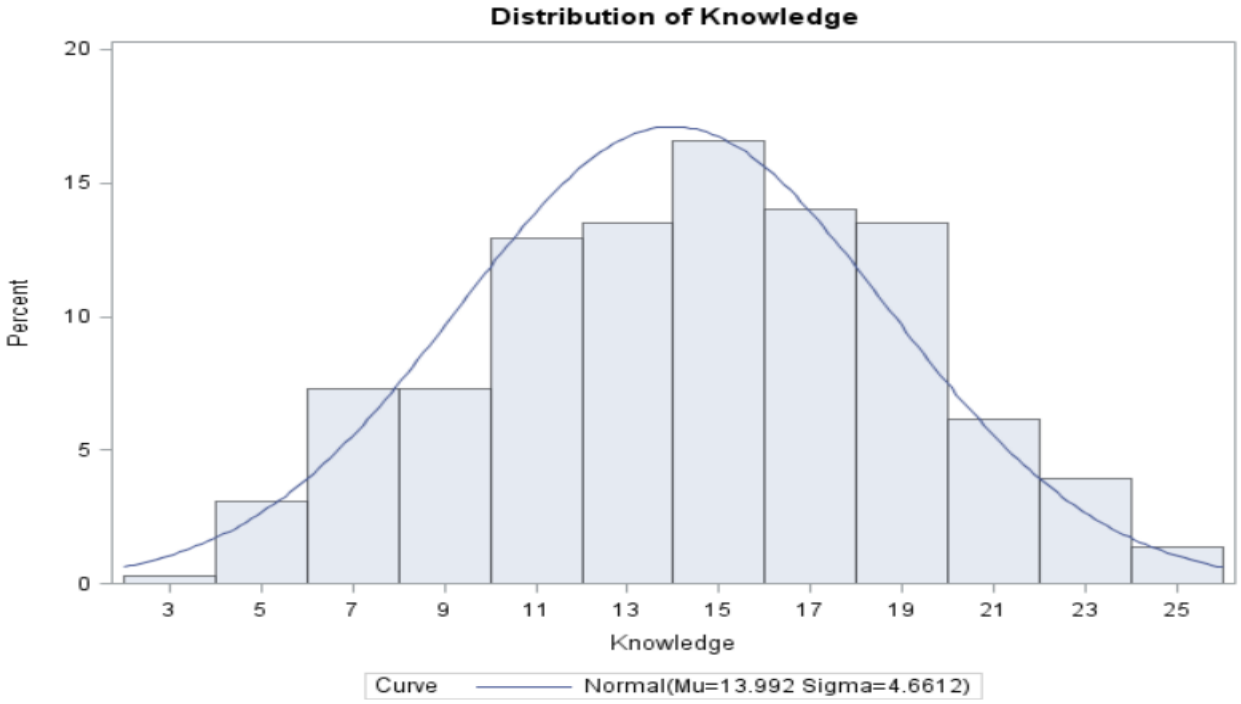
The evaluation of Goodness-of-Fit Tests for the Normal Distribution underwent an exhaustive examination, employing diverse statistical metrics such as the Kolmogorov-Smirnov, Cramer-von Mises, and Anderson-Darling tests. The collective results of these assessments consistently revealed that the distribution of knowledge scores closely conformed to a regular distribution pattern. The visual representation of the standard curve in Figure 4 vividly illustrates the close alignment of knowledge scores with an approximate normal distribution. This thorough analysis affirmed the statistical normality of knowledge scores and underscored the reliability of the findings concerning their distributional characteristics. This confirms that half of the respondents are aware and have knowledge, while the remaining respondents are still unaware and do not know enough about the prime vendor system.

Figure 4: Distribution of Knowledge



Factors associated with knowledge of implementers of the Prime vendor system.

We used linear regression to determine the factors associated with knowledge among the Prime Vendor System. The analysis uncovered significant relationships between knowledge and various factors, including the age of respondents (p=0.0012), their positions within the health facility (p<0.0001), the type of health facility (p=0.0005), and their region of affiliation (p=0.0008).

Specifically, age demonstrated an inverse correlation with knowledge, with each unit increase in age associated with a decrease in knowledge by 0.124 (β=-0.1239, p=0.0012). The health facility in charge exhibited notably higher knowledge (β=2.7511, p<0.0001), scoring 2.75 points higher than laboratory personnel and Storekeeper/pharmaceutical personnel.

Additionally, respondents from District hospitals and regional referral hospitals demonstrated a higher knowledge advantage (District hospitals (β=2.9351, p=0.0005) and regional referral hospitals (β=3.5004, p=0.0079)) compared to those from dispensaries and Health centres.

Additionally, respondents from the Dodoma and Morogoro regions exhibited higher knowledge (Dodoma region (β=2.3375, p=0.0008) and Morogoro region (β=1.5142, p=0.0145)) compared to

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those from the Mwanza region. However, variables such as respondents' gender, educational level, years of experience, and job transitions did not display significant associations with knowledge among Prime Vendor System implementers (See Table 5).

Table 5: Linear regression analysis for factors associated with knowledge.

Parameter	Estimate	Standard Error	t Value	p-value	R square
Intercept	17.55201	2.220012	7.91	<.0001	0.514206
Sex					
Male	0.170784	0.511804	0.33	0.7388	
Female	Ref				
Age	-0.12394	0.037917	-3.27	**0.0012**	
Education level					
Certificate	1.277644	1.43566	0.89	0.3741	
Diploma	2.070065	1.402545	1.48	0.1409	
Degree	1.3101	1.485413	0.88	0.3784	
Master	Ref				
Position in this health facility					
Health Facility In charge	2.751081	0.605365	4.54	**<.0001**	
Storekeeper/ Store In - Charge	0.269181	0.610743	0.44	0.6597	
Laboratory Personnel	Ref				
Experience	0.016164	0.044765	0.36	0.7183	
Type of health facility					
Dispensary	Ref				
Health center	0.81364773	0.53439636	1.52	0.1288	
District hospital	2.93512008	0.83168261	3.53	**0.0005**	
Regional referral hospital	3.50042624	1.30907680	2.67	**0.0079**	
Region					
Dodoma	2.337539	0.692619	3.37	**0.0008**	
Morogoro	1.514163	0.616393	2.46	**0.0145**	
Mtwara	-0.20063	0.625062	-0.32	0.7484	
Mwanza	Ref				
Transferred from one working station					
Yes	0.53066	0.505546	1.05	0.2946	
No	Ref				

Discussion

The study aimed at assessing the level of knowledge and influencing factors among implementers of the prime vendor system. The results were grouped into four aspects: understanding of basic

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knowledge of the prime vendor, transition of the prime vendor, the structure of the Prime Vendor, and contract management of their respective prime vendor.

Fundamental understanding of prime vendors

This study revealed that most respondents were familiar with the prime vendor system, recognizing its role in supplementing the medical store department. Many mentioned ordering health commodities from the prime vendor when facing shortages in the medical store department. However, despite this familiarity, most respondents lacked a clear understanding of the prime vendor system's history, particularly its national rollout.

The transition of the prime vendor

The circular for the transition of the prime vendor system, released in July 2021 by the minister of PORALG, aims to improve the prime vendor system's performance by modifying its operation. More than half of the respondents were aware of the amendments made in the prime vendor system. However, it was difficult for new employers (employed within 2022 – 2023) to be aware of any amendments made in the prime vendor system.

Regarding the prime vendor structure

Most respondents mistakenly thought the Ministry of Health was responsible for contracting the new regional prime vendor. Additionally, most were unsure whether the prime vendor could serve more than one region. Despite these misconceptions, respondents demonstrated awareness of certain aspects, such as the purpose of the prime vendor and the responsible party for contacting them.

Effective procurement of health commodities from the prime vendor necessitates a thorough understanding of the operational structures and principles involved. District pharmacists and laboratory technologists provide this understanding to healthcare workers under their supervision, facilitating smooth processes without encountering challenges.

This aligns with findings by (Elias, 2023) that highlighted PVS as a crucial complement to the work done by the Medical Stores Department in the Tanzanian health supply chain system. Additionally, the excellent reputation of prime vendors in the regions, close collaboration with district authorities, and participants' understanding of the intervention's role in complementing the public health supply chain enhance the acceptability of PVS in the regions.

Regarding the contractual terms of the prime vendor system

The study found that most respondents lacked awareness of key terms, such as the contract review period, the legality of amending the contract with the prime vendor, and the termination process. However, many were aware of the duration of the contract. The availability of prime vendor tools, including a copy of the contract with the respective vendor, significantly influenced awareness levels. It was noted that many health facilities visited did not possess these essential prime vendor tools. This contrasts with findings by (Arney et al., 2014) that emphasized the importance of clear contracts in implementing framework agreements like PVS for high performance and increased availability of essential health commodities at service delivery points.

The study revealed remarkable levels of awareness and knowledge regarding the Prime Vendor System, with all respondents indicating familiarity with the intervention. Only 30.9% of respondents have undergone formal orientation training, which indicates significant efforts in sensitizing and enhancing awareness among new and established staff across the regions. These findings echo those of Kuwawenaruwa et al. (2020), who highlighted that improved awareness and

knowledge directly contribute to better understanding and compliance with the operations of the Jazia Prime Vendor System.

Furthermore, this study identified various factors influencing knowledge of different aspects of PVS; these include age, position within healthcare facilities, type of health facility, and region. It was observed that older individuals had significantly lower levels of knowledge, and lower-level health facilities exhibited a lack of knowledge, suggesting the need for targeted sensitization efforts, particularly among younger personnel at grassroots levels of the health supply chain. Beyond knowledge, factors such as capacity building and supply chain management skills were crucial for effectively implementing the Prime Vendor System.

Conclusion

Respondents have a high level of knowledge and awareness of the prime vendor system's basic structure and transitional phases. However, there is a need for more sensitization and training in prime vendor contracts and continuous refresher training of the prime vendor system, especially for lower-level health facilities.

Study limitation.

The main limitation of the presented study is that it did not explore the level, scope, and extent of knowledge and awareness of other healthcare workers at Health facilities rather than selecting a few key implementers of the prime vendor system, which could have given us a clear picture of the level of knowledge and awareness of all cadres/healthcare workers working at health facilities.

List of Abbreviations

CHMT	Council Health Management Teams
CMTs	Council Management Teams
DHIS2	District Health Information System
eLMIS	electronic Logistics Management Information System
ERP	Enterprise Resource Planning
GPS	Global Positioning System
ILS	Integrated Logistics System
IMPACT	Information Mobilized for Performance Analysis and Continuous Transformation
IRB	Institutional Review Board
MoH	Ministry of Health
MSD	Medical Stores Department
ODK	Open Data Kit
PORALG	President's Office Regional Administration and Local Government
PVS	Prime Vendor System
RHMT	Regional Health Management Teams
RS	Regional Secretary
SAS	Statistical Analysis Software
TMDA	Tanzania Medicines and Medical Devices Authority

Availability of data and materials

The data sets used and/or analyzed during the current study are available from the corresponding author.

Declarations

Ethics approval and consent to participate.

The Ethical Clearance Committee of the University of Dodoma Tanzania gave the ethical clearance for the study in writing.

Competing interests

The authors declare that they have no competing interests.

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Authors contributions

MM developed the proposal and study design and participated in planning, data collection, and interpretation. MM was the principal investigator in all four regions visited and supervised the data collection process. MM contributed to the training and management of data collection. Research Assistants managed data entry and data analysis. RM and MM supported planning and organizing logistics. MM drafted the manuscript for input by the other authors. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests

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Development and rapid assessment of Community-Based Health Education Package for the Control of *Taenia solium* Taeniasis/Cysticercosis in Tanzania

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Abstract

Background: We conducted this study to develop and rapidly assess a community-based health education package (CHEP) to serve as a guide to improving knowledge, attitude, and practices (KAP) for controlling *T. solium* cysticercosis Taeniasis (TSCT) in endemic areas in Tanzania.

Methods: Data for the development of the (CHEP) was collected through a questionnaire and observation of household infrastructure. We conducted and analyzed 12 focus group discussions (FGDs) and 38 key informant interviews (KIIs) using ATLAS.ti 8. A household survey using a questionnaire was conducted on 480 respondents and analyzed using SPSS by conducting a chi-square test.

Results: The developed CHEP included the following key messages: (1) improving knowledge and attitudes towards TSCT transmission, causes, health effects, treatment, and control measures, (2) proper pork preparation and general food handling practices, (3) good pig husbandry practices, and (4) improving water, sanitation, and hygiene (WASH) practices. The CHEP developed comprises a Training of Trainers (TOT) manual, a leaflet/brochure, a poster, and a handbook. The results from the rapid assessment reported a statistically significant improvement in knowledge regarding the link between epilepsy and cysticercosis ($p<0.001$) and in the practice of washing fruits and vegetables ($p=0.025$).

Conclusion: Therefore, it is recommended that critical stakeholders conduct one health approach toward implementing CHEP in areas affected by TSCT to control the disease.

Keywords: *Taenia solium; cysticercosis; health education package; Tanzania*

Introduction

There are 2.4 million pigs in Tanzania, and 9% of Tanzanian households keep livestock (URT, 2015). Pig farming contributes significantly to income generation, food security, soil fertility improvement, asset storage, and intangible functions unrelated to community economic gains (Kimbi et al., 2015). Parasites expose free-ranging pigs to infection, such as *Taenia solium*, which hurts profits through the condemnation of infected carcasses and the zoonotic risk of the parasite. The parasite causes TSCT in humans (Roesel et al., 2017). The societal cost of TSCT in endemic communities is exceptionally high; in Tanzania, it has been reported to be USD 8 million annually (Trevisan et al., 2017). The costs comprise the economic loss because of the decline in the market value of infected pork, condemnation of infected pork, diagnosis, and treatment of

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human cases, and the severe impact on farmers' livelihoods (Atawalna & Mensah, 2015). An increase in the prevalence of porcine cysticercosis (PCC) in the Eastern and Southern Africa (ESA) region has been linked to the increase in smallholder pig farming and pork consumption (Phiri et al., 2003). Therefore, it is recommended that critical stakeholders conduct one health approach toward implementing CHEP in areas affected by TSCT to control the disease.

Taenia solium cysticercosis Taeniasis affects over 50 million people worldwide and leads to the death of about 50,000 people annually (WHO, 2013). The main obstacle to effective control of cysticercosis is the low knowledge of parasite transmission (Johansen et al., 2014). Health education plays an essential role in preventing and controlling infectious diseases (Alexander et al., 2012; Johansen et al., 2014; Ngowi et al., 2017). In some communities, various health education interventions have been implemented.

In some communities, various control strategies have been implemented to control TSCT. These strategies include the use and proper maintenance of latrines (Braae et al., 2015; Ngowi et al., 2017), treatment of taeniasis cases with praziquantel or niclosamide (Bustos et al., 2012), treatment of porcine cysticercosis with oxfendazole (Mkupasi et al., 2013), vaccination of pigs (Lightowlers, 2013; Kabululu et al., 2020) and confinement of pigs. Measures also focused on the immediate removal of children's feces in latrines, thorough hand washing with soap/detergents, boiling of drinking water, prohibition of consumption or sale of infected pork, and improved meat inspection. The effectiveness of the measures was low or short-lived, and other strategies were too expensive to apply on a large scale (Ngowi et al., 2008; Mkupasi et al., 2013; Braae et al., 2014; Carabin & Traoré 2014; Kabululu et al., 2020).

Despite control measures, the disease is still widespread in many pig farming areas in Tanzania (Flora et al., 2023; Wilson et al., 2023a). One reason for the endemicity is the low knowledge about TSCT in rural communities (Holst et al., 2022; Nyangi et al., 2022; Makingi et al., 2023; Wilson et al., 2023b). Most of them practice free-range pig farming under poor hygienic conditions (Carabin & Traoré 2014; Shonyela et al., 2017; Nyangi et al., 2022; Flora et al., 2023; Makingi et al., 2023; Wilson et al., 2023b). For effective and sustainable control of the parasite, the One Health approach is the way to go (García et al., 2007; Braae et al., 2016, Okello & Thomas 2017; Ramiandrasoa et al., 2020).

Health education in endemic regions is crucial for an effective and sustainable control program to improve the health and economic situation of the infected population (Sarti et al., 1997; Alexander et al., 2012; Mwidunda et al., 2015; Ngowi et al., 2017). Long-term change can only be successful if community participation accompanies health education programs (Sarti et al., 1997; Alexander et al., 2012; Mwidunda et al., 2015; Ngowi et al., 2017). In the health education studies conducted in Tanzania, the target groups were not fully involved in planning/development, implementation, and evaluation (Ngowi et al., 2008, 2011; Mwidunda et al., 2015). Therefore, there was a need to develop a community-based health education package (CHEP) that fully involves the communities.

The community-based health education package (CHEP), developed and rapidly assessed, is a conventional approach to improving community knowledge, attitude, and practices (KAP) in controlling TSCT. The health education package was developed based on information from the community in four districts in Tanzania, namely Mbulu, Mpwapwa, Mbinga, and Rungwe, on their KAP regarding TSCT control. The package was rapidly assessed through education intervention in the Babati district. Studies by Sarti et al. (1997), Ngowi. et al. (2008), and Alexander et al. (2012) reported poor KAP in India, Mexico, and Tanzania. It was, therefore, necessary to develop this structured CHEP to improve KAP, which will lead to behaviour change believed to be fundamental to controlling TSCT. Community members were involved in the development of the CHEP, from planning through implementation and continuing to evaluation and assessment. The CHEP comprises four components: a Training of Trainers (TOT) manual, posters, brochures, and a manual with illustrations (pictures) on critical TSCT control strategies. The package will be integrated with other existing TSCT control strategies.

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Communities in resource-poor, endemic countries can quickly adopt and implement the developed CHEP. This paper describes developing and rapidly assessing the community-based health education package for TSCT control in Tanzania.

Methods

Study area

Communities in Mbulu, Mpwapwa, Mbinga, and Rungwe districts provided information to develop this CHEP in four different Agroecological zones in Tanzania (Nyangi et al., 2022). Eight villages were purposively selected from four wards in the four districts for being PCC endemic areas and popular in small-scale pig rearing (Boa et al., 2006; Ngowi et al., 2008; Mwang'onde et al., 2014; Shonyela et al., 2017; Mwang'onde et a., 2018; Braae et al., 2015; Nyangi et al., 2022). We applied a simple random sampling technique to select households from each village in the quantitative component. We selected equal numbers of households from each hamlet. We interviewed the household heads; when the household head was absent, we interviewed an adult household member using a structured questionnaire (Nyangi et al., 2022). We purposively selected the participants for the qualitative part (Nyangi et al., 2024). We randomly selected the participants for the rapid assessment of the CHEP from two villages in the Babati district, and we selected the district for being a PCC endemic area and popular in small-scale pig rearing.

Study design

We conducted a cross-sectional survey in eight purposively selected villages in the four study districts. In developing the CHEP, we modified the guidelines (Sarti et al., 1997; Ngowi et al., 2008; Alexander et al., 2012; CDC, 2013). We developed the health education package in three main steps: (i) formative research (Figure 1) (ii) development of the health education package (iii) pilot test and revision (Figure 2). We conducted a rapid assessment between September and October 2021 in two selected villages from the purposely selected Babati district. We selected the district because it is endemic for porcine cysticercosis (PCC) and famous for small-scale pig-keeping.

Selection of households

For the quantitative study, we estimated the sample size using the formula by Fisher et al. (1991). The assumed prevalence of 50% of TSCT was used to compute the minimum sample size required for this study.

$$n = \frac{z^2 pq}{d^2}$$

Where: Zα = standard normal deviation = 1.96; p = estimated prevalence. = 0.5 (50%); q = (1 – p) = 0.5; d = (Precision) = 0.05

$$n = \frac{1.962 * 0.5 * 0.5}{0.052} = 385 \text{ respondents}$$

We added 25% for a design effect and yielded 480 households.

For the rapid assessment, we randomly selected 15 pig farmers and 15 non-pig farmers, 15 government officials and 5 pig butcher/pig traders to attend a two-day workshop on the rapid assessment of the developed CHEP. This makes 50 participants per village during pre-intervention and 50 during post-intervention. The overall objective of this workshop was to facilitate the training of potential resource persons on how to educate and guide community members in implementing measures for control of TSCT in their areas.

For sustainability, we conducted a two-day health education intervention for TSCT control. The first day of the workshop comprises training for local communities' trainers (TOTs). This was followed by a second day of training of the larger communities (villagers, including pig and non-pig farmers) by the trained local trainers (TOTs). Participants in the TOTs workshops included village and ward level health workers who usually conduct health education at the facility (health assistants, clinical officers, nurses, health educational officers), community development workers,

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primary and secondary school science (health) subject teachers, village/ward livestock field officers, animal scientists, few members of the village health committee (VHCs). The second day of the workshop was for a few selected TOTs to train the pig, non-pig farmers, and pig butcher/pig traders. One week before the workshop, we randomly selected a list of all smallholder pig-keeping and non-pig farmers from the village list with the help of local village leaders, ward livestock field officers, and ward executive officers (WEO).

Formative research

Using a formative research guide, we assessed the local context and risk factors for TSCT infection in the target community (Figure 1). Formative research is a process in which researchers identify a target community for study, decide how to access that community, and define the community characteristics essential to a particular public health problem (CDC, 2013).

For this study, we defined the risk factor as an aspect of personal behavior or lifestyle, environmental exposure, or inherited characteristic that epidemiological evidence has linked to one or more preventable health condition(s) (Skolnik, 2016).

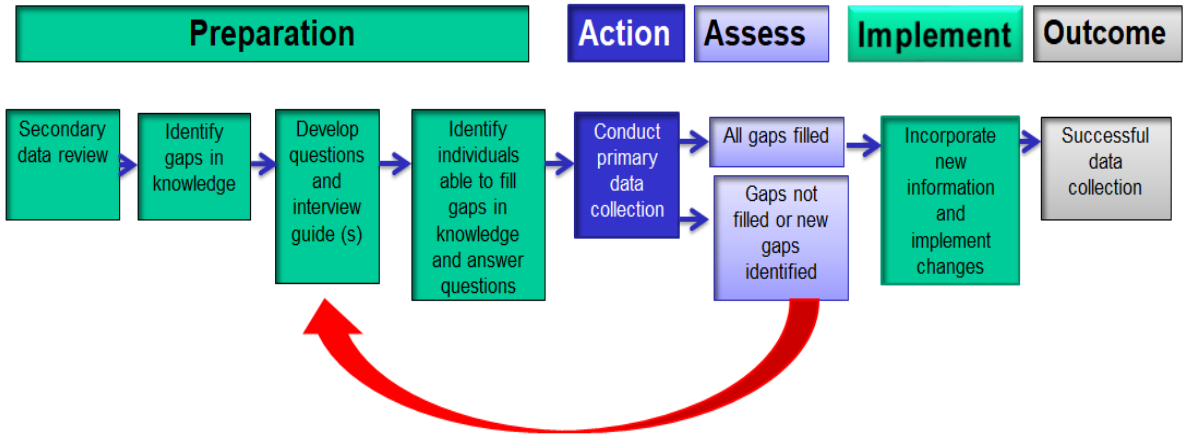

Figure 1: The iterative process of formative research, adapted from CDC (CDC, 2013).

Data collection

We used a community-based mixed-methods approach for this study, which included inputs from the household survey of pig farmers and non-pig farmers and interviews with key informants (KIIs), i.e. primary and secondary school headmasters, veterinary officers, health officers, environment and sanitation officers, community development officers and education officers at the community and district levels using a critical informant interview guide. We also conducted focus group discussions (FGDs) with the village health committee and primary and secondary school teachers to identify potential TSCT infection risks in the study area. We observed household infrastructure using an observation checklist in the same household that had taken part in the household survey. The information collected led to the formulation of critical messages for developing a health education package.

We used qualitative and quantitative triangulation approaches to validate the research findings through multiple data collection methods (CDC, 2013). One way to triangulate data from formative research is to compare information on the same topic from different data sources. Another strategy is to use at least two different data collection methods, such as KIIs, FGDs, and observations (CDC, 2013). We collected data to assess risk factors reflecting the natural and human environment, such as TSCT transmission and behaviors conducive to TSCT transmission through a household survey using semi-structured questionnaires, FGDs, KIIs, and a household infrastructure observation checklist (Nyangi et al., 2022).

For the rapid assessment, the farmer's workshop began with a questionnaire intended to identify farmers' knowledge and practices regarding *Taenia solium* life cycle, knowledge of signs

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of human infection of *Taenia solium,* the transmission of taeniasis and neurocysticercosis, the transmission of porcine cysticercosis, methods of pig keeping, and personal hygiene habits likely to affect the transmission of *Taenia solium* eggs from either pigs or people recognition of tapeworm segments in stool. Farmers received the question to describe what proportion of time they kept their pig tethered during the harvest, planting, and growing seasons of the year and whether the family always used a latrine for defecation, always washing hands with soap after defecating and before eating and washing fruits and vegetables. During the workshop, we conducted health education intervention after administering the questionnaire.

Household survey

We conducted the household survey using a structured questionnaire that included KAPs from pig farmers and non-pig farmers. The questionnaire included questions on demographics, medical history, previous sanitation projects (health policies, strategies, and plans), previous health education and knowledge about TSCT, its transmission, signs/symptoms, treatment, attitude, and practices related to TSCT. We administered the questionnaire to 480 respondents in Swahili, and then translated and recorded the information in English.

Key informant interviews

The key informants were livestock/veterinary officials, health workers/practitioners, community development, environment and sanitation officials, district and county education officers (primary and secondary schools), head teachers of primary and secondary schools, and local government officials who were to be involved in the study. Thirty-eight KIIs were conducted in the four districts with eight villages (two villages per district). A pre-tested interview guide was used to interview the KIIs on various aspects of TSCT. We collected data through the KIIs guide which was used to assess perceptions of actual problems related to factors influencing the prevention and control of TSCT. The same two researchers independently reviewed the written transcripts to improve the reliability of interpretation and reached a consensus before accepting the data for analysis.

Focus group discussions (FGDs)

Village health committee members and primary and secondary school science teachers were purposively selected to participate in the FGDs. Facilitators fluent in Swahili conducted and led the FGDs using an interview guide and a digital recorder. The participants in the Focus Group Discussion gave their consent before their discussions were recorded using a digital audio recorder. We typed the transcribed data into MS Word for further analysis.

Fourteen FGDs were conducted using an FGDs interview guide in all four districts. The plan was to perform 16 FGDs from the eight study villages. We ended with 14 FGDs as two villages had no active village health committee. Out of the 14 conducted FGDs, two had poor-quality audio that could not be heard clearly or transcribed. Therefore, we were left with 12 effective FGDs. The participants were asked to attend a 60- to 90-minute special session for FGDs. Each FGD comprised a minimum of six and a maximum of 12 participants. The same two researchers reviewed the written transcripts independently to improve interpretation reliability and reached a consensus before accepting them for analysis.

Household observation and infrastructure assessment

We conducted household observation and infrastructure assessment using a checklist for each household to capture high-risk behaviors/hygiene practices. Direct observations focused on the presence and quality of the toilet in terms of floor, roof, door, and pit cover, the presence of hand washing facilities with soap (Tippy Taps) in the latrines or outside the latrines, pig housing systems (confinement, tethering, or free-range), and general hygiene of the environment. The household observation was done in the same households where the household survey was conducted.

For the CHEP pilot, pig farmers, non-pig farmers, schoolteachers, and local leaders, including spiritual leaders and government officials at the community/village level, formed groups and completed a short FGDs interview on the key messages of the CHEP. Their responses formed the basis for the FGDs with 6-12 participants per group. Four groups were formed: (i) pig farmers, (ii) non-pig farmers, (iii) government officials, including spiritual leaders, and (iv) key informants (primary and secondary school science teachers, livestock extension/veterinary officials). The groups wrote on the flip chart what they had discussed in their respective groups; all participants then discussed this.

Health Education Intervention

The health education intervention (rapid assessment) for all participants began with a questionnaire intended to identify farmers' knowledge and practices regarding *Taenia solium* life cycle, knowledge of signs of human infection of *Taenia solium,* the transmission of taeniasis and neurocysticercosis, the transmission of porcine cysticercosis, methods of pig keeping, and personal hygiene habits likely to affect the transmission of *Taenia solium* eggs from either pigs or people and recognition of tapeworm segments in stool. Farmers were also asked whether the family is always using a latrine for defecation, constantly washing hands with soap after defecating and before eating, and constantly washing fruits and vegetables. The administration of the questionnaire was followed by a health education intervention workshop.

After the health education intervention, we conducted the post-intervention using the same questionnaire immediately afterwards. The purpose was to rapidly assess the effectiveness of the health education interventions using the developed CHEP.

Analysis of the data

We exported the data to a Microsoft Excel spreadsheet for cleaning and storage and used SPSS version 20.0 (Armonk, NY: IBM Corp) for statistical analysis. A chi-square test was used to test for associations between categorical variables. The frequencies and percentages of correct responses in the descriptive statistics were summarized. The household observation data were analyzed based on the chi-square test using SPSS version 20.0. (Armonk, NY: IBM Corp).

Participants gave their consent for the KIIs and FGDs interviews to be recorded using a digital audio device. The transcribing was done into Swahili, and later, the transcriptions were translated into English for analysis and reporting. To improve the reliability of the interpretation, the written transcripts were independently reviewed by the two researchers, who were also involved in the transcription, and accepted by consensus for analysis. We analyzed the KIIs and FGDs transcripts using ATLAS.ti 8 for Windows using inductive thematic analysis (Nyangi et al., 2024).

Theories used in the development of the health education package.

The study used the following health behavior theories to guide the process of transforming the assessed risk factors into effective health education messages that would promote behavior change in the community. The models were intended to provide the framework for interpreting the risk factors that make up the health education package.

Integrated behavioral model (IBM)

The Integrated Behaviour Model is recommended because it incorporates constructs from the Theory of Reasoned Action (TRA), the Theory of Planned Behaviour (TPB), the Health Behaviour Model (HBM), and the Rational Theory (KAP), as well as other influential theories. The Theory of Reasoned Action (TRA) and the Theory of Planned Behaviour (TPB) focus on theoretical constructs that deal with individual motivational factors as determinants of the likelihood of performing a particular behavior (Montaño & Kasprzyk, 2008). Rational (KAP) and TPB theories have shown that the best predictor of behavior is behavioral intention, which is determined by attitudes towards the behavior and social normative perceptions. TPB is an extension of TRA and

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includes an additional construct: perceived control over the performance of the behavior (Champion & Skinner 2008; Montaño & Kasprzyk, 2008; WHO, 2012). The most important element of behavior in IBM is the intention to change the behavior because without motivation, a person is unlikely to perform a recommended behavior (Montaño & Kasprzyk, 2008, WHO, 2012).

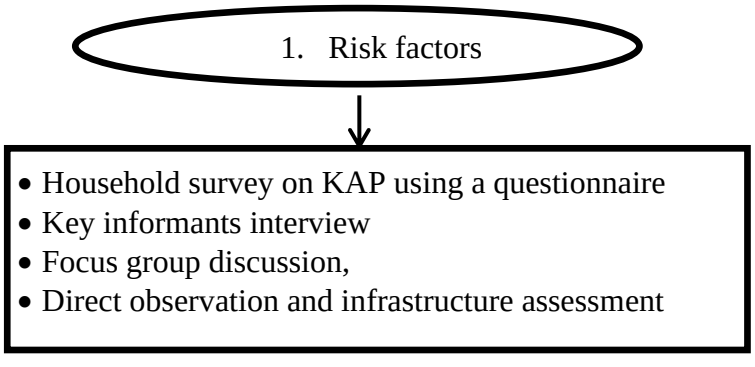
The Integrated Behavioural Model (IBM) lacks the principles of participation and targeting predisposing factors. The limitation is that this theory is only useful when considering individual health behavior, without considering other determinants of a person's health behavior and health status, such as race, socioeconomic status, or education. To complement this, we had to consult another model known as the PRECEDE-PROCEED Model, which is based on its fundamental principle of participation. We also consulted a third model that also forms a basis of our study and that is the health belief model (HBM) with its principle that people are more inclined to engage in healthy behavior when they think doing so can reduce a threat that is likely and would have severe consequences if it occurred. Thoughtful combinations of models may cause stronger interventions, as the models complement each other in describing the studied phenomenon (Champion & Skinner, 2008). However, a potential downside is a practical limit to how many theories can be combined (Champion & Skinner, 2008).

PRECEDE-PROCEED Model

PRECEDE-PROCEED Model relies on its principle of targeting the health education intervention to changeable factors that are most important and that predispose people to behaviours/practices instead of targeting the behaviours directly (Green & Kreuter, 1992). PRECEDE stands for 'Predisposing, Reinforcing, and Enabling Constructs in Educational/Environmental Diagnosis and Evaluation'. At the same time, PROCEED stands for Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development (Green & Kreuter, 1992) and was added to the framework to identify the importance of environmental factors that are determinants of health and health behavior.

Health Belief Model (HBM)

The Health Belief Model (HBM) was also consulted as it comprises several key concepts that foresee why people will take action to prevent, screen for, or control illness conditions. These include susceptibility, seriousness, benefits, and barriers to behaviour, clues to action, and self-efficacy (Champion & Skinner, 2008).



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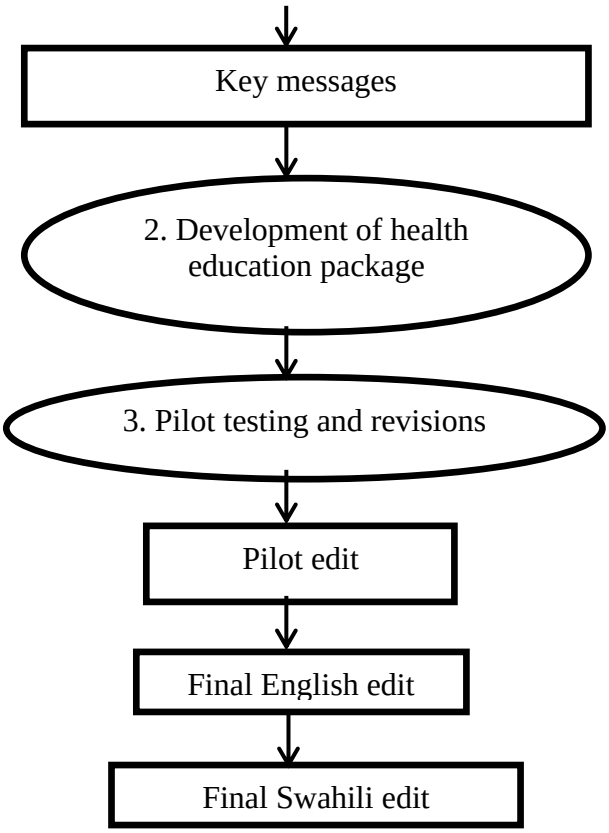

Figure 2: Flow diagram showing the steps involved in the development of the CHEP

Pilot testing of the developed health education package.

The CHEP was then pilot tested in another village far from the study villages. A pilot test was conducted on the CHEP (Community-based Health Education Program) in another village far away from the study villages. A pilot study is typically carried out before a more extensive study (Eldridge et al., 2016). A pilot project is closely linked to a feasibility study, which is the basis for planning a large-scale study (Thabane et al., 2010). Pilot projects are indeed a risk mitigation strategy to reduce a larger project's failure risk.

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Results

The results of the formative research informed the development of this health education package and included an assessment of risk factors (Figure 3).

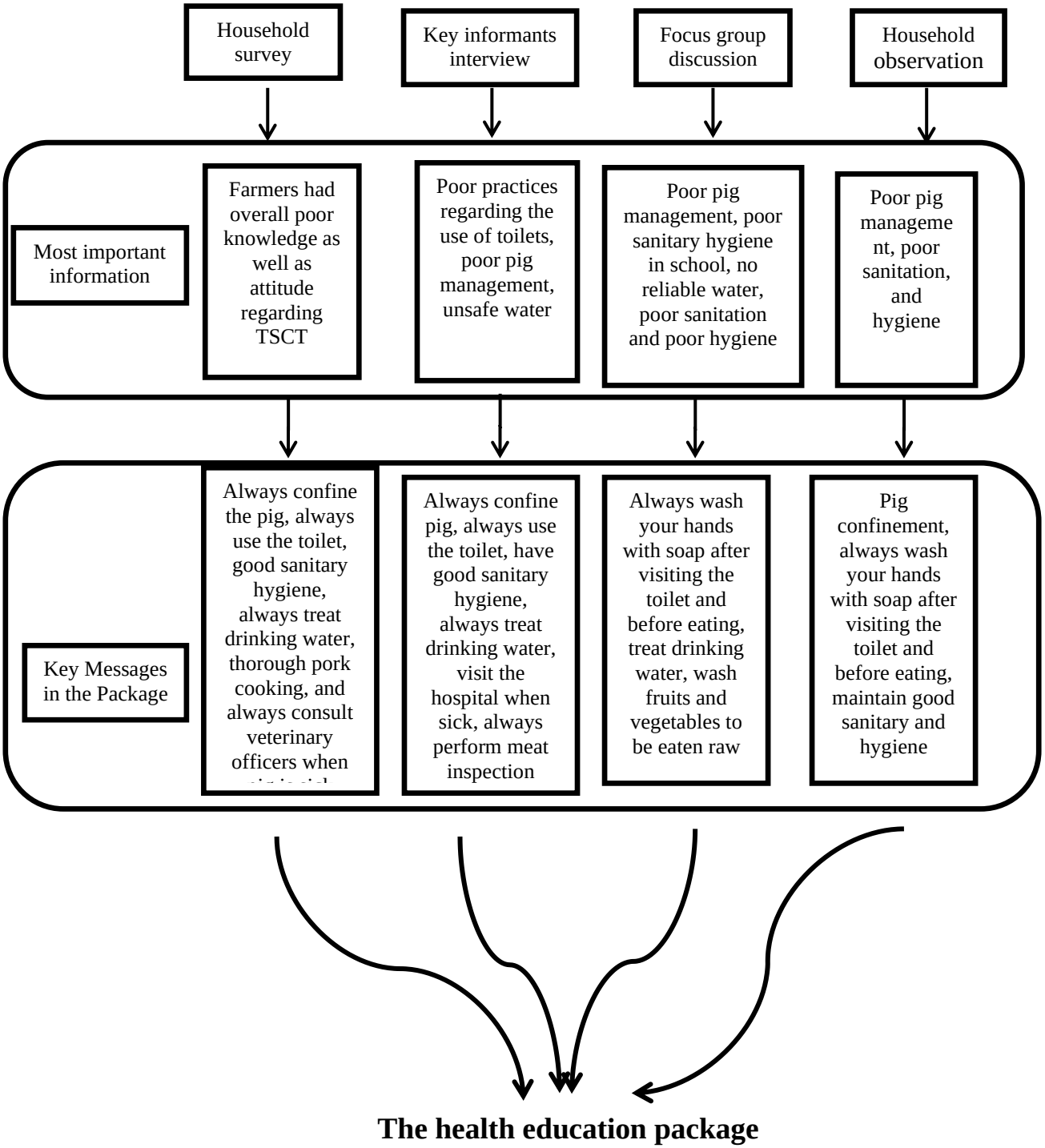

Figure 3: The process of development of a CHEP from defining risk factors to the key messages

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Key messages

Table 1: The formative research and risk factor assessment led to the formulation of the following key messages

Theme	Important information	Key messages
Clean and safe drinking water	Farmers and other community members were not treating drinking water	• Always boil (treat) drinking water
Pig management	Low knowledge of porcine cysticercosis transmission and control	• Always confine your pigs and feed them properly
Proper use of latrines	Some community members were practicing open defecation especially, on village open market day	• Always use latrines and they should be maintained in a good sanitation/hygiene
Personal hygiene	Farmers and other community members didn't have functional hand-washing facilities in the toilets	• Always wash your hands with water and soap after visiting the toilet and before eating
Food safety/hygiene	People in a local bar and open market were practicing improper cooking and poor handling of pork	• Proper cooking of pork (cooking then frying)
Food safety/hygiene	Washing fruits and vegetables that have to be eaten raw is very important.	• Always wash fruit and vegetables before eating them raw
Medical services	Most patients with epilepsy seek traditional treatment before visiting hospitals or churches, while most children visit the hospital when parents observe worms in their feces	• Visit the hospital when you feel sick
Food safety/hygiene	The practice of backyard slaughtering and unreliable meat inspection	• Always slaughter pigs in a slaughterhouse/slab and perform meat inspection
Extension services	People were self-treating their pigs while others were using traditional medicines	• Always consult the veterinary officer when your pigs are sick

Results of the pilot test of the education package

Results from the FGDs showed that participants understood the key messages, with most questions on transmission and the causes of PCC and tapeworm answered correctly (Nyangi et al., 2024). Feedback on the key messages was generally positive, with most participants having a significant problem with whether they had ever heard of tapeworm. This question was ambiguous because the Swahili term used was confusing to them since the word is used in the Swahili language for both tapeworm and cyst. Therefore, with the help of the district and ward livestock officers, the research team revised the message and made it clear and understandable.

Composition of the community-based health education package and the proposed main implementation steps

The ready-to-use community-based health education package (CHEP) developed by the community to control TSCT consists of a training manual for TOTs. The second component

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consists of a practical guide/booklet with illustrations (pictures) of critical TSCT control strategies distributed to all TOT participants, communities, and primary and secondary school teachers. The booklet is helpful for all community members, as it is easy to understand using pictures and a few captions in Swahili. The third component is a brochure (Appendix A in a Supplementary Materials File) with important TSCT control information, distributed to community members and students. The fourth component of CHEP is a poster (Appendix B in a Supplementary Materials File) showing the life cycle of the tapeworm (*Taenia solium*) and control points along the cycle.

Rapid assessment of the CHEP

For the rapid assessment, the pre-intervention survey was completed by 57 (45.7%) pig farmers, 16 (19.8%) TOTs, and 28 (34.6%) non-pig farmers. The post-intervention survey was completed by 45 (53.6%) pig farmers, 7 (8.3%) TOTs, and 30 (35.7%) non-pig farmers. Among the participants, 39 (23.6%) were female and 126 (76.4%). The majority, 114 (69.1%), had primary school education, and the majority, 50 (35%), were between the ages of 41 -50. There was an improvement in the knowledge and practices about tapeworm/taeniasis and cysticercosis, though most of the improvements were not statistically significant. Knowledge regarding tapeworm treatment increased from 61 (81.3%) pre-intervention to 76 (95.0%) post-intervention (P = 0.008), while the knowledge regarding the condemnation of infected pork increases from 65 (83.3%) pre-intervention to 73 (90.1%) post-intervention (P = 0.445). Practices about washing vegetables and fruits statistically significantly improved (P = 0.025), while that of pig confinement increased from 45 (77.6%) pre-intervention to 54 (88.5%) post-intervention, though the improvement was not statistically significant (Table 2).

Table 2: Comparison of knowledge and practices before and immediately after the health education intervention

	Correct response n (%)		
Question	**Pre-intervention**	**Post-intervention**	**P-value (χ^2)**
Knowledge-related questions			
Heard of human tapeworm	62 (77.5)	78 (95.1)	0.001
Tapeworm prevention	76 (96.2)	78 (96.3)	0.975
Tapeworm treatment	61 (81.3)	76 (95.0)	0.008
Heard of human cysticercosis	50 (62.5)	73 (89)	<0.001
Health effect of human cysticercosis	69 (93.2)	80 (98.8)	0.065
Heard of porcine cysticercosis	61 (79.2)	78 (64)	0.006
Prevention of porcine cysticercosis	76 (97.4)	78 (97.5)	0.980
A link between porcine cysticercosis and epilepsy	48 (64.9)	73 (92.4)	<0.001
At risk of getting tapeworm	40 (51.3)	48 (59.3)	0.057
At risk of getting human cysticercosis	44 (57.1)	48 (59.3)	0.328
Safe to eat infected pork	69 (88.5)	76 (93.5)	0.392
Condemnation of infected pork	65 (83.3)	73 (90.1)	0.445
Practice-related questions			
Confining pigs	45 (77.6)	54 (88.5)	0.109
The problem of roaming pigs	68 (89.5)	75 (94.9)	0.203
Wash vegetables and fruits	70 (99.3)	79 (100)	0.025
Using toilet	72 (94.7)	78 (98.7)	0.114
Wash hands after visiting the toilet	69 (92.0)	76 (95.0)	0.433
Wash hands before eating	68 (91.9)	76 (95)	0.433

All p-values are based on a Chi-square analysis of numbers across the four districts

Generally, there was an improvement in tapeworm/taeniasis and cysticercosis knowledge in all three groups. When the results were separately analyzed for the pig farmers, non-pig farmers and the TOTs group showed that during the pre-intervention survey, non-pig farmers had greater knowledge about tapeworm transmission (P<0.001), tapeworm treatment (P=0.394) and

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tapeworm health effect (P=0.394). Pig farmers were more aware of how tapeworms can be prevented and the health effects of porcine cysticercosis. The link between porcine cysticercosis and epilepsy was most likely to be understood by pig farmers, who were more likely to condemn infected pork. The post-intervention survey showed a significant improvement in most aspects of tapeworm/taeniasis and cysticercosis compared with baseline knowledge (Table 3).

Table 3: Comparison of knowledge of pig-farmers, non-pig farmers, and TOT

Variables	Correct response n (%)			P-value (χ^2)
	Pig-farmers	TOT's	Non-pig farmers	
1. Tapeworm transmission				
Pre-intervention	15 (41.7)	11 (68.8)	25 (92.6)	<0.001
Post-intervention	28 (63.6)	6 (85.7)	25 (86.8)	0.076
2. Tapeworm prevention				
Pre-intervention	34 (97.1)	16 (100)	26 (92.9)	0.455
Post-intervention	42 (93.3)	7 (100)	29 (100)	0.288
3. Tapeworm treatment				
Pre-intervention	24 (75.0)	13 (81.3)	24 (88.9)	0.394
Post-intervention	41 (93.2)	7 (100)	28 (99.6)	0.663
4. Tapeworm health effects				
Pre-intervention	29 (82.9)	15 (93.8)	27 (96.4)	0.176
Post-intervention	43 (97.7)	7 (100)	29 (100)	0.661
5. Health effect of human cysticercosis				
Pre-intervention	31 (93.9)	14 (93.3)	24 (92.3)	0.970
Post-intervention	44 (97.8)	7 (100)	29 (100)	0.667
6. Prevention of porcine cysticercosis				
Pre-intervention	37 (100)	14 (100)	25 (92.6)	0.144
Post-intervention	42 (95.5)	7 (100)	28 (100)	0.642
7. A link between porcine cysticercosis and epilepsy				
Pre-intervention	21 (63.6)	9 (60.0)	18 (69.2)	0.821
Post-intervention	42 (95.5)	7 (100)	24 (100)	0.229
8. At risk of getting tapeworm				
Pre-intervention	18 (51.4)	7 (43.8)	15 (55.6)	0.282
Post-intervention	32 (71.1)	4 (57.1)	12 (41.4)	0.051
9. At risk of getting human cysticercosis				
Pre-intervention	18 (52.9)	8 (50.8)	18 (66.7)	0.351
Post-intervention	32 (71.1)	4 (57.1)	12 (41.4)	0.103
10. Safe to eat infected pork				
Pre-intervention	31 (88.6)	13 (81.3)	25 (92.6)	0.788
Post-intervention	42 (93.3)	7 (100)	27 (93.1)	0.898

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*TOT: Training of trainers (government officials who will train the large community)
All p-values are based on a Chi-square analysis of numbers across the four districts

Regarding practices, pig farmers were more aware of the effect of free-roaming pigs while non-pig farmers were more aware of the practices related to washing fruits and vegetables before consumption, using toilets, and washing hands before eating and after visiting the toilet (Table 4)

Table 4: Comparison of practices of pig farmers, non-pig farmers, and TOT's

Variables	Correct response n (%)			P-value (χ^2)
	Pig-farmers	TOTs*	Non-pig farmers	
1.Do you completely confine your pigs				
Pre-intervention	7 (20)	3 (27.3)	3 (25)	0.855
Post-intervention	3 (6.8)	3 (60.0)	1 (8.3)	0.019
2. Do you think it is harmful if pigs roam free?				
Pre-intervention	32 (91.4)	14 (93.3)	22 (84.6)	0.607
Post-intervention	41 (93.2)	7 (100)	27 (96.4)	0.569
3. Do you always wash vegetables and fruits				
Pre-intervention	32 (94.1)	13 (86.7)	25 (96.2)	0.478
Post-intervention	43 (100)	7 (100)	29 (100)	**
4. Do you always use the toilet				
Pre-intervention	33 (94.3)	13 (86.7)	26 (100)	0.203
Post-intervention	42 (97.7)	7 (100)	29 (100)	0.541
5. Do you always wash your hands after visiting the toilet				
Pre-intervention	31 (91.2)	13 (92.9)	25 (92.6)	0.801
Post-intervention	42 (95.5)	7 (100)	27 (93.1)	0.627
6. Do you always washing hands before eating				
Pre-intervention	31 (91.2)	12 (92.3)	25 (92.6)	0.978
Post-intervention	42 (95.5)	7 (100)	27 (93.1)	0.627

All p-values are based on a Chi-square analysis of numbers across the four districts
*TOT: Training of trainers (government officials who will train the large community)
**: No statistics are computed because the variable is a constant.

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Discussion

The community participated in developing this health education package on TSCT control to bring about behavior change and promote community ownership of the program. The rapid assessment of the package resulted in a great improvement in knowledge and practices in all three groups assessed (pig farmers, TOTs, and non-pig farmers) (Table 2-4). This conventional approach is more suitable for most endemic areas where other approaches such as video and digital technology are not feasible because of poor infrastructures such as lack of electricity, internet, and computers/laptops/tablets/smartphones. The following health behaviour models were used to translate the measured risk factors into actionable educational messages to encourage the population to change their behaviour.

The Health Belief Model (HBM) includes several key concepts that predict why people will take action to prevent, screen for, or control health conditions (Champion and Skinner, 2008). These include susceptibility, seriousness, benefits, barriers to a behavior, incentives to act, and self-efficacy; all of which are strong predictors of preventive health behaviors (Champion & Skinner, 2008). Our results do not support this model, as most respondents/participants were not aware that they were at risk of contracting TSCT (perceived susceptibility); the majority were also unaware of the severity of the disease and its consequences (perceived severity) as most were unaware of the health effects of taeniasis on humans as well as cysticercosis to both pigs and humans. The study supports the model as most participants believed in the effectiveness of the recommended risk reduction measures (perceived benefits). However, most of them thought about the tangible costs of the measure (perceived barriers), such as the cost of building pig pens, access to pig feed, and the cost of building modern toilets. People had low self-efficacy in controlling TSCT, as the majority felt that some of the actions needed to control TSCT are difficult to achieve (self-efficacy). The education package developed was intended to influence the population's perceived susceptibility to TSCT to improve their behavior to prevent infection.

Therefore, the lack of knowledge and awareness and poor hygiene and sanitation in the study area would likely lead to infection with TSCT. This led to including the following messages in the package alongside the key points on TSCT prevention.

1) Raise awareness of TSCT among the study population. The messages included were the risk of infection" (perceived vulnerability) (Champion & Skinner, 2008).
2) Conviction of participants/respondents that it is within their choice to change their behaviour and reduce the risk of infection (self-efficacy) (Champion & Skinner, 2008). This implies that they can protect themselves from TSCT through improved hygiene practices.

In terms of the integrated behavioral model (IBM), the results of this study support the model as most respondents showed the intention to carry out the behavior, especially after they became aware of the consequences of TSCT for themselves and pigs. Individuals' habituation to scientific knowledge alone does not necessarily lead to behavior change. Rather, behavior is related to perceptions, values, power relations, and feelings and cannot be changed simply by acquiring knowledge (Gazzinelli et al., 2012). There is extrinsic motivation, when a person engages in an activity to achieve or avoid a particular outcome, many of the things you do every day are likely extrinsically motivated. Intrinsic motivation is where there is an internal drive for success or meaningfulness. Finally, the family is motivated to care for those they love (Rodgers & Loitz, 2008). The person will perform a recommended behavior (Rodgers & Loitz, 2008). The package will be shared with key stakeholders and policymakers involved from the beginning; these included politicians, ministries of health and education, and the critical informants mentioned in this paper. These are the key people who enforce the existing laws if people are unwilling to change their practices and behaviour.

Based on the **PRECEDE-PROCEED** model, the primary purpose of this model is to provide a framework for planning and evaluating health behavior change programs. This model is applied to the design of this study because its methodology addresses the problem of health education

focusing too much on program delivery and too little on program design. This is planned to meet evidenced needs (Bartholomew et al., 2006). The underlying principle of this model is participation, which states that success in achieving change is enhanced by the active involvement of the proposed target group in describing their priority problems and goals and in developing and implementing solutions (Green & Kreuter, 1992). In developing the package, much emphasis was placed on creating a community-based health education package that meets the target community's needs. Interventions that involve the community can promote behavior change and community ownership of programs (Gazzinelli et al., 2012). The CHEP is expected to be accepted by the community, as evidenced by the KAP baseline survey experience. The community showed that lack of education is a critical factor for TSCT infection, and they wanted more health education to raise awareness and improve KAP to control TSCT.

Conclusion

With community participation, we develop the community-based health education package (CHEP), which is expected to be an adequate population education intervention in remote areas where other educational tools, such as videos and digital tools, cannot be used. Practical educational tools must be integrated into interventions for combating TSCT infections and other neglected tropical diseases, as expressed in a Research Agenda for Helminths Disease (Boatin et al., 2012). Interventions, including health education to prevent TSCT and other worm infections, are urgently needed to improve the sustainability and effectiveness of other existing control strategies as part of an integrated approach. Communities in resource-poor endemic countries can quickly adapt and implement the developed CHEP. This paper describes the development and rapid assessment of the community-based health education package (CHEP) for TSCT control in Tanzania.

Ethical considerations and consent to participate

The National Institute of Medical Research (NIMR) approved the study with approval number NIMR/HQ/R.8a/Vol. IX/2802. The study also received approval from the ethics committee of the Klinikum rechts der Isar, Technical University of Munich, Germany, under the number 537/18 S-KK. We explained the study objectives to each participant and obtained verbal consent.

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Competing interests

None declared

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Blood utilization practice in elective orthopaedic surgeries at Muhimbili Orthopaedic Institute, Dar-es-salaam

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Abstract

Background: The average blood requirement and its products for a particular elective orthopaedic procedure are usually based on subjective anticipation of blood loss rather than an evidence-based estimate. There are no specific evidence-based guidelines for the appropriate amount of blood products to be ordered for particular procedures. Therefore, this study aimed to fill the knowledge gap in the effectiveness of blood utilization practice. It is expected to add information on formulating a practical institution-based protocol for properly optimizing the use of blood components.

Methods: A hospital-based descriptive study was done at Muhimbili Orthopedic Institute from July 2018 to April 2019, in which patients scheduled for elective orthopaedic surgeries for whom blood was requested were included. Demographic and blood utilization data were collected and analyzed using SPSS version 20. The following indices calculated blood utilization: (i) Crossmatch to transfusion ratio (C/T), (ii) Transfusion probability (%T), (iii) Transfusion index (TI), (iv) Maximum surgical blood ordering schedule (MSBOS).

Results: A total of 286 patients undergoing 27 different types of elective orthopedic surgeries were included in this study. Five hundred and twenty-seven units of blood were cross-matched, of which only 224 units (42.5%) of blood were transfused to 146(51%) patients. The overall crossmatch to transfusion ratio(C/T) calculated was 2.4, the transfusion index (TI) was 0.8 and the transfusion probability (%T) was 51.0%. All these figures were found to be within the optimal range.

Conclusion: This study revealed an adequate overall ratio of C/T, %T, and TI blood utilization that was considerable to significant, except for a few surgeries that showed transfusion above or below acceptable levels. Male patients and patients above 60 years of age had a higher transfusion rate. The highest proportion of blood transfusion was observed in lower limb surgeries. Knee arthroscopy showed the lowest blood transfusion rate, while pelvic and acetabular surgeries showed the highest. There is a need for formulating and practicing institution-based blood ordering policies to guide clinicians regarding blood usage.

Keywords: Blood utilization, Elective orthopedic, Muhimbili Orthopaedic Institute

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Introduction

Blood utilization is a common practice in elective orthopedic surgical procedures. During these procedures, most surgeons overestimate the anticipated blood requirement. There is subjective anticipation of the average requirement for a particular procedure rather than evidence-based estimates. Belayne et al. (2013) showed that over-ordering with minimal utilization squanders technical time and reagent and imposes extra expenses on patients and institutes.

The World Health Organization (WHO) Global Database on Blood Safety (GDBS) was established in 1998 to address global concerns about the availability, safety, and accessibility of blood for transfusion. The WHO (2017) report shows large differences in the amount of blood collected and transfused worldwide. Countries in the high-income group collected 47% of the global donations, and Countries in the low-income and lower-middle-income groups collected 2% and 22% of the global donations respectively. Annual rates of using blood are 32.0 units per 1,000 population in high-income countries, 12.5 units per 1,000 population in upper-middle-income countries, 5.38 units per 1,000 population in lower-middle-income countries, and 3.4 units per 1,000 population in low-income countries.

Osaro et al (2011) reported globally, approximately 80 million units of blood are donated each year whereas of this total, 2 million units are donated in Sub-Saharan Africa, where the need for blood transfusions is great because of maternal morbidity, malnutrition, and a heavy burden of infectious diseases such as malaria. It is essential that the use of blood and blood products is kept to a minimum and used only when indicated. Kuchhal et al (2016) showed that blood is a precious and scarce resource that should, therefore, be used rationally to avoid misuse and wastage.

Tayara in 2015 showed that very few studies have been conducted on blood ordering and transfusion practices in elective orthopedic surgeries which revealed over-ordering with little utilization. Akoko et al (2015) showed that blood was over-ordered by 76% of the patients who had elective surgical procedures where over 80% of these patients had hemoglobin levels of over 10g/dl.

The preoperative request for blood units is often based on worst-case assumptions. Consequently, if unnecessary blood orders can be reasonably avoided, it will reduce both workload and financial expenditure (Kuchhal et al., 2016). There is a need to minimize the quantity of blood being cross-matched without utilization by assigning each elective orthopedic surgical procedure a task of transfusion (Subramanian et al., 2010).

Currently, there are no specific evidence-based guidelines for the appropriate amount of blood products to be ordered for specific orthopedic surgical procedures. The objectives of this study include assessing blood utilization practices in elective orthopedic surgeries and identifying predictive factors for blood utilization.

This study will highlight the determinants of blood utilization practices in elective orthopedic procedures and provide evidence to support guidelines for standardization of blood utilization practices leading to better patient safety and management of resources.

Methods

A hospital-based descriptive study was done on adults who were scheduled for elective orthopaedic surgeries for whom blood and its products were ordered. Two hundred eighty-six patients (286) who met the inclusion criteria were recruited in the study after signing the informed consent. Demographic data were collected using a standard questionnaire. The data obtained were cleaned, coded, and entered into SPSS Statistics for Windows version 20 software.

Frequencies and percentages were obtained for categorical variables. The blood utilization indices were calculated as follows: A) Crossmatch to transfusion ratio (C/T ratio) was calculated as the number of units cross-matched per number of units transfused. Where the value is < 2.5, this shows

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that a significant portion of the cross-matched blood was utilized. B) Transfusion probability (%T) was determined as the number of patients transfused per number of patients cross-matched multiplied by 100 for which a value of 30% indicates the significance of the prepared blood used. C) Transfusion index (TI) was calculated as the number of units transfused per number of patients cross-matched - a value of > 0.5 was considered indicative of significant blood utilization. D) Maximal Surgical Blood Ordering Schedule (MSBOS) was calculated as 1.5 times TI.
Data was analyzed by t-test and the P value of <0.05 was considered statistically significant.

Ethical approval and consent
The institutional review board of the Muhimbili University of Health and Allied Sciences and other relevant bodies gave the ethical approval for this study under reference number DA.287/298/01A. Informed consent was taken from all participants.

Results
There was a total of 286 participants in the study, of whom 183 (64%) were males and 103(36%) were females. About a quarter of the participants were in the age group between 31-40 years (23.8%) whilst those aged above 60 years accounted for 23.1%. The mean age was 38 years with an SD of ± 7yrs. (Table 1). Patients above the age of 60 years had the highest proportion of blood transfusion but this was not statistically significant (p-value of 0.144). Around 2/3rd of all patients who underwent elective orthopedic procedures received at least 1 unit of blood. Males received a higher proportion (63%) of blood transfusion, but this was not statistically significant with a p-value of 0.351. (Table 1)

Table 1: Units of Blood utilization per demographic characteristics of patients

	Blood utilization (Units)		
Age (years)	**Transfused**	**Not transfused**	**Total**
18 – 20	4(33.3)	8(66.7%)	12
21 – 30	32(59.3%)	22(40.7%)	54
31 – 40	33(48.5%)	35(51.5%)	68
41 – 50	14(34.1%)	27(65.9%)	41
51 –60	20(44.4%)	25(55.6%)	45
Above 60	43(65.1%)	23(34.9%)	66
Sex			
Male	92	91	183
Female	54	49	103

Of all elective orthopedic surgeries, 527 units of blood were cross-matched whilst only 224(42.5%) units of blood were transfused. Lower limbs surgeries (such as intramedullary nailing of femur and tibia, angled blade plate and condylar buttress plate for femur & tibia, ankle reconstruction, lower limb amputation) constitute highest proportion of units cross-matched (49.7%) and transfused units of blood (50.9%) followed by arthroplasty surgeries where units of blood cross-matched 112(21.3%) while

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units transfused 55(24.6%). The lowest transfusions were for arthroscopic knee surgeries (Meniscectomy, Anterior cruciate ligament reconstruction) whereby only 2 patients received blood. The highest proportion (63%) of transfused versus cross-matched units of blood was observed in pelvic and acetabular surgeries followed by arthroplasty (49%) and open reduction and internal fixation of lower limb surgeries (43.5%) whereas the lowest was in arthroscopic knee surgeries. (Figure 1)

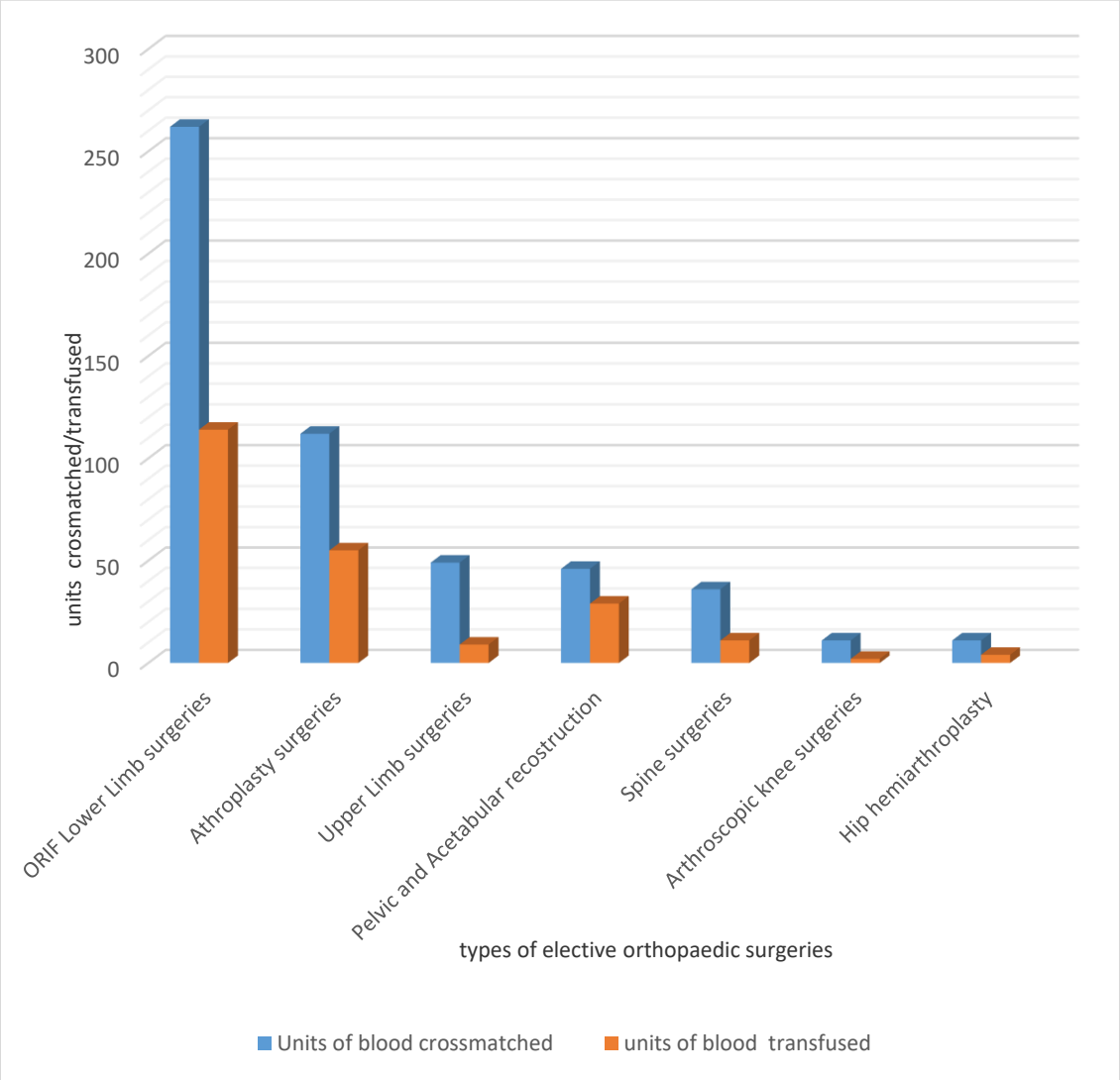

Figure 1: Units of blood cross-matched and transfusion for elective orthopedic surgeries

The average transfusion indices (CTR, %T, TI, and MSBOS) for elective orthopedic surgeries were 2.4, 51, 0.8, and 1.2 respectively. (Table 2)

The arthroscopic knee surgeries have the highest CT ratio of 5.5, lowest transfusion probability of 22.2%, transfusion index of 0.2, and lowest maximum blood surgical ordering schedule of 0.3, while the lowest CT ratio was observed in Pelvic and Acetabular reconstruction of 1.6 with higher transfusion probability of 89.5% and transfusion index 1.5. The highest maximum blood surgical ordering schedule was observed in the pelvic and acetabula with 2.3.

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Table 2: Transfusion indices by elective orthopedic surgeries

	Surgery type	Patients (n)	Percent	CTR	%T	TI	MSBOS 1.5 X TI
1.	Lower Limb surgeries	144	50.3	2.3	52.4	0.8	1.2
2.	Arthroplasty surgeries	59	20.6	2.0	62.1	0.9	1.4
3.	Upper Limb surgeries	32	11.2	5.4	19.4	0.3	0.5
4.	Pelvic and Acetabular reconstruction	19	6.6	1.6	89.5	1.5	2.3
5.	Spine surgeries	19	6.6	3.3	35	0.6	0.9
6.	Arthroscopic knee surgeries	7	2.4	5.5	22.2	0.2	0.3
7.	Hip hemiarthroplasty	6	2.1	2.8	50	0.7	1.1
	Total	286	100				

Key: C/T=cross-match to transfusion ratio, %T=Transfusion probability, TI=Transfusion Index, MSBOS= Maximal Surgical Blood Order Schedule

The highest percentage (21%) of the cross-matched blood was for open reduction and internal fixation of the femur and this particular surgery also had the highest percentage of transfused units (20.5%). Total hip arthroplasty patients constituted 12.1% of the cross-matched blood and 16.9% of the transfused. Some procedures including ankle arthrodesis, implant removal, patella tension band wiring open reduction, and internal fixation of the olecranon were not transfused despite a significant number of bloods being cross-matched. (Table 3)

Table 3: Blood cross-matched and transfused patterns for specific orthopedic surgeries

S/NO	Type Of Surgery	Patients (n)	Percent	Cross-matched		Transfused	
				Patients (n)	Units (n)	Patients (n)	Total (units)
1.	ORIF intramedullary nail femur	60	21.0	60	115	31	46
2.	Total hip arthroplasty	31	10.8	31	64	24	38
3.	Total knee arthroplasty	27	9.4	27	48	12	17
4.	Acetabular reconstruction	15	5.2	15	36	15	24
5.	Plating and screw radius/ulnar	13	4.5	13	19	2	4
6.	Exchange intramedullary nail femur	11	3.8	11	19	10	15
7.	Lumbar Discectomy	11	3.8	11	19	5	8
8.	Plating and screw humerus	11	3.8	11	18	2	2
9.	Implant removal intramedullary nail	10	3.5	10	15	1	1
10.	Arthroscopic knee surgeries	10	3.5	10	12	2	2
11.	Sequestrectomy	10	3.5	10	16	5	7
12.	Exchange intramedullary nail tibia	9	3.1	9	14	3	3
13.	Spine decompression & stabilization	9	3.1	9	17	2	3

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14.	ORIF buttress plate tibia	8	2.8	8	15	3	6
15.	Plate and screw femur	8	2.8	8	15	7	10
16.	Hip hemiarthroplasty	7	2.4	7	13	4	6
17.	ORIF intramedullary nail tibia	7	2.4	7	12	3	5
18.	Distal plate and screw femur	6	2.1	6	14	6	11
19.	ORIF of Olecranon	4	1.4	4	7	0	0
20.	Below knee amputation	3	1.0	3	7	3	6
21.	ORIF Hip screw femur	3	1.0	3	6	2	3
22.	Pelvic reconstruction	3	1.0	3	9	2	4
23.	Ankle Arthrodesis	2	0.7	2	4	0	0
24.	Implant removal	2	0.7	2	3	0	0
25.	Patella tension band wiring	2	0.7	2	3	0	0
26.	Plate and screw ankle	2	0.7	2	4	1	2
27.	SD+External fixation	2	0.7	2	3	1	2
	Total	286	100.0	286	527	146	224

The Implant removal of intramedullary nail has the highest CT ratio (15), lowest transfusion probability (10%), transfusion index (0.1) and lowest maximum blood surgical ordering schedule (0.2). On the other end of the spectrum, acetabular surgeries had the lowest CT ratio (0.6), highest transfusion probability (100%), transfusion index (1.6) and highest maximum blood surgical ordering schedule (2.4). (Table 4)

Table 4: Transfusion indices for specific elective orthopaedic surgeries

	Surgery type	Patients(n)	Percent	C:T RATIO	%T	TI	MSBOS 1.5 X TI
1.	ORIF intramedullary nail femur	60	21.0	2.5	51.7	0.8	1.2
2.	Total hip arthroplasty	31	10.8	1.7	77.4	1.2	1.8
3.	Total knee arthroplasty	27	9.4	2.8	44.4	0.6	0.9
4.	Acetabular reconstruction	15	5.2	1.5	100	1.6	2.4
5.	Plating and screw radius/ulnar	13	4.5	4.8	15.4	0.3	0.5
6.	Exchange intramedullary nail femur	11	3.8	1.3	90.9	1.4	2.1
7.	Lumbar Discectomy	11	3.8	2.4	45.5	0.7	1.1
8.	Plating and screw humerus	11	3.8	9	18.2	0.2	0.3
9.	Implant removal intramedullary nail	10	3.5	15	10	0.1	0.2
10.	Arthroscopic knee surgeries	10	3.5	6	20	0.2	0.3
11.	Sequestrectomy	10	3.5	2.3	50	0.7	1.1
12.	Exchange intramedullary nail tibia	9	3.1	4.7	33.3	0.3	0.5
13.	Spine decompression & stabilization	9	3.1	5.7	22.2	0.3	0.5
14.	ORIF buttress plate tibia	8	2.8	2.5	37.5	0.8	1.2
15.	Plate and screw femur	8	2.8	1.5	87.5	1.3	2.0
16.	Hip hemiarthroplasty	7	2.4	2.2	57.2	0.9	1.4
17.	ORIF intramedullary nail tibia	7	2.4	2.4	42.9	0.7	1.1
18.	Distal plate and screw femur	6	2.1	1.3	100	1.8	2.7
19.	ORIF of Olecranon	4	1.4	0	0	0	0
20.	Below knee amputation	3	1.0	1.2	100	2	3
21.	ORIF Hip screw femur	3	1.0	2	66..7	1	1.5
22.	Pelvic reconstruction	3	1.0	2.3	66.7	1.3	2.0
23.	Ankle Arthrodesis	2	0.7	0	0	0	0

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24.	Implant removal	2	0.7	0	0	0	0
25.	Patella tension band wiring	2	0.7	0	0	0	0
26.	Plate and screw ankle	2	0.7	2	50	1	1.5
27.	SD + External fixation	2	0.7	1.5	50	1	1.5
	Total	286	100.0				

Key: C/T=crossmatch to transfusion ratio, %T=Transfusion probability, TI=Transfusion Index, MSBOS= Maximal Surgical Blood Order Schedule

Discussion

Blood is a vital commodity that is limited in supply, and hence, its distribution and appropriate use is the key to ensure maximum benefit. In our study, 42.5% of the cross-matched units were transfused for elective orthopedic surgery. This was lower compared to studies done in Europe(Rosencher et al., 2003), Pakistan (Waheed et al., 2015), and India (Sonam et al., 2017) which showed 69%, 65.4%, and 57.1% of the cross-matched blood were utilized but higher than those done in Tanzania (Akoko et al., 2015) and Nepal (Karki , 2016) which had usage of 28.2% and 18% respectively.

This study showed that male patients were found to have a higher proportion of blood transfusion, however, this was not statistically significant. Some other studies (Soleimanha et al., 2016; Giriyan et al., 2017, Chalya et al., 2016 and Jumpotpong et al, 2015) have also shown that males were more likely to be transfused in elective orthopedic surgery whilst others including Belayneh et al (2013), Giriyan et al (2017) and Mwambungu et al (2015) showed that females were more likely to receive blood. Higher transfusion proportion was observed among the patients aged above 60 years, but again this was not found to be statistically significant.

The overall CT ratio was 2.4, which indicates significant blood utilization. Similar findings were observed in a study done in Nigeria by Adegboye et al. (2018), with an overall CT ratio of 2.3. The average transfusion indices in this study (%T, TI and MSBOS) for elective orthopedic surgeries were 51, 0.8 and 1.2 respectively. These values are indicative of significant blood usage. This was in contrast to studies done at Muhimbili National Hospital (Akoko et al., 2015), Bugando Medical center (Chalya et al., 2016) and another hospital in India (Sonam et al., 2017) which had CTR >2.5. Jumpotpong et al (2015) and Mwambungu et al (2015) showed T% of 22% and 26.1% respectively. (18,19) Published articles (8,11) Soleimanha et al (2016) and Waheed et al (2017) have shown TI of >0.5 whilst studies done by Adegboye et al (2018) have shown the reverse is true. It is possible that the disparity was due to different surgical practice at different centers and the guidelines for crossmatch for elective orthopedic procedures or different intraoperative techniques to minimize blood loss such as using tourniquet.

About 2/3rd (63%) of pelvic and acetabular surgeries and almost half (49%) of arthroplasty surgeries required blood transfusion whilst less than 1/5th (18.2%) of arthroscopic knee surgeries required blood and its products. Similar findings were found in studies done by Basnet et al. (2009), Tayara et al. (2015), Soleimanha et al. (2016) and Adegboye et al. (2018). Pelvic and acetabular surgeries are extensive and require soft tissue dissection, and have been known to have significant blood loss leading to higher proportion of blood needed for transfusion. Reasons for Pelvic and acetabular surgeries to have the highest proportion of transfusion can be because these are major orthopaedic surgeries involving extensive cutting of soft tissues and bone, hence leading to extensive blood loss, which needs a transfusion.

Despite optimal overall transfusion probability reported in this study, five types of elective orthopedic surgeries had inefficient blood utilization. These include fixation of radius and ulna, fixation of the humerus, implant removal of intramedullary nail, arthroscopic knee surgeries, and spine decompression (T% 10-22%). Adegboye, in 2016, observed five procedures have a low TI of < 0.5,

including fixation of radius and ulna, spine decompression surgery, total knee replacement, tibiofibular fracture and ankle fracture. These differences in blood utilization can be explained by the generalization of similar blood ordering in different orthopaedic procedures by a surgical team, which usually explains the provision of safety measures in the event of excessive unexpected blood loss during surgery.

Conclusion

This study assessed blood utilization in elective orthopedic procedures and at Muhimbili Orthopedic Institute. It showed an overall adequate (42.5%) blood utilization. Knee arthroscopy showed the lowest blood transfusion rate, while pelvic and acetabular surgeries showed the highest transfusion rate. A few categories of elective orthopedic surgeries showed transfusion indices above /below accepted levels. Therefore, the overall blood utilization was significant.

All patients going for elective orthopedic surgery should have their blood type checked. There are certain types of orthopaedic surgeries, such as pelvic and acetabular which have a high likelihood of transfusion being required. Hence, blood can be cross-matched, whilst others, such as knee arthroscopy, have shown a very low probability of transfusion, so cross-matching should not be routinely done unless clinically advised on an individual basis. There is a need for formulating and practicing institution-based blood ordering policies to guide clinicians regarding blood usage as there is an inadequate guideline.

List of abbreviations

C/T:	Crossmatch to transfusion ratio
GDBS:	Global Database on Blood Safety
MSBOS:	Maximum surgical blood ordering schedule
ORIF:	Open reduction and internal fixation
SD:	Surgical debridement
%T:	Transfusion probability
TI:	Transfusion index
WHO:	World Health Organization

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Author's contributions

Justice Mwambashi contributed to the research concept, wrote the proposal, collected data, and analyzed and wrote the manuscript. Mohamed Muhamedhussein contributed to the proposal, literature review, analyzing the data, writing up the discussion, and editing the manuscript. Billy Haonga contributed to developing the research concept, analyzing the data, and editing the manuscript.

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Dental Wastes and Practices Among Dental Students and Practitioners

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Abstract

Background: The increasing worldwide worry about dental waste stems from the widespread use of materials in dental treatments. Therefore, it was crucial to conduct a comprehensive analysis to evaluate how dental waste is handled by dentistry professionals and students, resulting in important discoveries.

Objectives: This study seeks to investigate dental waste management procedures among dental students and practitioners while assessing the various forms of dental waste produced in different departments. Moreover, it aims to explore possible strategies for improving the handling and disposal of dental waste.

Methods: Students, interns, teachers, and practitioners completed an online questionnaire to provide primary data. A survey was conducted using random sampling procedures to obtain a sample of 406 persons from different dental institutions and hospitals.

Results: The research findings indicated that a significant percentage of staff members and students exhibited awareness of appropriate disposal techniques for different categories of dental waste. The Department of Oral Medicine & Radiology faculty members have shown exceptional skill. In general, the participants demonstrated a significant understanding of proper disposal methods, especially for items linked to dentistry. However, there were differences in knowledge levels across other departments, as shown by a greater proportion of skilled staff in departments like Oral Pathology & Oral Microbiology and Orthodontics compared to the students in such departments.

Conclusion: This research highlights the need to include thorough waste management education in dentistry schools to tackle the increasing environmental and health issues related to dental waste.

Keywords: Dental Waste, Students, interns, teachers, practitioners, and Dental Department

Introduction

Dental waste is a major environmental and health concern. It includes a wide range of materials, from discarded dental instruments and materials to leftover clinical waste, such as syringes, needles, and dental amalgams (Ayub et al., 2019). This waste is generated by dental offices, laboratories, and other dental healthcare facilities. It is estimated that between 4 and 10 pounds of hazardous materials are generated by each dental patient visit, depending on the type of treatment. In addition to being

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hazardous to the environment, dental waste can be a source of occupational health and safety hazards for dental practitioners and students.

The improper disposal of dental waste can lead to contamination of the environment, as well as the spread of infectious diseases. Furthermore, improper handling of dental waste can also lead to accidental needle stick injuries, which can result in serious infections. Dental practitioners and students must adopt proper waste management practices for these reasons. This includes proper handling, storage, and disposal of dental waste (Borglin et al., 2021).

As the world's population grows, the need for different types of dental treatments has become increasingly important. This is especially true in highly populated civilizations, where the population size and density necessitate specialized and comprehensive dental services (Duane et al., 2020)In such contexts, dental waste generated can be substantial, and it is important to ensure that this waste is properly managed and disposed of to preserve the health of the population and the environment.

This article will explore the impact of population growth on dental waste, the need for different types of dental treatments, and the strategies that can be employed to manage dental waste in highly populated civilizations. In this section, the study will explore the influence of various kinds of dental wastes generated by different dental departments.

Impact of Population Growth on Dental Waste

As civilization's population increases, so does the amount of dental waste generated. This is because a larger population means more people are accessing dental services, and thus, more waste is produced. The increased demand for dental services also necessitates many dental care facilities, increasing the amount of dental waste generated. In highly populated civilizations, the amount of dental waste can be pretty substantial, and it is essential to make sure this waste is managed in a safe and effective way (Duane et al., 2019).

Need for Different Types of Dental Treatments

The demand for various forms of dental treatments is driven by the changing needs of a population over time. As populations evolve and develop, so too do their dental needs. For example, in highly populated civilizations, there is likely to be a greater demand for cosmetic dentistry, orthodontics, and restorative dentistry as people seek to improve the aesthetics of their smiles and correct any existing dental problems. Additionally, as people age, they may require more specialized treatments such as periodontal care, dental implants, and crowns. All these treatments generate a significant amount of waste, and it is crucial to ensure that this garbage is handled and disposed of correctly.

Strategies for Managing Dental Waste in Highly Populated Civilizations

To effectively manage dental waste in highly populated civilizations, it is essential to employ various strategies. These strategies should focus on reducing the amount of waste generated and ensuring that the waste generated is appropriately managed and disposed of. Some of the methods that can be employed include (Nimbulkar et al., 2020):

- **Implementing waste segregation policies:** Segregating dental waste into different categories allows for easier and more efficient disposal. It also reduces the risk of cross-contamination and helps to ensure that hazardous materials are disposed of safely and responsibly.
- **Utilizing waste reduction strategies:** Strategies such as reusing materials and recycling can help minimize the quantity of waste generated.
- **Adopting new technologies:** Technologies such as digital dentistry can help lessen the waste generated and make the disposal process more efficient.

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- **Investing in proper waste management systems:** Investing in proper waste management systems can help to ensure that dental waste is disposed of in an environmentally responsible manner (Pandis et al., 2021).

Literature review

In the literature section, many writers examined dental waste practices and types of dental waste created by different departments and examined the various methods of disposing of dental waste. Many studies discussed dental waste practices and types of dental waste generated from other departments. In one of the studies, applying green dentistry practices among graduate and postgraduate dental practitioners is insufficient. It aimed to assess dental practitioners' and final-year students' comprehension and safe practices of biomedical and dental waste. The participants' knowledge and habits of dental waste management were determined to be modest.

According to another study, interviews with the practitioners were conducted by the primary investigator with the use of a standardized questionnaire that had been prepared expressly for this research and was pre-tested (Naz et al., 2020). The author's goal in that research was to assess dental practitioners' degree of knowledge and attitude towards disinfection worldwide. Such research found that oral health professionals had a substantial and favourable attitude towards disinfection in the face of the coronavirus 2019 (COVID-19) pandemic, despite a lack of expertise in essential parts of disinfection procedures (Sarfaraz et al., 2020).

This research aimed to analyze the knowledge, attitude, and practice of dental practitioners in Chitwan and its neighbouring districts. From June to August 2020, 142 dental practitioners participated in this descriptive, cross-sectional survey in Chitwan (Khanal et al., 2022). Another study evaluated the efficacy of dental waste disposal bins such as Yellow Bins, Green Bins, Red Bins, and Black Bins regarding their ability to contain and dispose of hazardous dental waste.

The study found the Yellow Bin was the most effective in containing and disposing dental waste, while the Green and Red Bin were less effective. The Black Bin was the least effective in containing and disposing of dental waste. The study concluded that the Yellow Bin was the most suitable option for dental waste disposal due to its superior containment and disposal capabilities (Singh et al., 2011).

One more study showed that the red bin (for clinical waste) and Black bin (for infectious waste) were the most effective in disposing of dental waste. Additionally, the yellow and green bins were found to be less effective in containing dental waste.

The authors concluded that the red bin and black bin should be used for disposing of dental waste in dental clinics (Lakbala, 2020)Another study reviewed the use of dental waste disposal bins like the Yellow Bin, Green Bin, Red Bin, and Black Bin. The author found that these bins reduce the risk of environmental contamination and the cross-contamination of infectious materials. In addition, they are effective in reducing the workload of dental staff and providing a safe and efficient waste disposal system.

Research Gap

There is a lack of research on the amount of dental waste generated by dental students and practitioners and how it could be reduced through sustainable practices. Additionally, there is limited research on the types of dental waste generated by different departments and how this may affect the amount of waste produced. Furthermore, there is a need to explore dental students' and practitioners' knowledge and attitudes towards dental waste and to identify strategies to reduce the amount of waste produced. Although the practitioners are well aware and knowledgeable about the disposal techniques for the different types of dental waste, they don’t practically practice them.

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Aim of the study

This research aims to investigate dental waste practices through dental students and practitioners and assess the types of dental waste generated from different departments. Additionally, the study seeks to identify potential solutions for improving the management and disposal of dental waste, assess the different types of dental waste from different Dental departments, and assess the practices followed for the various types of dental waste from the different Dental departments.

Hypothesis

H1: Different types of dental waste are generated by different dental departments.

H2: The practices for managing various types of dental waste vary across different Dental departments.

Methodology

The primary purpose of this study is to investigate dental waste practices among dental students, faculty, and practitioners and find awareness of various types of dental waste from the different dental departments. The study will utilize a quantitative method. The research methodology used in this research is a quantitative approach. This will include a data collection approach and a study of several departments' many rules and norms governing dental waste disposal.

Data Collection

A structured questionnaire will be developed based on the research objectives, and items on the Likert scale will be used to measure variables from students, interns, faculties and practitioners. A sample of 406 students and faculty from different dental colleges and hospitals were selected for the survey. The questionnaires were formed by other departments which are mentioned.

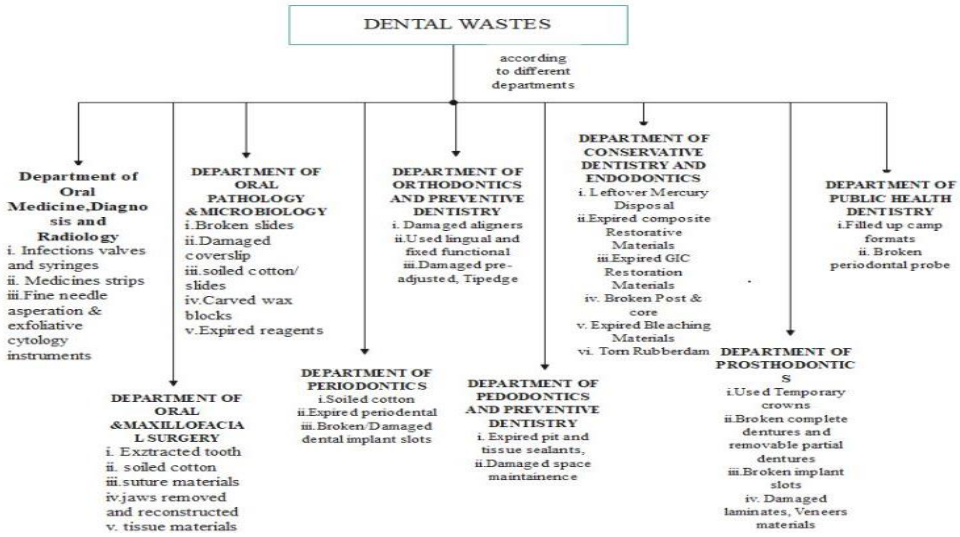

Figure 1: Dental wastes in different departments

Inclusion & Exclusion Criterion

The research comprises dental students in the first, second, third, and fourth years of their Bachelor of Dental Surgery (BDS) program. It also includes faculty members from dental institutions and practicing dentistry practitioners. Furthermore, the study invites those willing to participate, regardless of their personal information, and those who completed the questionnaire sent to them

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during data collection. On the other hand, the research excludes non-dental college associates and practitioners. Non-respondents who did not complete or return the questionnaire during data collection are excluded. Incomplete or inconsistent questionnaire answers are eliminated from the analysis. Participants who openly refused the study were also excluded.

Sampling Technique

Respondents will be asked to respond to this study, and the full questionnaire will be saved for future research. The data will be collected using a self-designed structured questionnaire and the random sample approach.

Random Sampling

For this study, we create a comprehensive list of dental colleges in the study area as part of the random sampling process. Next, a predetermined selection of colleges is chosen at random. Students from each BDS year, faculty, and practitioners are randomly selected within these colleges. We maintain a rigorous focus on fairness and transparency throughout the entire process. The sample size is determined through statistical analysis. Participants who have been chosen are encouraged to participate in the study by completing questionnaires or engaging in interviews. This approach seeks to offer a wide range of data to gain a comprehensive understanding of dental waste practices. In the case when a sample is only picked once, the formula for random sampling is as follows:

$$P = 1 - \left(\frac{N-1}{N}\right)\left(\frac{N-2}{N}\right).....\left(\frac{N-n}{N-(n-1)}\right)$$

Here, P is the probability, n is the sample size, and N represents the population.

Data Analysis

The study will utilize statistical methods to evaluate the types and quantities of dental waste generated by different dental departments. Additionally, it will assess the current practices employed for managing these wastes. Frequencies and percentages will be calculated using descriptive statistics to provide a comprehensive overview of the types of dental waste each department produces. Statistical methods, such as ANOVA, will be used to analyze and compare the variations in waste generation across various departments. The study uses quantitative methods to uncover significant findings regarding the discrepancies in dental waste practices among multiple departments. It also aims to offer recommendations for enhancing waste management and disposal strategies based on solid evidence.

Results

This study evaluates the dental waste practices followed among dental students, faculty, PGs (Postgraduate), and Interns. Also, it aims to raise awareness about the various types of dental waste in different dental departments such as the Department of Oral Medicine & Radiology, the Department of Oral & Maxillofacial Surgery, the Department of Orthodontics, the Department of Periodontology, the Department of Prosthodontics, the Department of Conservative Dentistry, and the Department of Pedodontics.

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H1: Different types of dental waste are generated by different dental departments.

Table 1 ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
Dept. of Oral Medicine Radiology	Between Groups	2.367	6	.394	10.805	.035
	Within Groups	195.452	399	.490		
	Total	197.818	405			
Dept. of Oral Maxillofacial Surgery	Between Groups	2.937	6	.489	8.077	.022
	Within Groups	181.381	399	.455		
	Total	184.318	405			
Dept. of Orthodontics	Between Groups	3.583	6	.597	11.014	.001
	Within Groups	235.079	399	.589		
	Total	238.662	405			
Dept. of Periodontology	Between Groups	1.632	6	.272	10.507	.031
	Within Groups	214.117	399	.537		
	Total	215.749	405			
Dept. of Prosthodontics	Between Groups	3.819	6	.636	11.301	.026
	Within Groups	195.167	399	.489		
	Total	198.986	405			
Dept. of Conservative Endodontic & Dept. of Pedodontics	Between Groups	1.833	6	.306	9.641	.015
	Within Groups	190.078	399	.476		
	Total	191.911	405			

The analysis of variance (ANOVA) table shows the findings of a study on the differences in the types of dental waste created by various dental departments. Each department was evaluated, including Oral Medicine Radiology, Oral Maxillofacial Surgery, Orthodontics, Periodontology, Prosthodontics, and a united department of Conservative Endodontics and Pedodontics. The table displays each department's total squares, degrees of freedom, mean squares, F-values, and significance levels. The F-values show considerable disparities between departments in terms of dental waste output. The departments of Orthodontics, Prosthodontics, and Conservative Endodontic & Pedodontics reveal substantial differences, with F-values of 11.014, 11.301, and 9.641, respectively, with p-values less than 0.05. As a result, the analysis validates the idea that there are differences in the types of dental waste generated by different dental departments, focusing on Orthodontics, Prosthodontics, and Conservative Endodontics & Pedodontics.

H2: The practices for managing various types of dental waste vary across different Dental departments.

For this hypothesis, a descriptive analysis is used, which is shown below

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Department of Oral Medicine & Radiology

Table 2 Statement-wise frequencies of the Department of Oral Medicine & Radiology

Statements		1st BDS	2nd BDS	3rd BDS	4th BDS	Faculty	PG	Intern	Total
Do you know where to dispose the lead apron, x-ray film's lead cover and undeveloped x-ray films into:	Black Bin	28	38	46	53	93	27	35	320
	Common Dustbin	3	0	6	4	2	3	3	21
	Don't Know	6	7	13	12	21	4	2	65
Do you know where to dispose the medicines (Antibiotic, analgesic), expired and discarded medicines into:	Black Bin	27	31	45	40	85	25	33	296
	Common Dustbin	2	2	7	5	9	5	4	34
	Don't Know	8	12	13	14	22	4	3	76

Table 2 shows waste disposal knowledge from students (1st BDS, 2nd BDS, 3rd BDS, 4th BDS), teachers, postgraduates (PGs), and interns at the Department of Oral Medicine & Radiology. Disposal of the lead apron, x-ray film's lead cover, undeveloped x-ray films and antibiotics, analgesics and expired and abandoned pharmaceuticals were investigated. 320 respondents knew how to dispose of lead aprons and associated objects, most preferring the "Black bin." Notably, instructors were more informed than BDS students. For pharmaceuticals, 296 respondents selected the "Black bin," showing instructors are more knowledgeable than BDS students. The data indicate that Oral Medicine & Radiology professors know more about waste disposal. Accordingly, comprehensive trash disposal education for all stakeholders, including students and professors, is necessary to encourage sustainable waste management in the department.

Department of Oral & Maxillofacial Surgery

Table 3 Statement-wise frequencies of the Department of Oral and Maxillofacial Surgery

Statements		1st BDS	2nd BDS	3rd BDS	4th BDS	Faculty	PG	Intern	Total
Do you know where to dispose the dental tooth and post-operative oral tissues into:	Yellow bin	27	39	52	51	83	30	34	316
	Common dustbin	2	1	1	0	5	0	2	11
	Don't know	8	5	12	18	28	4	4	79
Do you know where to dispose the	Yellow bin	28	39	48	55	83	27	34	314
	Common dustbin	2	0	3	2	4	2	3	16

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infected suture material into:	Don't know	7	6	14	12	29	5	3	76
Do you know where to dispose the expired local anesthetics reagent into:	Black bin	24	31	48	48	88	27	33	299
	Common dustbin	8	7	5	13	6	3	4	46
	Don't know	5	7	12	8	22	4	3	61

Table 2 shows the waste disposal expertise of Oral and Maxillofacial Surgery students (1st BDS, 2nd BDS, 3rd BDS, 4th BDS), instructors, postgraduates (PGs), and interns. The disposal of dental teeth and post-operative oral tissues, infectious suture material, and expired local anaesthetic reagents were assessed. 316 respondents knew how to dispose of dental teeth and post-operative oral tissues, most preferring the "Yellow bin." Several responders, especially 3rd BDS students and teachers, were unsure about the proper disposal technique. 314 respondents selected the "Yellow bin," indicating great awareness of contaminated suture material. However, many across all groups, notably 3rd BDS students and teachers, were unsure about the best disposal strategy. For expired local anaesthetic reagents, 299 respondents preferred the "Black bin," suggesting a majority of knowledge of proper disposal. However, many responders, especially 3rd BDS students and teachers, were unsure about disposal techniques. These results emphasize the necessity of trash disposal education and awareness, especially for students and teachers who are uncertain of correct waste disposal techniques.

Department of Orthodontics

Table 3 Statement-wise frequencies of the Department of Orthodontics

Statements		**1st BDS**	**2nd BDS**	**3rd BDS**	**4th BDS**	**Faculty**	**PG**	**Intern**	**Total**
Do you know where to dispose of orthodontic wires into:	Blue bin	26	34	46	48	80	25	32	291
	Common dustbin	3	2	9	2	5	4	2	27
	Don't know	8	9	10	19	31	5	6	88
Do you know where to dispose the used metallic orthodontic brackets into:	Blue bin	27	36	47	46	79	26	31	292
	Common dustbin	2	1	6	4	6	2	5	26
	Don't know	8	8	12	19	31	6	4	88

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Do you know where to dispose the plastic brackets, bands used in orthodontic treatment & the used night guard into:	Red bin	28	35	39	43	76	27	31	279
	Common dustbin	1	2	9	2	9	1	1	25
	Don't know	8	8	17	24	31	6	8	102

Table 3 shows how students (1st, 2nd, 3rd, and 4th BDS), teachers, postgraduates (PGs), and interns at the Department of Orthodontics responded to waste disposal questions. Three assertions were evaluated: disposal of orthodontic wires, metallic and plastic brackets, orthodontic bands, and night guards. 291 respondents knew how to dispose of orthodontic wires, most preferring the "Blue bin." Many responders, especially 4th BDS students and professors, were unsure about the proper disposal technique. 292 respondents preferred the "Blue bin" for metallic orthodontic brackets, indicating excellent knowledge. However, many across all groups, especially 3rd BDS students and teachers, were unsure about the disposal procedure. For plastic brackets, bands, and worn night guards, 279 respondents preferred the "Red bin," suggesting a majority of knowledge of proper disposal. However, many responders, particularly 3rd BDS students and staff, were unsure about disposal. These results emphasize the necessity of trash disposal education and awareness, especially for students and teachers who are uncertain of correct waste disposal techniques.

Department of Periodontology

Table 4 Statement wise frequencies of the department of Periodontology

Statements		**1st BDS**	**2nd BDS**	**3rd BDS**	**4th BDS**	**Faculty**	**PG**	**Intern**	**Total**
Do you know where to dispose the broken scalar points into:	Blue bin	24	31	44	41	76	23	29	268
	Common dustbin	3	0	6	3	8	3	2	25
	Don't know	10	14	15	25	32	8	9	113
Do you know where to dispose post perio-surgical waste materials into:	Yellow bin	30	39	47	54	89	28	33	320
	Common dustbin	2	0	4	1	4	1	4	16
	Don't know	5	6	14	14	23	5	3	70

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In the table-4, 1st, 2nd, 3rd, and 4th, BDS students, teachers, postgraduates (PGs), and interns in the Department of Periodontology answer questions on waste disposal. Broken scalar point disposal and post-period-surgical waste disposal were assessed. For broken scalar points, 268 respondents knew how to dispose of them, with most preferring the "Blue bin." A significant number of all groups, notably 4th BDS students and professors, were unsure about the proper disposal technique. 320 respondents preferred the "Yellow bin," demonstrating great awareness for post-period-surgical trash. Many responders, especially 3rd BDS students and professors, were unsure about the best disposal strategy. These results emphasize the need to reinforce awareness of trash disposal, particularly among students and teachers unsure about correct disposal techniques.

Department of Prosthodontics

Table 5 Statement-wise frequencies of the Department of Prosthodontics

Statements		1st BDS	2nd BDS	3rd BDS	4th BDS	Faculty	PG	Intern	Total
Where do you dispose impression materials, dental waxes, green stick compound, impression pastes; shellac base plates into:	Yellow bin	32	35	39	53	84	28	31	302
	Common dustbin	2	4	11	4	10	2	3	36
	Don't know	3	6	15	12	22	4	6	68
Where do you dispose the rubber base impression material, investment material, pumice, acrylic, metal dust, alginate, old models and casts, old acrylic dentures and acrylic teeth into:	Black bin	28	32	41	52	87	28	34	302
	Common dustbin	6	4	13	5	8	3	2	41
	Don't know	3	9	11	12	21	3	4	63

Table 5 shows the waste disposal knowledge of Department of Prosthodontics students (1st BDS, 2nd BDS, 3rd BDS, 4th BDS), instructors, postgraduates (PGs), and interns. Disposal of impression materials, dental waxes, and related things, as well as rubber-based impression material, investment material, and related items, were analyzed. Most respondents across all categories knew how to dispose of imprint materials, with 302 suggesting the "Yellow bin." However, many responders, especially 3rd BDS students and teachers, were unsure about the proper disposal technique. For rubber base imprint material and associated products, 302 respondents preferred the "Black bin,"

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indicating high knowledge. However, many responders, including 3rd BDS students and teachers, were unsure about the disposal technique. These results highlight the need to increase awareness of garbage disposal, especially among students and teachers unsure about safe disposal techniques.

Department of Conservative &Endodontic, along with the Department. of Pedodontic
Table 6 Statement wise frequencies

Statements		1st BDS	2nd BDS	3rd BDS	4th BDS	Faculty	PG	Intern	Total
Do you know where to dispose both the deciduous and permanent dental tooth into:	Yellow bin	31	38	48	54	84	25	34	314
	Common dustbin	4	3	5	3	6	3	2	26
	Don't know	2	4	12	12	26	6	4	66
Do you know where to dispose the orthodontic appliances into:	Black bin	31	36	47	57	86	28	32	317
	Common dustbin	1	3	4	1	4	1	2	16
	Don't know	5	6	14	11	26	5	6	73
Do you know where to dispose the files and reamers into:	Blue bin	22	27	43	32	73	23	26	246
	Common dustbin	1	4	5	1	5	0	4	20
	Don't know	14	14	17	36	38	11	10	140

The table displays the frequency of replies from students (1st BDS, 2nd BDS, 3rd BDS, 4th BDS), teachers, postgraduates (PGs), and interns about their understanding of waste disposal methods within the Department of Conservative & Endodontic and the Department of Pedodontics. Three claims were evaluated: the disposal of deciduous and permanent dental teeth, orthodontic equipment, and files and reamers.

Regarding the disposal of dental teeth, most respondents from all groups demonstrated knowledge of the correct disposal technique, with 314 replies indicating a preference for the "Yellow bin." Nevertheless, a significant percentage, especially among 3rd and 4th BDS students and professors, acknowledged their lack of assurance about the appropriate manner of disposal. Similarly, out of the 317 respondents, most preferred the "Black bin" when it came to orthodontic equipment, indicating a significant degree of knowledge among the respondents. Nevertheless, a substantial proportion of students and staff members voiced their confusion over the appropriate way of disposal.

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About files and reamers, the "Blue bin" was the preferred disposal method for most respondents, with 246 replies. Nevertheless, a notable percentage of 3rd and 4th BDS students, along with staff members, expressed a deficiency in their understanding of appropriate disposal methods. These results indicate both positive aspects and places for development in waste disposal awareness within the departments. This suggests the need for focused educational activities to promote correct waste management practices among students and teachers.

Discussion

The study on dental waste management among dentistry students and practitioners found that faculty and students were aware of proper disposal methods for various types of dental waste. The Department of Oral Medicine & Radiology has the most faculty awareness. Most responders knew how to dispose of lead aprons, x-ray films, pharmaceuticals, dental teeth and oral tissues, suture material, local anaesthetics, needles, scalpel blades, and other objects. However, some departments have more knowledgeable staff than pupils.

These results emphasize the need for comprehensive waste management instruction in dentistry schools. The results we obtained match prior research and advance dental waste management knowledge. First, our findings on awareness and behaviour inequalities among dental students and professors across departments support past studies on knowledge-practice gaps among dental practitioners. Our analysis also shows that dental waste disposal containers vary in effectiveness, supporting previous studies.

Some dumpsters, like the Yellow Bin, are better at containing and disposing of dental waste. As discussed in the literature and our study, department-specific waste management approaches are essential due to these differences in disposal container reactions. Our findings also support the literature's need for complete dental waste management education and training, including disinfection. Our study did not examine disinfection procedures, but it supports the literature's demand for targeted educational interventions to bridge knowledge and practice gaps. This study illuminates dentistry students' and faculty's waste management knowledge and actions in various departments, adding to the body of research. Comparing our findings to the literature emphasizes the need for sustainable dental waste management approaches and department-specific education programs.

Conclusion

The research aimed to analyze differences in dental waste practices and awareness across different dental departments, particularly emphasising waste generation and disposal techniques. The findings show considerable variations in waste generation and administration strategies among departments.

First, the ANOVA analysis revealed significant differences between departments, specifically in Conservative Endodontics & Pedodontics, Orthodontics, and Prosthodontics, with respect to the hypothesis that different dental departments generate distinct types of dental waste (H1). These departments produced variable amounts of garbage, indicating the necessity for specific waste management techniques. Second, the descriptive analysis confirmed substantial variations in waste management procedures amongst dental departments, supporting the hypothesis that the techniques used to handle distinct forms of dental waste varied (H2).

Faculty members regularly demonstrated better levels of awareness and knowledge than students in all disciplines. This shows a possible knowledge gap and emphasizes the significance of focused education and training initiatives to enhance waste management practices among students. In conclusion, the research underscores the need for department-specific waste management policies and educational activities to raise awareness and assure safe disposal methods in dental settings. In

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promoting sustainable waste management practices among dental students, faculty members assume a pivotal role as educators and role models.

This, in turn, contributes significantly to advancing public health and preserving the environment. The difference may be explained by the faculty members' long track records of working in dentistry. The health and safety of healthcare workers and the well-being of their patients depend on the institution's adherence to best waste management practices.

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Multiple Risk Exposure and Chronic Obstructive Pulmonary Disease Characteristics among Men in a Mining Community in Northern Tanzania

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Abstract

Background: Chronic obstructive pulmonary disease (COPD) contributes to a substantial burden of diseases globally. The existing unregulated small-scale mining activities in Africa could expose miners to excessive air pollution and the subsequent development of COPD. Understanding the co-existent multiple risk factors for COPD is crucial for local public health action.

Methods: This cross-sectional study was conducted in a small-scale, informal mining site in Tanzania. The eligible participants were active miners, ex-miners and non-miners aged ≥30 years. The participants were assessed for respiratory symptoms and risk factors and underwent testing for spirometry, with COPD defined based on post-bronchodilator (BD) $FEV_1/FVC<70\%$. The air pollution was monitored based on PM_{10} level in mining pits using TSI Side Pak^{TM} AM510 samplers.

Results: 702 men [480 active miners, 170 ex-miners and 52 non-miners] were recruited with a mean age and standard deviation (SD) of 40.95 ± 9.21 years, and two-thirds were cigarette smokers. The prevalence of COPD was estimated to be 15.20%, 17.10% and 15.40% in active miners, ex-miners and non-miners, respectively. Over 18% of current cigarette smokers had significant nicotine dependence, which was associated with the duration of smoking (p= 0.028) and the number of pack years (p = 0.002). Many COPD patients presented with cough and had frequent exacerbations but with mild to moderate airway limitation. The survey revealed up to 20,000µg/m^3 of PM_{10} in the underground microenvironment, exceedingly higher than the acceptable limits.

Conclusion: The prevalence of COPD among the mining communities is substantial in Tanzania. The patients are largely young, and the majority are cigarette smokers. The mining activities are typically carried out without protective gear, underscoring the critical role of a multi-sectorial approach in preventing COPD.

Keywords: Air pollution, chronic obstructive pulmonary disease, cigarette smoking, mining, spirometry

Background

Chronic obstructive pulmonary disease (COPD) is a significant cause of morbidity and mortality globally, albeit scarce data in sub-Sahara Africa (SSA) (Chan-Yeung, Ait-Khaled, White, Ip, & Tan, 2004; Groenewald *et al.*, 2007; Mehrotra et al., 2009). In 2019, the overall prevalence of COPD in SSA was estimated to be 10.3 million (Alemayohu, Zanolin, Cazzoletti, Nyasulu, & Garcia-Larsen, 2023). Globally, cigarette smoking and occupational exposure to air pollution are well-known risk factors for developing COPD (Becklake, 1989; Boschetto *et al.*, 2006). However, exposure to biomass smoke and traffic pollution has recently been recognized as significant risk factors for developing COPD in low- and middle-income countries (LMICs) (Burki, 2011; Fullerton, Gordon, & Calverley, 2009; Salvi, 2015). In parallel, the current social and economic transitions in SSA characterized by increased urbanization, industrialization and extensive mineral explorations in

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the context of a lack of work safety standards are likely to contribute to air pollution and increased risk of developing occupational lung diseases, including COPD (Alemayohu *et al.*, 2023).

COPD is characterized by progressive and irreversible airway limitation resulting from chronic airway inflammatory response due to prolonged exposure to air pollutants (Agusti & Hogg, 2019; Nakamura, 2011). COPD is a recent phenomenon in SSA, as many patients with the disease are often misdiagnosed (Salvi, 2015). The ageing populations, together with increased cigarette smoking habits and the rising trends in air pollution are potential drivers for the continued rise in COPD in developing countries (Agusti & Hogg, 2019; Ngweina Francis Magitta, 2018). Prolonged exposure to inhalational pollutants in specific occupational groups, who often do not use proper protective gear, exposes individuals to an increased risk of developing COPD.

Patients with COPD present with chronic cough and sputum production with or without dyspnoea (Isidro Montes *et al.*, 2004; Koichi Nishimura, 2002). This clinical presentation tends to be ignored by patients until they present late at advanced stages of the disease, often after developing intolerable dyspnoea (Koichi Nishimura, 2002). Regrettably, due to a lack of expertise and diagnostic capacity, such as spirometry (Agusti *et al.*, 2023; Mehrotra *et al.*, 2009), patients with COPD are often misdiagnosed with pulmonary tuberculosis, interstitial lung diseases or even heart failure and offered inappropriate treatment (Chan-Yeung, Ait-Khaled, White, Tsang, & Tan, 2004). The current management of COPD requires stepwise administration of bronchodilators and steroids, preferably via the inhalational route during stable states and exacerbation (Agusti *et al.*, 2023). However, due to shortages of expertise and resources, Global Initiative on Chronic Obstructive Lung Diseases (GOLD) guidelines are often not adhered to in routine clinical practice in LMICs (Agusti *et al.*, 2023; Chan-Yeung, Ait-Khaled, White, Tsang *et al.*, 2004).

Currently, there are widespread, unregulated artisanal mining sites in Tanzania. A lack of proper protective gear and weak regulatory authorities with a greater risk of exposure to excessive inhalational pollutants characterize the mining activities. This study is set to determine the burden of COPD in this high-risk population and assess the air quality within the underground microenvironment where mining activities are undertaken. We sought to provide evidence for advocacy for regulatory policy change to improve occupational mining standards in Tanzania.

Methods

Study design and study area

This cross-sectional descriptive study was conducted in a small-scale hard-rock mining site in Northern Tanzania. The mining site consists of large-scale and small-scale sites operated by large-scale investors and small-scale local miners, respectively. The small-scale mining site is organized into 100 mining pits across the site. Besides other minerals, tanzanite is a significant mineral ore extracted from the area. In the current study, we recruited three groups of participants: active miners, ex-miners, and non-miners. The study was preceded by conducting community sensitization meetings at the selected study sites.

Sampling and sample size estimation

A total of 702 men (480 active miners, 170 ex-miners and 52 non-miners) were recruited. Twenty mining pits from the available 100 were randomly selected, from which we recruited a sample size of 480 active miners on a consecutive basis. The number of workers in each mining pit was pre-determined, and all eligible participants were selected. 170 ex-miners and 52 non-miners aged ≥ 30 years were randomly selected and recruited from the local area. All households were visited in the same study population, and eligible ex-miners were identified for interview. Active miners were operationally defined as men actively mining during the study and having been in active mining for at least six consecutive months. Ex-miners were men who had engaged in mining activities at the same site for at least six months. Whenever permissible, a comparison group of eligible individuals who reported never being involved in the mining activities were recruited.

Fieldwork and data collection

The study collected information about respiratory symptoms, occupation, respiratory diagnoses, co-morbidities, health care utilization, medication use, activity limitation, health status, primary demographic data, and personal particulars. The participants were assessed for anthropometry, which measured blood pressure and pulse. The burden and determinants of COPD were assessed using the BOLD protocol (www.boldstudy.org) with slight modifications on demographic details and socioeconomic variables. The interviewers administered a set of BOLD-validated questionnaires.

The participants underwent spirometry using a 3L-syringe daily calibrated NDD EasyOneTM spirometer (www.nddmed.com), which was repeated 15 to 20 minutes after inhalation of 200µg of salbutamol via a spacer. The diagnosis of COPD was made based on a history of exposure to risk factors and the presence of airflow limitation that is not fully reversible, with or without the presence of symptoms (Agusti et al., 2023). A post-bronchodilator (BD) FEV_1/FVC <70% and a post-BD FEV_1 <80% predicted confirmed the presence of airflow limitation that is not fully reversible (Agusti et al., 2023).

Pollution monitoring

The mining pits were monitored for air pollution in the underground microenvironment based on particulate matter with an aerodynamic diameter <10 µm (PM_{10}) using TSI SidePak^{TM} AM510 personal aerosol monitors (www.tsi.com) with a sampling rate of one minute. The volunteer mining workers took two pre-programmed air sampler units into the underground pits and positioned them at the drilling point and at the rear of the shaft where the rest of the miners hide during active drilling. The monitors were left at these positions for up to 8 hours until the mining shift was over and then carried back to the field workers.

Statistical analysis

The statistical analysis was performed using SPSS software version 18 (SPSS Inc., Chicago, IL). All quantitative variables were summarized as mean and standard deviation. Percentages and absolute numbers were used for summarizing continuous and categorical variables. The χ^2 test was used to compare categorical groups. Regression analysis modelling was used to determine the role of presumed independent variables. A p-value of less than 0.05 was considered statistically significant.

Results

Recruitment and flow chart of the study participants

A total of 851 eligible participants were invited to participate in the study. Of these, 752 completed the questionnaire and underwent spirometry. A total of 702 participants had acceptable post-BD spirometry for whom the final analysis was carried out, as highlighted in Figure 1.

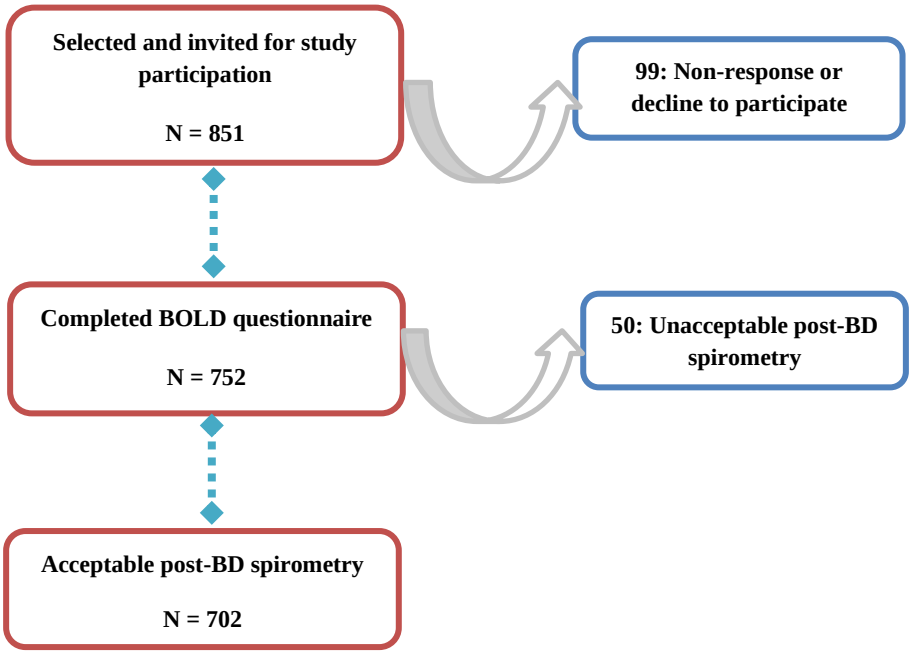

Figure 1: Flow chart for recruiting participants from the mining site and the nearby community.

Essential demographic and clinical characteristics of participants who completed the BOLD questionnaire and underwent post-BD spirometry

The current COPD survey recruited 702 male participants [(480 active miners; 170 ex-miners and 52 non-miners)], with a mean age ± SD of 40.95 ± 9.21 years. Over 53% of participants were in the 31-40 age group, and two-thirds of all participants were either former or current cigarette smokers (Table 1). Eighty-eight per cent (752 of 851) of all respondents who completed the questionnaires underwent post-BD spirometry. Of these, 75% had received primary education, and 73% had good nutritional status. About 68%, 25% and 7% of active miners, ex-miners and non-miners, respectively, reported either current or former cigarette smoking status (Table 1). Notably, over 40% of active miners were current smokers, while about 48% of ex-miners were former cigarette smokers (Table 1).

Table 1: Basic demographic characteristics of responders who completed BOLD questionnaire and post-BD spirometry (N = 702)

Variable		Exposure status			
		Active miners	Ex-miners	Non-miners	Total
Sex	Male	480 (68.40%)	170 (24.20%)	52 (7.40%)	702 (100%)
Age categories	20-30	9 (1.88%)	4 (5.71%)	5 (9.62%)	18 (2.56%)
	30-40	300 (62.50%)	57 (33.53%)	12 (23.08%)	369 (52.56%)
	40-50	132 (27.5%)	56 (32.94%)	15 (28.85%)	203 (28.92%)
	50-60	28 (5.83%)	37 (21.76%)	13 (25.0%)	78 (11.11%)
	60+	12 (2.50%)	15 (8.82%)	7 (13.46%)	34 (4.84%)
Mean age ± SD		36±14.63	45±19.35	48±16.12	40.95+-9.21
Education	Primary	359 (74.70%)	137 (80.60%)	33 (63.50%)	529 (75.30%)
	Secondary	53 (11.10%)	17 (10.00%)	8 (15.40%)	78 (11.10%)
	Others	14 (2.92%)	2 (1.18%)	6 (11.54%)	22 (3.14%)
	No education	52 (10.90%)	14 (8.20%)	5 (9.60%)	71 (10.10%)
	Unknown	2 (0.40%)	0 (0.0%)	0 (0.0%)	2 (0.30%)
Body Mass Index	Underweight	27 (5.70%)	13 (7.70%)	5 (9.60%)	45 (6.50%)
	Normal weight	369 (77.70%)	112 (66.30%)	26 (50.00%)	507 (72.80%)
	Overweight	65 (13.70%)	37 (21.90%)	16 (30.80%)	118 (17.00%)
	Obesity	14 (2.90%)	7 (4.10%)	5 (9.60%)	26 (35.90%)
Smoking status	Non-smokers	163 (34.00%)	45 (26.50%)	28 (53.80%)	236 (33.60%)
	Former smokers	123 (25.60%)	81 (47.60%)	10 (19.20%)	214 (30.50%)
	Current smokers	194 (40.40%)	44 (25.90%)	14 (26.90%)	252 (35.90%)

Prevalence of COPD among exposure groups of study participants based on three diagnostic criteria

The prevalence of COPD, based on the criteria of post-BD FEV1/FVC <70%, was estimated at 15.20%, 17.10% and 15.40% for active miners, ex-miners and non-miners, respectively (Table 2). However, the prevalence of COPD varied depending on the criteria used. Irrespective of the exposure category, the overall prevalence of COPD was 15.70%, 11.00% and 20.80%, respectively, based on post-BD FEV1/FVC ≤70%, post-BD FEV_1/FVC<LLN and post-BD age category criteria (Table 2).

Table 2: Prevalence rates of COPD among three exposure groups based on different diagnostic criteria (N = 702)

Variable	COPD+/-	Mining status			
		Active miners	Ex miners	Non-miners	Total
COPD[1] Post Test Result	Yes	73 (15.21 %)	29 (17.10%)	8 (15.38 %)	110 (15.67 %)
	No	407 (84.79%)	141 (82.94%)	44 (84.62%)	592 (84.33%)
COPD[2]LLN PB Post Test Result	Yes	56 (11.67 %)	17 (10.00%)	4 (7.70%)	77 (10.97 %)
	No	424 (88.33%)	153 (90.00%)	48 (92.31%)	625 (89.03%)
COPD[3] Age Post Test Result	Yes	104 (21.67 %)	35 (20.59 %)	7 (13.46 %)	146 (20.80%)
	No	376 (78.33%)	135 (79.41%)	45 (86.54%)	556 (79.20%)

1: Post-BD $FEV_1/FVC<70\%$; 2: Post-BD $FEV_1/FVC<LLN$; and 3: Age <40 years; Post-BD $FEV_1/FVC<75\%$;

Age (40-60) years; Post-BD $FEV_1/FVC<70\%$ and Age <60 years Post-BD $FEV_1/FVC<65\%$.

The prevalence of COPD generally increased with age in all exposure categories. Intriguingly, ex-miners had the highest prevalence (Table 3). Over 18% of all current cigarette smokers had significant nicotine dependence on the Fagerstrom scale (Table 4). This dependence was significantly associated with the duration of cigarette smoking (p=0.028) and the number of pack years (p=0.002) (Table 5).

Table 3: Prevalence rates of COPD by exposure group and age-categories among respondents (N = 702)

Exposure status	COPD+/-	Age categories					
		≥30	30.1-40	40.1-50	50.1-60	60+	Total
Active miners	Yes	0 (0.00%)	26 (8.70%)	30 (22.70%)	9 (32.10%)	8 (66.70%)	73 (15.20%)
	No	9 (100.00%)	272 (91.30%)	102 (77.30%)	19 (67.90%)	4 (33.30%)	406 (84.80%)
Ex-miners	Yes	0 (0.00%)	3 (5.30%)	12 (21.40%)	8 (21.60%)	5 (33.30%)	28 (16.60%)
	No	4 (100.00%)	54 (94.70%)	44 (78.60%)	29 (78.40%)	10 (66.70%)	141 (83.40%)
Non-miners	Yes	0 (0.00%)	0 (0.00%)	3 (20.00%)	2 (15.40%)	3 (42.90%)	8 (15.40%)
	No	5 (100.00%)	12 (100.00%)	12 (80.00%)	11 (84.60%)	4 (57.10%)	44 (84.60%)

1 Post-BD FEV1/FVC<70%

Cigarette smoking and tobacco dependency among study participants who were current smokers

Table 4: Distribution of Fagarstrom nicotine score scale and nicotine dependence among ever cigarette smokers by mining exposure groups (N = 186)

Variable	Frequency	Exposure status			
		Active miners	Ex-miners	Non-miners	Total
FNS	0	37 (17.31%)	4 (14.81%)	0 (0.00%)	41 (16.67%)
	1	30 (19.23%)	5 (18.52%)	1 (33.33%)	36 (19.35%)
	2	25 (16.03%	2 (7.41%)	0 (0.00%)	27 (14.52%)
	3	24 (15.38%)	4 (14.81%)	0 (0.00%)	28 (15.05%)
	4	24 (15.38%)	6 (22.22%)	0 (0.00%)	30 (16.13%)
	5	12 (7.69%)	4 (14.81%)	1 (33.33%)	17 (9.14%)
	6	8 (5.13%)	0 (0.00%)	1 (33.33%)	9 (4.84%)
	7	2 (1.28%)	1 (3.70%)	0 (0.00%)	3 (1.61%)
	8	4 (2.56%)	1 (3.70%)	0 (0.00%)	5 (2.69%)
	Total	156 (83.87%)	27 (14.52%)	3 (1.61%)	186 (100.00%)
NDS	Low to Moderate Dependency (score 0 to 4)	130 (83.33%)	21 (77.78%)	1 (33.33%)	152 (81.72%)
	Significant Dependency (score ≥5)	26 (16.67%)	6 (22.22%)	2 (66.67%)	34 (18.28%)

FDS – Fagarstrom Dependency Scale; NDS – Nicotine Dependency Score

Table 5: Association between nicotine dependence and selected variables among current cigarette smokers

Variable	NAS	N	Mean	SD	XD	95% LCI	95% UCI	p-value
Age	Low to Moderate	152	39.96	8.21	-2.929	-6.109	0.251	0.071
	Significant Dependence	34	42.89	9.71				
Number of smoking years	Low to Moderate	152	19.28	9.58	-4.113	-7.778	-0.449	**0.028**
	Significant Dependence	34	23.39	10.72				
Number of pack years	Low to Moderate	152	8.33	7.86	-30.742	-72.536	11.052	**0.002**
	Significant Dependence	34	39.08	119.73				

NAS - Nicotine Addiction Scale; SD – Standard Deviation; XD – Mean Deviation; LCI – Lower Confidence Interval; UCI – Upper Confidence Interval

Respiratory symptoms and COPD characteristics among study participants

Moreover, as highlighted in Table 6, it was noted that cough, followed by phlegm, were the most common respiratory symptoms presented by patients with COPD, irrespective of exposure categories. Moreover, shortness of breath was the least presenting symptom among all exposure categories reported by 46.4% of ex-miners and about 25% of both active and non-miners. The majority of COPD patients had an increased frequency of 3 or more exacerbations within the preceding 12 months, which was highest among active miners. The worst mean FEV_1 and FVC parameters among ex-miners and non-miners had the best mean spirometry parameters. Notwithstanding the exposure status, most COPD patients had mild to moderate airway limitation, reported in 84.9%, 79.2% and 87.5%, respectively, among active miners, ex-miners and non-miners. Noteworthy, the highest proportion of severe to very severe airway limitation was observed in ex-miners and active miners.

Table 6: Respiratory symptoms, exacerbations, spirometry indices and COPD severity based on GOLD classification among all study population

Clinical characteristics	Exposure categories		
	Active miners (n=73)	Ex-miners (n=28)	Non-miners (n=8)
Respiratory symptoms			
Cough	38 (52.1%)	18 (64.2%)	7 (87.5%)
Phlegm	34 (46.6%)	15 (53.6%)	5 (62.5%)
Wheeze	29 (39.7%)	15 (53.6%)	3 (37.5%)
Shortness of breath	17 (25.8%)	13 (46.4 %)	2 (25.0%)
Exacerbation in the past 12 months			
0	3 (12.0%)	3 (23.1%)	0 (0.0%)
1	4 (16.0%)	1 (7.7%)	1 (33.3%)
2	4 (16.0%)	5 (38.5%)	1 (33.3%)
3 or more	14 (56.0%)	4 (30.7%)	1 (33.3%)
Post-test spirometry			
FVC (% predicted)	92.90 ± 19.79	88.73 ± 25.14	104.72 ± 23.07
FEV1 (% predicted)	70.18 ± 18.31	62.98 ± 17.09	78.68 ± 18.85
Severity of airway limitation in GOLD classification			
1 - Mild obstruction	22 (30.1%)	6 (20.7%)	4 (50.0%)
2 - Moderate obstruction	40 (54.8%)	17 (58.6%)	3 (37.5%)
3 - Severe obstruction	10 (13.7%)	4 (13.8%)	1 (12.5%)
4 - Very severe obstruction	1 (1.4%)	2 (6.9%)	0 (0.0%)

Air pollution monitoring in the underground mining pits

The 8-hour measurements of air quality in underground mining microenvironments both at the rear of shaft and drilling points revealed levels of PM_{10} well beyond the acceptable 50µg/m^3 World Health Organization (WHO) safety limits (Figures 2, 3, and 4). The average exposure to PM_{10} was revealed to be nearly 5,000µg/m^3 while the maximum exposure was beyond 20,000µg/m^3 (Figures 3 and 4).

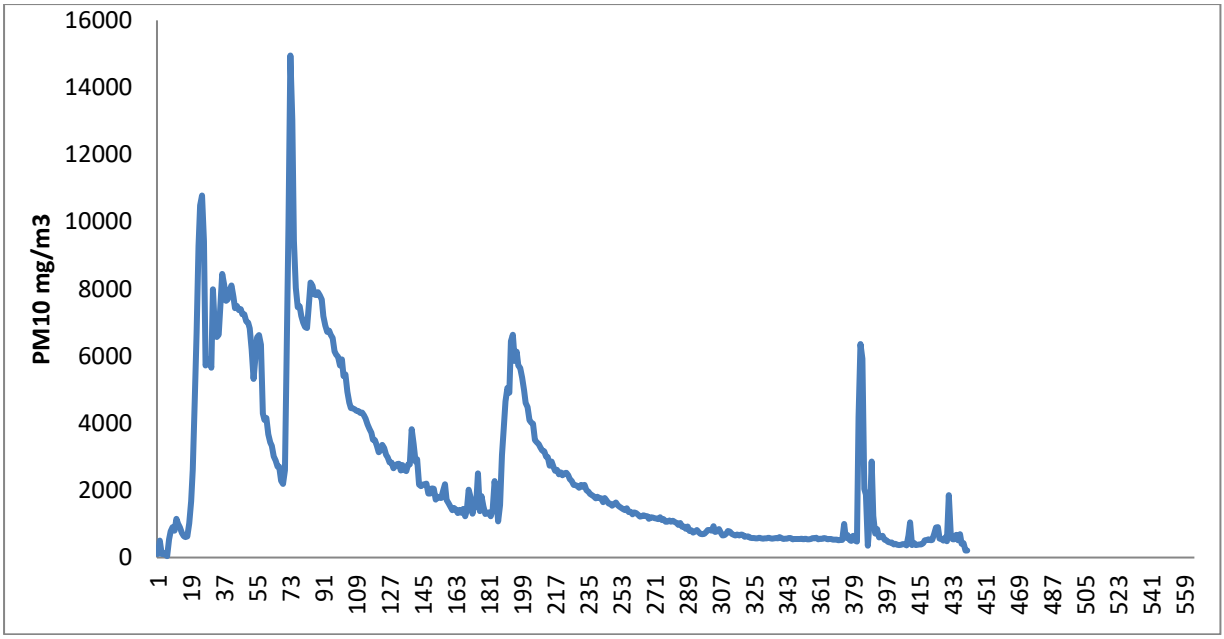

Figure 2: Graphical variation of PM_{10} in a typical 8-hour monitoring session in underground mining pit in a hard-rock mining site

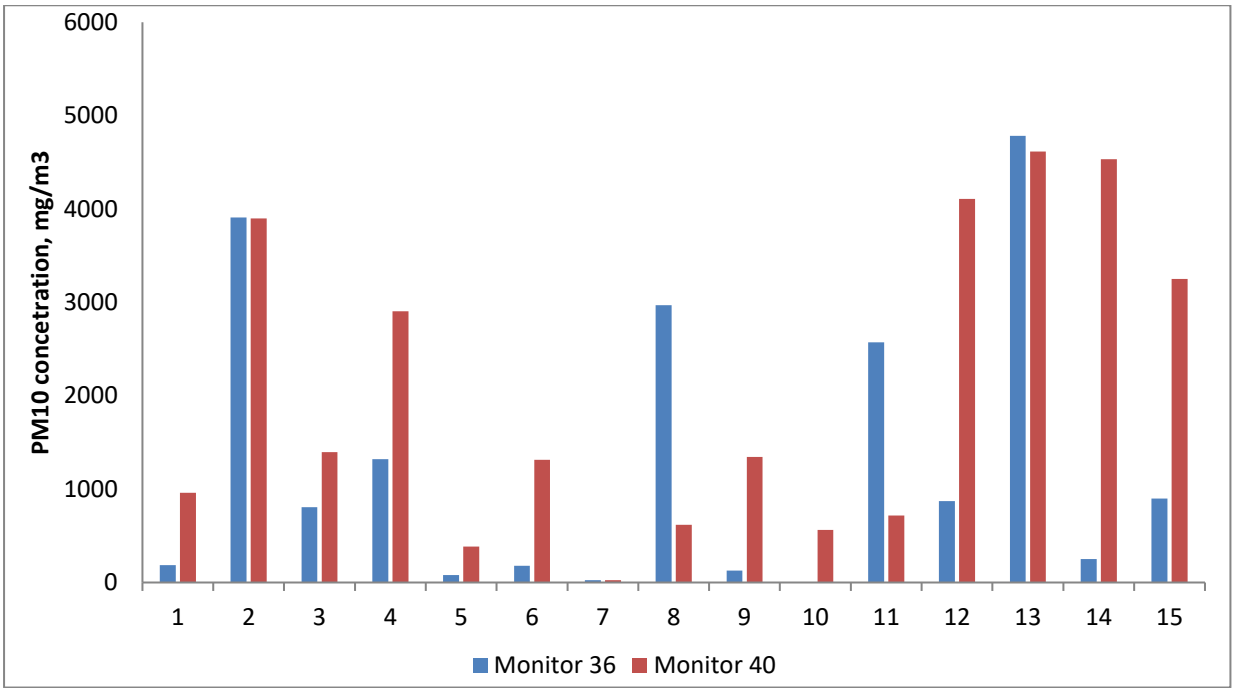

Figure 3: Variation in daily average PM_{10} concentrations for the two monitors situated at the drilling point (monitor serial 40) and rear of shaft (monitor serial 36) in a typical underground microenvironment in 15 selected hard-rock mining pits

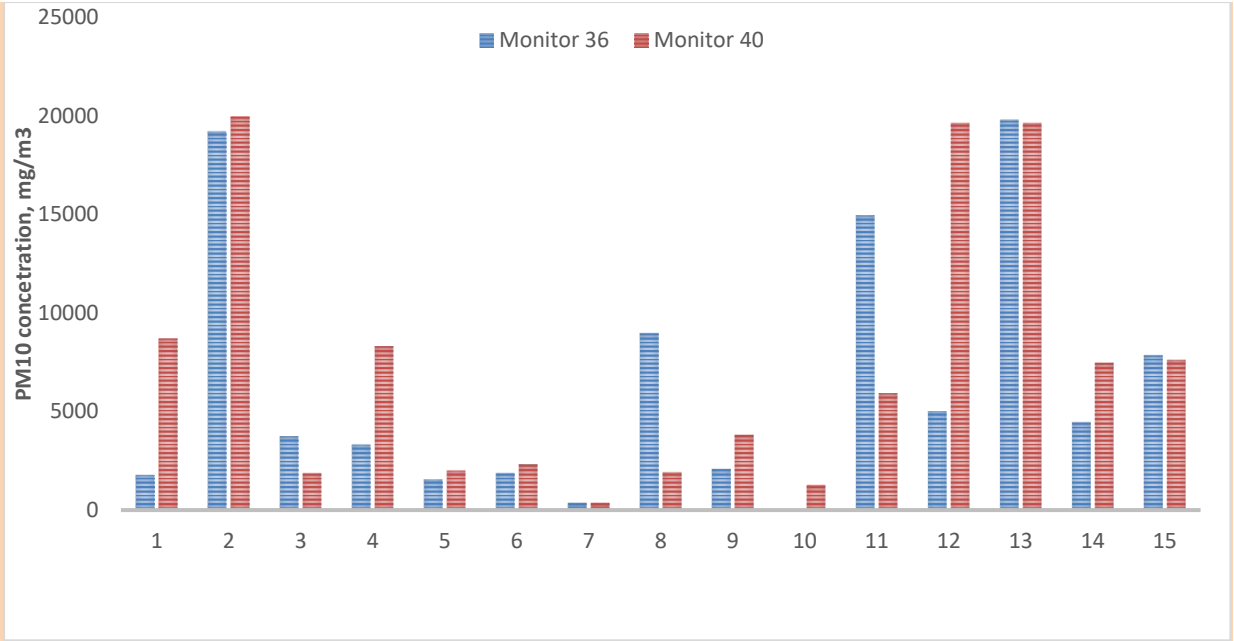

Figure 4: Variation in daily maximum values of PM_{10} concentrations for two monitors situated at the drilling point (monitor serial 40) and rear of shaft (monitor serial 36) in a typical underground microenvironment in 15 selected hard-rock mining pits

Discussion

The prevalence of COPD ranged from 15.20% to 16.60% in the studied mining population in Tanzania, similar to the previously reported studies (Balmes *et al.*, 2003; Chan-Yeung, Ait-Khaled, White, Ip *et al.*, 2004). For instance, our results are comparable to reports from community surveys conducted in Uganda and Tanzania, which estimated the prevalence of 16.2% and 17.5%, respectively (N. F. Magitta *et al.*, 2018; van Gemert *et al.*, 2015). Interestingly, this prevalence did not appear to differ significantly regarding exposure status in our study. Individuals who responded as non-miners might have worked intermittently in the mining activities and were thus misclassified as non-exposed. Nearly all study populations, irrespective of exposure status, were exposed to biomass fuel, and up to half of them were ever smokers, indicating that other risk factors could have contributed to the development of COPD in this study group.

The current study reported 40% and 48% of active and ex-miners as current and former cigarette smokers, respectively. However, a study in Nigeria reported the prevalence of cigarette smoking in a community-based study to range from 8.7% in the current smokers to 22% in ever smokers (Adeloye *et al.*, 2015). Likewise, a review by Magitta, NF estimated the prevalence of cigarette smoking among men to be 13.9% in SSA (Ngweina Francis Magitta, 2018). Thus, it is observed that the prevalence of cigarette smoking is exceedingly high among miners compared to the general population.

Moreover, the current study highlights that a substantial proportion of all current cigarette smokers have nicotine dependence based on the Fagarstrom Nicotine Dependency Scale. These individuals are less likely to quit smoking, thus constituting an at-risk population for developing COPD in the absence of purposeful intervention for smoking cessation (Laniado-Laborin, 2009). Given the high prevalence of cigarette smoking in this study community, the prevalence of COPD would be expected to be considerably high due to the co-existence of multiple risk factors. One possible explanation would be the early retirement of miners upon developing intolerable dyspnoea and emigration from the local population to their place of permanent residence, keeping in mind that miners hailed from across Tanzania and nearby countries.

The interplay between cigarette smoking and occupational exposure to pollutants among miners accelerates the deterioration in lung function and subsequent development of COPD (Santo Tomas, 2011). This observation highlights the importance of integrating smoking cessation

programs into the overall strategy for the prevention of COPD (Liu, Lee, Perez-Padilla, Hudson, & Mannino, 2008; Tonnesen, 2013). Inadvertently, despite efforts made on the implementation of the WHO strategy on tobacco control, there is a plethora of tobacco adverts and tobacco use still soars in the majority of LMICs (Brathwaite, Addo, Smeeth, & Lock, 2015). Specifically, smoking cessation programs are virtually nonexistent in most SSA countries. Typically, smoking cessation programs comprise a combination of psychotherapy and pharmacotherapy, the latter constituting nicotine replacement therapy (NRT) together with specific pharmacological agents (Strassmann *et al.*, 2009; Tonnesen, 2013).

A shortage of skilled healthcare personnel in psychology and psychiatry could partly hinder such strategies. Besides cigarette smoking, ex-miners were more likely to be older than active miners; thus, age, as a determinant for cumulative risk exposure, could be contributing to their increased COPD risk (Geijer *et al.*, 2006)Further explanation would be the fact that in an unregulated mining industry, people tend to retire from mining activities when they develop intolerable dyspnea due to undiagnosed COPD. It is thus prudent to suspect that some ex-miners retired from working after developing COPD, thus contributing to a higher burden of disease among the ex-miners compared to the active miners.

Similar to other studies conducted elsewhere, patients with COPD commonly presented with cough (Isidro Montes *et al.*, 2004). Cough is a recognized predictor of COPD progression, while breathlessness or dyspnoea signifies the severity of airway limitation (Smith & Woodcock, 2006). In the current study, it was revealed that the majority of ex-miners with COPD presented with dyspnoea, which could indicate that disease severity is probably also associated with inadequate treatment. This observation is in line with other previous studies which reported dyspnoea as a predictor of disease severity (Grosbois *et al.*, 2022; O'Donnell, Milne, James, de Torres, & Neder, 2020). Most COPD patients had an increased frequency of exacerbations regardless of their exposure status, which could indicate inadequate or inappropriate disease management. Moreover, it was observed that ex-miners had the worst mean spirometry parameters, including $FEV_{1,}$ FVC and FEV_1/FVC. However, the clinical manifestation and disease severity did not reflect these poor spirometry results. Notwithstanding the exposure status, most COPD patients had mild to moderate airway limitation as assessed by the GOLD classification. The small proportion of patients with severe COPD in this study could partly be explained by the increased mortality of patients with severe disease phenotype.

The 24-hour measurements of air quality in underground mining tunnels and blasting sections revealed excessively high levels of $PM_{10,}$ well beyond WHO-acceptable safety limits (WHO, 2021). The miners, who are invariably without protective gear, are constantly exposed to these extreme levels of air pollution (Koong *et al.*, 2009)The existing weak health regulatory authorities and minimal monitoring of mining or occupational safety practices potentially expose miners to high levels of dust and particulate matter and increase their risk of developing chronic respiratory diseases, including COPD.

Conclusions

There is a substantial burden of COPD among young miners in Tanzania, coupled with high rates of cigarette smoking and exceedingly high levels of occupational exposure to filterable particulate matter in the mining fields. These findings underscore the urgent need for a national social protection and legal framework for occupational health in Tanzania. This could be achieved by designing and enforcing vigilant approaches for safety regulations, promoting workers' health and preventing occupational diseases in Tanzania.

Declarations

Ethics approval and consent to participate: This study was approved by the National Institute for Medical Research (NIMR) Ethics Committee in Tanzania and conducted by the Helsinki Declaration. All participants consented to participate in the study.

Consent to publish: All participants have requested permission to publish and consented to the study findings.

Availability of data and materials: All raw data about this study are stored in an institutional repository with a secure backup. According to institutional regulations, both raw and processed data can be retrieved and made available to a third party upon reasonable request.

Competing interests: No competing interests.

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Authors' contributions: NFM conceptualized and designed the study and obtained research grants. NFM developed training materials and offered training to the research assistants. He performed statistical analysis and wrote the manuscript's first and final versions.

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Phytochemical screening of selected medicinal plants of the West Usambara Mountains in Tanzania

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Abstract

Background: Medicinal plants have been vital for human health for many years due to their restorative properties. Phytochemicals contribute to medicinal plants' healing power, including flavonoids, tannins, glycosides, exudates, terpenes, alkaloids, and phenolics. Several medicinal herbs used by the local community have unknown phytochemical compositions. Knowing the phytochemical composition helps identify bioactive compounds that can be further developed into pharmaceutical drugs. Hence, this study aims to look into the phytochemical composition of *Vernonia iodocalyx* and *Myrica. salicifolia,* which is extensively used in Tanzanian traditional medicine.

Methodology: The extracts from methanol and petroleum ether were obtained through the Soxhlet extraction technique. Preliminary phytochemical screening was conducted using standard methods, while GC-MS analysis was used for in-depth analysis of the identified phytochemicals.

Results: According to the test tube reaction method data, methanolic extract outperformed petroleum ether extracts regarding phytochemical compositions. GC-MS analysis revealed that *Vernonia iodocalyx* and *Myrica salicifolia* contained 21 and 22 phytochemicals, respectively. Out of the identified phytochemicals, 7 from *Vernonia iodocalyx* and 5 from *Myrica salicifolia* have been reported to possess different bioactive compounds essential for drug synthesis.

Conclusion: Methanolic leaf extract of both *Vernonia iodocalyx* and *Myricasalicifolia* has the satisfactory number of phytochemicals. Hence, these plants are recommended for the isolation of active compounds for pharmacological studies.

Keywords: Medicinal plants, Phytochemical, GC-MS, leaf extract

Introduction

In various cultures all over the world, plants are used as medicine and as a source of many potent drugs due to the presence of certain phytochemicals (Anand, Jacobo-Herrera, & Altemimi, 2019). Phytochemicals present in plants are useful in treating certain disorders through individual effects, synergic action, or additives to improve human health(Olivia, Goodness, & Obinna, 2021). Phytochemical analysis involves the quantification and determination of bioactive compounds within the extracts of the plant (Manandhar, Luitel, & Dahal, 2019).

Several medicinal plants in Tanzania have had a fair number of phytochemicals where new drugs have been approved from them (Kilonzo, Rubanza, & Richard, 2019). Due to chemotherapy

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failure in recent years, an increasing occurrence of antibiotic-resistant organisms has been recorded (Arulmozhi, Vijayakumar, & Kumar, 2018). Hence it is important to improve the method of treatment and prevent the spreading of these organisms (Arulmozhi et al., 2018). Hence searching for not only new drug targets but also for improved versions of available drugs has been an urgent need. (The World Health Organization (WHO), 2013). Natural product-derived compounds are still proving to be an invaluable source of medicine for humans regardless of the recent drug discovery research using computational chemistry, molecular modelling and other synthetic chemical methods (Lahlou, 2013). Recently several studies have reported medicinal plants having diverse phytochemicals essential for drug discovery, for example, terpenoids, phenolics and alkaloids are known to be the source of antibacterial and antifungal drugs (Kurmukov, 2013). However, these phytochemicals cannot be generalized to be found in a wide range of plants. This is because the phytochemical composition of medicinal plants can be affected by several factors. including climate, soil quality and altitude. In this respect, two plant species (*V. iodocalyx* and *M. salicifolia*) were selected based on ethnobotanical information from local people of Lushoto and previous literature.

V. iodocalyx O. Hoffm belong to the Compositae family. The plant is an erect shrub with coarsely dentate leaves and spread over East Africa (Amri & Kisangau, 2012). Traditionally this plant has been employed for numerous pharmaceutical applications to treat various ailments. The roots and back serve as antibacterial agents for the treatment of diarrhea and stomach, they are also used as painkillers to treat headaches in eastern Tanzania (Amri & Kisangau, 2012).

Myrica salicifolia Hochst. is an aromatic and resinous medicinal shrub(Silva, Seca, Barreto, & Pinto, 2015) normally grown in humid lower highlands and is found in Ethiopia, South Africa, Kenya, Malawi, Zambia, Saudi Arabia and many mountain ranges in Tanzania that are above 1200 m. It grows well in shallow soils, heath and rocky areas (Silva et al., 2015). This plant has been traditionally utilized for numerous pharmaceutical applications to treat various ailments. Leaf extracts of this plant have been tested for mutagenicity, toxicity and antimicrobial activities. A study by Amri and Kisangau, (2012) based on the local community knowledge revealed that leaves and backs of *V. iodocalyx* have been used to treat stomach ache, diarrhoea and headache. On the other hand, other studies on *M. salicifolia* indicated the presence of steroids, terpenoids, tannins, phlobatannins, saponins and phenolics (Emiru, Periasamy, Karim, Ur Rehman, & Ansari, 2020)The study of the phytochemical constituents of V. iodocalyx and M. salicifolia leaf extracts, especially the GC-MS analysis to determine these constituents, is scarce.

Therefore, the current study aimed to evaluate the phytochemical composition of the methanolic leaf extracts of V. iodocalyx and M. salicifolia.

Materials and Methods

Preparation and extraction of plant extracts

Plant materials of *V. iodocalyx* and *M. salicifolia* were collected from Vitti and Irente villages respectively in Lushoto District. Identification of plant species was done by a botanist and Voucher specimens coded VI-0001 for V. iodocalyx and MS-0002 for *M. salicifolia* were collected and transported to the Department of Biology of the University of Dodoma. In the laboratory, the plant materials were air-dried and then ground into powder using an electric blender. Pulverized materials (250g roots & leaves) were macerated in petroleum ether sequentially for medium-polar and non-polar extraction (Arulmozhi et al., 2018). The extracts were filtered using Whatman No 1 filter paper on a plug of glass wool in a column of glass and a rotary evaporator was used to evaporate solvents

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through the vacuum. 250g of roots and leaves of the same pulverized materials were added to 1 L of pure water at 70°C and left to cool in a water bath until reaching 40°C. The extracted samples were decanted and subjected to centrifugation at 5000 rpm for 10 minutes (Zhang, Lin, & Ye, 2018). The supernatant was gathered and passed through filter paper (Whatman No. 1) before undergoing freezing to remove water through sublimation. All samples were preserved in a deep freezer set at -20°C for more procedures. Each solution underwent shaking every half-hour to ensure thorough extraction for six hours and then was left to settle for 48 hours as explained by Nugraha et al., (2020). The obtained extracts were sieved using Whatman No. 1 filter paper; also, the solvent was removed via a rotary evaporator under the vacuum. The resulting residues underwent preliminary phytochemical screening and GC-MS analysis.

Calculation of yield percentage

Percentage yield which is the amount of the extract in percentage obtained after the extraction and evaporation process was obtained by taking the weight of crude extract (dry) divided by the dry weight of plant material as follows:

$$\text{Percentage Yield } (\%) = \frac{\text{Dry weigh of extract}}{\text{Dry weight of plant material}} \times 100$$ (Manandhar et al., 2019)

Initial phytochemical screening

Screening of Alkaloids

Three drops of Wagner's reagent (solution of iodine in potassium iodide) were separately added into three drops of methanolic and petroleum ether plant extracts and the formation of a reddish brown precipitate signalled the presence of alkaloids(Gupta, Thakur, Sharma, & Gupta, 2013; Karmakar et al., 2020)

Screening of Flavonoids

To test the flavonoid presence an alkaline reagent test was used. (Oshadie, Silva, Abeysundara, Minoli, & Aponso, 2017). One ml of sodium hydroxide 20% was added to the two ml of the extracts. The presence of flavonoids was signalled by a yellow colour which disappeared after the addition of dilute sulphuric acid (Selvakumar et al., 2019; Karmakar et al., 2020)

Screening of Saponins

The 50 mg of extract was diluted using distilled water to make 20 ml of the suspension. The suspension was shaken in a graduated cylinder for 15 minutes. The formation of a 2 cm layer of permanent foam indicated the presence of saponins (Banu & Cathrine, 2015; Karmakar et al., 2020; Oshadie et al., 2017; Selvakumar et al., 2019).

Screening of Tannins

Two ml of 5% ferric chloride was added into one ml of plant extract. The appearance of dark blue/green/black colour indicated the presence of tannins. Hydrolysable tannins were indicated by the formation of a dark blue colour while the presence of condensed tannin was indicated by the formation of a green colour (Selvakumar et al., 2019; Karmakar et al., 2020)

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Screening of phenols

A ferric chloride test was used to test the presence of phenols. Adding 2 ml of distilled water to 1 ml of plant extract was followed by two drops of 10% ferric chloride. The formation of blue/green colour indicated the presence of phenols (Selvakumar et al., 2019; Karmakar et al., 2020).

Screening of terpenoids

The terpenoids were tested by mixing 0.5 ml of the plant extract with 2 ml of chloroform and concentrated sulphuric acid. The presence of terpenoids was signalled by the formation of a reddish-brown colour at the interface (Wadood, 2013).

GC-MS analysis

The GC-MS analysis was done using Agilent 5975C (Agilent technologies, USA) with a capillary column (HP-5) of a length of 30 meters, diameter of 0.25 mm and thickness of 0.25 µm film connected to the Agilent 6890N GC. The gas used as a carrier was helium gas (99.999%) at 1Ml/minute constant flow and the employed volume of injection was 1 µL. The injector temperature was constant at 250°C and the ion source temperature was 280°C, the oven temperature being programmed starting from 110°C to 200°C with an increase of 10°C/min, then 5°C/minutes to 280°C ending with 9 minutes isothermal at 280°C. The mass spectrometer operated in electron ionisation mode with an ionising energy of 20eV and the ion source temperature was 230°C. The inlet line temperature was 200°C and the running time of the GC-MS was 45 minutes. Mass spectrum interpretation was done through the database of the National Institute of Standards and Technology (NIST) with 62,000 patterns and more. Mass spectra of plant extracts from two selected medicinal plants, namely, *Myrica salicifolia and Vernonia iodocalyx* were compared with spectra compounds stored in the NIT 05 L mass spectra library which are known and published literature. Finally, the percentage of each constituent was determined based on the relative peak area observed in a chromatogram.

Results

Extraction Yield of the Plant Extracts

Through the cold percolation technique, the highest yield was from *M. salicifolia* methanolic extracts at 10.83% while the lowest yield was petroleum ether extracts of *V. iodocalyx* with 4.73% (Table 1)

Table 1: Percentage yield of selected medicinal plant samples

Plants	Solvent used	Part used	% Yield
Vernonia iodocalyx	Methanol	Leaf	10.35
	Petroleum ether	Leaf	4.73
Myrica salicifolia	Methanol	Leaf	10.83
	Petroleum ether	Leaf	7.22

The Preliminary phytochemical screening of *V. iodocalyx* and *M. salicifolia* methanolic leaf extracts showed the presence of phytochemical compounds which are terpenoids, alkaloids, flavonoids, phenols, tannins and saponins (Table 2). Moreover, the GC-MS technique was employed to identify the volatile phytochemical compound within the extract. Peak areas, time of retention, molecular formulas, and the molecular weight of these compounds are presented in Table 3 and Table 4 for *V. iodocalyx* and *Myrica salicifolia* leaf extracts respectively.

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Table 2: Examination of phytochemicals in selected medicinal plants from the West Usambara Mountains

Plant	Solvent	Phytochemicals					
		Alkaloids	Terpenoids	Flavonoids	Phenols	Tannins	Saponins
Vernonia iodocalyx	Methanol	+	+	-	+	+	-
	P. Ether	-	-	+		-	-
Myrica salicifolia	Methanol	+	-	-	+	+	+
	P. Ether	-	+	+		+	-

Key: +=Presence of the compound, - =Absence of the compound

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Table 3: Bioactive constituents found in the methanolic extract of *M. salicifolia*

S/N	Peak name	Peak no	RT (min.	Peak area %	Molecular Formula	Similarity %	MW(g mol.$^{-}$)
1	3-Cyclohexen-1-ol, 4-methyl-1-(1-methylethyl)-, (R)-	1	4.248	0.25	$C_{10}H_{18}O$	93	154.246
2	Alpha-terpinyl isovalerate	4	5.301	0.41	$C_{15}H_{26}O_2$	94	238.37
3	Phenol, 2-methoxy-3-(2-Propenyl)-	5	5.347	0.32	$C_{10}H_{12}O_2$	98	164.2
4	Trans-Cinnamic acid(Ruwizhi & Aderibigbe, 2020)	6	5.410	0.33	$C_9H_8O_2$	97	148.16
5	Caryophyllene	8	5.931	0.36	$C_{15}H_{24}$	99	204.35
5	Aromadendrene	9	6.062	0.24	$C_{15}H_{24}$	95	204.35
6	.Beta.-Guaiene	13	6.537	0.72	$C_{15}H_{24}$	94	204.35
7	.Alpha.-Calacorene		7.001	0.30	$C_{15}H_{20}$	98	200.32
8	Bicyclo[4.1.0]heptan-3-ol,4,7,7-trimethl-, [1R-(1.alpha.,3.alpha.,4.alpha.,6.alpha.)]-	21	7.395	0.79	$C_{10}H_{16}$	70	152.2334
9	Caryopyllene oxide	23	7.544	1.37	$C_{15}H_{24}O$	92	220.35
10	Cyclohexene, 1-methyl-4-(11-methylethylidene)-	26	7.996	0.92	$C_{10}H_{18}$	91	138.25
11	Epizonarene	27	8.065	3.87	$C_{15}H_{24}$	94	204.35
12	Azulene, 1,4-dimethyl-7-(1-methyllethyl)-	32	8.740	0.64	$C_{15}H_{18}$	95	198.3034
13	Isolongifolene, 9,10-dehydro-	39	11.916	0.51	$C_{15}H_{22}$	92	202.33
14	9-Octadecen-1-ol, (E)-	40	12.242	2.41	$C_{18}H_{36}O$	70	268.4778
15	1-Hexadecyne	42	13.037	0.61	$C_{16}H_{30}$	70	222.41
16	3,7,11,15-Tetramethyl-2-hexadecen-1-ol	44	13.684	0.99	$C_{20}H_{40}O$	80	296.5
17	n-Hexadecanoic acid	48	17.014	2.33	$C_{16}H_{32}O_2$	99	256.4241
18	9-Octadecenoic acid, (E)-	51	22.158	0.27	$C_{18}H_{34}O_2$	96	282.46
19	Di-n-octyl phthalate	55	30.249	39.60	$C_{24}H_{38}O_4$	91	390.55
20	Isolongifolene, 9,10-dehydro-	58	32.469	0.22	$C_{15}H_{22}$	83	202.33
20	Squalene	59	32.561	0.80	$C_{30}H_{50}$	99	410.7
21	Pregn-5-en-3-ol, 21-bromo-20-	62	39.393	2.09	$C_{22}H_{35}BrO$	93	395.4

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	methyl-, (3.beta.)-						
22	Olean-12-ene	63	40.205	2.22	$C_{30}H_{50}$	83	410.7

Table 4: Bioactive compounds found in the methanolic extract of V. *iodocalyx*

S/N	Peak name	Peak no	RT (min)	Peak area %	Molecular formula	Similarity %	MW (g mol.$^{-}$)
1	2(3H)-Furan one	1	3.407	0.02	$C_4H_4O_2$	46	84.07
2	Silane, ethenyldiethylmethyl-	2	3.962	0.03	$C_7H_{16}Si$	52	128
3	Phytol	3	4.060	0.04	$C_{20}H_{40}O$	38	296.5
3	Trans-2-Decen-1-ol, methyl ether	3	4.060	0.04	$C_{11}H_{22}O$	38	170.29
3	Isophytol	3	4.060	0.04	$C_{20}H_{40}O$	38	296.5
4	Butanoic acid, ethyl ester	4	4.180	0.02	$C_6H_{12}O_2$	72	116.16
5	9-Tricosene	5	4.260	0.03	$C_{23}H_{46}$	83	322.6
5	Eugenol	5	4.260	0.03	$C_{10}H_{12}O_2$	98	164.20
6	Benzhydrazide	13	5.482	0.02	$C_7H_8N_2O$	79	136.15
7	Longipinene epoxide	14	5.565	0.02	$C_{15}H_{24}O$	60	220.35
8	Benzene	15	5.633	0.17	C_6H_6	98	78.11
9	Vanillin	16	5.690	0.05	$C_8H_8O_3$	95	152.15
10	Benzhydrazide	13	6.120	0.04	$C_7H_8N_2O$	42	136.15
11	Silane, trichlorooctadecyl-	25	7.487	0.01	$C_{18}H_{37}Cl_3Si$	93	387.94
12	Bicyclo(6,1,0)non-1-ene	26	7.539		C_9H_{14}	86	122.21
13	3-Eicosyne	38	13.02	0.05	$C_{20}H_{38}$	76	178.5
14	Hexadecanoic acid, 14-methyl-, methyl ester	40	15.49	0.06	$C_{18}H_{36}O_2$	97	284.47
15	9,12-Octadecadienoic acid (Z,Z)-, methyl ester	42	20.92	0.01	$C_{19}H_{34}O_2$	94	294.47
16	Methyl 7,10,13-hexadecatrienoate	43	21.077	0.02	$C_{17}H_{28}O_2$	93	264.4
17	(3-Methylbenzoyl) carbamic acid	51	25.088	0.09	$C_6H_{11}NO_2$	91	165.19
18	Urs-12-en-3-ol, acetate, (3, beta.)	52	25.408	0.30	$C_{32}H_{52}O_2$	70	468.8
19	8-Isopropenyl-1,3,3,7-tetramethyl-	53	22.041		$C_{15}H_{12}O$	82	218.33
20	Farnesyl bromide	74	32.206	2.07	$C_{15}H_{25}Br$	86	285.26
21	4,4,6a,6b,8a,11,12,14b-octamethyl-	95	40.451	0.47	$C_{30}H_{48}O$	99	424.7

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1,4,4a,5,6,6a,6b,7,8,8a,9,10,11,12,12a ,14,14a,14b-octadecahydro-2H-picen-3-one

Discussion

Screening the phytochemicals in methanolic extracts of *M. salicifolia* and *V. iodocalyx* revealed the existence of various phytochemicals which are recognized for their medicinal and physiological effects.

Using gas chromatography linked with a mass spectrometer, secondary metabolites belonging to Phenolic compounds, Sesquiterpenoids, Fat acids, triterpenoids, Monoterpenoids, and Acyclic-diterpenoid were identified. Most of the phytochemicals identified have been documented as the source of drugs against non-communicable and infectious diseases of humans.

Among the identified bioactive components, Caryopyllene oxide and Aromadendrene from *Aquilaria rassna* in Malaysia have been documented to exhibit antifungal and antibacterial activities respectively (Dahham et al., 2015; Sobrinho et al., 2020). Additionally, Trans-Cinnamic acid has been reported to exhibit anticancer, neuroprotective and antidiabetic (Ruwizhi & Aderibigbe, 2020). Furthermore, Squalene has been reported to exhibit skin dehydration and antioxidant properties (Lozano-grande, Gorinstein, Espitia-rangel, Gloria, & Mart, 2018). On the other hand, aromadendrene and beta.-Guaiene have been respectively documented to exhibit antidepressant and anti-inflammatory activity (Hordyjewska, Ostapiuk, Horecka, & Kurzepa, 2019; Sahi, 2016). Also, n-hexadecanoic acid has been documented to exhibit antipsychotic and ant-androgenic activities (Tyagi & Agarwal, 2017). Eugenol and Vanillin have been reported to exhibit antiviral and cardioprotective respectively (Derong, Xiao, Zhao, Li, & Xing, 2016; Olatunde, Mohammed, Ibrahim, Tajuddeen, & Shuaibu, 2022).

The findings of the study on the phytochemical composition of selected medicinal plants resemble those of Ndanyi, et al., (2021) The study on phytochemical screening and acute oral toxicity of *Myrica salicifolia* (Bayberry) extracts done in Kenya, showed the presence of flavonoids, alkaloids, saponins, steroids, tannin and phenolics from methanolic extract of Myrica salicifolia.On the other hand, the study from Kenya showed the presence of only alkaloids from petroleum ether extract contrary to our study which revealed the absence of alkaloids but the presence of terpenoids, flavonoids and tannins. Differences in phytochemical composition between these two studies may be influenced by geographical area and seasons of harvesting which influence the content of plant extracts,. Temperature, humidity, sunlight and precipitation can all impact the synthesis of phytochemicals in plants(Pant, Pandey, & Dall'Acqua, 2021).

Most of the phytochemical constituents identified from *M. salicifolia* and *V. iodocalyx* are sources of drug synthesis. Some sesquiterpenoids show potential as lead compounds for the development of drugs for conditions including diabetes, Alzheimer's disease and cardiovascular diseases (Adelusi et al., 2022). Fatty acids are known as a source of drugs for skin disorders, neurological disorders and skin diseases (Taylor, 2009)

Possession of Sesquiterpenoids, Fat acid, triterpenoids, Monoterpenoids, and Acyclic-diterpenoid by *M. salicifolia* and *V. iodocalyx* which have diverse pharmacological activities make them valuable sources for drug synthesis and development

Conclusion

In this study, the methanolic leaf extract of *M. salicifolia* and *V. iodocalyx* demonstrated a range of secondary metabolites, exhibiting numerous pharmacological properties. The GC-MS analysis revealed the presence of 22 and 21 phytochemical constituents from *M. salicifolia* and *V. Iodocalyx, respectively,* which contribute to drug synthesis and development. Hence, the presence of phytochemicals is responsible for their therapeutic effects. However, the characterization and

isolation of phytochemical compounds from these plants need further investigation since they could contribute to drug discovery.

Competing interests: The authors declare that there are no competing interests

Ethical approval: Ethical clearance for conducting this study was obtained from the University of Dodoma

Consent for publication: Not applicable

Availability of data and materials: The data sets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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Contributions of the authors: This study was conducted in collaboration between all authors out in collaboration between all authors. EM and NM were responsible for designing the study. Author HN managed the searches of the literature and analysis of the study. EM authored the initial draft of the manuscript. All authors reviewed and endorsed the final manuscript

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Prevalence, predictors and management of pre-eclampsia among pregnant women attending antenatal clinics in Zanzibar

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Abstract

Background: Pre-eclampsia is a significant public health concern worldwide that is responsible for severe maternal and neonatal morbidity and mortality. This study determined pre-eclampsia's prevalence, predictors, and management among pregnant women attending antenatal clinics in Zanzibar.

Methodology: This was a cross-sectional study involving 138 pregnant women attending antenatal clinics randomly selected from all levels of healthcare facilities in Zanzibar. A protein-in urine test and blood pressure measurement were performed to diagnose pre-eclampsia, and the patient's case files were reviewed to assess pre-eclampsia management. The Chi-square test and logistic regression models determined the association between variables. The adjusted odds ratio and a 95% confidence interval were reported, and the significance level was set at 5%.

Results: The prevalence of pre-eclampsia was 20(14.25%), and it was predicted by a family history of pre-eclampsia (adjusted odds ratio=5.7, 95% confidence interval: 1.34-24.7), a previous history of pre-eclampsia (adjusted odds ratio =12.9, 95% confidence interval: 2.5-55.6), and current medication use (adjusted odds ratio =19.3, 95% confidence interval 3.9-95.6). A slight majority of mild pre-eclampsia cases were properly managed 7(53.8%), while only 9(29.50%) of severe pre-eclampsia cases were adequately managed. The proportion of cases of severe pre-eclampsia that were managed correctly was higher among cases admitted to national referral hospitals (68.5%) compared to those admitted to district hospitals (22.8%) and health centres (10.83%) ($p < 0.002$). However, for mild pre-eclampsia, there was no statistically significant difference in its management between facility levels ($p>0.05$).

Conclusion: The prevalence of pre-eclampsia among pregnant women attending antenatal clinics is high. The possible risk factors for pre-eclampsia are having a family history of pre-eclampsia, having a previous history of pre-eclampsia, and current medication use. The standard guidelines for the management of pre-eclampsia are not followed, and severe pre-eclampsia is mostly mismanaged at lower-level healthcare facilities. The findings are relevant to identifying high-risk pregnancies, improving maternal healthcare delivery, and saving lives.

Keywords: preeclampsia, eclampsia, prevalence, predictors, management, Zanzibar, Tanzania

Introduction

Pre-eclampsia is a significant public health concern that causes severe maternal and neonatal morbidity and mortality and contributes significantly to fetal prematurity (Kuklina et al., 2009). Pre-eclampsia is a hypertensive disorder of pregnancy that occurs after the 20th week of gestation. High blood pressure readings of at least 140 mmHg systolic and 90 mmHg diastolic measured 4-6 hours apart, accompanied by proteinuria of at least +1 mg on dipstick or at least 300 mg per 24 hours, or with

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signs of liver dysfunction, thrombocytopenia, pulmonary oedema, new onset of kidney dysfunction, or new onset of cerebral or visual disturbance (WHO, 2011). Eclampsia is when a woman with pre-eclampsia has a new onset of grand mal seizures (ACOG, 2002).

Pre-eclampsia affects about 2–8% of pregnancies globally, and it is associated with 10–15% of direct maternal deaths and up to 25% of stillbirths and newborn deaths (Say et al., 2014; WHO, 2017). The prevalence of pre-eclampsia in developed countries ranges from 2.2% to 6% (Fingar et al., 2006), while in developing countries, the prevalence is higher, ranging from 1.8 to 16.7% (Belay & Wudad, 2019; Otieno, 2012; Raghuraman et al., 2014; Wandabwa et al., 2010). In northern Tanzania, the prevalence of pre-eclampsia is 4.2% (Frank et al., 2020) and in Zanzibar (a united part of Tanzania), the prevalence among prenatal women is 9% (Tufton & Patel, 2011) and that of severe pre-eclampsia among postnatal women is 26.3% (Machano & Joho, 2020). The high prevalence of pre-eclampsia is reflected in the number of deaths and complications associated with it.

Tanzania has a maternal mortality rate of 556 per 100,000 live births, (Herklots et al., 2017; MoHCDGEC, 2016) with eclampsia-related complications accounting for 18.9% (Makuwani et al., 2020). And in Zanzibar, maternal mortality is 155 per 100,000 live births (MoHASWZ, 2018) and severe pre-eclampsia contributes to 25.8% of maternal morbidity and 21.8% of maternal mortality (Herklots et al., 2017).

Predictors of pre-eclampsia have been reported in many studies, and they include obesity, null parity, urinary tract infection, family history of pre-eclampsia, history of pre-eclampsia from a previous pregnancy, history of hypertension, occupation as a housewife, fewer Antenatal Clinic (ANC) visits, use of traditional medicine, multiple pregnancies, maternal age, anemia, pregnancy from a new partner, family history of high blood pressure, diabetic prior conception, paternal age of over 45 years, a pregnancy interval of more than 10 years, gestational age at presentation and pre-existing vascular disease (Adeline et al., 2018; Grum et al., 2017; Kashanian & Baradaran, 2011; Machano & Joho, 2020; Serrano et al., 2020). However, because women's social-cultural and lifestyle characteristics differ across regions, the determinants of pre-eclampsia or eclampsia may vary. Considering the different coastal-Islamic-based traditions in Zanzibar, which reflect differences in lifestyle, socioeconomic status, cultural norms, and the seeking and provision of medical care, it is important to explore more about the determinants of pre-eclampsia in Zanzibar.

Early diagnosis and management can help to reduce the dangers of pre-eclampsia and its complications; the majority of deaths related to this condition are avoidable when care is given in good time. In this regard, avoiding delays and "bottlenecks" that are currently occurring in diagnosis and management is critical (Baker et al., 2015). The definitive treatment of pre-eclampsia or eclampsia is delivery of the fetus based on the severity of pre-eclampsia, gestational age, and maternal and fetal conditions (Sarsam et al., 2008). In contrast, conservative treatment includes blood pressure control and seizure prevention. A management guideline has been developed (TMOH, 2013; 2017), and if adhered to, it is expected to minimize pregnancy-related complications, minimize prematurity, and promote maternal and infant survival. However, approximately half of the healthcare providers in Dodoma, Dar es Salaam, and Zanzibar, Tanzania, reported inadequate knowledge of pre-eclampsia and eclampsia management protocols (Joho et al., 2020; Maembe & Pembe, 2015; Seif & Rashid, 2022).

Unavailability of equipment and supplies, laboratory facilities, and medication required for the management of pre-eclampsia, inadequate knowledge and skills among healthcare providers, and non-adherence to the treatment guidelines are reported to fail to diagnose and provide proper management of pre-eclampsia (Barua et al., 2011; Oguntunde et al., 2015). According to the Zanzibar Ministry of Health Guidelines, the type of management of pre-eclampsia differs at different healthcare facility levels based on the severity of the illness. Mild pre-eclampsia is treated in the primary health facilities, and the severe cases are referred to the next level of district hospital, regional hospital, and national hospital (Goverment of Zanzibar, 2019).

Despite the government initiatives to address maternal and neonatal mortality and morbidity in Zanzibar, including the implementation of Focused Antenatal Care Plus (FANC), sensitizing the community on the effective utilization of Antenatal Care (ANC) services, birth preparedness, and complications readiness, pre-eclampsia is still a significant problem that is associated with high morbidity and mortality (Herklots et al., 2017). To the best of the author's knowledge, only two studies about pre-eclampsia and eclampsia were published in Zanzibar, with one focusing on severe eclampsia only among postpartum women, (Machano & Joho, 2020) and the other focused on women at prenatal but neither identified the associated factors nor described how pre-eclampsia is managed at different healthcare facility levels. As a result, this study aimed to fill a knowledge gap about the prevalence of pre-eclampsia, its associated factors, and management in Zanzibar. The findings of this study will have a significant role in targeted interventions for overcoming the problems associated with pre-eclampsia, which in turn will help to reduce the maternal morbidity and mortality associated with pre-eclampsia.

Methods

This study employed an analytical cross-sectional study design and was conducted within healthcare facilities in Zanzibar- a united part of Tanzania. The health delivery system in Zanzibar is organized into three levels: primary, secondary, and tertiary. The primary level includes primary health care units (PHCU), primary health care units plus (PHCU+), and primary health care centres or cottages (PHCC). The secondary level includes district and regional hospitals, and the tertiary level includes national referral hospital. According to the Zanzibar Ministry of Health, all facilities offering reproductive and child health services are supposed to screen for pre-eclampsia. Women detected with signs of pre-eclampsia in the PHCU and PHCU+ are sent to health centres, where they are given initial treatment and then referred to hospitals for further investigations and management. Those with severe pre-eclampsia are referred urgently to a hospital after receiving emergency treatment with anticonvulsants, preferably magnesium sulphate and a selected antihypertensive (Government of Zanzibar, 2019).

Study population

The study population consisted of all pregnant women attending ANC at all levels of healthcare facilities in Zanzibar. The inclusion criteria were a gestational age of at least 20 weeks and consent to participate in the study.

Sample size estimation Sampling procedure

The sample size was calculated by using the Cochran formula (Cochran, 1977), which is $n=Z^2P(1-P)/e^2$, where: n = minimum sample size, Z score value = 1.96 for 95% confidence level, P = proportion of pre-eclampsia in Zanzibar, which is 9% (Tufton & Patel, 2011), and e = the acceptable margin of error, which is 5%. Therefore, this study's sample size was 138 pregnant women.

A census method was used to obtain all health centres (n=4), district hospitals (n=2), regional hospitals (n=1) and national hospitals (n=1). At the same time, the PHCUs were selected using a systematic random sampling in which the k^{th} interval of 3 was used, which was calculated using the formula $k^{th.} = N/n$ (Iachan, 1982), whereby N is the sampling frame (total number of PHCUs) = 154, n is the total number of PHCUs for this study = 46, which is 30% of the total number of PHCUs, (WHO, 2009). The number of pregnant women per selected healthcare facility level was calculated using the formula ni = (Ni/Nt)*n (Pandey & Verma, 2008), where ni = the number of pregnant women required in each facility level, Ni = the total number of pregnant women attending ANC in each selected facility per month, Nt = the total number of pregnant women attending ANC in all selected facilities per one month, and n = the estimated sample size of pregnant women.

Simple random sampling was used to select study participants within healthcare facilities. Table 1 summarizes the sample selection of pregnant women per selected healthcare facility level.

Table 1: Summary of Sample Selection of Pregnant Women Per Each Selected Healthcare Facility Level

Level of Healthcare Facility	Number of pregnant women attending ANC per month	Number of pregnant women selected for each facility
Tertiary level	501	8
Secondary level	412	7
Primary level	7381	123
Total	**8294**	**138**

Data collection procedure and data collection tools:
Data was collected within the selected healthcare facilities for four weeks in 2021. The principal investigator and six research assistants who are registered nurses collected the data. This study used several data collection methods depending on the data type needed to answer a particular study objective.

Interviewer-administered questionnaire: This method was used to obtain data from pregnant women to assess their background characteristics and signs and symptoms related to hypertensive disorders of pregnancy—a pre-tested, standardized, structured questionnaire with 18 closed-ended questions adopted from Andarge et al. (Andarge et al., 2020) and a Cronbach alpha of 0.79 was used.

Measurement: This method was used to get data on blood pressure readings of pregnant women to be used for making diagnoses of pre-eclampsia. In this method, a research assistant instructed a pregnant woman to relax for at least ten minutes and sit comfortably upright with her back and arms supported and both legs flat on the floor. A woman was then instructed to remove tight clothes around her arm. The proper cuff size was used to ensure that the cuff encircles at least three-fourths of the circumference of the arm, about 2 cm above the elbow area. The measurement was then taken using a digital blood pressure machine. The measurement was repeated if it was equal to or greater than 140/90 mm Hg by the same two observers (Tufton & Patel, 2011).

Chemical investigations: Urinalysis with a visual reagent strip, " the dipstick," was used to collect data on protein in urine. The data were used to make a diagnosis of pre-eclampsia. In this method, a pregnant woman was given a urine bottle and was instructed on how to collect a clean-catch urine sample. The research assistant dipped the end of the dipstick into the urine sample and shook off any excess urine by tapping the dipstick on the side of the urine bottle. After thirty seconds, a comparison of the dipstick pad with the colour chart on the dipstick container was made to check for the presence of protein in the urine, where the colour change was interpreted according to the manufacturer's guidelines.

Documentary review: This method was used to obtain information on managing pre-eclampsia provided to women diagnosed with pre-eclampsia. The principal investigator or research assistant reviewed the case files of all patients diagnosed with pre-eclampsia admitted during the study period.

The selection of the case files considered the patient to be still admitted. It confirmed that she is suffering from pre-eclampsia, whether mild or severe and has already started receiving pre-eclampsia management in the admitted hospital. The management was judged against the standard treatment guideline using a pre-prepared checklist during the review. The tool was developed based on the guidelines (TMOH, 2013;2017;). The documentary review was only conducted at healthcare facility levels that admit and provide management of patients with pre-eclampsia: three health centres, two district hospitals, one regional hospital, and one referral hospital.

Variables Definition and Measurement

Pre-eclampsia: In this study, refers to pregnancy complications that include high blood pressure after 20 weeks of pregnancy, excess protein in the urine and/or swelling of lower limbs, severe headache and or upper abdominal pain, blurred vision or light sensitivity. This was measured by a blood pressure reading of greater than or equal to 140 mmHg systolic and greater than or equal to 90 mmHg diastolic, accompanied by proteinuria of at least +1 mg on the dipstick, and/or swelling of the lower limbs, severe headache, upper abdominal pain, blurred vision, or light sensitivity in an individual with previously normal blood pressure and proteinuria in pregnancy. A woman who screened positive for pre-eclampsia was sent to a medical doctor on duty for confirmation of her diagnosis. The endpoint was dichotomized into positive and negative for pre-eclampsia.

Management of pre-eclampsia: In this study, "management" refers to all treatment provided, measurements taken, and tests done on a pregnant woman with signs of pre-eclampsia as per the Ministry of Health- Zanzibar guideline. This was measured by 16 YES/NO items on a ratio scale assessing whether pre-eclampsia management was carried out as per the established guidelines, which include providing appropriate medications, monitoring blood pressure and foetal heart rate, checking protein in urine, and performing liver and kidney function tests. Five items were for mild pre-eclampsia, and thirteen items were for severe pre-eclampsia. One point was awarded for the correct management carried out and zero for the incorrect or missed management. For mild pre-eclampsia, a total score of 4-5 points was regarded as proper management, and for severe pre-eclampsia, a total score of 11–13 points was regarded as proper management.

Data Analysis

The data was analyzed using SPSS version 25. Descriptive statistics were used to describe the magnitude of pre-eclampsia and its distribution within the background characteristics of pregnant women. The same statistics were used to describe the management of pre-eclampsia, and the results were reported in frequency and percentage. The chi-square test was used to show the relationship between pre-eclampsia and background characteristics of pregnant women, and the logistic regression model was used to determine the predictors of pre-eclampsia. The Odds Ratio (OR) and Adjusted Odds Ratio (AOR) with their 95% Confidence Intervals (CI) were computed, and the level of significance was set at 5%.

Results

Background characteristics of pregnant women

A total of 138 pregnant women participated in this study. This makes a response rate of 100%. The mean age was 28.96 (SD =7.105), with an age range of 17 to 46 years. Of these, a large majority, 121 (87.7%), were married, and half of them, 73 (52.9%), lived in rural areas. Most of the respondents, 98 (71.0%), had a secondary level of education, and a slight majority, 71 (51.4%), were unemployed. Further, for obstetric characteristics, a slight majority of the respondents, 72 (52.8%), were null parity, and 77

(55.5%) had a gestation age of between 20 and 30 weeks (Table 2). **Table 2: Background Characteristics of Pregnant Women (N=138)**

Variable	Number	Percentage
Maternal age (years)		
<20	12	8.7
20-29	60	43.5
30-34	33	23.9
> 35	33	23.9
Education level		
Non-formal education	4	2.9
Primary education	23	26.7
Secondary education	98	71
College and university	13	9.8
Place of residence		
Urban	65	47.1
Rural	73	52.9
Marital status		
Ever married	17	12.3
Married	121	87.7
Occupation		
Employed	25	18.1
Not employed	71	51.4
Self employed	42	30.4
Parity		
Null parity	72	52.8
Multi parity	66	47.8
Gestation age (weeks)		
20-30	77	55.8
≥31	61	44.2
Antenatal care visit		
1-3	112	81.1
4-8	26	18.9
Has family history of pre-eclampsia		
Yes	21	15.2
No	117	84.8
Has history of chronic illness		
Yes	22	15.9
No	116	84.1

Has previous history of pre-eclampsia		
Yes	18	13.1
No	120	86.9
Has history of using medication in the current pregnancy		
Yes	28	20.3
No	110	79.7
Has history of using supplement in the current pregnancy		
Yes	93	67.4
No	45	32.6

The prevalence of pre-eclampsia and its relationship with background characteristics of pregnant women

The results of this study showed that 20 (14.5%) women out of 138 screened had systolic blood pressure greater than or equal to 140 mmHg and diastolic blood pressure greater than or equal to 90 mmHg, had proteinuria of 1+ mg or more, and/or had swelling of the lower limbs, severe headache, upper abdominal pain, or blurred vision, and thus were marked as positive for pre-eclampsia. Moreover, results showed that pre-eclampsia was related to maternal age, having a family history of pre-eclampsia, having a previous history of pre-eclampsia, having a history of chronic illness, and having a history of using medication in the current pregnancy.

Specifically, the results showed that the proportion of pregnant women who had pre-eclampsia was higher among women of 35 years (27.3%) vs. (15.2%) (p-value = 0.03), women with a family history of pre-eclampsia (47.61%) vs (8.7%) (p-value <0.001), women with a history of chronic illness (31.82%) vs (11.2%) (p-value = 0.01), women with a history of using medication in the index pregnancy (42.9 %) vs. (7.3%) (p-value <0.001)], and women with a previous history of pre-eclampsia (50%) (p-value <0.001). Other variables did not significantly correlate with pre-eclampsia (Table 3).

Table 3: The relationship between pre-eclampsia and background characteristics of pregnant women (N=138)

Variable	Total (%)	Positive pre-eclampsia n(%)	Chi square	p-value
Maternal age (years)			6.57	0.03
≤ 29	72	6(8.33)		
30-34	33	5(15.2)		
≥ 35	33	9(27.3)		
Education level			2.77	0.43
No formal education	4	1(25)		
Primary education	23	4(17.4)		
Secondary education	98	15(15.3)		
College and university	13	0(0.0)		
Place of residence			1.56	0.21
Urban	65	12(18.5)		
Rural	73	8(11.0)		
Marital status			0.12	0.7

Ever married	17	2(11.8)		
Married	121	18(14.9)		
Occupation			1.51	0.5
Employed	25	5(20.0)		
Not employed	71	11(15.5)		
Self employed	42	4(9.5)		
Parity			0.44	0.83
Null parity	72	10(13.9)		
Multi parity	66	10(15.2)		
Antenatal care visit			0.02	0.89
1-3	112	16(14.3)		
4-8	26	4(15.4)		
Gestation age at first booking(weeks)			0.15	0.69
≤20	113	17(15.0)		
≥21	25	3(12.0)		
Has family history of pre-eclampsia			21.9	<0.001
Yes	21	10(47.61)		
No	117	10(8.7)		
Has history of chronic illness			6.34	0.01
Yes	22	7(31.82)		
No	116	13(11.2)		
Has previous history of pre-eclampsia			21.06	<0.001
Yes	18	9(50.0)		
No	120	11(9.2)		
Has history of using medication			22.81	<0.001
Yes	28	12(42.9)		
No	110	8(7.3)		
Has history of using supplement in the current pregnancy			3.3	0.69
Yes	93	17(18.28)		
No	45	3(6.7)		

Predictors of pre-eclampsia among pregnant women

A simple binary logistic regression model was applied to determine predictors of pre-eclampsia, and the results showed that having a family history of pre-eclampsia, a history of chronic illness, a history of pre-eclampsia in the previous pregnancy, and a history of using medications in the index pregnancy were statistically significantly associated with pre-eclampsia ($p<0.05$).

In a multiple logistic regression model, which allows controlling for the effect of other variables, results showed that pregnant women with a family history of pre-eclampsia were 5.7 times more likely to have pre-eclampsia compared to those without a family history (AOR: 5.7, 95% CI: 1.3–24.7). Furthermore, pregnant women with a history of pre-eclampsia from previous pregnancies were 12.9 times more likely to have pre-eclampsia than those with no history (AOR: 12.9, 95% CI: 2.5-55.5),

and pregnant women with a history of using medication in the index pregnancy were 19.3 times more likely to have pre-eclampsia than those without a history (AOR: 19.3, 95% CI: 3.9-95.7) (table 4).

Table 4: Predictors of pre-eclampsia among pregnant women (N=138)

Variable	OR	95 %CI	p-value	AOR	95 %CI	p-value
Maternal age (years)						
≤ 29	**Ref.**					
30-34	1.96	0.5-6.9	0.24	0.71	0.1-3.6	0.68
≥ 35	4.13	1.3-12.8	**0.01**	2.89	0.6-13.8	0.18
Family history						
Yes	9.73	3.3-28.4	**<0.001**	5.77	1.3-24.7	**0.01**
No	**Ref.**					
History of Pre-eclampsia						
Yes	9.90	3.2-30.1	**<0.001**	11.9	2.5-55.5	**0.001**
No	**Ref.**					
History of chronic illness						
Yes	3.69	1.2-10.7	**0.01**	0.22	0.03-1.4	0.121
No	**Ref**					
History of using medication in the current pregnancy						
Yes	9.56	3.3-27.0	**<0.001**	19.3	3.9-95.6	**<0.001**
No	**Ref**					

OR = Odds Ratio, AOR: Adjusted Odds Ratio

Management of Pre-eclampsia at Health Centers, Districts, Regional and Referral Healthcare Facilities

Seven healthcare facilities were assessed for the management of pre-eclampsia, and a total of 43 cases of pre-eclampsia were reviewed. Out of these cases, 12(27.9%) were mild pre-eclampsia and 31(72.1%) were severe pre-eclampsia. The distribution of reviewed cases per facility level is shown in Table 5.

Table 5: Distribution of reviewed cases in each facility level (N = 43)

Facility level	Mild pre-eclampsia (n=12) n(%)	Severe pre-eclampsia(n=31) n(%)
Health center	2 (16.7)	12(38.7)
District hospital	3(25.0)	7(22.5)
Regional hospital	0(0)	5(16.1)
Tertiary hospital	7(58.3)	7(22.6)

Description of management in the reviewed files

All 12 cases of mild pre-eclampsia (100%) were kept on methyldopa and received dexamethasone as per protocol, and the slight majority of the cases, 8(66.7%) were checked for protein in urine and 7(58.3%) had their fetal heart rate monitored, while only 5(41.7%) had their blood pressure monitored. As for severe pre-eclampsia, all 31 cases (100%) received a magnesium sulphate loading dose, and a large majority 30(96.8%) received methyldopa and had their blood pressure monitored. However, only 4(12.9%) were evaluated for magnesium toxicity, and 14(45.2%) were checked for liver function tests (Table 6). When the score of each management was summed up and categorized, the results revealed

that a slight majority, i.e., 7(53.8%) of mild pre-eclampsia cases, were properly managed and 9(29.0%) of severe pre-eclampsia cases were properly manage

Table 6: Management of Mild Pre-eclampsia and Severe Pre-eclampsia (N= 42)

Variable	Yes n(%)	No n(%)
Mild pre-eclampsia (n=12)		
Blood pressure monitoring	5(41.7)	7(58.3)
Fetal heart rate monitoring	7(58.3)	5(41.7)
Urine for protein monitoring	8(66.7)	4(33.3)
Dexamethasone is given for pregnant women with GA 24-34 weeks	12(100)	0(0)
Patients are kept on methyldopa 500 mg TDS	12(100)	0(0)
Severe pre-eclampsia (n=31)		
Hydralazine 5mg started	14(45.2)	17(54.8)
Patient kept nifedipine on 20mg (PO) eight hourly	28(90.2)	3(9.7)
Patient kept on methyldopa 500mg (PO) eight hourly	30(96.8)	1(3.2)
Loading dose (14g) of magnesium sulphate started	31(100)	0(0)
Patient received / on maintenance dose	25(83.3)	5(16.7)
Protein in urine measured	28(90.3)	3(9.7)
Blood pressure monitoring	30(96.8)	1(3.2)
Fetal heart rate monitoring	28(90.3)	3(9.7)
Given maintenance dose (5gm) magnesium sulphate IM	25(83.3)	5(16.7)
Magnesium sulphate toxicity evaluation	4(12.9)	27(87.1)
Full blood count checked	30(96.8)	1(3.2)
Renal function test checked	16(51.6)	15(48.4)
Liver function test checked	14(45.2)	17(54.8)

Comparing the difference between healthcare facility levels on the management of pre-eclampsia

When comparing the management of pre-eclampsia between different healthcare facility levels using a Fisher exact test, the results showed that the proportion of patients with severe pre-eclampsia who were properly managed was higher among those who were admitted to referral national hospital compared to those who were admitted to district hospitals and health centres [n = 6 (85.7%) vs 2(28.6%) vs 1(8.3%), p = 0.002]. However, for mild pre-eclampsia, there was no statistically significant difference in its management between facility levels (p>0.05) (Table 7).

Table 7: Comparison of the difference between healthcare facility levels on the management of pre-eclampsia (N=43)

Health facility level	Total	Properly managed n(%)	Not properly managed n(%)	p-value
Mild pre-eclampsia				**1.0**
Health centre	**2**	1(50)	1(50)	

District hospital	**3**	2(66.6)	1(33.3)	
Tertiary hospital	**7**	4(57.1)	3(42.9)	
Severe pre-eclampsia				**0.002**
Health centre	**12**	1(8.3)	11(91.7)	
District hospital	**7**	2(28.6)	5(71.4)	
Regional hospital	**5**	0(0)	5(100)	
Tertiary hospital	**7**	6(85.7)	1(14.3)	

Discussion

The present study estimated the prevalence of pre-eclampsia, diagnosed by blood pressure readings, investigation of protein in urine, and assessment of signs and symptoms. Moreover, the possible predictors of pre-eclampsia were assessed, along with how pre-eclampsia is managed at all levels of healthcare facilities in Zanzibar. The findings of this study will play a significant role in reducing pregnancy complications, which will help decrease maternal morbidity and mortality.

The overall prevalence of pre-eclampsia among pregnant women attending ANC in this study is 14.5%. That means one in every ten pregnant women attending ANC in Zanzibar has abnormal placentation related to either immunological factors, genetic factors, a lowered threshold of placental perfusion, or increased demand on the placenta, which brings up the signs and symptoms of pre-eclampsia (Lavallee, 2015). This prevalence is higher compared to the global prevalence of 1.8%–4.4% (Umesawa & Kobashi, 2017), and higher compared to the prevalence reported in northern Tanzania of 4.2% (Mahande et al., 2013). However, the prevalence in this study is lower compared to the prevalence reported in Zanzibar, which was 26.3% (Machano & Joho, 2020). This disparity could be attributed to differences in study settings (resourced vs. under-resourced settings), participant types (age group differences, parity, gestation age), and methodological differences such as the method of case identification (use of secondary data vs. primary data). Our finding is more similar to the prevalence reported in Ethiopia of 12.4% (Andarge et al., 2020) and in Bangladesh, at 14.4% (Dutta Mou et al., 123 C.E.) both involved using primary data for pregnant women attending ANC at gestational weeks of 20 weeks and above.

In this study, pre-eclampsia was predicted by having a family history of pre-eclampsia or eclampsia. This is consistent with the findings in the literature (Adeline et al., 2018; Grum et al., 2017; Kashanian & Baradaran, 2011; Machano & Joho, 2020; Serrano et al., 2020). Family history represents the combination of risk within a family from shared genetic susceptibilities and clustering of environmental exposures, lifestyles, and behaviours (Serrano et al., 2020). The heritability of pre-eclampsia is estimated to be 30%–55% (Redman & Sargent, 2005), and it is suggested that its etiology involves both maternal and paternal genetic contributions and a substantial environmental component (Graves et al., 1993; Nilsson et al., 2004; Williams & Broughton Pipkin, 2011). To find a family history as a predictor of pre-eclampsia in this study was expected due to the widespread intermarriage practice in this setting grounded in the Islamic religion, which favours the marriage of close relatives, a permission which is welcomed by the majority. This suggests that healthcare providers should emphasize the use of family history in clinical risk assessments for pre-eclampsia to target available interventions to high-risk groups best.

This study also found that having a previous history of pre-eclampsia is a risk factor for pre-eclampsia in subsequent pregnancies. This has been well established in the literature. For example, a woman who had severe pre-eclampsia during her first pregnancy, the recurrence rate is very high, approaching 50%, and significant maternal and fetal complications are more common in recurrent pre-eclampsia than in the first episode (Dildy et al., 2007). The presence of risk factors from the initial pregnancy increases the risk for recurrent pre-eclampsia, with the majority of these factors reported to persist in subsequent pregnancies (Dildy et al., 2007; Mostello et al., 2008). This finding suggests

that healthcare providers should emphasize conducting a systematic evaluation of underlying risk factors for women who have experienced a pregnancy complicated by pre-eclampsia. Moreover, more research is needed to identify and refine a specific pathway suitable for a specific intervention to prevent the recurrence of pre-eclampsia.

Furthermore, this study found that having a history of using medications in the index pregnancy predicts pre-eclampsia. The use of certain drugs during pregnancy (e.g., antidepressants, antiretrovirals, migraine medications, antihistamines and antibiotics) has been linked to an increased risk of pre-eclampsia (Klln et al., 2011; Sahlman et al., 2019; Tooke et al., 2016; Uguz, 2017). The role of drugs in pre-eclampsia is still controversial, but some research explains that antidepressants have the effect of increasing placental chorionic vein and umbilical artery vasoconstriction, which could lead to uteroplacental under-perfusion and ischemia, which are associated with pre-eclampsia (Bernard et al., 2019). While antibiotics may alter the immunological profile and affecting placentation, which is associated with pre-eclampsia (Benner et al., 2021; Minassian et al., 2013). It is more common that pregnant women tend to use over-the-counter drugs or herbal medicine to alleviate symptoms caused by the physiological changes of pregnancy or to treat some medical conditions they may have. Therefore, more information about the types of drugs used during pregnancy and their role in pre-eclampsia is an area of concern for future studies. The findings suggest that healthcare providers should closely monitor pregnant women who are taking medication to reduce the risk of pre-eclampsia.

Although obesity, primigravida, pre-existing hypertension, advanced maternal age, and chronic illness are common risk factors for preeclampsia, we did not find any of them significantly associated with it. This variation between our study and other studies may be resulted from the relatively small number of participants in this study.

Findings from this study revealed that pre-eclampsia is not managed as per the established standard guidelines in many healthcare facilities. Severe pre-eclampsia cases are more mismanaged than mild pre-eclampsia. The underperformed management, i.e., in more than 50% of cases for mild pre-eclampsia, was monitoring of blood pressure. In contrast, for severe pre-eclampsia, it was magnesium sulphate toxicity evaluation, starting hydralazine at 5 mg, and a liver function test. A similar finding was reported in Afghanistan, where not all women with severe and mild pre-eclampsia were monitored for blood pressure and proteinuria as needed (Ansari et al., 2019). The reasons for not following the guidelines in this study were not assessed; however, they could be linked to either unavailability of the guidelines, functional equipment and reagents, well-functioning laboratory facilities, a high healthcare provider-patient ratio, or inadequate knowledge and skills among healthcare providers. Evidence shows that most low-resource settings do not have a well-functioning laboratory facility.

In this study, the availability of laboratory facilities was not assessed. However, the underperformance of liver and kidney function tests suggests inadequate functioning laboratory facilities. This creates challenges in distinguishing between pre-eclampsia with severe and without severe features, which may hinder proper and timely management, and consequently, pregnant women present emergently with eclamptic seizures (Machano & Joho, 2020).

On the other hand, all cases of mild pre-eclampsia and 96.8% of severe pre-eclampsia received antihypertensive medication as per the standard guideline. The conservative treatment of pre-eclampsia is essential for controlling blood pressure in order to minimize pregnancy-related complications, minimize prematurity, and promote maternal and infant survival. This finding is different from what is reported in Afghanistan and in six sub-Saharan African countries, in which 31% of cases of mild pre-eclampsia and 5% of cases of severe pre-eclampsia did not receive antihypertensive medication, respectively (Ansari et al., 2019),(Rawlins et al., 2018).

Furthermore, this study's findings show a significant difference in the management of severe pre-eclampsia between higher and lower-level healthcare facilities. Most cases were managed correctly at higher healthcare facility levels than at lower levels. The difference could be due to the unequal distribution of resources between different levels. Healthcare facility levels are categorized based on the services provided, which determines the allocation of resources to a particular facility, including healthcare providers with advanced professional qualifications. It is therefore suggested that the government should strive to reduce the resource allocation disparity in the ANC departments between healthcare facility levels for a significant reduction of morbidity and mortality related to pre-eclampsia.

This study's strength was that it focused on the critical topic of pre-eclampsia magnitude and how it is managed at all levels of healthcare in Zanzibar, which is poorly documented. The use of a standardized questionnaire enabled us to study the most critical risk factors, and we were able to adjust for some potential confounders. Despite its strength, this study has few limitations worth mentioning. The sample size was relatively small, so we did not find a significant association with common risk factors established in the literature.

Furthermore, this study was conducted in healthcare facilities. Thus, our findings may not represent all pregnant women in the catchment area. The diagnosis of pre-eclampsia, on the other hand, relied on a combination of blood pressure elevation, protein in the urine, and clinical findings without using laboratory tests such as thrombocytopenia, liver, and renal function tests for severe features, which limited the classification of the identified pre-eclamptic cases. The pre-eclampsia management assessment was based only on admitted patients; thus, we missed information on the comprehensive management practice at different healthcare facility levels. However, our findings may be helpful for further studies in this area.

The information obtained from this study, particularly on how pre-eclampsia is managed at different healthcare facility levels, is critical for policymakers and health planners to rethink the quality of maternal care quality and strive to improve care by reducing disparities between healthcare facility levels and ensuring lab equipment and supplies for pre-eclampsia management are available at all healthcare facility levels.

Conclusions

The prevalence of pre-eclampsia among pregnant women attending ANC in Zanzibar is high. The predictors for pre-eclampsia in this setting are having a family history of pre-eclampsia, a previous history of pre-eclampsia, and a history of medication use in the index pregnancy.

The standard guidelines for the management of pre-eclampsia are not adequately followed, and severe pre-eclampsia is mostly mismanaged at lower healthcare facility levels. The findings are relevant for identifying high-risk pregnancies, improving maternal healthcare delivery, and saving lives. As a result, a multifaceted approach is urgently needed in this setting to support frontline healthcare providers and healthcare facilities, especially of the lower levels, in providing quality care to pregnant women, promoting community engagement in ANC, and raising awareness about high-risk pregnancy and complication readiness.

Ethics consideration

Ethical permission for this study was obtained from the University of Dodoma Research Ethics Committee (UDOM-REC) with reference number MA.84/261/02/218 and Zanzibar Health Research Institute (ZAHRI) with a reference number ZAHREC/04/ST/JAN/2021/02. Written consent was given to pregnant women after explaining the purpose of the study and being told that their participation was

voluntary and that they would be able to withdraw at any time from the study. The authors declare that this is an original work and have no interest in disclosing it.

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Author's contribution:
SAR conceived the study, SAS and SAR designed the study, and SAR collected the data. SAS and SAR did the data analysis, and SAS and RBO wrote the final draft of the manuscript. All authors reviewed the manuscript and accepted it for publication

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Erythrocyte indices under conditions of energy drink consumption in Ukraine

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Abstract

Background: The consumption of energy drinks, especially among young people, is constantly growing worldwide despite warnings about their safety. Therefore, determining the consequences of their impact on the human body and well-being is an actual issue. This work aimed to study the state of endogenous intoxication and the antioxidant system of erythrocytes in experimental animals that consumed energy drinks.

Methods: The study was conducted on rats that consumed energy drinks for a month. Samples for analysis were taken on the 10th day after the end of the experiment. The biochemical methods of analysis were used to assess the state of endogenous intoxication by the erythrocyte intoxication index and the content of middle mass molecules (MMM), the state of oxidative modification of proteins, and the state of the antioxidant system by the fermentative activity of catalase (CAT) and superoxide dismutase. Statistical methods were used to determine the reliability of the study results.

Results: It was found that the value of the erythrocyte intoxication index significantly increased by 1.8 times ($p<0.001$), the content of MMM254 by 1.2 times ($p<0.001$), and the content of MMM280 – by 3 times ($p<0.001$), indicating the development of endogenous intoxication. The activation of the processes of oxidative modification of proteins is proved by the increase in the oxidative modification of the protein index by 1.1-1.3 times. It was shown that the enzymatic activity of superoxide dismutase decreased by 1.1 times, and CAT activity increased by 1.3 times ($p<0.001$). A 1.5-fold decrease in the ratio between superoxide dismutase and CAT enzymes was also found.

Conclusions: The results indicate damage in the antioxidant system, a decrease in the effectiveness of antioxidant protection, and the development of oxidative stress. The results obtained in this work may help study the potential adverse health effects of energy drinks consumption.

Keywords: erythrocytes; endogenous intoxication; oxidative stress; antioxidant system; oxidative modification of proteins

Introduction

Energy drinks (EDs) are part of the broader category of soft drinks, which includes carbonated beverages, fruit and vegetable juices, bottled water, sports drinks, beverage concentrates, and ready-to-drink tea and coffee. Most EDs contain a combination of caffeine, sugar, B vitamins, minerals, and amino acids. These components work synergistically to provide a quick energy boost. For instance, caffeine is a central nervous system stimulant, enhancing alertness and reducing fatigue, while sugars offer a rapid energy source. B vitamins play essential roles in metabolism, aiding food conversion into energy, while minerals and amino acids contribute to overall physiological function. Some energy drinks incorporate herbal extracts, such as ginseng and guarana, which are believed to enhance energy levels and cognitive function. It's crucial to note

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that the specific formulation of energy drinks can vary significantly between brands, leading to differences in taste, effectiveness, and potential health implications (Alsunni, 2015).

Since the early 90s of the last centuries, when this product appeared on the global market, the consumption of energy drinks has increased rapidly worldwide. With it, the variety of available products has increased. The global ED market size was estimated at 68.1 billion USD in 2021 and is expected to grow at a CAGR (compound annual growth rate) of 7.0% from 2022 to 2032 (Energy Drinks Market…, 2024). Energy drinks are a popular product among all age groups. However, most segments of society that consume large doses of these energy drinks are athletes, teenagers, and students hoping to boost energy levels or compensate for lack of sleep (Jouda *et al.*, 2019). During the COVID-19 pandemic, the overall consumption of ED experienced a slight decline due to widespread closures and restrictions affecting social activities, including schools, gyms, and sports arenas (Koh, 2020). However, the demand for EDs containing caffeine or enriched with vitamins and minerals remained relatively high as consumers sought these beverages for their perceived energy-boosting or nutritional benefits amidst the challenging circumstances of isolation and limited access to traditional sources of stimulation and nutrition (Bakaloudi *et al.*, 2022).

The energy drink market in Ukraine is already showing signs of maturity with moderate growth in retail sales (Jagtap *et al.*, 2022). This is due to the potential shift of consumers from other categories, such as low-alcohol beer, coffee, and carbonated drinks, to energy drinks, attracted by their energy properties. However, economic pressures, including the impact of Russia's invasion of Ukraine and the ongoing pandemic, have led to increased price competition (Zhou *et al.*, 2023). This has resulted in consumers switching from premium brands to cheaper mass products to save money. The market size of Energy Drinks in Ukraine has been impacted by various factors such as health considerations, changing social attitudes, legislation (e.g., sugar tax), demographics, and the changing retail landscape. The COVID-19 pandemic and social restrictions have harmed the consumption of Energy Drinks in Ukraine. Additionally, energy drinks are used in Ukraine, particularly in the military, as a vital asset for forces fighting an exhaustive war. Caffeine in energy drinks is a short-term solution for exhaustion (Leal Filho *et al.*, 2023).

In general, the safety of energy drink consumption remains debatable and has been discussed in several studies (Ehlers *et al.*, 2019; Sikalidis *et al.*, 2020; Soós *et al.*, 2021; Nadeem *et al.*, 2021; Svikis *et al.*, 2022). Limited complex literature reviews illustrate the suitability and risks of energy drink consumption, especially among young people (Ghozayel *et al.*, 2020; Oberhoffer *et al.*, 2022; Khouja *et al.*, 2022). Potential benefits of ED consumption include improved performance and mood due to the content of caffeine, ginseng, taurine, or natural products with high caffeine content, such as guarana (Sikalidis *et al.*, 2020). On the other hand, energy drinks have many side effects on health, including increased heart rate and levels of dopamine and adrenaline, which can lead to hypertension, dehydration, increased urination, and gastrointestinal disorders (Mohammed, 2018). Palpitations, seizures, headaches, strokes, type 2 diabetes, and kidney dysfunction have also been associated with ED use (Edrees *et al.*, 2022). In the study of electrocardiographic and hemodynamic parameters, it was found that the use of energy drinks increases platelet aggregation, blood pressure, and QTc prolongation, which puts patients at increased risk of developing torsades de pointes, which can lead to fatal ventricular arrhythmias (Shah *et al.*, 2019). Frequent energy drink consumption affects blood pressure, heart rate, and blood glucose levels in healthy adults exercising in the gym (Verma *et al.*, 2021).

Almost all works presented in the literature related to the effects of ED on the cardiovascular system, gastrointestinal tract, or neurophysiological parameters, and data on the impact on hematological blood indices are very limited (Khayyat *et al.*, 2014; Posokhov *et al.*, 2019; Bertolone *et al.*, 2020). Erythrocyte indices are important indicators as they provide information on red blood cell size and haemoglobin concentration and characterize erythropoiesis. They are digital characteristics of morphological changes in cells. The results obtained from the study (Khayyat *et al.*, 2014) showed a significant decrease in the number of red blood cells, hemoglobin content, hematocrit, platelets, and neutrophils in animals consuming certain brands of ED. Ultrastructural

changes were also observed, including peripheral blood cells' nucleus and cytoplasm. Prolonged oral administration of caffeinated energy drinks to rats caused an increase in erythrocyte membrane viscosity (Posokhov *et al.*, 2019). Energy drink consumption increased plasma and erythrocyte taurine levels and increased glycolysis and glutathione metabolism in erythrocytes (Bertolone *et al.*, 2020). However, the presented works lack data on the effect of ED on the oxidative modification of proteins (OMP) and the state of antioxidant defence of the body.

Although existing research extensively explores the impact of ED consumption on cardiovascular, gastrointestinal, and neurophysiological parameters, limited attention has been given to erythrocyte indices, which are crucial for understanding erythropoiesis and morphological changes in cells. Therefore, this work aimed to study the changes in erythrocyte indices of rats after using ED to assess the state of endogenous intoxication and the development of oxidative stress. The main questions for this study could be formulated as:

1. How does the consumption of energy drinks affect erythrocyte indices in experimental rats, and what insights does this provide into the development of endogenous intoxication and oxidative stress?
2. What are the specific changes observed in the antioxidant system of experimental rats following the consumption of energy drinks, and how do these changes contribute to the development of oxidative stress?

Methods

Experimental design

The research was conducted by directive of the European Parliament and of the Council No. 2010/63/Eu "On the Protection of Animals Used for Scientific Purposes" (2010), based on the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (1991). The experiments were conducted according to the Law of Ukraine No. 3447-IV "On the Protection of Animals from Cruelty" (2006), as well as the recommendations of the First National Congress of Ukraine on Bioethics (Reznikov *et al.*, 2006).

The experiments were conducted on adult male Wistar rats weighing 180-250 g, kept in a vivarium under standard conditions on a standard diet and free access to water at 20 ml per day per rat. All experimental animals showed weight gain. According to the experimental conditions, the animals were divided into two groups (each group consisted of 7 animals): the intact (control) group received only drinking water; the experimental group received an energy drink for a month. The required amount of the drink was calculated based on the conversion per kg of adolescent body weight. The ED contained water, caffeine, taurine, carbon dioxide, citric acid, and sodium citrate as acidity regulators, anthocyanin and sugar color IV as natural colorants, sugar, natural and identical to natural flavors, preservative potassium sorbate, glucuronolactone, inositol, ascorbic acid, vitamins B3, B5, B6 and B12. The duration of ED use was 1 month. Material for analysis was collected on the 10th day after the end of the experiment. For this purpose, rats were anesthetized by intramuscular injection of sodium thiopental (60 mg/kg), and blood samples were taken and centrifuged. Plasma and erythrocyte masses were selected separately, from which the hemolysate necessary for analysis was prepared.

Ethical approval

The Scientific Committee of Ethics of the Ivano-Frankivsk National Medical University, Ukraine, revised and approved all animal procedures.

Hematological and biochemical analysis

To assess the state of endogenous intoxication, two leading indicators were determined: erythrocyte intoxication index (EII) and the content of middle mass molecules (MMM). The basis of the method used to determine the EII is the idea of the erythrocyte as an adsorbent; that is, the

erythrocyte membrane can absorb and pass-coloured substances, namely methylene blue (Kazimirko and Maltsev, 2007). The content of MMM in hemolysate was determined at wavelengths of 254 nm (incomplete protein breakdown products) and 280 nm (aromatic amino acids), according to the method of Habryielian *et al.* (1985). The intensity of oxidative modification of proteins in erythrocyte hemolysate was estimated according to the process of Dubinina and Shuhalei (1993).

The optical density of the formed dinitrophenylhydrazones, expressed in conventional units, was recorded using a SPECORD M 40 spectrophotometer (Germany) at wavelengths 356 nm and 370 nm (aldehyde and ketone derivatives of neutral character) and 430 nm and 530 nm (aldehyde and ketone derivatives of essential character). Catalase activity (CAT) [KF 1.11.1.6] was determined as the ratio of catalase number to the number of red blood cells in 1 ml of blood.

CAT was expressed in units according to the method, which is based on determining the amount of hydrogen peroxide split in the catalase reaction. Quantitative determination of catalase was performed using methods A. Bakh and S. Zubkova (Babenko, 1999). The activity of superoxide dismutase (SOD) [KF 1.15.1.1] was calculated based on the level of inhibition of the reduction process of nitro blue tetrazolium in the presence of NADH (nicotinamide adenine dinucleotide, H for hydrogen) and phenazine methosulfate (Chevary *et al.*, 1991).

Statistical analysis

Statistical calculations were performed using STATISTICA 7 software with Student's t-test. Given the small sample size and the assumption of normal distribution, the t-test was chosen as a suitable statistical method to analyze the observed differences in EII, content of MMM, OMP, CAT, and SOD. The p-values ($p<0.001$) indicate statistically significant differences in EII and MMM between the two groups, confirming the appropriateness of using the t-test for comparing means in this experimental context.

Results

The results of determining the content of middle mass molecules and erythrocyte intoxication index in the erythrocytes of experimental animals under conditions of energy drink consumption are presented in [Table 1].

Table 1: Indicators of endogenous erythrocyte intoxication in rats of intact and experimental groups.

Indicators	Intact group (n=7)	Experimental group (n=7)
MCM_{254}, unit.	0.108 ± 0.005	0.132 ± 0.005*
MCM_{280}, unit.	0.017 ± 0.002	0.051 ± 0.015*
EII, %	29.16 ± 2.34*	51.75 ± 2.35*

***Note:** * – the reliability of the experimental group compared to the intact group of animals <0.001; MMM_{254} and MMM_{280} – the content of middle mass molecules at wavelengths of 254 and 280 nm, respectively; EII – erythrocytes intoxication index*

The obtained values for the intact and experimental groups are expressed as ± the mean value of standard deviation (M±m). As can be seen from the results of Table 1, an increase in endogenous intoxication products was observed during the study. Indicators of MMM_{254} and MMM_{280}, which reflected, respectively, the content of incomplete breakdown products of proteins and aromatic amino acids, increased in experimental animals that consumed energy drinks during the month, compared to the control group. Thus, the content of MMM_{254} in the blood of rats of the experimental group significantly increased from 0.108±0.005 units to 0.132±0.005 units ($p<0.001$). This is 1.2 times more compared to the intact group. As for the content of MMM_{280}, this indicator increased much more – 3 times ($p<0.001$), from 0.017±0.002 to 0.051±0.015 units. At the same time, a significant increase of 1.8 times ($p<0.001$) in the level of EII in the experimental group relative to the intact group was noted. The erythrocyte intoxication index increased from 29.16 2.34% to 51.75 2.35%.

The functioning of red blood cells is primarily determined by how well-balanced the oxidation processes of lipids and membrane proteins are and how active the antioxidant system is. Proteins are essential in metabolic processes in living organisms. They are essential ferments for various metabolic and regulatory processes in the body. However, they react rapidly with oxidants, and their abundance in cells, extracellular tissues, and body fluids makes them the primary target for oxidation reactions. Due to the influence of various exo- and endogenous factors, reactive oxygen species (ROS) are constantly formed in the body, the functions of which can be both positive (mobilization of the immune system) and negative (oxidation processes in proteins and lipids). In the body, under normal conditions, ROS formation and neutralisation processes are in a balanced state. Under the influence of stress or other factors, the existing balance is disturbed, oxidized products accumulate, and the body does not have time to neutralize them. As a result, the work of almost all organs is disrupted. With such an imbalance between the generation and disposal of ROS, oxidative stress develops, which is the cause of many pathologies. Due to the development of oxidative stress caused by the excessive generation of ROS, the processes of uncontrolled modification of proteins are actively developing. The negative consequences of this process are not only the denaturation and fragmentation of proteins but also the formation of primary amino acid radicals, which can enter secondary reactions with adjacent amino acid residues. In other words, proteins lose their biological activity.

The intensity of oxidative modification of proteins in erythrocyte hemolysate was studied since this value, that is, the indicator of oxygen-dependent oxidation of proteins directly indicates damage to organs and tissues of the body. The results are shown in [Figure 1]. In the animals of the experimental group on the 10th day after the completion of ED administration, the value of optical density at a wavelength of 356 nm increased from 0.23 to 0.26 units, i.e., a significant increase in the level of OMP by 1.1 times ($p<0.001$) was observed. A significant increase in the level of OMP by 1.2 times ($p<0.001$) compared to the intact group was noted at a wavelength of 530 nm. The value of optical density increased from 0.14 to 0.17 units. A similar pattern of increase in the level of OMP is characteristic of the wavelengths of 370 nm and 430 nm. The analyzed indicators increased by 1.3 times ($p<0.05$) and 1.2 times ($p<0.05$), respectively. Such a significant increase in oxidative modification indicates a pronounced activation of free radical oxidation of proteins in experimental animals that consumed energy drinks.

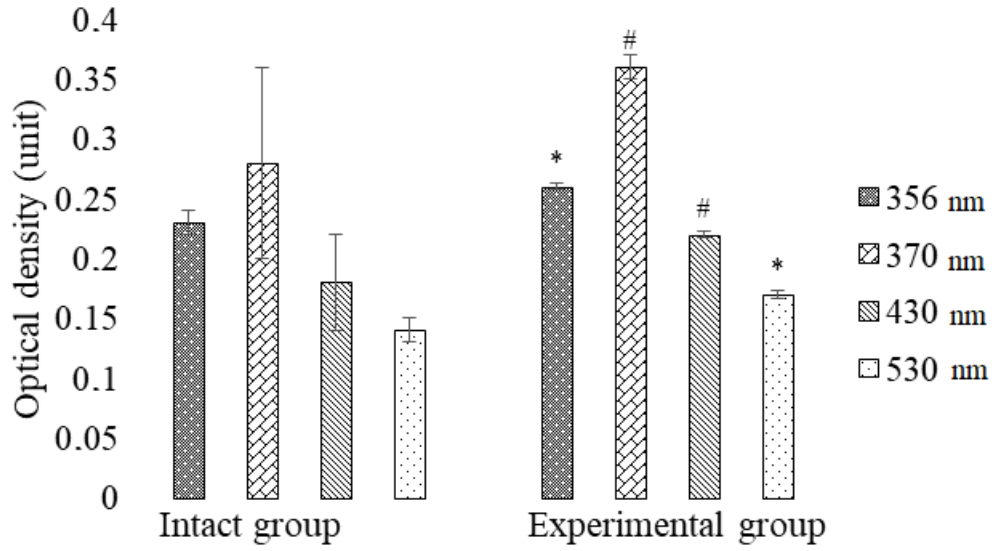

Figure 1: The level of oxidative modification of proteins in the hemolysate of erythrocytes of rats of intact and experimental groups, units (M±m; n=7)

Notes: *symbols in the experimental group mean: * – reliability of the experimental group compared to the intact group of animals <0.001; # – reliability compared to the intact group of animals <0.05.*

The next stage of research was to study the state of the antioxidant system of red blood cells, which are among the first to respond to various influences. The antioxidant system plays a protective role against the harmful effects of various factors, including ROS. The antioxidant system includes both antioxidant enzymes, such as catalase, superoxide dismutase, and glutathione peroxidase, and non-enzymatic antioxidants, such as vitamin E, vitamin A, vitamin C, glutathione, flavonoids, carotenoids, and uric acid. Antioxidant enzymes neutralize the action of hydrogen peroxide and superoxide radicals, which are the leading cause of harmful oxidative damage. By reducing their concentration to a minimum, they thereby reduce the likelihood of the formation of reactive OH• radical.

The activity of antioxidant defence ferments largely determines how intense the processes of free radical oxidation are. Enzyme's superoxide dismutase and catalase play prominent roles as antioxidant defenders. Superoxide dismutase has a high catalytic rate of the superoxide radical dismutation reaction with subsequent hydrogen peroxide and oxygen formation. As a critical cellular antioxidant, SOD is mainly responsible for the removal of O_2^-, which damages cells when it is in excessive concentration. Therefore, SOD maintains and controls not only free radical levels but also the oxygen homeostasis of the body. The regulation of SOD activity is based on the principle of reversible feedback, i.e., an excessive amount of H_2O_2, which is formed, significantly reduces the activity of superoxide dismutase. SOD is a metalloprotein found not only inside cells and intercellular space of tissues but also in biological fluids such as plasma or lymph. In blood cells, SOD successfully deactivates reactive oxygen species. As mentioned above, after the breakdown of ROS, hydrogen peroxide is formed, which can destroy SOD molecules, which is why superoxide dismutase always functions together with catalase. Catalase (CAT) is an enzyme that belongs to the class of oxidoreductases. Its peculiarity is that it has both catalase and peroxidase activity. CAT reduces hydrogen peroxide to water and molecular oxygen quite rapidly, i.e., its main function is the accelerated decomposition of hydrogen peroxide, which is formed because of various oxidative processes in the body, in red blood cells. Since this enzyme has a key responsibility for neutralizing hydrogen peroxide through decomposition, it, therefore, maintains the optimal level of the molecule in the cell, which is also important in the processes of cell signalling.

[Figure 2] shows the change in the activity of SOD and CAT in the erythrocyte hemolysate of rats after the use of energy drinks compared to the intact group. It should be noted that on the 10th day after the end of the experiment, there was a decrease in SOD activity from 58.19% to 52.47%. That is, in animals that received the energy drink for a month, compared to the intact (control) group, SOD decreased by 1.1 times ($p<0.05$). When analyzing CAT activity, it was noted that there was a significant increase in this indicator by 1.3 times ($p<0.001$) in rats of the experimental group relative to animals of the control group. CAT value increased from 13.96 mg H_2O_2/ml to 18.38 mg H_2O_2/ml. Thus, according to the results obtained, multidirectional changes occur in the antioxidant system of erythrocytes.

 https://dx.doi.org/10.4314/thrb.v25i3.13

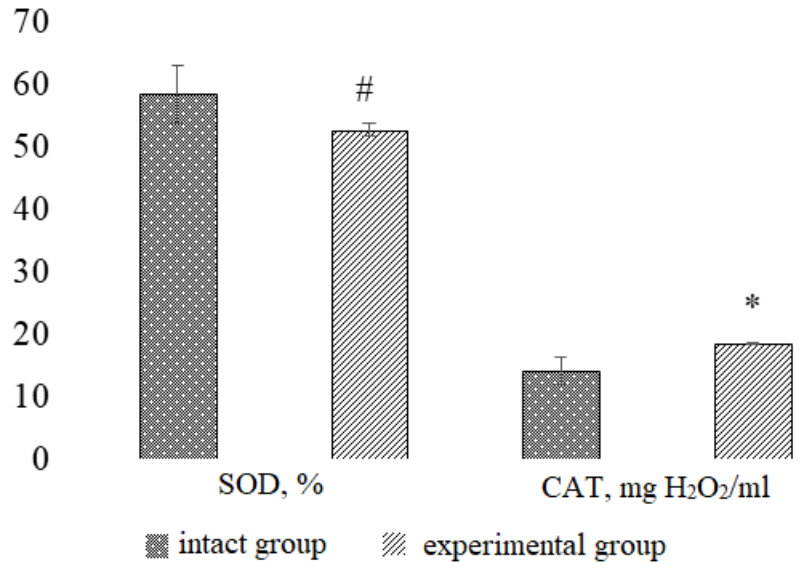

Figure 2: Changes in the activity of antioxidant enzymes SOD and CAT in erythrocyte hemolysate of rats of intact and experimental groups (M±m; n=7)
Notes: *symbols in the experimental group mean: * – reliability of the experimental group compared to the intact (k) group of animals 0.001; # – reliability compared to the intact (k) group of animals 0.05.*

Analyzing on the 10th day the dynamics of changes in the activity of the studied enzymes in the hemolysate of rats when they consumed the energy drink during the experimental period, significantly higher ($p<0.001$) values of SOD against catalase were found [Figure 3].

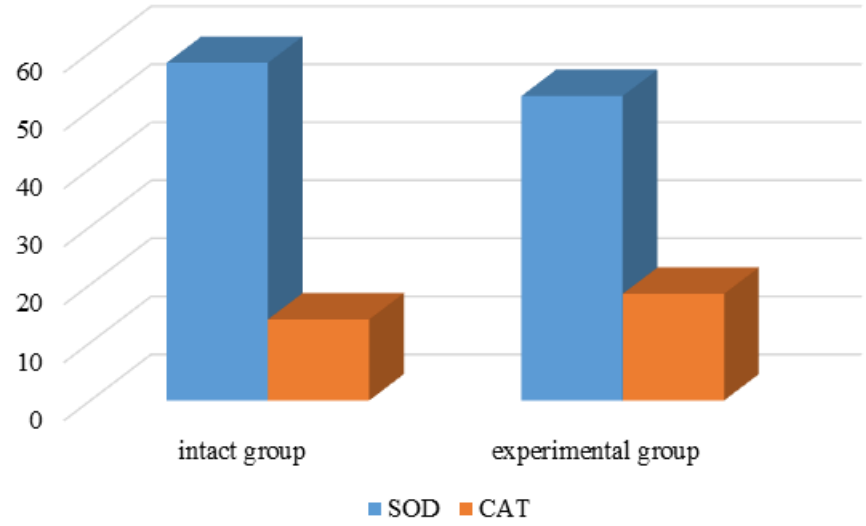

Figure 3: Dynamics of changes in the activity of antioxidant enzymes in erythrocyte hemolysate of rats of intact and experimental groups (M±m; n=7)

The ratio of SOD/CAT in rats of the experimental group decreased approximately 1.5 times (from 4.17 to 2.85) compared to this value in rats of the intact group.

Discussion

Since MMM have high biological activity, they can block cell receptors by binding to the active centers of albumin molecules and thus disrupt the process of humoral regulation. The increase in MMM content indicates the development and spread of endogenous intoxication. A significant

increase in MMM_{254} and MMM_{280}, revealed during the study, indicates a substantial increase in endogenous intoxication of experimental animals during the experimental period. Moreover, the increase in the content of MMM_{280} was more intense than that of MMM_{254}, indicating a higher content of aromatic amino acids in the composition of medium molecules. This may be due to the loss of aromatic amino acids by proteins because of oxidative modification and fragmentation of molecules. A similar trend in the relationship between MMM content and the development of endotoxemia has been noted in the study of the effect of drugs on indicators of endogenous intoxication (Lys and Regeda, 2019; Demkovych *et al.*, 2021) or in the assessment of cardiovascular risks (Strilchuk and Kondratyuk, 2021). In these works, it is noted that with increasing levels of endogenous intoxication, the permeability of erythrocyte membranes increases, and the content of middle mass molecules increases. Such changes are associated with direct injury, destructive changes, inflammation, activation of hypoxia and peroxia, and lipid oxidation. The study of the data presented in the literature allows us to state the lack of special studies on the effect of ED consumption on the development of endotoxemia in the body of experimental animals and the development of oxidative stress.

Oxidative stress triggers the mechanisms of free radical oxidation, which leads to the accumulation of reactive oxygen species. The latter activates the processes of oxidative modification of proteins and lipid peroxidation. Both exogenous and endogenous toxins accumulate in the body. This deepens the endogenous intoxication of the body, which is accompanied by the accumulation of aldehyde and keto derivatives of a neutral and basic nature in erythrocytes (Demasi *et al.*, 2021). The obtained research results confirm this conclusion. The increase in OMP values determined in the work indicates the activation of protein modification. The likely consequence of such modification may be losing their biological activity, fragmentation, and denaturation (Hawkins and Davies, 2019). In turn, intoxication causes changes in protective systems, particularly antioxidant and immune systems (due to the formation of many compounds with antigenic properties). It is known from the literature (Al Yacoub *et al.*, 2020) that the level of MMM depends on both the intensity of biopolymer breakdown and the decrease in the rate of their excretion through the detoxification organs, which are the kidneys and liver. Given the experimental data obtained in this work, it can be assumed that both process components are affected.

The results of the analysis of the obtained values of the erythrocyte intoxication index show an increase in this value, which indicates the sensitivity of red blood cells to the action of energy drinks. Changes in the level of destruction of erythrocyte membranes (the level of dye absorption) are caused by the fact that after sufficiently long use of ED in erythrocytes, energy metabolism is affected, transport of substances is impaired, and the permeability and sorption capacity of membranes increases. These conclusions are consistent with the results of previous studies of the authors on the effect of ED on the state of erythrocyte membranes and hemolytic parameters (Partsei *et al.*, 2017). Other authors have also reported changes in the state of erythrocyte membranes due to the use of energy drinks (Posokhov *et al.*, 2019). Oxidative stress, which reduces the antioxidant capacity, irreversibly damages red blood cells, particularly susceptible to its effects due to the high polyunsaturated fatty acids in the membrane and the auto-oxidation of hemoglobin inside the cell. This leads to the final damage of red blood cells by hemolysis and their removal by circulation (Maurya and Namdeo, 2021). Red blood cells are equipped with an antioxidant defence system in the form of enzymatic and non-enzymatic antioxidants to prevent damage.

The experimental results obtained indicate an unclear effect of ED on the state of antioxidant defence in the body of experimental animals. On the one hand, the enzymatic activity of SOD, an enzyme that is the main obstacle to the formation of ROS, decreased. Such a decrease is a characteristic feature of damage to the antioxidant system and reduced protection of red blood cells from the toxic effects of superoxide radicals. The decline in SOD activity is likely associated with an increase in the generation of superoxide radicals, resulting in the formation of

hydrogen peroxide and oxygen. Hydrogen peroxide can be easily converted into hydroxyl radical, which is highly reactive and damages the metal-protein complex of the enzyme (Islam *et al.*, 2021). On the other hand, catalase activity in rats of the experimental group increased. It cannot be excluded that the consumption of energy drinks initiates the formation of hydrogen peroxide, increasing CAT enzymatic activity, which can be considered an adaptive response.

A review of the reactions of catalases with their primary substrate, hydrogen peroxide, and with various oxidants, such as hydroxyl radical, superoxide, nitric oxide, peroxynitrite, hypochlorous acid, and singlet oxygen, was conducted by Gebicka and Krych-Madej (2019). Another possible reason for the increase in catalase activity may be the course of glycosylation reactions by glucose oxidation products. When consuming ED, blood glucose levels increase significantly, which is confirmed by the results of studies by various authors (Nowak *et al.*, 2018; Graneri *et al.*, 2021), which activates CAT activity. Since both superoxide dismutase and catalase are the main components of the enzymatic link of antioxidant protection, their ratio indicates changes in oxidative protection. A decrease in the ratio of SOD and CAT enzymes, which in this case is due to an increase in the activity of catalase, is possible evidence of a disorder in the coordination of enzymatic antioxidants and confirms a decrease in the level of antioxidant protection (Aliiev, 2023).

According to the authors, the presence of taurine as a component in ED can, to some extent, compensate for the decrease in the activity of antioxidant enzymes. This assumption is confirmed by the data presented in the literature (Bertolone et al., 2020) on the antioxidant activity of taurine in erythrocytes. Taurine is an amino acid that is not synthesized in the human body. It promotes weight loss, helps muscle recovery, and improves oxygen transfer in the body. The authors of this work suggest using taurine to counteract oxidative stress. Non-enzymatic low molecular mass antioxidants may also contribute, one of which is ascorbic acid, also present in the ED taken for the study. Ascorbic acid has antioxidant effects, protecting cellular structures from free radical damage (Vora Axita *et al.*, 2022). In general, several studies in the literature review the impact of individual ED ingredients such as caffeine, taurine, guarana, and/or their combinations.

Most of these studies focus on caffeine, whose mechanism of action is almost entirely studied, and its effects on the body have been examined (Soós *et al.*, 2021). Such studies regarding the impact of other components are rare (Jouda *et al.*, 2019). The effects of guarana have not been sufficiently studied, although it is well known that the beans of this plant contain about twice as much caffeine as coffee beans, which is why the caffeine content in energy drinks increases (Sikalidis *et al.*, 2020). The morphological and biochemical effects in vitro of caffeine, taurine, and guarana, alone or in combination with taurine, have been studied, and their cytotoxicity has been evaluated (Zeidán-Chuliá *et al.*, 2013). Evidence of both positive and negative effects of the main components of energy drinks or their cumulative effect on the state of erythrocytes and the development of oxidative stress was not found in the literature. Therefore, the experimental results indicate that energy drinks can have potential adverse health effects and are accompanied by a pronounced increase in endogenous intoxication and changes in the state of the antioxidant system.

The study's findings advocate for comprehensive policy reforms targeting energy drink regulation. It necessitates the development of stringent guidelines for ingredient disclosure, health risk warnings, and consumption advisories on packaging. The evidence supports advocating for age-restricted sales to protect young consumers from potential adverse effects. Moreover, it underscores the importance of public health campaigns to educate consumers about the risks associated with energy drink consumption and encourages further scientific research to inform policy decisions. These measures aim to mitigate health risks and promote safer consumption practices.

Conclusions

Experimental studies of changes in erythrocyte indices in experimental rats after the use of ED were conducted to evaluate the state of endogenous intoxication and the development of oxidative stress. The data obtained indicate the activation of endogenous intoxication processes and changes in the state of the antioxidant system. Endotoxemia develops in the body of experimental animals, manifested by the accumulation of endotoxins in the blood hemolysate. This fact is confirmed by clearly expressed changes in the leading indicators of endogenous intoxication – EII and MMM. A significant increase in the value of EII by 1.8 times ($p<0.001$) was found, indicating the sensitivity of erythrocytes to ED. The content of MMM_{254} in the hemolysate of the rats of the experimental group significantly increased by 1.2 times ($p<0.001$) compared to the intact group, and the content of MMM_{280} – by 3 times ($p<0.001$).

It should be noted that the higher intensity of the increase in the content of MMM_{280}, compared to MMM_{254}, indicates an apparent rise in the concentration of aromatic amino acids present in the middle molecules. The activation of the processes of oxidative modification of proteins is proved by the increase in the OMP index by 1.1-1.2 and 1.2-1.3 times, determined by aldehyde and keto derivatives of neutral and essential character, respectively. It is shown that the state of the antioxidant system shows multidirectional changes. SOD activity decreases by 1.1 times, and CAT activity increases by 1.3 times. The decrease in the SOD/CAT ratio by almost 1.5 times is caused by disturbances in the consistency of enzymatic antioxidants and a decrease in the level of antioxidant protection. Reduction of antioxidant and superoxide dismutase activities in the blood hemolysate of experimental rats after using energy drinks confirms the development of oxidative stress and the effect of endogenous intoxication. The increase in catalase activity may be due to adaptive synthesis as a response to the increase in ROS or possible glycosylation by glucose oxidation products. The results obtained in this work may help study the potential adverse health effects of ED consumption.

The study was limited by its small sample size of only 14 rats divided into two groups and the short duration of 1 month for ED consumption. To further validate the results, the study should be expanded to include more animals, additional experimental groups with varying durations of ED intake, and more extended follow-up periods after ceasing consumption. There is also a need for research on the effects of individual ingredients like caffeine or taurine, comparison of different types of energy drinks, and tracking changes over extended periods after stopping intake. Studies on actual ED consumption patterns and amounts in human populations are also warranted.

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Conflict of interest: The authors declare no conflict of interest.

Data availability statement: The data supporting this study's findings are available on request from the corresponding.

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Inspection Practices for Regulating Prescription Handling and Antibiotics Control in Ilala Community Pharmacies of Dar es Salaam, Tanzania: Qualitative Assessment

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Abstract

Aim: The study aimed to explore inspection practices of prescription handling and antibiotics control in the context of Tanzania's community pharmacies.

Design: Qualitative exploratory study.

Methods: This qualitative study held 14 in-depth interviews with pharmacists (three), pharmaceutical technicians (seven), and pharmacy council representatives (four) to collect data on the inspection processes for regulating prescription handling and antibiotic control in community-based pharmacies. The data was then subjected to content analysis with the help of NVivo12.

Results: The study found that even though routine inspections were conducted to regulate prescription handling and antibiotic control in community pharmacies, there were inconsistencies in prescription retention, inadequate documentation in the inventory system, and improper antibiotic storage, with less attention paid to inspecting antibiotic sales practices. Implicitly, the efficiency and effectiveness of such inspections were open to question. Moreover, many clients frequented these visits to community pharmacies without prescriptions, yet they were dispensed with non-over-the-counter antibiotics. Furthermore, there were generally disparities between regulatory expectations and practical implementation in community pharmacies.

Conclusion: More emphasis is necessary on antibiotic prescriptions and retention in community pharmacies coupled with standardized inspection protocol to help enhance inspection regulation activities and promote better dispensing practices for prolonged medicine life, improved efficacy, and health outcomes.

Keywords: Inspection practices, prescription handling, antibiotics control, community pharmacies

Introduction

Antibiotics, since their discovery in 1928, have helped to reduce global mortality rates caused by bacterial infections (da Cunha et al., 2019). Although classified as prescription-only medication, antibiotics are frequently accessible without prescriptions in community pharmacies (Auta et al.,

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2019). This loophole significantly challenges regulating their rational use, contributing to the alarming rise in Antimicrobial Resistance (AMR), recurrent infections, increased treatment costs, and poor health outcomes (Aljeldah, 2022; Morrison & Zembower, 2020). AMR is a critical global public health threat, accounting for about 700,000 annual deaths due to drug-resistant infections. The over-the-counter (OTC) sale of antibiotics is a grave global public health concern, particularly in low- and middle-income countries (LMICs), where such practices persist despite having regulations in place (Vazquez-Lago et al., 2017a). According to the World Health Organisation (WHO), the inappropriate use of antibiotics largely stems from suboptimal pharmacy practices (Miller & Goodman, 2016).

In Africa, where healthcare infrastructure is often inadequate, community pharmacies are the primary point of contact for healthcare services (Ayukekbong et al., 2017). Thus, these regions need robust inspection practices to regulate prescriptions and the sale of antibiotics. Even though regulatory bodies in many of these countries have appointed inspectors to oversee and check for compliance with the antibiotics-selling regulations (Porter et al., 2021), how they operate, and their experience enforcing antibiotic-selling regulations are not well-documented. Inspection of community pharmacies in LMICs has proven to be daunting due to resource constraints in these countries. Specifically, a critical shortage of well-trained human resources for conducting inspections has been compounded by poor financial support to execute inspection activities (Ayukekbong et al., 2017). When such inspections occur, they are often sporadic and deviate from the recommended frequency as outlined in the guidelines (Oseni, 2021).

Studies conducted in African countries show that most community pharmacies sell and dispense medications without regulatory authorities' permit and use unauthorized—sometimes even unqualified—personnel or authorized personnel who lack a clear understanding of prescription medication regulations against AMR (Wafula et al., 2014). Antibiotics are prescription-only medications in Tanzania, and a valid prescription is required for sale in Part I and Part II pharmacies. Antibiotic prescription regulations fall under the Ministry of Health (MoH) and the Pharmacy Council. The authorities are mandated to safeguard the public by ensuring acceptable standards of pharmacy practice through regular inspections and enforcement of prescription handling guidelines.

In April 2020, the Tanzania MoH introduced the prescription handling and control regulations (Crabbe, 2021) to enforce the sale of prescription-only medications, including antibiotics. These regulations require that patients present a valid medical prescription before medication can be dispensed. Moreover, the dispensers must check the validity of those prescriptions, retain the original handwritten prescription and give the patient a copy.

Despite the availability and clarity of the regulations on antibiotic dispensing, studies in Tanzania show that a high proportion of pharmacies dispense antibiotics without prescription (Nkinda et al., 2022), with figures reaching a staggering 88.2% [95%CI 86.3–89.9%] (Ndaki et al., 2021). In practice, people can access a variety of medicines, including antibiotics, from community pharmacies without any valid prescriptions (Nkinda et al., 2022). In other words, the prescription-only medication classification and dispensing guidelines are largely ineffectual. Consequently, the rate of national consumption of antibiotics in the private sector, including community pharmacies in the country, remains high, with 80.8 ± 39.35 defined daily doses (DDDs) per 1,000 inhabitants each day, with amoxicillin and doxycycline being the most widely dispensed antibiotics (Mbwasi et al., 2020), As a result, the consumption rate far outstrips that of high-income countries (Mbwasi et al., 2020; Westbrook & Kirk, 2007). This alarmingly high consumption of these prescription-only

drugs will continue to contribute to the emergence and spread of AMR (Poyongo & Sangeda, 2020), particularly in the absence of effective curbs, and negatively impact people's health and well-being as well as public health generally.

The external and internal factors have accounted for dispensing antibiotics without prescriptions. The factors external to the pharmacist include the client's inability to obtain a prescription (Bianco et al., 2021), self-prescription and medication practices (Nepal & Bhatta, 2018) and inadequate regulatory inspections and enforcement, as well as the absence of accountability mechanisms (Torres et al., 2020). On the other hand, internal factors include capitalizing on the available openings to maximize sales and gain supper profits (Poyongo & Sangeda, 2020), and negative attitudes, insufficient knowledge, and fear of disappointing clients (Vazquez-Lago et al., 2017b). Other internal factors include irrational dispensing and misuse of antibiotics aggravated by the community pharmacists' poor knowledge, attitude, and practices related to antibiotics (Nkinda et al., 2022).

As such, a better understanding of the modus operandi of the community pharmacies in handling prescriptions in the face of existing control mechanisms could yield valuable insights into informed approaches to dealing effectively with irrational dispensing of antibiotics. After all, regulatory infringement on antibiotic dispensing without prescription is joint in Tanzania (Horumpende et al., 2018; Mboya et al., 2018; Myemba et al., 2022) with several dispensers perceiving the regulatory authorities as lenient, hence leading to intentional, unauthorised dispensing of prescription-only medications to augment their sales and income (Poyongo & Sangeda, 2020). As a rule, and in theory, antibiotic prescriptions should be retained at the pharmacies upon dispensing, and the patient should only get a copy of that prescription.

Antibiotic prescription retention is a critical aspect of regulatory adherence that needs monitoring during inspections; however, information on how prescription handling and regulations are implemented, particularly in community pharmacies, remains scarce in Tanzania. This study aimed to bridge this knowledge gap by understanding how inspection practices designed to regulate prescription handling and antibiotic control are enforced in community-based pharmacies. Understanding these practices could inform targeted interventions to enhance the enforcement of prescription handling and antibiotic control regulations for improved dispensing practices and general health and well-being.

Significantly, this study was carried out to identify loopholes within the regulatory framework of Tanzania and how to plug them. An efficient and effective antibiotic regulatory framework is critical for improving rational antibiotic prescription and use, and improved patient health outcomes.

Materials and Methods

Study design and settings

The study employed qualitative research design and in-depth interviews to collect data. This qualitative research suited the study due to its exploratory nature intended to elicit participants' experiences and views (Mack et al., 2005) on the inspection practices for regulating prescription handling and controlling the dispensing of antibiotics in community pharmacies. The use of in-depth interviews elicited a detailed understanding of the phenomena in question (Rutledge & Hogg, 2020) and enabled the study to gain a comprehensive grasp of the participants' views and experiences, which was essential in addressing the research objective.

The study was conducted in the Ilala district of Dar es Salaam City, a densely populated area with about 1,649,912 residents as of the 2022 census (NBS, 2022). Ilala district had the highest number of registered pharmacies, about 311 establishments, compared to the remaining four administrative councils in the Dar es Salaam region of Kinondoni, Kigamboni, Temeke, and Ubungo. Such a high concentration of registered pharmacies made Ilala a unique context in which to explore the inspection practices for regulating prescription handling and antibiotic control in community pharmacies.

We conducted in-depth interviews with the regulators inspecting the community pharmacies to understand how they enforced the inspection regulations on prescription handling and control in community pharmacies. In addition, we engaged with dispensers working in community pharmacies, who included pharmacists and pharmaceutical technicians, to share their experiences of being inspected on antibiotics prescription handling and control by the regulatory authorities.

Recruitment of participants

The study participants were purposively recruited based on their position and experiences with prescription handling and control in community pharmacies. In consultation with the Pharmacy Council, a regulator which works to ensure adherence to the standards of pharmacy practice in the public interest, the research team identified individuals who were directly involved in regulating community pharmacies.

These individuals were also involved in community pharmacy inspections and regulating antibiotic prescription handling and control. In addition, we purposively recruited dispensers comprised of pharmacists and pharmaceutical technicians to gain insights into their experiences with regulating prescription handling and control practices. All these participants were informed in detail about the nature of the study and its objectives before they could provide their informed consent.

During such briefings, they had ample opportunities to ask questions or seek clarification from the research team before affirming their willingness to participate in the study. The recruitment process ended after reaching data saturation, with only those who provided consent participating in the study.

Data collection and analysis

The researcher (LC), supported by a research assistant, collected the data. Both have a pharmacist background and broad-based experience in qualitative data collection in various health-related fields in urban and rural settings of Tanzania. Before data collection, the research assistant was informed about the study objectives and trained on data collection guides, data handling, data storage, and ethical considerations during data collection activities. An interview guide, refined after a pilot study, facilitated the interviews.

The guide covered several themes to explore how the inspection of community pharmacies was done, who did the inspection, the challenges experienced during the inspection, and suggestions for improving these inspections. In all, 14 interviews (four with interviewees from the pharmacy council, three pharmacists, and seven pharmacy technicians) were conducted in Kiswahili, a language spoken by all the study participants. During interviews, probing questions helped better understand the participants' opinions and experiences.

The researcher conducted all the interviews while the research assistant took field notes to help identify any data inconsistencies during the data collection process. The interviews were audio-recorded with the participant's permission and lasted 25 to 55 minutes. The interviews were conducted until the data saturation point was reached when no new information could further be generated (Mwita, 2022). Even though the data saturation point was reached at the 12 interviews, we added two more interviews to confirm such saturation.

The audio-recorded files were transcribed verbatim within 48 hours of being generated and saved into Swahili Word files. The Swahili word files were then translated into English. The transcriptions and translations were crosschecked by the principal researcher (LC) for quality and clarity before importation into NVivo 12 software for further management and analysis. We adopted and applied Graneheim and Ludman's approach to qualitative content analysis (Graneheim & Lundman, 2004).

Content analysis enabled the inductive generation of the codes and categories essential in capturing the participants' unique experiences (Bengtsson, 2016). After selectively dividing the text into meaning units, data was condensed, abstracted, and labelled with codes. Codes were compared for similarities and differences based on the discussions and agreement among all authors before being applied to the remaining transcripts. The resulting codes were further compared, merged to form sub-categories, and eventually consolidated into categories through a collaborative agreement with all the authors (Stahl & King, 2020)

Ethical clearance

The study received ethical clearance from the Muhimbili University of Health and Allied Sciences (MUHAS) Institutional Review Board (DA/282/298/01.c/1633). Permission to conduct the study in the community pharmacies was obtained from the Tanzania Pharmacy Council and the managers of the privately-owned community pharmacies in the Ilala district council. All the methods in the study were performed following the relevant guidelines and regulations (Declaration of Helsinki). Before their involvement in the study, we explained the research objectives and procedures to the participants before obtaining their written informed consent.

Results

The study results describe the main categories that emerged from the data: inspection of antibiotic prescription retention, inspection of inventory management, inspection of proper antibiotic storage, and challenges to inspection for regulating prescription handling.

Inspection of antibiotics prescription retention

The interviews with the regulators at the Pharmacy Council revealed that they usually conducted routine inspections to check whether the pharmacies received, retained, and stored prescriptions after dispensing prescription-only antibiotics. In most cases, they said, only a few pharmacies received and retained such prescriptions.

The regulators reported that the main reasons for the pharmacies not keeping the records included government restrictions imposed on getting prescriptions outside the health facilities. The government promotion policy "get everything in the hospital" discourages the provision of prescriptions to patients to obtain medicines outside the health facilities. In consequence, most of the customers visiting pharmacies to buy antibiotics lack such prescriptions, and the pharmacists dispense the medicines accordingly:

> *"The government, on the other hand, says that prescriptions should not leave the facility. So, you find someone sitting in a pharmacy with investments, but no prescriptions are forthcoming. What do you expect will happen? Someone will demand medication, and without a prescription, they will be listened to. The medicines dispensed to them because the government doesn't allow prescriptions to get out of the [health] facilities"* (R04, Regulator Pharmacy Council).

Interviews with community pharmacies affirmed that most of the clients they attended to did not have a prescription but were knowledgeable about the type of antibiotics they needed. Moreover, they reported being inspected routinely on prescription retention but also noted that the regulators emphasized inspecting the pharmacy premises, the permit, and the surrounding environment in addition to ascertaining the qualifications of pharmaceutical technicians and pharmacists:

> *"In the case of the Pharmacy Council, they routinely visit us to inspect prescription retentions, but they mostly check for personnel registration, whether or not they have paid for their licences and the validity of premises registrations. They rarely check general practice when it comes to antibiotics. They mainly inspect controlled drugs"* (R07 Pharmaceutical technician).

Inspection of Inventory Management

Regulators reported that they usually checked the medicine registry and inventory systems during inspections. They reported experiencing challenges because some pharmacies neither kept dispensing registers nor had a computer record system. They further pointed out that the absence of a dispensing register was a punishable offence, yet enforcement was largely lacking:

> *"During routine inspections, we check for medication registers and inventory systems. Some pharmacies do not have any form of inventory management, meaning dispensing registers and computer systems. Although this is a punishable offence in pharmacy practice, this enforcement is not stringent because we usually see the medication register. Still, it contains incomplete information"* (R03, Regulator Pharmacy Council).

During interviews with community pharmacies, most pharmacists and pharmaceutical technicians expressed concern about the relative lack of emphasis on documenting antibiotics in the inventory system. The pharmacists cautioned that inspectors needed to be careful when reviewing the pharmacy records to ensure the numbers for what had been ordered tallied with what appeared in records as sold or in stock. They insisted that doing so could help to ensure that there were no antibiotics that could be dispensed without prescriptions:

> *"Regulators should carefully review the pharmacy records during inspections. If, let's say, a certain pharmacy has bought a given number of antibiotics orders, upon selling, the number of prescriptions should match the amount sold or present in stock, just like medications such as diazepam; they can't be dispensed without prescriptions…"* (R02, Pharmacist).

Inspection of Proper Storage of Antibiotics

Inspection of proper storage of antibiotics is one of the critical areas that receive special attention during these inspections. Regulators reported that they pay more attention to inspecting the proper storage conditions of the antibiotics to maintain their quality and efficacy. They ensure these antibiotics are not displayed in the public area (over the counter). Instead, they emphasize designating secure storage space for these antibiotics away from public view:

> *"We have been inquiring about where prescriptions are stored, and medications dispensed based on prescriptions should be stored in the designated store space, not displayed on the counter. When these medications are dispensed, it must be done according to the established procedures, which require a valid prescription"* (R02, Regulator, Pharmacy Council).

The dispensers at community pharmacies also reported similar ideas that the regulators are diligent in verifying whether pharmacies have established adequate measures to secure antibiotics in designated storage areas:

> *"Regulators are keen on checking for antibiotic storage. They do not want us to display antibiotics out in the open together with other over-the-counter medications. This is the first thing they ascertain after ensuring we have the necessary certification for conducting business and premise permits"* (R04, Pharmaceutical Technician).

Inspection Challenges to Regulating Prescription Handling

Pharmacists and technicians faced challenges in adhering to regulations mandating the retention of antibiotic prescriptions. They reported often receiving incomplete prescriptions with insufficient information that the prescription handling and control regulations required them to retain:

> *"I have seen several prescriptions with antibiotics; they are incompatible and are not well written, and this is why we do not keep the prescriptions. Because most of them are incomplete, they do not give you a clue"* (R04, Pharmaceutical Technician).

In addition, those near hospital settings received just a single copy from patients, contrary to guidelines specifying the availing of two copies:

> *"We do receive a few prescriptions from patients coming from the hospital, usually when medications are out of stock in these hospitals. We dispense these medications according to the prescription requirements, and we cannot retain this prescription as regulations demand because patients must return them to their respective wards"* (R05, Pharmacist).

Regulators also reported the challenges emerging from the comprehensive nature of prescription regulations, which involve all areas of health service provision, including hospitals. They noted that no inspections were conducted in hospital settings, limiting the distribution of vital guidelines, including the issuance of prescriptions to patients. As a result, they implored the Pharmacy Council inspectors to assess hospital pharmacies to enforce compliance with regulations and facilitate the effective dissemination of essential guidelines:

"The prescription handling and control regulation cuts across all areas of health service provision, so most hospitals and health centres are unaware of this regulation. There is a need for effective communication between these institutions and the Council" (R02, Regulator, Pharmacy Council).

Discussion

This study explored the inspection practices in regulating prescription handling and antibiotic control in community pharmacies in Tanzania. Using in-depth interviews, the study generated comprehensive information on the participants' insights into their experiences with pharmacy inspections and the regulation of antibiotics. This study comes in handy because qualitative studies assessing the inspection regulations and antibiotic control in Tanzania's community pharmacies are limited. Such study results are critical in informing targeted interventions for strengthening pharmacy inspection practices, regulations, and antibiotic control measures to promote the rational use of medicines for better health outcomes, prolonged medicine life, and improved efficacy.

The study found that, even though routine inspection ensures community pharmacies comply with the national regulations and guidelines on prescription and antibiotic control, such oversight was primarily limited, undermining its effectiveness. On the one hand, the participants reported that during the inspection process, inspectors focused not only on prescription and antibiotic dispensing but also on various aspects such as personnel qualifications, registration permits, and antibiotic storage conditions to ensure medication safety in the pharmacies.

Similar observations were also reported in Lebanon (Badro et al., 2020) and Uganda (Trap et al., 2016), where regular inspections of community pharmacies were conducted to ensure adherence to good pharmacy practices, including prescription handling and antibiotic control. This similarity underlies the multifaceted nature of these routine inspections, which cover dimensions of diverse pharmacy operations. When conducted properly, these inspections can serve as an effective regulatory practice to control irrational medicine use, reduce preventable deaths and improve the quality of health services and people's quality of life (Alhusein & Watson, 2019). Strengthening inspection practices in community pharmacies is necessary to ensure public access to safe and effective medications.

On the other hand, the participants reported disparities in inspection practices related to the dispensing and using antibiotics regardless of the routine inspections conducted. The routine inspections covered qualifications and medication quality but without necessarily paying specific attention to antibiotic handling and control. This finding is consistent with a study that reported inspections often prioritizing general compliance with registration regulations at the expense of antibiotic-specific practices in community pharmacies (Jacobs et al., 2019a). Yet enhancing inspection practices related to antibiotic use is a common theme across multiple studies, which signals the need to address this gap in regulatory oversight functions. Such efforts could be strengthened by the engagement of all stakeholders in antimicrobial stewardship to monitor, influence, guide, and encourage responsive antibiotic use.

The challenges related to inspecting prescription retention in community pharmacies emanated from failure to receive and document prescriptions, particularly after antibiotics issuance by established procedures and regulatory requirements. This shortcoming is evident in prior research (Torres et al., 2020), where incomplete or missing prescription details hindered the

community pharmacies' adherence to prescription retention ability. Based on the testimonies from the participants, this anomaly arose because of various factors, including patients receiving only a single copy of the prescription from healthcare facilities. This practice contravenes the regulatory mandate for pharmacies to maintain a copy for documentation and accountability purposes. (Servia-Dopazo & Figueiras, 2018) reported similar documentation struggles in community pharmacies because hospitals emphasised electronic systems and streamlining the prescription process within the health facilities.

As a result, community pharmacies struggled to receive and ensure proper documentation. Notably, the regulatory body in our study acknowledged this discrepancy, emphasizing the imperative for collaboration between private sectors (community pharmacies) and healthcare institutions to address this issue effectively(Servia-Dopazo & Figueiras, 2018). This observation aligns with previous research underscoring the significance of enhancing cooperation between stakeholders in the healthcare system to bridge the gap between regulatory requirements and practical implementation (Monnier et al., 2019).

The study results further suggest that inspecting inventory management constitutes an essential area during routine inspections. However, inspecting inventory management continued to present a challenge as some pharmacies had no dispensing register or computer system, resulting in incomplete inventory information documentation. In this regard, our study found that inspectors lacked focus in inventory management due to inherent challenges, contrary to a study that established documentation and inventory management practices as critical focus areas during routine inspections (Shrestha & Ghale, 2018). Usually, and as standard practice, inspectors pay close attention to the accuracy and completeness of recorded information to ensure proper record-keeping and inventory management (Jacobs et al., 2019b). In this study, drug dispensers similarly called on pharmacy inspectors to scrutinize medicine registers or inventory systems to verify the proper recording of antibiotics and stock levels. Documentation and inventory management should be a universal concern in regulatory inspections.

Furthermore, the study found that inspectors prioritized checking antibiotic storage conditions to ensure they were not displayed in the over-the-counter area and away from public access. These results coincide with a study conducted in Boston (Ching et al., 2023) that highlighted the significance of designated storage areas for antibiotics, away from direct sunlight and public access, to prevent misuse or unauthorized handling (Badro et al., 2020). This correlation indicates a consensus among studies regarding the importance of proper antibiotic storage practices. One might argue that the conclusions from this study reflect what could be happening in many parts of the country. However, the study results may have limited application to other parts of the nation, considering that the study was conducted in a predominantly urban area (Ilala) of Tanzania's business hub, Dar es Salaam.

The less stringent enforcement of the inspections to regulate prescription handling and antibiotics control in community pharmacies of a readily accessible metropolitan area suggests that the situation in the distant hard-to-reach areas might be much worse. Therefore, a more comprehensive study covering urban and rural settings could further broaden our understanding of the regulation practices for antibiotic prescription and control for even more informed strategies for improving the practices.

Conclusion

This study unveiled challenges to effectively regulating antibiotic prescriptions, notably in prescription retention, inventory management, and oversight of antibiotic sales. These challenges suggest a need for the Pharmacy Council to develop standardized inspection protocols accentuating the critical aspects of prescription handling, including proper storage, prescription retention, and meticulous documentation of antibiotic transactions. This measure could encourage best practices in community pharmacies and enhance compliance with prescription handling regulations.

Furthermore, fostering effective communication between hospital settings and community pharmacies is crucial in aligning practices with prescription handling regulations. Such communication should also facilitate sharing guidelines, including prescription issuance, and ensure consistent adherence to regulatory standards. Implementing these actions can substantially reduce over-the-counter antibiotic sales and dispensing, safeguard public health, and support global efforts to combat antimicrobial resistance.

Data availability

Available on reasonable request

Funding

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Conflict of interest

The authors declare no conflict.

Authors contribution

LC: Conceptualisation of the study, data acquisition, and manuscript drafting. EM and GF: Conceptualised the study, coordinated and supervised data acquisition, and drafted the manuscript. All authors read and approved the final manuscript

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High Mumps virus IgG seropositivity among women with spontaneous abortion attending health care facilities in Mwanza, Tanzania

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Abstract

Introduction: Mumps virus infection is a public health concern mainly in low- and middle-income countries and has been associated with complications such as spontaneous abortion and post-pubertal orchitis that may result in testicular atrophy and, consequently, infertility. Mumps vaccination is not currently implemented in Tanzania, and the data regarding its magnitude is limited, with no data among women with spontaneous abortions.

Objective: This study aimed to determine seropositivity and factors associated with specific mumps virus IgG antibodies among women with spontaneous abortion in Mwanza, Tanzania.

Methodology: From July to August 2022, a laboratory-based analytical cross-sectional study involving 212 sera collected between 2015 and 2019 from women with spontaneous abortions in Mwanza was conducted. Mumps IgG antibodies were detected by an indirect Enzyme-Linked Immunosorbent Assay. Descriptive data analysis was done using Stata version 15.

Results: The median age of enrolled participants was 27 [IQR: 24-32] years. The overall seroprevalence of mumps virus IgG antibodies was 117/212(55.19%) [95% CI: 48.39-61.80]. Being an urban resident (OR: 3.23, 95% CI 1.83-5.96, P= 0.000) and an increase in the number of household members (OR: 1.18, 95% CI: 1.01-1.38, P=0.040) predicted seropositivity of mumps IgG antibodies among women with spontaneous abortion in Mwanza, Tanzania.

Conclusion: More than half of the women with spontaneous abortion live in the urban settings in the city of Mwanza, Tanzania, and those living in houses with a high number of household members are Mumps virus IgG seropositive. More studies on the causal effect relationship between women with spontaneous abortion and mumps virus are warranted.

Keywords: Mumps virus; Spontaneous abortion, Mwanza, Tanzania

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Background

Mumps virus (MuV), the causative agent of mumps is an enveloped Ribonucleic acid (RNA) virus that belongs to the genus Rubulavirus in the family Paramyxoviridae (Hviid *et al.*, 2008). The virus has a 100-600 nm diameter with 15384 nucleotides. The viral genome is in a linear molecule of single-stranded, negative-strand RNA. The genome encodes six structural proteins and two non-structural proteins.(Rubin and Carbone, 2003). Mumps are acquired through contact with the body fluids of infected individuals, such as saliva and nasal secretions. (Hviid *et al.*, 2008, Rubin *et al.*, 2015).

Before the implementation of the immunization program, Mumps was a severe disease that caused significant morbidity and mortality worldwide.(Fields *et al.*, 2019). In the pre-vaccine era, mumps had a high morbidity of approximately 40–726 cases per 100,000 population per year.(Su *et al.*, 2020). In the absence of vaccination, mumps viral infections have been circulating endemically with a periodic spike of two to five years, and a peak incidence of the disease has been among children aged five to seven years old in several regions worldwide(Betakova *et al.*, 2013). Risk groups for MuV infection include unvaccinated individuals and ones living in crowded populations, for example, boarding schools, prisons, refugee camps and orphan houses.

Several risk factors have been reported in mumps infection, including age, exposure, compromised immunity, time of the year, travel, and vaccination status.(Su *et al.*, 2020). Mumps is prevalent among adolescents and adults; however, the disease mainly affects children aged 5–9. Mumps orchitis develops in 14- 35 % of post-pubertal males with mumps (Manson, 1990) while spontaneous abortion, as well as embryonic and fetal death, increase with MuV infection during pregnancy(Lozo *et al.*, 2012). About 20% of women experience spontaneous before 20 weeks, most occurring within the first 12 weeks of gestation.(Lulandala *et al.*, 2017).

By December 2010, 118 out of 193 member states of the World Health Organization (WHO) had included mumps vaccination in their national immunization programs, with the vast majority using the combined measles-mumps-rubella (MMR) vaccine.(Su *et al.*, 2020, Organization, 2012)In countries where large-scale immunization against mumps has been implemented, disease incidence has dropped dramatically.(Organization, 2012). Tanzania is among the countries where mumps vaccination has not been implemented in the national immunization program. Only a few studies documented its magnitude in Tanzania, and it has been reported to be 77% among unvaccinated children in Dar es Salaam.(Buberwa *et al.)* 15.0% among children in Dar es salaam(Minja, 1998b) and 21.4% among school children in Mwanza(Rakiru *et al.*, 2020).

This study aimed to determine seropositivity and factors associated with mumps virus IgG antibodies among women with spontaneous abortion in Mwanza, Tanzania. The generated information helps provide evidence-based policy recommendations.

Materials and methods

Study Design, duration, population and inclusion criteria

A laboratory-based analytical cross-sectional study was conducted from July to August 2022. The study used achieved sera collected from five hospitals in the city of Mwanza region (Bugando Medical Centre, Sekou Toure, Sengerema DDH, Buzuruga and Butimba Hospital) between 2015 and 2019 from women with spontaneous abortion to determine MuV IgG antibodies. All samples with insufficient volume and incomplete sociodemographic data were excluded.

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Data and sample collection
Samples (-80°C storage) were obtained from the CUHAS Microbiology laboratory. Sociodemographic information (study number, age, residency, location, marital status, level of education, occupation, etc.) and clinical data (history of fever, headache, etc.) were extracted from the existing database.

Specimen analysis
Sera were analyzed for mumps virus antibodies using Indirect ELISA test kits per the manufacturer's instructions (Vircell, S.L. Parque Technologico de la Salud, Avicena 8, Granada, Spain). The test kit has a sensitivity of 98% and a specificity of 95%.

Data management and analysis
Laboratory results were recorded in the laboratory logbook and then sorted and transferred into a Microsoft Excel sheet for cleaning and coding. Descriptive data analysis was done using statistical software for data analysis (Stata Corp, Texas-USA, version 15). Proportions were used to summarize categorical variables, including sex, employment, residence, and marital status, while the median (IQR) was used for continuous variables, including age and number of households. Univariable and multivariable logistic regression were used to show factors associated with mumps antibodies, whereby factors with P value <0.2 on Univariable analysis were subjected to multivariable analysis. Odds ratio and 95% confidence intervals were determined, and variables with a P-value of <0.05 were considered statistically significant.

Ethical considerations
Ethical clearance for conducting this study was sought from the CUHAS/BMC research ethics and review committee (CREC) with the CREC/2336/2022 ethical clearance number. The Head of the Microbiology Department and B1 laboratory management sought permission to use the archived samples for this study. Confidentiality information was maintained throughout the study.

Results
Sociodemographic and clinical characteristics
A total of 212 archived samples collected from women with spontaneous abortion in Mwanza were analyzed in this study with a median age of 27 [IQR: 24-32] years. More than half of the participants, 120/212 (56.6%), resided in the urban areas of the city of Mwanza. Most of the participants, 201/212 (94.81%), attained formal education ranging from primary to tertiary education. Moreover, over three-quarters of 176/212 (83.02%) participants were married. The median number of household members for the enrolled participants in this study was 4 [IQR: 3-6] members. 87/212 (41.04%) reported fever, and about one-third, 70/212 (33.02%) reported experiencing headache during pregnancy.

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Table 1: Socio-demographic and clinical characteristics of enrolled participants

Variables/Characteristics		Frequency(n)	Percentage (%)
Median (IQR) age in years		27[24-32]	
Residence	Rural	92	43.4
	Urban	120	56.4
Education	No education	11	5.19
	Primary	124	58.49
	Secondary	58	27.36
	Tertiary	19	8.96
Median [IQR] House hold members		4 [3-6]	
Occupation	House wife	72	33.96
	Peasant	31	14.62
	Self employed	18	8.49
	Business	65	30.66
	Employed	26	12.26
Marital status	Married	176	83.02
	Single	34	16.04
	Widow	27	0.94
Fever	No	125	58.96
	Yes	87	41.04
headache	No	142	66.97
	Yes	70	33.03

Laboratory results

Of 212 participants, 117/212(55.19%) [95% CI: 48.39-61.80] were seropositive for IgG MuV antibodies.

Factors associated with Mumps IgG antibodies seropositivity among women with spontaneous abortion in Mwanza, Tanzania

By univariable logistic regression analysis, an increase in household members (OR: 1.21, 95% CI: 1.06-1.37, P=0.005) was significantly associated with Mumps IgG seropositivity. Being an urban resident (OR: 3.23, 95% CI 1.83-5.96, P= 0.000), being self-employed (OR: 11.07, 95% CL: 2.16-56.76, P=0.04) and being a businesswoman (OR: 2.71, 95% CL: 1.12-6.52, P=0.026) were significantly associated with Mumps IgG seropositivity. By multivariable logistic regression analysis being urban residents (OR: 3.64, 95% CI: 2.01-6.62, P= 0.000) and increase in the number of household members (OR: 1.21, 95% CI: 1.01-1.38, P=0.011) independently predicted Mumps IgG seropositivity among women with spontaneous abortion **(Table 2).**

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Table 2: ***Univariate and multivariate logistic regression analysis on the factors associated with Mumps virus IgG antibodies seropositivity***

Characteristics		Mumps IgG antibodies		Univariable logistic analysis		Multivariable logistic analysis	
		Negative n (%)	Positive n (%)	cOR[95%CI]	P value	aOR[95%CI]	P value
Age				1.04[1.00-1.09]	0.071	1.01 [0.96-1.06]	0.667
N/ household				1.21[1.06-1.37]	0.005	1.21 [1.01-1.38]	0.011
Residence	urban	39 (32.5%)	81 (67.5%)	3.23[1.83-5.96]	0.000	3.64 [2.01-6.62]	0.000
	Rural	56 (60.87%)	36 (39.13%)	1			
Marital status	Married	78 (44.32%)	98 (55.68%)	0.99[0.47-2.078]	0.983		
	Single	15(44.12	19(55.88%)	1			
	Widow	2(100%)	0 (100%)	1			
Education	none	6(54.55%)	5 (45.45%)	0.75[0.17-3.33]	0.705		
	Primary	48(38.71%)	76 (61.29%)	1.43[0.54-3.76]	0.474		
	Secondary	32 (55.17%)	26 (44.83%)	0.73[0.26-2.07]	0.555		
	Tertiary	9 (47.37%)	10(52.63%)	1			
Occupation	h/wife	40 (55.56%)	32 (44.44%)	1.11[0.47-2.59]	0.814	0.91 [0.73-1.12]	P=0.364
	Employed	13 (50%)	13 (50%)	1.38[0.49-3.95]	0.543		
	s/employ	2 (11.11%)	16 (88.89%)	11.07[2.16-56.76]	0.004		
	Business	22 (33.85%)	43 (66.15%)	2.71[1.12-6.52]	0.026		
	Peasant	18 (58.06%)	13(41.94%)	1			
Fever	Yes	38 (43.68%)	49(56.32%)	1.08[0.62-1.87]	0.782		
	No	57 (45.6%)	68(54.4%)	1			
Headache	Yes	32 (45.71%)	38 (54.29%)	0.85[0.49-1.47]	0.556		
	No	63 (44.37%)	79 (55.63%)	1			

Discussion

In efforts to control viral diseases, it is important to understand the magnitude and epidemiology of infectious agents. Here, we report MuV IgG seropositivity among women with spontaneous abortion in Mwanza, Tanzania. More than half of the women in this study were found to be MuV IgG seropositive which is low compared to the previous reports from Tanzania among unvaccinated children and from other studies in Colombia, USA, Turkey and Brazil in an epidemic period, adult population, unvaccinated adolescents and among school-aged children respectively(Santacruz-Sanmartín *et al.*, 2015, Lebo *et al.*,

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2015, Kanbur *et al.*, 2003, Buberwa *et al.*). The possible explanations for these variations could be due to differences in the study population, seasonality, and geographical and climatic conditions. Compared to previous studies in Africa(Rakiru *et al.*, 2018; Minja, 1998a; Doshi *et al.*, 2017), the prevalence reported in the current study is high. The observed difference could be explained by the current research involving adults compared to previous studies focusing on children. As in many other infections, the risk of virus exposure increases as the age increases.

Among the factors assessed in the current study, residing in urban was significantly associated with MuV IgG seropositivity, which is inconsistent with a previous report in Mwanza, Tanzania, among children(Rakiru *et al.*, 2018). This could be explained by the high rate of interactions in urban settings compared to rural settings, which might increase the risk of transmission. Furthermore, this can be partly explained by the high number of participants from urban areas in the current study compared to a previous report.

Moreover, in the current study, MuV IgG seropositivity was significantly associated with an increase in the number of household members, which is in agreement with previous reports in the Democratic Republic of Congo (DRC), Spain and Turkey among unvaccinated children(Doshi *et al.*, 2017, Arroyo *et al.*, 1986, Gurgoze *et al.*, 2006). This could be explained by the fact that as the number of household members increases, the risk of transmission also increases due to overcrowding, which facilitates the transmission of the viruses. However, these findings are different from previous reports in Mwanza and Dar es Salaam (Rakiru *et al.*, 2018, Buberwa *et al.*).

Furthermore, in the current study, we observed more than half of the participants who were seropositive to MuV IgG antibodies had neither a history of fever nor headache, similar to the study done in Mwanza among school-aged children(Rakiru *et al.*, 2018). This can be explained by the fact that mumps is asymptomatic in 20-30% of individuals(FOY *et al.*, 1971).

Limitations of the study

The high seropositivity of Mumps IgG antibodies observed among women with spontaneous abortion is not an indication of active mumps infection. Further studies in the Mwanza region are warranted to establish active infection and causal effect relationships.

Conclusion

This study observed that the seropositivity of MuV IgG antibodies among women with spontaneous abortion in the Mwanza region is high and is predicted by residing in urban areas and an increase in the number of household members. This calls for more prospective studies in the study area and other regions across the country to provide more epidemiological data that might be useful in devising control measures, including introducing the Mumps vaccine in the national Immunization programmes.

Declaration

Ethical approval

Ethical clearance for conducting this study was sought from the CUHAS/BMC research ethics and review committee (CREC), with ethical clearance number CREC/2336/2022. The Head of the Microbiology Department and B1 laboratory management sought permission to use the archived samples for this study. Confidentiality was maintained throughout the study.

Consent for publication: Not applicable

Availability of data and material: All data generated/ analyzed during this study are included in this manuscript

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Authors contributions

HN and MMM participated in designing the study. EGK, HN, EC, FM, PS, and BM participated in data/sample curation. EGK, HN, EC, FM, PS, and BM participated in laboratory analysis of samples. MMM and SEM analysed data, and DK, MM, and AEC participated in data interpretation. MMM and EGK wrote the first draft of the manuscript. SEM, MM and MM did the critical review of the manuscript. All authors approved the last version of the manuscript

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List of Abbreviation

BMC	Bugando Medical Center
CUHAS	Catholic University of Health and Allied Sciences
ELISA	Enzyme-Linked Immunosorbent Assay
IgG	Immunoglobulin G
IgM	Immunoglobulin M
MMR	Measles-Mumps-Rubella
RNA	Ribonucleic Acid
RT-PCR	Reverse Transcriptase Polymerase Chain Reaction
WHO	World Health Organization

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Understanding Implementers' Perceptions on the Prime Vendor System: A Case Study of Tanzania Mainland

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Abstract

Introduction: Access to safe, effective, quality and affordable essential medicines for all is a central component of Universal Health Coverage (UHC). However, the availability of quality medicines in low and middle-income countries is often limited, especially in peripheral health facilities. MSD, as the sole supplier of drugs and medical supplies to all public health facilities, has been facing difficulties that hinder its efficiency in supplying 100% of all facility's needs. Despite significant reforms, including introducing the Prime Vendor System in 2018, challenges persist, leading to regional disparities in commodity availability at the facility level. Successfully establishing an intervention based on PPPs within the public sector in the health commodities supply chain system mostly requires high acceptability by the Government, implementers, and beneficiaries. Furthermore, the effectiveness of any activity is primarily influenced by the participants' attitudes. While most studies have extensively researched the effectiveness of the prime vendor system in bridging the supply chain gap, none have researched implementers' perceptions of the prime vendor system in complementing health commodities. This study seeks to understand the Implementer's perceptions of the prime vendor system implementation.

Materials and Methods: This was a quantitative cross-sectional study. Data was collected from June to September 2023 using the ODK application from 356 respondents from Dodoma, Morogoro, Mtwara, and Mwanza in Tanzania. The data was analysed using SAS version 9.4. Statistical significance was determined at a 95% confidence level.

Results: 77.84% of study participants strongly agreed that involving the private sector in health commodities supply chain management is the best approach to solving supply chain problems. Additionally, 81.53% of all study participants believe that the Prime Vendor System has contributed positively to the improved availability of health commodities at the facility level.

Conclusion: Perceptions regarding the prime vendor system vary across different areas, including its impact on the overall availability of health commodities, streamlining of procurement processes, and the role of the private sector in addressing supply chain challenges within the country. Notably, the level of experience in the workplace emerges as a considerable influence on respondents' perceptions regarding the Prime Vendor System and its implementation nationwide.

Keywords: Prime Vendor System, perception, implementer

Introduction

Access to safe, adequate, quality, and affordable essential medicines for all is a central component of Universal Health Coverage (UHC). However, the availability of quality medicines in low and middle-

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income countries is often limited, especially in peripheral health facilities (Kuwawenaruwa et al., 2020). The availability of medicines and medical equipment is a significant indicator of the quality of health care for most people in the country (Tanzanian-German Programme to Support Health, 2011). However, shortages and stock-outs of medicines are persistent problems in delivering health services in Tanzania.

According to The National Health Policy of 2017, its main objective is to reach all households with essential services to attain the needs of the population, adhering to objective quality standards and applying evidence-informed interventions through resilient systems for health, precisely adequate and accessible quality medicines and health commodities which necessitate proper system supply of medicines and health commodities to health facilities (MoHSW, 2017).

The Medical Stores Department (MSD) was established by Act of Parliament no. 13 of 1993 as an autonomous department under the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) responsible for developing, maintaining, and managing an efficient and cost-effective system of procurement, storage, and distribution of approved medicines and medical supplies required for use by all public health facilities.

MSD, as the sole supplier of medicines and medical supplies to all public health facilities, has been facing difficulties that hinder its efficiency in supplying 100% of all facility's needs (HRSC-2017). Challenges like inaccurate forecasting of medicines needed at facility levels and ineffective systems for fulfilling back-ordered items, so alternative strategies were needed to fill the gap (Kuwawenaruwa et al., 2021).

In Tanzania, the Public Supply Chain System for Health Commodities has evolved from a push system to a pull system. The introduction of the prime vendor system in 20218 complemented all health commodities out of stock and reduced the burden from MSD. Observation shows that continuous monitoring implementation of the prime vendor system in piloted regions revealed that the complementary prime vendor system has effectively increased the availability of essential medicines in public health facilities. Improving commodity availability was the main criterion in 2018. The Government decided to roll out the prime vendor system to all 26 regions of Tanzania's mainland (Wiedenmayer et al., 2019) (Kuwawenaruwa et al., 2020).

Therefore, it is evident that the pharmaceutical supply chain system in these countries has attracted substantial attention focusing on health system strengthening, specifically targeting options of redesigning and optimising the supply chain's performance (Kuwawenaruwa et al., 2021) (Kuwawenaruwa et al., 2020) and (USAID, 2015). Such interventions include expanding funding sources, staff training and re-training, improving supply chain procurement and distribution processes, promoting the responsible use of commodities, and improving data visibility and utilization to make well-informed decisions.

Furthermore, the effectiveness of any activity is primarily influenced by the participants' attitudes. While most studies have extensively examined the impact and effectiveness of the prime vendor system on health commodities availability, few of them have researched Understanding implementers' perceptions of prime vendor system implementation. This study seeks to understand implementers' perceptions of the fidelity of implementing the prime vendor system in Tanzania's Mainland.

Materials and Methodology

Study Design

The research adopts a quantitative cross-sectional design, focusing on four regions on the mainland of Tanzania: Dodoma, Morogoro, Mtwara, and Mwanza. Within these regions, the study encompasses thirteen diverse local government authorities, including Dodoma (Dodoma City Council, Kondoa District Council, Kongwa District Council), Morogoro (Morogoro Municipal Council, Mvomero District Council, Kilosa District Council), Mtwara (Mtwara District Council, Mtwara Municipal Council, Newala Town Council, Masasi District Council), and Mwanza (Magu District Council, Nyamagana District Council, Ukerewe District Council).

Study Population

The study population consisted of purposively selected members from various levels of the health facilities. The population included healthcare workers directly involved in the health commodities supply chain at their facility level and their crucial role in implementing the Prime Vendor system in Tanzania, such as Health facilities in charge, Storekeepers/ Pharmaceutical personnel, and Laboratory personnel per Health facility level.

Sample Size and Sampling

The sample size for this study was determined using Yamane's formula (1967), which considers the study population, marginal error, and confidence level. With a total study population (N) of 3,203 individuals and a chosen marginal error (e) of 0.05, the calculated sample size (n) is 356. Applying the formula, $n = N/ [1 + N (e)^2]$, the calculated sample size (n) is 356. Regarding sampling strategy, regions were purposively selected based on their relevance to the research objectives, including regions with and without medical store department zonal offices and regions with facilities with high health commodity consumption rates. From these regions, councils were chosen randomly, ensuring the representation of rural and urban settings to capture diverse perspectives. This random selection of councils enhances the study's representativeness.

Facilities and individuals were also randomly chosen within these councils, contributing to the inclusivity and generalizability of the study findings. This comprehensive approach ensures that a wide range of experiences and characteristics are represented within the selected regions and councils, thereby improving the validity and reliability of the research outcomes.

Study Approach

The study employed a quantitative research approach. Before data collection, informed consent was obtained, and strict confidentiality protocols were followed. Ethical clearance was secured from the University of Dodoma's Institutional Review Board.

Data collection and data processing

In May 2023, enumerators were trained for three days to ensure the tools' validity, followed by piloting/pre-testing at Chamwino District Council Hospital, Mlowa Barabarani Health Centre, and Manzase Dispensary.

A face-to-face interview was conducted from June to September 2023 with all purposefully selected respondents using a guided and constructive questionnaire containing both open-ended and closed-ended questions. All quantitative data was 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.

At the end of each data collection day, the data collectors compared the written records with the listening to the voice records. The necessary corrections were made to the typed documents before submitting the electronic data for that day to the supervisor.

Dependent variable

The dependent variable of this study was obtained from a set of thirteen 13 questions that were measured. Each of them had a response indicating whether they strongly disagreed, disagreed, neutral, agreed, or strongly Agreed. Those questions were divided into four areas: the Prime vendor system operational structure, Procurement Procedures under the Prime Vendor System, Managerial and authorisation under the Prime Vendor System, and the Transition period in the Prime Vendor System. The mean score was calculated from those sets of questions; the score had a possible minimum value of 0 and a possible maximum score of 5. The score was then categorised into two categories. Those respondents who scored three or less were coded 0 and regarded to have a negative perception, while those who scored 4 or 5 were coded one and regarded to have a positive perception.

Independent Variables

The independent variables in this study encompass numerous factors: demographic indicators such as sex, age, and education level; professional attributes such as position within the health facility and years of experience; and contextual elements including the type of health facility, region, and mobility-related factors. The study aimed to gain insights into the perceptions and various influencing factors among users of the prime vendor system in this context, thereby gaining a comprehensive understanding of the various regions and local authorities.

Data Analysis

In explaining the baseline information of the respondents, fundamental descriptive statistics, including frequencies and percentages for categorical variables and means and standard deviation for non-categorical variables, were computed. Given that the outcome variable had two categories (0=Negative, 1=Positive), A binary logistic regression model was used to assess factors associated with the perception of implementers on the prime vendor system. The model results are regression parameter estimates and odds ratios (OR). The data analysis was conducted using SAS version 9.4, and the significance of all statistical tests was established at a 5% significance level.

Ethical Considerations

The University of Dodoma Ethics Committee granted ethical approval and registration for the study. In addition, The President's Office, Regional Administration and Local Government, and the Ministry of Health in Tanzania granted permission for access to all facilities supporting/implementing the Prime Vendor System within the Regional Secretariat and Local Government Authorities as well as four regional referral hospitals (Mwanza, Dodoma, Morogoro, and Mtwara). Finally, informed consent was obtained from respondents during data collection, and confidentiality was maintained throughout the study.

Results

The study was conducted in all four regions: Dodoma, Morogoro, Mtwara, and Mwanza. A total of 356 respondents were interviewed from health facilities visited; vast numbers of respondents are from Mwanza (27.81%) and Morogoro (27.81%), followed by Mtwara (26.40%) and with a few participants from Dodoma (17.98%).

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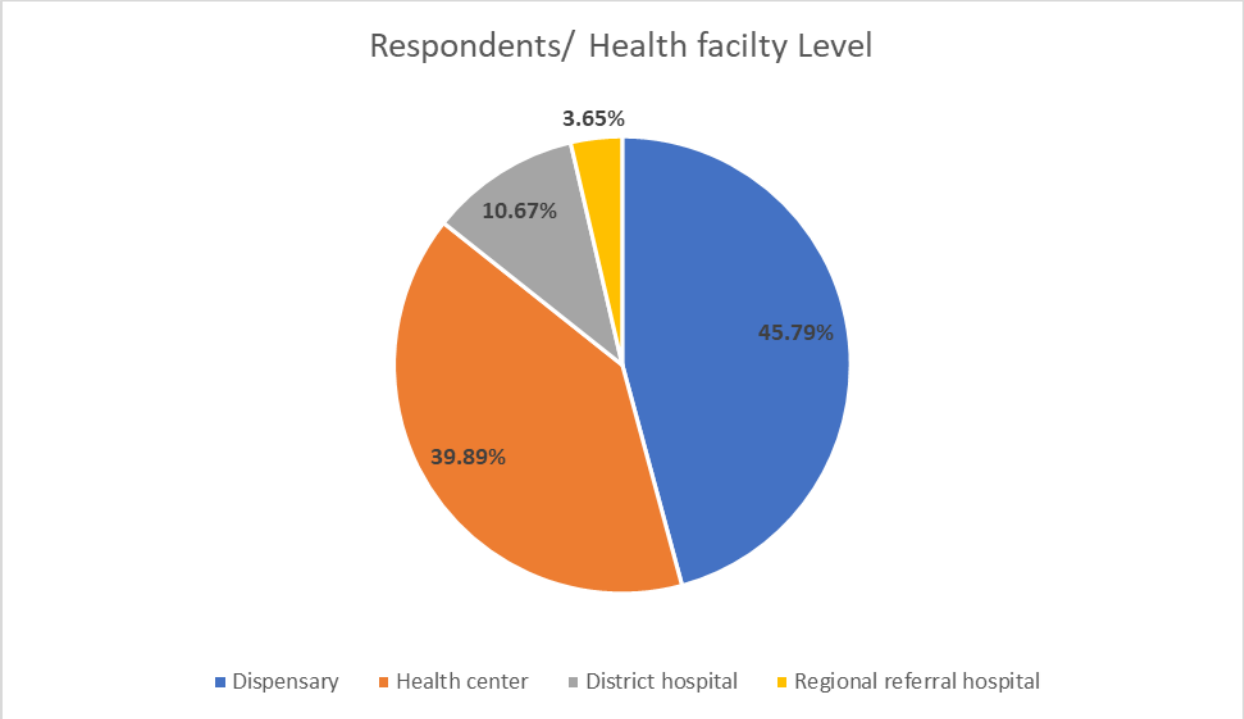
In Tanzania, there is a decline in health facilities when transitioning from lower to upper levels. This trend was particularly evident in my study, where a significant portion of the visited health facilities were dispensaries, in contrast to the Regional Referral Health facilities. This pattern is also mirrored in the distribution of respondents from our results, with the majority coming from dispensaries (45.79%) and health centres (39.89%). A smaller percentage of participants were associated with District hospitals (10.67%), and the least were from Regional Referral Hospitals (3.65%).

Figure 1: Respondents Interviewed per Health Facility Level



Demographic Results of Respondents

All 356 intended respondents (100% of the sample) participated throughout the data collection process. Notably, a substantial proportion of the participants were females, accounting for 181 (50.84%), while males constituted 175 (49.16%) in the study. Most respondents fell within the 30-34 age range, comprising 33.71% of the total. Subsequently, individuals aged 35-39 constituted 20.79%, and those above 45 accounted for 19.10%. In contrast, a smaller % of participants, 8.71%, belonged to the 40-44 age group.

During data collection, we aimed to interview the Health Facility in charge, the storekeeper, and Laboratory personnel at each health facility. The findings across all visited health facilities revealed that 41.85% were Health Facility In charge, followed by Storekeepers at 32.58%. A smaller percentage, 25.56%, represented Laboratory personnel, as many of the observed dispensaries lacked standard laboratories. The results noted that most respondents had no upper level of education; only 3.37% had a master's degree, 14.61% had a first-degree mean, 55.06% had a diploma, and 26.97% had a certificate (See Table 1).

Table 1: Demographic results

Demographic Results			
Variable	**Frequency**	**Percentage (%)**	**Mean ±SD**
Sex			
Male	181	50.84	
Female	175	49.16	
Total	**356**	**100.00**	
Age category			36.74±8.33
<30	63	17.70	
30-34	120	33.71	
35-39	74	20.79	
40-44	31	8.71	
45+	68	19.10	
Education level			
Certificate	96	26.97	
Diploma	196	55.06	
Degree	52	14.61	
Master	12	3.37	
Position in this health facility			
The Health Facility In charge	149	41.85	
Storekeeper/ Store In – Charge	116	32.58	
Laboratory Personnel	91	25.56	

General Information of respondents

Table 2 shows that among the interviewed respondents, the majority had 5 – 9 years (40.17%) of experience as government officials working as healthcare workers. Half of the interviewed respondents (59.27%) had transferred from one working station to another during their working period. Most transferred once (56.40%) or twice (22.27%), while 40.73% had never transferred to any station since their employment.

Table 2: General Information of respondents Interviewed.

General Information of Respondents			
Variable	**Frequency**	**Percentage (%)**	**Mean ±SD**
Experience			9.72±7.30
<5	66	18.54	
5-9	143	40.17	
10-14	85	23.88	
15+	62	17.42	
She was never transferred from one working station.			
No	145	40.73	
Yes	211	59.27	
How many Times? (n=211)			
1	119	56.40	
2	47	22.27	
3	17	8.06	
4	28	13.27	

Throughout the data collection process, the study aimed to assess implementers' perceptions of the Prime Vendor system; we used the Likert scale to measure implementers' perceptions of various aspects: the prime vendor system's operational structure, procurement, procurement procedures

under the prime vendor system, Managerial and authorisation under the prime vendor system, and Transition period. All these aspects will conclude how the implementers perceive the prime vendor system and the factors that drive their influence.

The perception of implementer on Prime Vendor System operational structure

From the Table below. Most prime vendor systems are perceived positively in the prime vendor structure. 77.84% of respondents strongly agreed that involving the private sector (for example, prime vendor) was the best approach to solving problems in the supply chain, and 81.53% of respondents agreed that the prime vendor system contributed to an increase in the availability of health commodities.

Additionally, 80.97% of respondents strongly agreed that since establishing the prime vendor system, the community/clients have built trust and started to seek health services at public health facilities. All respondents strongly agreed that the structure of the prime vendor system enables the reduction of all bureaucratic activities, making the supply chain system smooth and transparent (78.98%) and reducing unnecessary use of funds (54.26%). When asked if the availability of huge debts from health facilities to the prime vendor could affect its performance, half of the respondents (58.52%) strongly agreed that that factor could probably cause the prime vendor's sometimes poor performance.

Table 3: Perception of implementors on Prime vendor system operational structure

Variable	1	2	3	4	5
Involving the Private sector in the supply chain and establishing a Prime vendor is the best approach to solving problems in the supply chain and increasing the availability of medicines.	16(4.55)	17(4.83)	10(2.84)	35(9.94)	274(77.84)
The establishment of prime vendors in various regions has contributed to the availability of health commodities.	6(1.70)	6(1.70)	11(3.13)	42(11.93)	287(81.53)
Since establishing the Prime vendor system, the community/clients have built trust and returned to the health facility.	5(1.42)	7(1.99)	14(3.98)	41(11.65)	285(80.97)
The Prime vendor system cut down all Bureaucratic activities and has made the process of procuring health commodities smooth and transparent	1(0.28)	4(1.14)	28(7.95)	41(11.65)	278(78.98)
The existence of PVS has reduced unnecessary use of Funds	12(3.41)	32(9.09)	59(16.76)	58(16.48)	191(54.26)
Huge debts from health facilities affect the performance of Prime vendor System	23(6.53)	20(5.68)	35(9.94)	68(19.32)	206(58.52)

Note: 1 – Strongly Disagree, 2 – Disagree, 3 – Neutral, 4 – Agree and 5 – Strongly Agree

The perception of Implementers on procurement procedures under the Prime Vendor system

During the study, we wanted to see respondents' perception of procurement procedures under the prime vendor system: The majority of the respondents, 169(48.01%), preferred the prime vendor system rather than the quotation system for the procurement of health commodities at public health facilities, 166(47.16%) strongly disagree that there are times health facility procure outside the prime vendor system when they face out of stock from medical store departments.

Additionally, most respondents believed that the prime vendor system was performing well in the procurement process: 112(31.82%) strongly agreed that the prime vendor could deliver health commodities within the agreed lead time. It confirmed that the health facilities could pay the prime vendor for health commodities within the agreed time.

Table 4: Perception of Implementors on Procurement Procedures under the PVS

Variable	1	2	3	4	5
Health facilities prefer the Prime vendor system more than the Quotation system for the procurement of health commodities	22(6.25)	33(9.38)	97(27.56)	31(8.81)	169(48.01)
At times, health facilities tend to purchase Health commodities from outside the prime vendor system	166(47.16)	74(21.02)	25(7.10)	47(13.35)	40(11.36)
The PV has been able to deliver Health commodities within the agreed lead time	26(7.39)	68(19.32)	60(17.05)	86(24.43)	112(31.82)
Health facilities can pay for the health commodities to the PV within the agreed timeline	6(1.70)	35(9.94)	80(22.73)	87(24.72)	144(40.91)

Note: 1 – Strongly Disagree, 2 – Disagree, 3 – Neutral, 4 – Agree and 5 – Strongly Agree

Implementers' perceptions of the Prime vendor system's managerial, authorisation, and transition aspects.

Half of the respondents firmly (192, 54.55%) said that the council Health service board/Council coordination committee supports them regarding all matters of the prime vendor system. Additionally, 199(72.73%) strongly agreed that having more than one prime vendor is the best approach to improving the availability of medicines at our health facilities.

Table 5: Perception of Implementers on managerial and authorisation of prime vendor system and transition of Prime vendor system

Variable	1	2	3	4	5
Managerial and authorisation of the Prime vendor system					
The Council Health Service Board/ Council Coordination Committee supports you on all matters regarding the Prime vendor system	6(1.70)	3(0.85)	92(26.14)	59(16.76)	192(54.55)
The transition period in PVS					
Having more than one Prime vendor is the best approach in improving the availability of medicines at Health facility	9(2.56)	7(1.99)	44(12.50)	36(10.23)	256(72.73)

Note: 1 – Strongly Disagree, 2 – Disagree, 3 – Neutral, 4 – Agree and 5 – Strongly Agree

Factors associated with the perception of implementers on Prime Vendor System

As presented in the methodological section, binary logistic regression was used to assess factors associated with the perception of implementers on prime vendor system results in Table 5. It was observed that the perception of implementers on the prime vendor system was significantly associated with years of experience (p=0.0012), region (p=0.0013), and knowledge (p=0.0109). Concerning years of experience, it was shown that implementers who had 5 to 9 years of experience were significantly more likely to have positive perceptions on prime vender system as compared to those with experience of less than five years (AOR=3.29, p=0.0012), the same those who had 10 to 14 years of experience, whereby those respondents who had 10 to 14 years of experience were significantly more likely to have positive perceptions on prime vender system as compared to these with less than five years (AOR=2.74, p=0.0258).

Regarding region, those respondents from Dodoma were significantly more likely to have positive perceptions of the prime vendor system as compared to these from Mwanza (AOR=3.46, p=0.0013), and those implementers from Morogoro were significantly more likely to have positive perceptions of prime vendor system as compared to these from Mwanza (AOR=2.13, p=0.0193). Concerning respondents' knowledge with adequate knowledge, they were significantly more likely to have positive attitudes than those with inadequate knowledge (AOR=1.86, p=0.0109). Other factors like respondents' sex, age, education level, position in the health facility, type of health facility, and ever transferred from one facility to another were not significantly associated with the perception of implementers on the prime vendor system (Table 6).

Table 6: Binary logistic regression for factors associated with the perception of implementers on the prime vendor system.

Variable	Negative	Positive	Unadjusted analysis		Adjusted analysis	
	n (%)	n (%)	OR [95%CI]	p-value	AOR [95%CI]	p-value
Sex						
Male	67(36.61)	116(63.39)	1.03[0.67, 1.59]	0.8971		
Female	63(37.28)	106(62.72)	ref			
Age category						
<30	29(46.77)	33(53.23)	ref		Ref	
30-34	47(38.84)	74(61.16)	1.38[0.75, 2.57]	0.3035	0.97[0.48, 1.95]	0.9236
35-39	19(27.14)	51(72.86)	2.36[1.14, 4.87]	0.0205	1.43[0.60, 3.41]	0.4151
40-44	13(41.94)	18(58.06)	1.22[0.51, 2.91]	0.6586	0.73[0.25, 2.15]	0.5641
45+	22(32.35)	46(67.65)	1.84[0.90, 3.75]	0.094	1.38[0.51, 3.74]	0.5293
Education level						
Certificate	40(43.01)	53(56.99)	ref		Ref	
Diploma	70(36.08)	124(63.92)	1.34[0.81, 2.21]	0.2591	1.04[0.60, 1.81]	0.8882
Degree	15(28.85)	37(71.15)	1.86[0.90, 3.85]	0.0939	2.01[0.89, 4.57]	0.0936
Master	5(38.46)	8(61.54)	1.21[0.37, 3.97]	0.7562	1.25[0.34, 4.56]	0.7314
Position in the health facility						
In charge	50(33.33)	100(66.67)	ref			
Laboratory	45(39.13)	70(60.87)	1.29[0.78, 2.13]	0.3298		
Storekeeper	35(40.23)	52(59.77)	0.96[0.54, 1.69]	0.8743		
Experience						
<5	35(52.24)	32(47.76)	ref		ref	
For 5 – 9	44(31.43)	96(68.57)	2.39[1.31, 4.34]	0.0043	3.29[1.59, 6.75]	0.0012
For 10 -14	29(35.37)	53(64.63)	1.99[1.03, 3.87]	0.0395	2.74[1.13, 6.66]	0.0258
15+	22(34.92)	41(65.08)	2.04[1.01, 4.13]	0.048	2.34[0.83, 6.59]	0.1062
Type of health facility						
Dispensary	66(41.25)	94(58.75)	ref			
Health center	49(34.27)	94(65.73)	1.35[0.84, 2.15]	0.2116		
District hospital	13(33.33)	26(66.67)	1.40[0.67, 2.93]	0.3662		
RR hospital	2(20.00)	8(80.00)	2.81[0.58, 13.7]	0.2005		
Region						
Dodoma	16(24.62)	49(75.38)	2.76[1.38, 5.51]	0.0039	3.46[1.63, 7.35]	0.0013
Morogoro	27(28.13)	69(71.88)	2.31[1.27, 4.19]	0.0061	2.13[1.13, 4.02]	0.0193
Mtwara	41(43.62)	53(56.38)	1.17[0.66, 2.06]	0.5976	1.29[0.69, 2.38]	0.4175
Mwanza	46(47.42)	51(52.58)	ref		ref	
Ever transferred						
No	58(39.19)	90(60.81)	ref			
Yes	72(35.29)	132(64.71)	1.18[0.76, 1.83]	0.455		
Knowledge						
Inadequate	68(44.74)	84(55.26)	ref		ref	
Adequate	62(31.00)	138(69.00)	1.80[1.16, 2.79]	0.0084	1.86[1.15, 3.01]	**0.0109**

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Discussion

Following the nationwide implementation of the prime vendor system in Tanzania, there has been a notable increase in the availability of health commodities at healthcare facilities, leading to greater transparency and visibility within the supply chain system. Despite the positive impact observed in the supply chain, it became necessary to evaluate the perceptions of implementers regarding various aspects of the prime vendor system. This evaluation encompassed operational structure, procurement procedures, managerial and authorization processes, and the transition to the prime vendor system.

Operation structure: Most respondents strongly agreed with the best operational structure of the prime vendor system, which they perceive as a complementary system of the medical store department. Respondents noted that since the national rollout of prime vendors, the availability of health commodities has increased, and both respondents strongly agreed with that. This confirms that the prime vendor system is the best approach to filling the gap in stock from the Medical Store. However, some factors can hinder the performance of the prime vendor, such as huge debts from health facilities, and this was confirmed by 52.58% of respondents who firmly agreed with that statement. The challenge of huge debts from health facilities still exists in some areas that affect the performance of the prime vendor, but this issue was not much assessed during this study.

Procurement procedures: The study found that most implementers, specifically 48.01% who strongly agreed, favoured the prime vendor system over the quotation method. This preference stemmed from several factors, including the lengthy steps involved in the quotation method, lack of transparency within the system, non-standardized pricing leading to procurement uncertainties, and concerns about potential audit issues while using the quotation method. Also, 31.82% strongly agreed that all consignments from the prime vendor were delivered within the agreed time, and 40.91% of respondents strongly agreed that they could pay the prime vendor whenever they ordered.

This confirms that the prime vendor system procurement procedures are transparent and dependable in improving the performance of the supply chain. Despite many respondents affirming their ability to pay for health commodities, complaints regarding outstanding debts from health facilities persist. Additionally, prices of certain health commodities through the prime vendor system are notably higher than those offered by the Medical Stores department. The paper-based system poses challenges for implementers, adding to the complexity of procurement processes within the prime vendor system. Furthermore, a lack of education among some implementers remains a significant challenge, hindering their effective system utilisation.

Managerial, authorisation and transition of Prime vendor system: 54.55% of respondents strongly agreed that the council, including the CHMTs, offers support whenever challenges arise while using the prime vendor system. At the district level, district pharmacists and district laboratory technologists are regarded as pivotal figures within the prime vendor system. Furthermore, 72.75% strongly agreed that having more than one regional prime vendor optimises the system's performance. Respondents highlighted that this approach alleviates the distribution burden on individual regional prime vendors and reduces the lead time for delivering health commodities.

Factors associated with the perception of implementers of the Prime Vendor System: Several factors are reported to influence the implementation of the Prime Vendor System, including good governance, contract management and compliance with prime vendors, acceptability of intervention by implementers in the regions and councils, and implementers' knowledge of the scheme.

However, this study found that evaluating the characteristics of implementers at a personal level, age, and years of experience positively impacts implementers' perceptions of the central supplier system. Nonetheless, the literature suggests that providing internal and external support to the PVS from the conception of the initial idea up to the implementation level is very crucial to meeting the required objectives as far as supply chain management and availability of health commodities are concerned (Ghana Ministry of health, 2012), (Kuwawenaruwa et al., 2020 and 2021).

Moreover, it is being reported that the careful selection of prime vendors is mandatory to ensure effective implementation of the system to meet its intended objectives, the major one being increased availability of health commodities for uninterrupted health service delivery at the points of care (Mathew et al., 2013) and (Shayo, 2021).

Conclusion

Perceptions regarding the prime vendor system vary across different areas, including its impact on the overall availability of health commodities, streamlining of procurement processes, and the role of the private sector in addressing supply chain challenges within the country. Notably, the workplace experience level significantly influences respondents' perceptions regarding the Prime Vendor System and its implementation nationwide.

List of Abbreviations

CHMT	Council Health Management Teams
CMTs	Council Management Teams
DHIS2	District Health Information System
eLMIS	electronic Logistics Management Information System
ERP	Enterprise Resource Planning
GPS	Global Positioning System
ILS	Integrated Logistics System
IMPACT	Information Mobilized for Performance Analysis and Continuous Transformation
IRB	Institutional Review Board
MoH	Ministry of Health
MSD	Medical Stores Department
ODK	Open Data Kit
PORALG	President's Office Regional Administration and Local Government
PVS	Prime Vendor System
RHMT	Regional Health Management Teams
RS	Regional Secretary
SAS	Statistical Analysis Software
TMDA	Tanzania Medicines and Medical Devices Authority

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Authors contributions
MM developed the proposal and study design and participated in planning, data collection, and interpretation. MM was the principal investigator in all four regions visited and supervised the data collection process. MM contributed to the training and management of data collection. Research Assistants managed data entry and data analysis. RM and MM supported planning and organising logistics. MM drafted the manuscript for input by the other authors. All authors read and approved the final manuscript.

Competing interests
The authors declare that they have no competing interests.

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Retrospective Study of Epidemiological Profiles of Cardiorespiratory Pathologies Before and After the Covid-19 Era at Kenitra Provincial Hospital, Morocco

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Abstract
Background: The present study aims to assess the impact of COVID-19 on the epidemiological profile of circulatory, respiratory, and haematological pathologies at the provincial Hospital of Kenitra, Morocco, utilizing a before-and-after comparative approach.
Methods: This work consists of a retrospective investigation involving 13,067 cases (excluding cases related to COVID-19) admitted to the provincial hospital of Kenitra between January 1, 2017, and April 30, 2022.
Results: The findings revealed a substantial reduction in the overall number of consultations, decreasing from 11,956 consultations before the emergence of COVID-19 to 1,111 consultations afterwards, indicating a 90% decline. Furthermore, there was a notable shift in the gender distribution for respiratory diseases, transitioning from a male predominance with a sex ratio of 2.03 before the COVID-19 pandemic to a female predominance with a sex ratio of 0.83 post-pandemic. Regarding age group distribution, no significant difference was observed between before and after Covid-19. A comparison of the duration of hospital stays before and after Covid-19 pandemic revealed a notable decrease in respiratory ($t = 4.96$; $p < 0.001$) and haematological ($t = 3.62$; $p < 0.001$) pathologies, with no significant difference for circulatory pathologies. Before COVID-19, patients with circulatory pathologies had a twofold higher risk of mortality compared to other patients, whereas respiratory patients faced a three times higher risk of death. No significant risk of death was associated with haematological pathologies. Following the COVID-19 pandemic, the mortality risk increased for respiratory pathologies but decreased for circulatory pathologies. The risk of mortality for haematological pathologies remained insignificant.
Conclusion: the COVID-19 pandemic substantially impacted the epidemiological profile of circulatory, respiratory, and haematological pathologies.

Keywords: Covid-19, Epidemiological profile, Risk of Mortality, Hospitalization, Morocco.

Introduction

The COVID-19 pandemic, caused by the SARS-CoV-2 coronavirus first identified in China in December 2019 (World Health Organization, 2021), swiftly spread across the globe (Lai *et al.*, 2020). Faced with this global health crisis, governments worldwide initiated management plans to mitigate the transmission of SARS-CoV-2 by adopting countermeasures such as physical distancing, banning mass

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gatherings, shutting down transportation, and closing extensive community facilities. According to Morocco's National Response to the COVID-19 Pandemic: Public Health Challenges and Lessons Learned, in Morocco, since the declaration of the first COVID-19 case in March 2020, the government has integrated itself into this operation by closing borders, limiting social interactions, and creating Covid-19 isolation rooms in hospitals (Barkia *et al.*, 2021). The impact of the pandemic in Morocco has been less profound, with only 1,274,180 confirmed cases and 16,297 deaths reported (MHSP., 2023).

The spread of the coronavirus disrupted healthcare systems worldwide, forcing countries to cope with the contagion while maintaining the integrity of their healthcare systems. Hospitals faced immense pressure to balance the ongoing healthcare needs of their communities with the additional burden of Covid-19 cases, necessitating a shift in care priorities. Healthcare facility preparedness is a critical element in responding to the Covid-19 pandemic. It was crucial to ensure appropriate space, supplies, and staffing, prioritize care, activate triage procedures, and provide training for staff in infection prevention, control, and Covid-19 clinical management (Baum *et al.*, 2020). Previous studies reported the impact of Covid-19 on the total number of hospitalizations, consultations, and fewer patients visiting the emergency room. For instance, Baum *et al.* (2020) discussed a 41% decline in hospital admissions in the United States due to emergencies in the first 16 weeks of 2020 compared to the same period in 2019. In Germany, the number of patients admitted to the emergency room declined by approximately 30% from February to April 2020 (Tschaikowsky *et al.*, 2020), and in Guinee, by approximately 71,1 % from March to April 2020 (Barry *et al.*, 2021). The results of a survey in Morocco on the impact of COVID-19 on ophthalmology consultation activity show that most ophthalmologists report a 90% drop in the number of consultations compared with their usual activity (Shamil *et al.*, 2020).

In Morocco, the pandemic strained healthcare systems and disrupted the supply and accessibility to healthcare (Ababsa and Aouissi, 2020; WHO, 2023). In response to this situation, the Moroccan government has taken steps to adapt the provision of hospital care to align with the prevailing circumstances. The Provincial Hospital of Kenitra was designated a COVID-19 treatment centre, admitting patients with COVID-19-related illnesses requiring hospitalization. Moreover, most Moroccan hospitals established COVID-19 isolation units, and most hospital beds were designated for Covid-19 cases.

In this context, this study aimed to assess the impact of the COVID-19 pandemic on the epidemiological profiles of circulatory, respiratory, and haematological pathologies at the Provincial Hospital of Kenitra through a comparative analysis before and after the pandemic. This attempt tried to answer the following questions: (i) What are the changes in epidemiological profiles before and after the COVID-19 Era? (ii) How did the haemo-cardio-respiratory pathologies feature during the pandemic? and (iii) Is the "before-and-after comparison" approach enough to investigate trends of epidemiological profiles caused by the COVID-19 countermeasures?

Methods

Study design and population: The present research comprises a retrospective investigation encompassing 13,067 cases admitted to the Provincial Hospital of Kenitra between January 1, 2017, and April 30, 2022.

Study variables:

The study focused on various variables, including pathology-related variables such as the type of pathology and the duration of hospitalization, patient-related factors like age and gender, and outcome variables related explicitly to mortality. The admission period was categorized into two phases: before COVID-19 (spanning from January 1, 2017, to March 1, 2020) and after the onset of COVID-19 (from March 2, 2020, to April 30, 2022). Notably, the investigation concentrated on circulatory, respiratory, and haematological pathologies directly associated with Covid-19.

Inclusion and exclusion criteria:

- Inclusion criteria:
    - patients admitted to the Provincial Hospital of Kenitra from January 1, 2017 to April 30,

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2022
    - patients residing in the province of Kenitra
- Exclusion criteria:
    - patients admitted to the Provincial Hospital of Kenitra before January 1, 2017
    - patients admitted to the Provincial Hospital of Kenitra after April 30, 2022
    - patients not residing in the province of Kenitra

Study area: The study site, the Provincial Hospital of Kenitra, situated in the city of Kenitra in North West Morocco, represents one of the country's largest hospitals. The Province of Kenitra encompasses an area of 3,052 km² with a population of 1,061,435 (High Commission for Planning of Morocco, 2023).

Data collection and Ethical considerations

After being informed about the purpose and duration of the study and how data will be collected, the Provincial Hospital of Kenitra administration authorized us to use the data contained in the patient care charts with full respect to the confidentiality of the information and patients' anonymity. Data collection was carried out from January to April 2022. The ethical approval was obtained on December 15th, 2021, at the level of the Biology department of Kenitra University, where the present work was done.

Data analysis

For qualitative variables such as gender, pathologies, and mortality, data were presented as numbers and percentages. In contrast, for quantitative variables like length of hospital stay and age, mean ± standard deviation was employed. The association between qualitative variables was assessed using the Chi-square test. To compare the means of length of hospital stay and age across various pathologies, the ANOVA test was utilized. Additionally, a two-proportion Z-test was conducted to compare frequencies before and after the onset of COVID-19 for each pathology, age group, and gender. This test, commonly applied to compare two proportions from independent groups under the null hypothesis of equality, was performed for each pathology independently (Ryeji, 2018). The significance levels for the Z-test and Chi-square test were set at 0.05 and 0.001, respectively.

To quantify the strength of the association between an event and an exposure, the odds ratio (OR) was calculated. It is calculated as the ratio of the odds of the event occurring in an exposed group to the odds of occurring in a non-exposed group. Essentially, the OR helps assess exposure's impact on the likelihood of a specific event. An odds ratio (OR) greater than one implies that the event is more likely to occur with the exposure, indicating an increased risk. Conversely, an OR less than one suggests that the event is less likely to occur with the exposure, signifying a reduced risk (Szumilas, 2010; Andrade, 2015). In the present work, OR was used to analyze the risk for each pathology (presence/absence) according to admission period (before and after the occurrence of COVID-19) and patient gender (male/female). Statistical analyses were performed using SPSS software version 25.0.

Results

Repartition of COVID-19 according to pathology types:

A comparison of the repartition of patients according to the type of pathology before and after the occurrence of COVID-19 showed that digestive and cardiovascular pathologies were the most frequent before Covid-19, with 20.6% and 14.6%, respectively, followed by trauma and fractures, kidney and excretory pathologies and otorhinolaryngology pathologies with 12.5%, 9.2% and 6.9% respectively. A minimum frequency was observed for psychiatric pathologies. After COVID-19, digestive and cardiovascular pathologies remained at the top of the ranking with 33.8% and 30.5%, respectively, while kidney and otorhinolaryngology pathologies gave way to respiratory and haematological pathologies with 6% and 5%, respectively, whereas psychiatric pathologies remained the least frequent. It should be noted that specific pathologies significantly decreased in frequency after Covid-19, notably dermatological pathologies, which dropped from 2.3% to 0.3%,

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and infectious pathologies from 2.6% to 0.6%. On the other hand, circulatory and digestive pathologies saw a significant increase in frequency, from 14.6% to 30.5% and from 20.6% to 33.8%, respectively (Table 1).

In the following results, only circulatory, respiratory, and haematological pathologies will be considered.

Table 1: Repartition of patients' hospitalization according to the type of pathology before and after the occurrence of the COVID-19 pandemic.

Pathologies	Before		After		Total	
	Number	Rate (%)	Number	Rate (%)	Number	Rate (%)
Circulatory system	1750	14.6	339	30.5	2089	16.0
Digestive system	2457	20.6	375	33.8	2832	21.7
Respiratory system	584	4.9	67	6.0	651	5.0
Surgery	710	5.9	0	0.0	710	5.4
Dermatology	271	2.3	3	0.3	274	2.1
Endocrinology	481	4.0	6	0.5	487	3.7
Gynaecology and obstetrics	82	0.7	10	0.9	92	0.7
Haematology	456	3.8	55	5.0	511	3.9
Neurosurgery	413	3.5	30	2.7	443	3.4
Ophthalmology	666	5.6	19	1.7	685	5.2
Otorhinolaryngology	822	6.9	23	2.1	845	6.5
Infectious diseases	311	2.6	7	0.6	318	2.4
Psychiatry	18	0.2	1	0.1	19	0.1
Kidney and excretory tract	1097	9.2	65	5.9	1162	8.9
Rheumatology	152	1.3	33	3.0	185	1.4
Trauma and fractures	1525	12.8	76	6.8	1601	12.3
Tumors	161	1.3	2	0.2	163	1.2

Quarterly trends of circulatory, respiratory, and haematological cases before and during Covid-19:

The analysis of the quarterly trends in the percentage of circulatory, respiratory, and haematological pathologies during the study period is presented. It must be noted that for the year 2017, only the last quarter was taken into consideration because of a substantial number of missing data in the previous quarters. The Figure 1 reveals a significant decrease in the overall frequency of pathologies following the onset of Covid-19. Particularly striking was the more pronounced decline observed in circulatory pathologies, where the average quarterly frequency decreased from 167 cases before the occurrence of Covid-19 to 44 cases after its onset.

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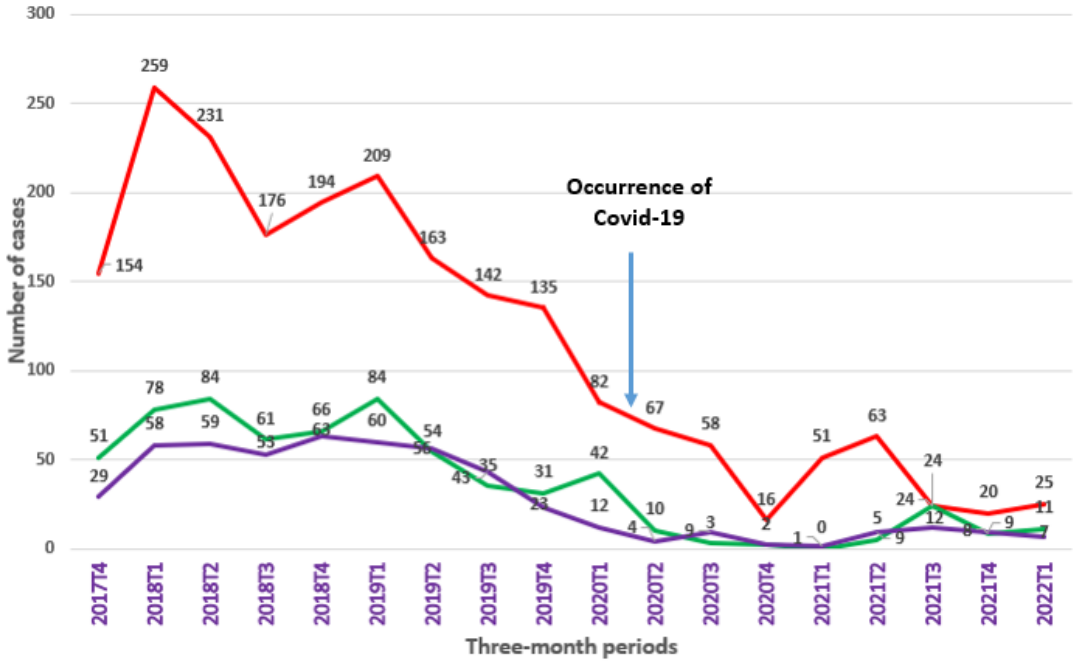

Figure 1: Quarterly trends of circulatory (red line), respiratory (green line), and haematological (violet line) cases before and during the COVID-19 pandemic

Impact of Covid-19 according to gender:

Of the 13,067 patients admitted to Kenitra Provincial Hospital from 2017 to 2022, 3,251 cases were diagnosed with circulatory, respiratory, or haematological diseases. Among these, 1,759 (54.3%) were male and 1,482 (45.7%) were female, yielding an average male-to-female sex ratio of 1.2. As shown in Table 2, the post-Covid-19 gender repartition remained relatively unchanged for circulatory and haematological pathologies. However, a substantial shift was observed for respiratory pathologies. The male-to-female ratio dropped from 2.03 before Covid-19 to 0.86 after the pandemic. A Z-test revealed a significant change in both male and female distributions, with Z-values of 2.34 (p-value < 0.05) and 2.32 (p-value < 0.05), respectively.

Further risk analysis based on gender and pathology unveiled the following associations: i) Circulatory pathologies: After the emergence of Covid-19, a statistically significant association was observed in both men and women. The likelihood of circulatory issues doubled post-Covid-19, with average odds ratios (OR) of 2.7 [2.23 - 3.28] for men and 2.35 [1.92 - 2.89] for women; ii) Respiratory pathologies: Among women, a significant association between Covid-19 and respiratory issues was identified. The risk doubled after Covid-19 (OR = 1.9 [1.3 - 2.8]). Conversely, as shown in Table 2, no notable link was found for men; and iii) Haematological pathologies: Both in men and women, there was no significant association observed between the occurrence of Covid-19 and Haematological pathologies.

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Table 2: Association between pathologies and hospitalization rate depending on gender before and after the Covid-19 pandemic.

Pathologies	Gender	Before Covid-19		After Covid-19		Z-value (p-value)	Chi-square (p-value)	Odds Ratio (Confidence Interval 95%)
		Number (%)	Male/ Female Ratio	Number (%)	Male/Female Ratio			
Circulatory	Male	888 (50.7 %)	1.03	175 (51.7 %)	1.07	0.24 (p>0.05)	110.7 (p<0.001)	2.7 (2.23 - 3.28)
	Female	862 (49.3 %)		164 (48.3 %)		0.23 (p>0.05)	72.42 (p<0.001)	2.35 (1.92 - 2.89)
Respiratory	Male	391 (67 %)	2.03	31 (46.2 %)	0.86	2.34 (p<0.05)	1.08 (p=0.29)	0.81 (0.54 - 1.2)
	Female	193 (33 %)		36 (53.2 %)		2.32 (p<0.05)	11.47 (p<0.001)	1.9 (1.3 - 2.8)
Haematology	Male	253 (55.5 %)	1.25	28 (51 %)	1.04	0.45 (p>0.05)	1.49 (p=0.22)	1.28 (0.86 - 1.9)
	Female	203 (44.5 %)		27 (49 %)		0.44 (p>0.05)	2.68 (p=0.1)	1.41 (0.9 - 1.9)

Impact of COVID-19 according to age:

Regarding age distribution, the 60-79 and 40-59 age groups were the most prevalent for all three pathologies, both before and after the onset of Covid-19. However, there were no significant differences in age distribution before and after the Covid-19 period. The average ages of patients were 62.2 ± 16.9 years before COVID-19 and 61.6 ± 16.3 years after COVID-19 for Circulatory pathologies, 50.8 ± 21.7 years before COVID-19 and 47.9 ± 25.7 years after Covid-19 for Respiratory pathologies, and 51.3 ± 19.7 years before Covid-19 and 47.9 ± 19.6 years after Covid-19 for Haematological pathologies (Table 3). T-tests revealed no significant difference in mean age before and after COVID-19 for all three types of pathologies (p-value = 0.53, p-value = 0.33, and p-value = 0.25, respectively).

Table 3: Repartition of patients according to their age before and after the Covid-19 period

Age groups (years)	Circulatory pathologies			Z-test	Respiratory pathologies			Z-test	Haematological pathologies			Z-test
	Before	After	Total		Before	After	Total		Before	After	Total	
Under 20	23 (1.3%)	6 (1.8%)	29 (1.4%)	0.09 (p>0.05)	50 8.6%	12 (18 %)	62 (9.5%)	0.96 (p>0.05)	13 (2.9%)	5 (9.1%)	18 (3.5%)	0.56 (p>0.05)
20 to 39	187 (10.7%)	26 (7.7%)	213 (10.20%)	0.47 (p>0.05)	135 23.1%	12 (18 %)	147 (22.6%)	0.40 (p>0.05)	141 (30.9%)	13 (23.6%)	154 (30.1%)	0.55 (p>0.05)
40 to 59	465 (26.6%)	102 (30.1%)	567 (27.2%)	0.72 (p>0.05)	178 30.5%	13 (19.4%)	191 (29.3%)	0.85 (p>0.05)	113 (24.8%)	19 (34.5%)	132 (25.8%)	0.89 (p>0.05)
60 to 79	819 (46.8%)	164 (48.4%)	983 (47%)	0.37 (p>0.05)	177 30.3%	25 (37.3%)	202 (31 %)	0.71 (p>0.05)	162 (35.5%)	17 (30.9%)	179 (35%)	0.38 (p>0.05)
80 and over	256 (14.6%)	41 (12.9%)	297 (14.2%)	0.29 (p>0.05)	44 7.5%	5 (7.5%)	49 (7.5%)	<0.001 (p>0.05)	27 (5.9%)	1 (1.8%)	28 (5.5%)	0.17 (p>0.05)

Impact of Covid-19 according to the length of hospitalization:

According to the results, after the occurrence of Covid-19, the mean hospitalization time period decreased significantly for respiratory pathologies (t = 4.96 days; p-value < 0.001) and for

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haematological pathologies (t = 3.62 days; p-value < 0.001), but not for circulatory pathologies (t = 0.55 days; p-value = 0.58). Indeed, it went from 10.79 to 5.58 days for respiratory pathologies and from 5.90 to 2.73 days for haematological pathologies.

Impact of COVID-19 according to the mortality

Following the Covid-19 era, the mortality rates exhibited noticeable shifts. For circulatory pathologies, the death rate increased from 28% before Covid-19 to 42% after the pandemic. Similarly, in cases of respiratory pathologies, the death rate escalated significantly from 13% before COVID-19 to 22.5% after the pandemic. Conversely, there was no recorded risk of death for haematological pathologies during the occurrence of COVID-19. Analysis of odds ratios based on pathology exposure revealed the following patterns: i) Prior to Covid-19, patients with circulatory pathologies faced a twofold higher risk of death compared to other conditions (OR = 2.3 [1.88 - 2.91], on average), while those with respiratory issues had a threefold higher risk (OR = 3.11 [2.31 – 4.18]), as depicted in Table 4. Notably, haematological pathologies did not exhibit a significant risk of death. ii) Post the COVID-19 period, the odds ratios increased from 3.1 to 5.6 for respiratory diseases, decreasing from 2.3 to 1.7 for circulatory diseases. After COVID-19, the risk of death for respiratory pathologies surged to five times higher (OR = 5.62 [2.54 - 12.42]). As before, no significant risk of death was observed for haematological pathologies.

Table 4: Impact of COVID-19 on death. The table covers the number of deaths (N) and the related percentage (%) and Odds Ratio (OR) with a 95% Confidence Interval (CI 95%) by pathology. * stands for statistical significant values.

Pathologies	Before			After		
	Deaths Number (%)	Odds Ratio	Confidence Interval 95%	Deaths Number (%)	Odds Ratio	Confidence Interval 95%
Circulatory	188 (28%)	2.3*	1.88 -2.91	17 (42.5%)	1,7	0.8 – 3.22
Respiratory	55 (13%)	3.1*	2.31 – 4.18	9 (22.5%)	5.6*	2.54 -12.42
Haematology	10 (2.4%)	0.6	0.32 – 1.13	0 (0%)	1.04	0.9 – 1.05

Discussion

The study findings revealed a significant decrease in consultations for various pathologies, indicating a substantial impact on hospital service utilization due to pandemic countermeasures. These observations align with similar outcomes reported in numerous studies. For instance, Burt *et al.* (2021) reported that during the 3-month lockdown, the number of antenatal attendances significantly decreased in Uganda. In Italy, the use of pediatric healthcare decreased by 77.5% from 2019 to 2020 (Cozzi *et al.*, 2020; Iozzi *et al.*, 2020), while the decrease was 40.6% in Japan compared to the number of emergency room visits in 2020 to the number over the previous 3 years (Yamamoto *et al.*, 2021).

Notably, challenges in maintaining normal service levels, even in essential sectors like maternal health, oncology, and mental health, have been highlighted in several studies (Shakespeare *et al.*, 2021; Benjamen *et al.*, 2021; Khan *et al.*, 2021; Gichuna *et al.*, 2020; Hailemariam *et al.*, 2021; Ahmed *et al.*, 2020; Das Neves *et al.*, 2021; Abdelbadee & Abbas,2020). This global impact has been particularly felt in middle- and low-income countries, a point emphasized in various opinion pieces (Krushna et al., 2021; Kobiané, JF *et al.*, 2020; Pêgo,AC, *et al.*, 2024). Discrepancies between healthcare systems and geographical contexts have potentially played pivotal roles in driving these observed changes. For instance, in regions such as Africa and South Asia, sexual and reproductive health services have experienced a significant decline in accessibility. This recession is not limited to maternal and child health services but extends to other healthcare areas, such as family planning and treatment for sexually transmitted diseases (Riley *et al.*, 2020).

At Kenitra's hospital, a noticeable decline in hospitalization rates has been observed. This decrease in consultations can be attributed, firstly, to the heightened anxiety and stress among

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patients during the health crisis. Secondly, the challenges in accessing the hospital during the confinement period following its designation as a COVID-19 centre have contributed to this decline (Riley *et al.*, 2020; Lazzerini *et al.*, 2020). Initial measures primarily focused on controlling the spread of COVID-19 and managing the surge in medical attention demand. Consequently, certain services and procedures were deemed non-essential, leading to a reduction in resources allocated to meet these healthcare needs (Linn *et al.*, 2020; Ma *et al.*, 2020; Teslya *et al.*, 2020). One of the critical individual factors creating new barriers during the pandemic is the fear of contagion (Kahraman *et al.*, 2021; Nicholson *et al.*, 2020; Benjamen *et al.*, 2021; Halley *et al.*, 2021; Ahmed *et al.*, 2020). This aspect has been extensively discussed in various publications, including opinion articles (Riley *et al.*, 2020; Lazzerini *et al.*, 2020; Shayganfard *et al.*, 2020; Mauro *et al.*, 2020; Goyal et al., 2021), and has historically played a significant role in causing delays or problems in seeking medical care during previous epidemics. For instance, in South Africa, Jensen *et al*. (2020) observed notable decreases in clinic attendance and hospital admissions for children under 5 from April to June 2020.

Similarly, a study conducted in Italy by Marzia *et al.* (2020) reported significant declines in the number of pediatric emergency consultations, ranging from 73% to 88%, during the period from March 1 to 27, 2020, compared to the same timeframe in 2019 and 2018 (Ly *et al.,* 2016; Chang *et al.,* 2004; Jensen *et al.,* 2020; Shakespeare *et al.,* 2021). Other reported factors include the stigma associated with seeking care (Khan *et al.,* 2021; Gichuna *et al.,* 2020; Hailemariam *et al.,* 2021; Nicholson *et al.,* 2020), as well as individuals underestimating the necessity for medical treatment (Hailemariam *et al.,* 2020; Das Neves et al, 2021) and perceiving a lack of responsiveness from health services (Kahraman *et al.*, 2021; Karavadra *et al.*, 2020).

The male predominance in respiratory pathology before COVID-19 might be linked to differences in social and cultural activities between genders. In Moroccan society, men often serve as the primary financial providers for their families, consequently exposing them to a higher risk of infection. Many researchers (Guan *et al.,* 2020; National Institute of Public Health of Quebec (inspq) 2023) suggested that the lower hospitalization rates of women in intensive care units could be attributed to their reduced susceptibility to viral infections and the higher prevalence of smoking among men. Conversely, the shift in the male-to-female ratio of respiratory diseases post-Covid-19 is likely influenced by the SARS-CoV-2 virus, known for its respiratory impact, affecting women more than men (Guan *et al.*, 2020; Underner *et al.*, 2020).

Piva *et al.* (2020) indicated that men and women exhibit differing susceptibilities and responses to viral infections, leading to variations in disease incidence and severity. Regarding the age of patients, this study demonstrated that circulatory pathologies primarily affect the older population, with an average age of 62.2 years and ranged from 50 to 76, lower than that observed in the USA (mean age, 70 years and range [43-92] years) (Arentz *et al.,* 2020) and Europe (median age, 63 [56-70] years) (Grasselli *et al.,* 2020; Agostoni *et al.,* 2020). This difference may be attributed to the higher life expectancy in those regions.

Another significant finding was the reduction in hospital stay durations for respiratory and haematological pathologies following COVID-19. This decline primarily stems from the overwhelming demand for hospital beds and a scarcity of medical resources, notably personal protective equipment. As a result, health control measures emphasizing distancing and hygiene were recommended, consequently leading to shortened hospital stays. Additionally, hospital admission was typically conditional on the severity of the illness. Conversely, the length of hospital stays remained unchanged for circulatory pathologies. This could be explained by the critical condition of patients upon hospitalization, particularly as cardiac pathologies heighten the risk of mortality, necessitating more frequent intensive care and more extended hospital stays (Lippi *et al.,* 2020).

Regarding the impact of COVID-19 on mortality rate, our study revealed that following the onset of the pandemic, the risk of death remained significantly linked to respiratory and circulatory pathologies. However, it increased for respiratory and decreased for circulatory pathology. The heightened risk of death for respiratory pathologies is directly attributed to their correlation with Covid-19. Conversely, the decrease in risk for circulatory pathologies might be attributed to reduced

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admissions of patients with chronic circulatory conditions due to limited access to hospital services or the general population's anxiety about SARS-CoV-2 infection while seeking medical care. Some studies have highlighted instances of non-hospitalized patients with mild symptoms found deceased at home during lockdown periods (Marijon *et al.,* 2020; DeRosa *et al.,* 2020; Ciacchini *et al.,* 2020; Lynn *et al.,* 2021; Duncanson *et al.,* 2020; Wise, 2020).

Regarding the study limitation, the study was conducted at the provincial hospital, which represents the public health sector of Kenitra province. The study did not cover the private health sector. Therefore, results are not necessarily generalizable to the province population.

From a research perspective, the present work could be completed by a similar study in the private healthcare sector of Kenitra province. That would provide more generalizable results and allow comparison of pathology profiles between the public and private healthcare sectors in this province.

Conclusion

This study provides a comprehensive insight into the far-reaching impact of the COVID-19 pandemic on healthcare dynamics, particularly evident in the notable decrease in hospital consultations for various pathologies. The findings resonate with a global trend underlining the unprecedented challenges healthcare systems face. At the Provincial Hospital of Kenitra, a discernible decline in hospitalization rates underscores the multifaceted impact of the pandemic on healthcare-seeking behavior. Contributing factors include heightened patient anxiety during the health crisis and logistical challenges in accessing healthcare facilities designated as Covid-19 centres. The overarching measures to control the spread of the virus, including the reclassification of specific services as non-essential, have led to a reduction in resources allocated to meet broader healthcare needs.

The findings underscore the adverse impact of the COVID-19 pandemic on hospital consultations, which is a cause for significant concern, particularly for pathologies demanding effective hospital treatment to avert adverse consequences. Reducing hospital admissions for such critical medical pathologies raises severe implications for patient well-being. In response, public health system managers must focus on devising effective strategies to ensure that patients requiring hospital care continue to receive it during the ongoing pandemic. Key measures should be directed toward a comprehensive approach from the government and its partners, focusing on rebuilding healthcare structures, restoring user confidence through awareness initiatives, and securing additional resources for sustained service provision during this critical period.

Author Contributions:

- Conceptualization, methodology, writing—original draft preparation M.Z., A.A., A.B., and M.T.;
- formal analysis, M.Z., A.A., H.H., and M.T.;
- resources, I.A.;
- writing—review and editing, A.A., M.T., and A.B.;
- supervision, A.Q., M.T., A.A.
- All authors have read and agreed to the published version of the manuscript

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Prevalence of Type II Topoisomerase Mutations Among Quinolone Resistant *Escherichia coli* from Broiler Chickens in Dar es Salaam, Tanzania

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Abstract

Background: Quinolone-resistant *Escherichia coli* may easily be transmitted from poultry to humans and animals. Quinolone misuse in veterinary medicine, therefore, poses a significant public health risk. This study aimed to assess the prevalence of type II topoisomerase mutations commonly associated with resistance to quinolones in *E. coli*; in Dar es Salaam, Tanzania.

Methods: One hundred sixty E. coli samples isolated from broiler cloacal swabs in Dar es Salaam between March and August 2022 were evaluated and analyzed for quinolone resistance by disc diffusion and genetic methods. The study used two Polymerase Chain Reaction (PCR) techniques, one a Mismatch Amplification Mutation Assay (MAMA-PCR) and the other employing enzyme digestion of amplified products (PCR-RFLP). Both approaches targeted regions in type II topoisomerases (*gyr*A and *par*C) to determine quinolone resistance (QRDR).

Results: Results showed considerable levels of quinolone resistance among *E. coli* isolated from broiler chickens, where 42.5% of the strains demonstrated non-susceptibility to both ciprofloxacin and norfloxacin. Moreover, a significant minority of isolates (5%) were non-susceptible only to ciprofloxacin. All isolates non-susceptible to both drugs harboured a substitution mutation (S83L) at the *gyr*A Ser-83 target site (a resistance marker) as revealed by PCR-RFLP. The genotypic-to-phenotypic agreement ratio for norfloxacin was 100%, in contrast to that of ciprofloxacin, which was 89.47%. However, as revealed by MAMA-PCR results, none of the isolates under study harboured parC80 (S80I) substitution mutation (a resistance marker) on the topoisomerase IV gene.

Conclusion: Type II topoisomerase mutations other than the ones assayed in this study (*gyr*A Ser-83 or *par*C80) or other mechanisms of resistance might be contributing to the resistance against quinolones in *E. coli* strains circulating in broiler chickens in Dar es Salaam. The level of quinolone resistance revealed by this study calls for immediate intervention to mitigate its spread.

Keywords: Quinolone resistance; *Escherichia coli*; MAMA-PCR; Dar es Salaam; Tanzania

Introduction

Escherichia coli is a bacterial species widespread among humans and animals. Like other enterobacteriaceae, it is part of the intestinal microbiota, commonly released in the environment, contaminating food and water (Malabadi *et al.,* 2024). Because of its location in the body and its high capacity for acquiring antimicrobial resistance, indiscriminate use of antimicrobials both in human and animal husbandry increases the risk of spread of anti-microbial resistant *E. coli* strains but also transmission of the resistance to other bacteria through horizontal gene transfer (Lawal *et al.,* 2024). In developing countries, antibiotics are often empirically prescribed for *E. coli* diseases which include gastrointestinal and extra-intestinal infections (Diarra *et al.,* 2024).

Since the introduction of fluoroquinolones such as norfloxacin and ciprofloxacin in the mid 1980's, they have been widely used both in human and animals (Tang & Zhao, 2023). This has sparked the emergency of bacterial resistance against them by several mechanisms. Such mechanisms include chromosomal mutations in type II topoisomerase enzymes, the DNA gyrase and DNA topoisomerase IV (Bush *et al.*, 2020). Other chromosomal mutations have been reported in genes that regulate the

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expression of efflux pumps localized in bacterial membranes or porin genes. Among them are mutations in the Mar regulon which influence the expression of both the AcrAB-TolC pump complex in *E. coli* and the OmpC and ompF porin diffusion channels affecting quinolone permeation into the cytoplasm (Millanao *et al*., 2021). In addition, plasmid mediated quinolone resistance mechanisms (PMQR) are also very common. Even though these tend to impart low-level resistance, they are known for selecting for higher-level mutation-based resistance and significantly contribute to treatment failure (Aworh *et al*., 2023). These PMQR mechanisms include those coded for by *qnr* (*qnr*A, *qnr*B, *qnr*C, *qnr*D, *qnr*S) genes, the aminoglycoside acetyltransferase (*aac(6')-Ib-cr*), and the quinolone efflux pumps (QepA and OqxAB) (Bush *et al*., 2020).

DNA gyrase and DNA topoisomerase IV are both heterotetramers, each made up of two domains of GyrA and B or ParC and ParE respectively. They both catalyze double strand breaks and resealing in DNA to allow DNA replication, transcription and recombination. The DNA passing domains for these two enzymes are the GyrA and ParC domains. Quinolones block the resealing activity (Spencer & Panda, 2023). However, point mutations in either enzyme can lead to resistance against quinolones. These point mutations tend to occur in quinolone resistance determining regions (QRDR) which span amino acid residue 67 to 106 in *gyr*A and residue 63 to 102 in *par*C gene, based on the *E. coli* genomic sequence numbering. The DNA gyrase of *E. coli* is more readily inhibited by fluoroquinolones than the topoisomerase IV (Neyestani *et al*., 2023). In addition, the mutations that change the 83 serine to leucine (S83L) and the 87 aspartate to asparagine (D87N) are among the most commonly observed in quinolone resistant gram negative bacteria. In quinolone resistant *E. coli*, the mutation at 83 serine is the most common (Das *et al*., 2023).

In a previous study conducted in Dar es Salaam, Tanzania, where the *qnr*A gene was used as a marker for quinolone resistance, only 1.61% of quinolone-resistant isolates from broiler chickens harboured the gene (Kiula and Makene, 2023). The *qnr*A gene is a plasmid mediated form of resistance. This study embarked on analyzing isolates from broiler chicken for chromosomal mediated resistance mechanisms.

Materials and Methods

Study Area

This study was done in Dar es Salaam, a Tanzanian city with a population of 5.3 million people (The Population and Housing Census, 2022). The city has the highest poultry meat and egg consumption in the country.

Study design

This cross-sectional study was conducted from March to August 2022. Broiler chickens were selected for the study because they are reared mostly in densely populated settings. In addition, there is a significant misuse of antimicrobials for prophylaxis, growth enhancement, and infection management in poultry.

Sample size calculation

The minimum sample size (n) of 156 broiler chickens was obtained after assuming a prevalence (p) of 88.5% and a Z-score (Z) of 1.96 for a 95% confidence level within 5% margin of error (d). The following formula "$(n) = Z^2pq/d^2$" was applied, where $q = (1 - p)$.

Sample collection

A total of 160 cloacal swab samples were collected from major six poultry slabs in Dar es Salaam, namely Kisutu and Buguruni in Ilala district, Mwenge and Magomeni in Kinondoni district, Stereo in Temeke district, and Shekilango in Ubungo district. All cloacal swab samples were collected aseptically and kept in separate sterile tubes containing 5 ml of prepared tryptic soy broth (Oxoid, Basingstoke, UK). Immediately the samples were transported to the University of Dar es Salaam, Department of Molecular Biology and Biotechnology laboratory and incubated for 24 hours at 37°C.

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Isolation and Identification of Enterobacteria

Following overnight culture, one loop full of each culture was streaked on MacConkey agar (Oxoid, Basingstoke, UK) and incubated overnight at 37°C. Subsequently, pink or red colonies were assumed to be lactose-fermenting *E. coli* colonies. Three colonies were picked for inoculation on eosin methylene blue (EMB) agar, followed by overnight incubation at 37°C. *E. coli* colonies that peaked for further characterisation displayed a metallic sheen appearance. Characterization was done by catalase, indole, methyl red, oxidase, and the Voges-Proskauer tests. Isolates tentatively identified as *E. coli* were then inoculated into 4 ml of nutrient broth for overnight enrichment. Two aliquots were made, one for immediate antimicrobial susceptibility analysis and another stored in nutrient broth containing 15% glycerol at -20°C for later DNA extraction and molecular characterization. The *E. coli* ATCC 25922 obtained from the department culture collection was used as a positive control.

Antimicrobial susceptibility testing

Following overnight enrichment, 150µl of 0.5 McFarland standards matching *E. coli* suspension was inoculated onto Mueller-Hinton agar by even distribution using sterile swabs. The standard Kirby-Bauer disk diffusion method was used to screen for susceptibility to ciprofloxacin and norfloxacin, representing quinolone antibiotics, following the Clinical and Laboratory Standards Institute (CLSI) guidelines 2021. A disc dispenser was used to place ciprofloxacin (5µg) and norfloxacin (10µg) antibiotic discs on the agar plates. Following overnight incubation at 37°C, the zones of growth inhibition were scored and interpreted as per CLSI guidelines.

Molecular characterization of E. coli isolates

E. coli culture aliquots stored in glycerol, representing all isolates screened for drug susceptibility, were characterized further by PCR using primers described in Table 1.

DNA extraction

E. coli culture aliquots from storage were recovered by resuspension in 4 ml of nutrient broth and incubated at 37°C for 24 h. From each nutrient broth culture, 1.5ml was centrifuged at 13,000xg for 10 minutes to pellet the cells. The pellets were then washed with a sterile 0.9% sodium chloride solution and ready for DNA extraction using the boiling method (Ahmed and Dablool, 2017). Briefly, the pellets were reconstituted in 300µl of sterile distilled water. Subsequently, the suspensions were heated for 10 minutes at 100 °C. A final centrifugation at 13,000xg for 10 minutes was done to obtain supernatant and discard debris. The concentration and purity of DNA in the supernatant were determined using the NanoDrop One (Thermo Fisher Scientific, USA). The samples with a DNA concentration ≥100ng/µl were stored at -20°C for further analysis by PCR.

Species confirmation by PCR

E. coli species confirmation was done by PCR targeting the 16S rRNA gene on all DNA samples using species-specific primers as described by Yousef et al. (2023). Amplification reactions were done in a total volume of 25µl each. The reaction mixture contained 3µl of DNA template, 400µM each primer, 12.5µl of Taq 2X Master Mix (New England Biolabs), and 7.5µl of nuclease-free water (BioConcept). The thermal cycling (Applied Biosystems, USA) conditions included a denaturation step of 10 minutes at 95°C, followed by a 30s annealing time at a temperature specific for each primer pair, and an extension temperature at 72°C for 1 minute. The reaction was finally extended for 10 minutes at 72°C. Visualization and documentation of the PCR products were done under the Gel. LUMINAX Gel documentation system (BioZen Labs/Zenith).

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Table 1: Primers for Molecular Characterization of *E. coli* isolates

Primer	Gene	Primer sequence 5'-3'	Size (bp)	Ta (°C)
Species specific PCR	*16S rRNA*[a]	F- GACCTCGGTTTAGTTCACAGA	585	56
		R- CACACGCTGACGCTGACCA		
PCR -RFLP	*gyrA*[b]	F- GACCTTGCGAGAGAAATTACAC	540	55
		R- GATGTTGGTTGCCATACCTACG		
MAMA-PCR	*par*C80[b]	F- CGGAAAACGCCTACTTAAACTA	466	55
		R- GTGCCGTTAAGCAAAATGT		
		R- ATCGCTTCATAACAGGCTCT	217	

[a]Yousef *et al*., 2023; [b]Jazeela *et al*., 2019

MAMA-PCR of the topoisomerase IV gene

Mismatch Amplification Mutation Assay Polymerase Chain Reaction (MAMA-PCR) assay was done in a total volume of 25µl to target the *par*C80 mutation site using primers described in Table 1 according to Jazeela *et al*., (2019). Briefly, the reaction mixture contained 3µl of DNA template, 400µM each primer, 12.5µl of Taq 2X Master Mix (New England Biolabs), and 7.5µl of nuclease-free water (BioConcept). The thermal cycling conditions included a denaturation step of 5 minutes at 95°C, followed by 35 cycles of denaturation at 95°C, annealing at 55°C and extension at 72°C, each for 40s. The reaction was finally extended for 10 minutes at 72°C.

PCR-RFLP of DNA gyrA gene of E. coli

PCR amplification was done in a total volume of 25µl using primers described in Table 1, according to Jazeela et al. (2019). Briefly, the reaction mixture contained 3µl of DNA template, 400µM each primer, 12.5µl of Taq 2X Master Mix (New England Biolabs), and 7.5µl of nuclease-free water (BioConcept). The thermal cycling conditions included a denaturation step of 5 minutes at 95°C, followed by a 40s denaturation step at 95°C, a 30s annealing time at 55°C, and an extension of 40s at 72°C for a total of 35 cycles. There was a final extension step of 10min at 72°C.

The obtained *gyr*A PCR products were digested with *Hinf*I (Thermo Fisher Scientific) to screen for point mutations at position Ser-83. Enzyme digestion was performed in a 20µl mixture containing 16µl (0.1–0.5µg) of the PCR product, 0.5µl (2IU) of enzyme, 2µl of 10x buffer, and 1.5l µl of sterile ultrapure water at 37oC for 2h, followed by termination of enzyme activity at 65oC for 10 min on a thermocycler (Applied Biosystems, USA).

Visualization and documentation of the PCR and restriction products

Visualization and documentation of the PCR products were done under the Gel. LUMINAX Gel documentation system (BioZen Labs/Zenith). Agarose gel electrophoresis was run on 1.5% agarose gels at 100V for 45min and was stained with Safe view™ and classic dye. GeneRuler 1kb Plus DNA Ladder (Thermo Scientific™) was used for sizing PCR and digestion products.

Data analysis

The data were entered into Microsoft Excel; proportions of isolates showing phenotypic resistance and carriage of the respective genetic marker were calculated. Descriptive statistical analysis and charts were constructed.

Results

Prevalence of antibiotic resistant E. coli isolated from broiler chickens

All 160 samples grew colonies that were presumptively identified as *E. coli* by culture and biochemical methods. Following antimicrobial susceptibility testing, the observed rates of phenotypic resistance against ciprofloxacin and norfloxacin were 47.5 and 42.5% respectively. Of the resistant isolates, 5% were resistant only for ciprofloxacin.

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Species confirmation by PCR

DNA from all 160 samples produced an expected PCR product of 585bp for *E. coli* following amplification by *E. coli* specific PCR primers targeting the 16S rRNA region (Fig. 1).

MAMA-PCR of the topoisomerase IV gene

Following MAMA-PCR amplification of all 120 PCR confirmed *E. coli* isolates targeting the topoisomerase IV gene mutation site (*par*C80), two PCR products were observed for each one of them irrespective of their susceptibility profiles. The two products, 466bp and 217bp are only expected for isolates with no mutation at this site. Isolates with mutation at this site only show one product of 466bp (Fig. 2).

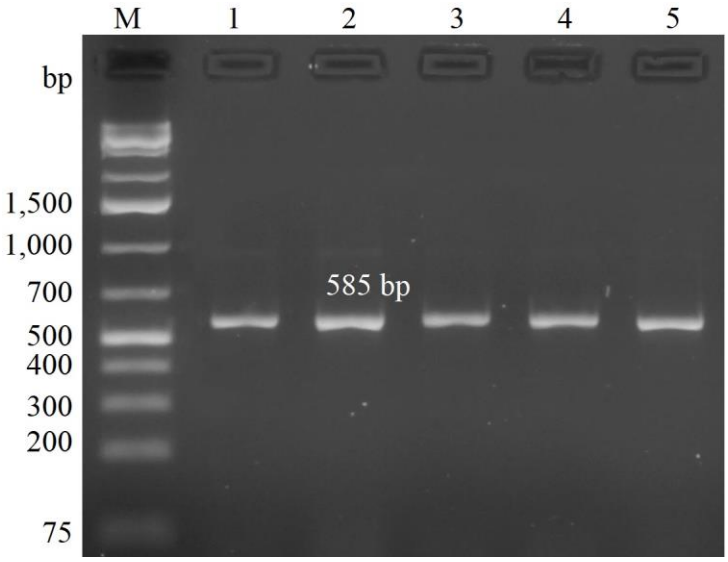

Figure 1: Representative agarose gel electrophoresis image of *E. coli* specific 16S rRNA PCR products. Lane 1-4: All isolates show the expected 585bp product. Lane 5: The *E. coli* ATCC 25922 positive control. Lane M is GeneRuler 1kb Plus DNA Ladder.

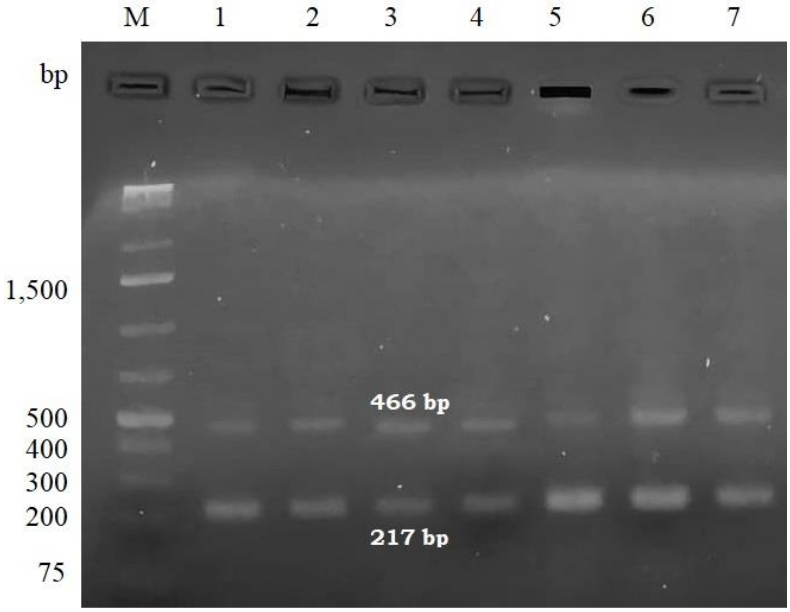

Figure 2: Representative agarose gel electrophoresis image of MAMA-PCR products generated for *par*C80. Lane 1- 7: All isolates showing 466 and 217bp products expected for *E. coli* strains wild-type for this mutation. Lane M is GeneRuler 1kb Plus DNA Ladder.

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PCR-RFLP of DNA gyrA gene of E. Coli

Following PCR amplification of all 120 PCR confirmed *E. coli* isolates targeting the *gyr*A gene, an expected PCR product of 540bp was observed (Fig. 3-A). After *Hinf*I digestion of the PCR products, three digestion products of 239, 202, and 99bp were observed for 57.5% of isolates (Fig. 3-B). This was the expected result for isolates wildtype at the target mutation site (*gyr*A Ser-83). However, 42.5% of isolates showed two digestion products of 337 and 203bp as expected for isolates with a mutation at the target site (Fig. 3-C).

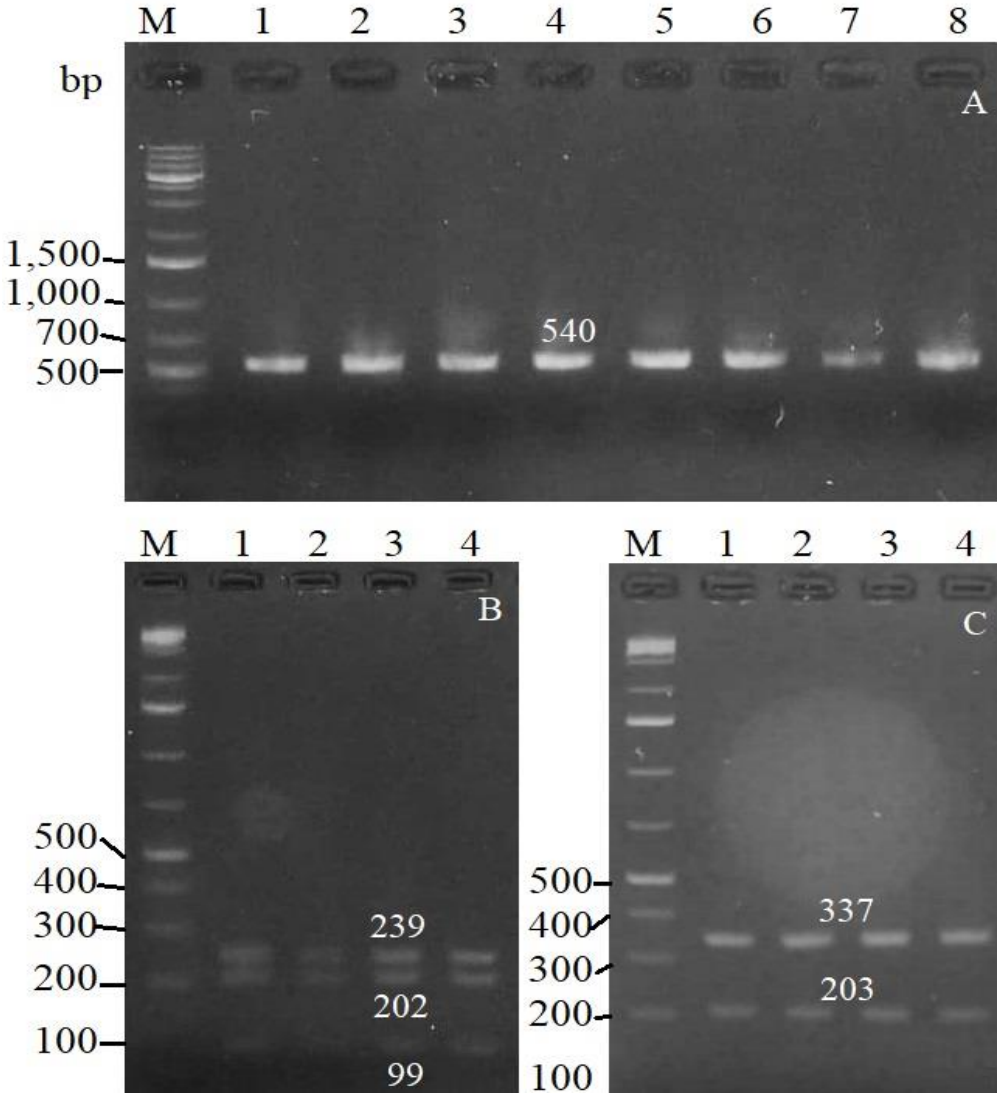

Figure 3: Representative agarose gel electrophoresis images showing results of PCR-RFLP targeting the *gyr*A 83 with mutation. (A) Lane 1-8: isolates showing an expected 540bp PCR product for the targeted region. (B) PCR-RFLP for *gyr*A. Lane 1-4: showing expected *Hinf*I digestion products of *gyr*A (540bp) for isolates wildtype for the targeted *gyr*A 83 mutations. (C) PCR-RFLP for *gyr*A. Lane 1-4: showing expected *Hinf*I digestion products of *gyr*A (540bp) for isolates mutant for the targeted *gyr*A 83 mutations. For A-C: Lane M is the GeneRuler 1kb Plus DNA Ladder.

Genotypic to phenotypic agreement

Comparisons between results from phenotypic susceptibility assays and genetic analysis showed very high concordance for the *gyr*A target mutation. All isolates observed to be phenotypically resistant for both ciprofloxacin and norfloxacin (42.5%) had a mutation at the assayed target site (*gyr*A Ser-83) giving a genotypic to phenotypic ratio of 100% for norfloxacin (Table 2). However, no such mutation was demonstrated for the 5% of isolates that showed phenotypic resistance only against ciprofloxacin, which led to a genotypic to phenotypic ratio for ciprofloxacin resistance to be 89.47%

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(Table 2). In contrast, no isolate, irrespective of the phenotypic resistance profile, was observed to have mutation at the analysed mutation site (*par*C80) on the topoisomerase IV gene (Table 2).

Table 2. Prevalence of genetic resistance markers among isolates under study

Antibiotic	Phenotypic resistance	Target Gene Mutation		Genotypic/Phenotypic agreement
Norfloxacin	68 (42.5%)	*gyr*A *(Ser-83)*	68 (42.5%)	100.00%
		*par*C80	0	0
Ciprofloxacin	76 (47.5%)	*gyr*A *(Ser-83)*	68 (42.5%)	89.47%
		*par*C80	0	0

Discussion

The emergence and spread of antimicrobial resistance pose significant challenges to public health worldwide (Asghar *et al*., 2024; Sartorius *et al*., 2024). In this study, the prevalence and mechanisms of chromosomal-mediated quinolone resistance among *Escherichia coli* isolates obtained from broiler chickens in Dar es Salaam, Tanzania were investigated. The findings from this study were comparable to two recent studies in Dar es Salaam (Kimera *et al*., 2021; Kibwana *et al*., 2023). The Kibwana *et al*., (2023) study associated the observed resistance to chromosomal mutations in *gyr*A, *par*C, and *par*E, whereas the Kimera *et al*., (2021) associated the resistance with plasmid mediated markers at 15% for *aac(6)-lb-cr*, 10% for *qnr*B, and 5% for *qep*A. In addition, studies in Arusha and Mwanza (Tanzania) have also reported ciprofloxacin resistance among *E. coli* isolates from chickens and humans at the rates of 40% and 68.6% (Kiiti *et al*., 2021; Sonola *et al*., 2022). Extending our comparison to East Africa, similar resistance patterns were observed. For instance, a sample-level prevalence for quinolone resistance of 48.3% among food animals was documented in Rwanda (Manishimwe *et al*., 2021). Furthermore in Kenya, rates of resistance against ciprofloxacin as high as 68% were recently reported, and these were mostly associated with PMQR genes at 60% for *aac(6')lb-cr*, 24% for *qnr*B, 22% for *oqx*AB, 16% for *qnr*S and 6% for *qep*A (Kariuki *et al*., 2023).

Expanding the comparison beyond East Africa, similar trends were observed across the continent. In Ghana, 50% and 51.1% resistance rates against ciprofloxacin and 38.8% against norfloxacin among *E. coli* isolates were reported (Deku *et al*., 2022; Sah & Fegio, 2022), while in Nigeria, an even higher rate of resistance (68.2%) was recently reported (Aworh *et al*., 2023). This later study observed PMQR genes in 63.6% of isolates and among isolates with mutations in the quinolone-resistance determining regions (QRDRs), 46.5% had the S83L and D87N substitutions in *gyr*A and S80I substitution in *par*C as the most common mutations. Earlier studies in Nigeria had reported high rates of quinolone resistance and associated the rates with PMQR genes (Ayandiran *et al*., 2018; Eghieye *et al*., 2020; Nsofor *et al*., 2021). Similar findings have also been reported from other countries in Africa, including Cameroon (Mbamyah *et al*., 2020), Egypt (Khalil *et al*., 2017; Kotb *et al*., 2019; Esmaeel *et al*., 2020; Masoud *et al*., 2021), Malawi (Choonara *et al*., 2022), Mozambique (Faife *et al*., 2020), South Africa (McIver *et al*., 2020; Abdalla *et al*., 2021) and Togo (Salah *et al*., 2019).

Numerous studies outside Africa have also extensively explored fluoroquinolone resistance in *Escherichia coli* isolates, uncovering a multifaceted landscape of genetic mutations linked to resistance. Notably, investigations in Australia (Cheng *et al*., 2012), China (Qiu *et al*., 2018), Germany (Juraschek *et al*., 2021), India (Jazeela *et al*., 2019; Dasgupta *et al*., 2018; Varughese *et al*., 2018), Iran (Rezazadeh *et al*., 2016; Lorestani *et al*., 2018; Mirzaii *et al*., 2018; Shenagari *et al*., 2018; Yousefi *et al*., 2018; Hajihasani *et al*., 2022), Japan (Uchida *et al*., 2010), Philippines (Belotindos *et al*., 2021), South Korea (Na *et al*., 2019), Thailand (Onseedaeng & Ratthawongjirakul, 2016) and in the USA (Fuzi & Sokurenko, 2023) have consistently revealed QRDR mutations within *gyr*A and *par*C genes, such as Ser83Leu and Asp87Asn in *gyr*A, as contributing significantly to heightened resistance levels. In addition to elucidating genetic markers of resistance, some studies highlight the effectiveness of policy interventions in curbing resistance rates. For instance, Cheng *et al*., (2012) illustrate how stringent regulations on quinolone use in Australia have led to reduced resistance rates. However, despite these efforts, challenges persist, as

evidenced by findings from Thailand (Boueroy *et al*., 2023) and North Macedonia (Kerluku *et al*., 2023), where high resistance rates are still being reported alongside multiple resistance determinants.

The extensive body of research presented in this discussion underscores the global challenge posed by fluoroquinolone resistance in *Escherichia coli* populations. The prevalence of quinolone-resistant strains, as demonstrated across diverse geographic regions, emphasizes the urgent need for multifaceted strategies to combat antibiotic resistance effectively. Particularly in developing countries with limited healthcare resources, where quinolone-resistant strains often exceed 50%, the challenges for treatment and control are formidable. This study's findings, alongside those from numerous investigations worldwide, provide critical insights into the genetic basis of resistance and transmission pathways, informing strategies for antimicrobial stewardship, infection control with minimal use of antibiotics, and targeted interventions. Urgent action at local, national, and global levels is imperative to address antimicrobial resistance comprehensively, with continued surveillance, research, and evidence-based interventions essential for preserving antimicrobial efficacy and safeguarding public health.

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Conflict of Interest

No conflict of interest

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Lived experiences of women who had hysterectomy for uterine prolapse in Southeast Nigeria

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Abstract
Background: Hysterectomy aims to relieve symptoms and improve patients' lives. Yet, the lived experiences of women who had a hysterectomy for uterine prolapse in sub-Saharan Africa have primarily been unexamined. This study explored their experiences after hysterectomy at a specialist hospital in Southeast Nigeria.
Objective: To explore the women's physical, psychological, social, and economic experiences after hysterectomy.
Method: Individual in-depth interviews were conducted on 21 women aged 31-72 at 3- 6-month check-ups after hysterectomy. The interview transcripts were subjected to hermeneutic phenomenological interpretation.
Results: Loss of the uterus was particularly distressing to the women. They questioned their womanhood at its loss. Some continued to experience body pains and symptoms of depression months after hysterectomy, making them limit their economic activities. Their narrations showed dissonant grieving: consoled by the relief of the prolapse but bothered by uncertainty about the surgery and poor empathy from their spouses. Expecting stigmatisation, they reduced their social relationships. They tried to cope by depending more on their children and parental family members, seeking guidance and support from other women who previously underwent hysterectomy, and increasing their spiritual relationship.
Conclusion: The findings suggest that pre- and post-surgery counselling, incorporating verbalization and problem sharing, and self-help groups can be helpful to women who have had hysterectomy.
Keywords: culture; hysterectomy; lived experiences; prolapse; uterus

Introduction

One of the goals of Health for All the World Health Organization (1997) is the improvement of well-being. Care provision is usually patient-centred, relating to enhancing their personal and social life. Therefore, surgical processes aim to relieve symptoms and improve the patient's well-being and life experiences. Uterine prolapse, the progressive loss of anatomic support for the uterus that causes the uterus to protrude out of the vagina gradually, occurs in both pre-and post-menopausal women and is usually accompanied by urinary, bowel, sexual or local symptoms

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(Desai et al., 2019; Li et al., 2023; Yakubu et al., 2017). Advanced uterine prolapse is often managed by hysterectomy, the surgical removal of the uterus. Hysterectomy is considered adequate and relatively safe (Omokanye et al., 2012; Usman et al., 2017), with almost all European women who had hysterectomy returning to work after 12 weeks (Dedden et al., 2022; Shehmar, 2016).

Hysterectomy, however, could change the physiological functions or wholeness of the body and therefore affect the sense of self and life experiences of the woman (Desai et al., 2019; Gün & Kömürcü, 2013; Uçar et al., 2016). It has also been linked to a sense of reduction in feminine properties, loss of creativity, emptiness and prolonged depression, especially among younger women (Azadeh-Ghamsari et al., 2002; Li et al., 2023). Most studies on personal experiences of women who had a hysterectomy for uterine prolapse were conducted in Western and Asian countries (e.g., Afiyah et al., 2020; Gün & Kömürcü, 2013; Li et al., 2023), with a few in Africa (Ntihabose & Twahirwa, 2021; Pilli et al., 2020). However, lips and Lawson (2019) note robust differences in women's life contexts across cultures. There was, therefore, the need for studies on the personal life experiences of women who had hysterectomy due to uterine prolapse in sub-Saharan Africa.

This study explored the subjective physical, psychological, social and economic life experiences of women who underwent hysterectomy due to uterine prolapse at the National Obstetric Fistula Centre (NOFIC), Abakaliki, Southeast Nigeria. NOFIC is the foremost specialist centre in Southeast Nigeria where women who have uterine prolapse undergo a hysterectomy. Gauging their experiences after hysterectomy can be helpful in matching professional care with their needs.

Method

Participants

The participants were 21 women who met the inclusion criteria out of 50 women who had hysterectomy for uterine prolapse at NOFIC between June and December 2022. The inclusion criteria were check-up attendance 3-6 months after the surgery, being without any co-morbidity, and willingness to participate in the study. The participants' demographics are presented in Table

Ethical Consideration

Ethical approval was obtained from the research and ethics committees of NOFIC and Alex-Ekwueme Federal University Teaching Hospital, Abakaliki, which is the teaching hospital to which NOFIC is affiliated (HREC approval number NHREC/16/05/22/200). Participants voluntarily signed a consent form and were informed that withdrawal at any research stage is permitted. They were assured that their information would be treated with utmost confidentiality.

Data collection

With information from the hospital's records, each participant was approached while waiting for the doctor when they came for a check-up. Adequate rapport was established before the participant was given the goal and instructions of the study. Data were collected through two stages of interviews for each participant. The first stage was for participant demographic data and assignment of number codes. The second stage was the in-depth interview on their experiences after the hysterectomy. The two stages of interviews were done on the same day for each participant at the Outpatient Department, anchored by one of the researchers (P.N.E.). The interview lasted for 3-6 months as the women visited for check till 21 participants were interviewed, and no new information emerged, reaching data saturation.

Data analysis

The interview transcripts were independently read and re-read, coding and identifying meaningful themes by an inductive approach, demanding themes be rooted in the data (Patton,

2002). Codes were used on the socio-demographic forms filled out by the participants, such that P1 and P21, for instance, represented the first and twenty-first participants, respectively. These codes were used to vivify the integrated narrative. Transcripts with identified themes were re-analyzed, aggregating themes to piece together the women's experiences.

Interpretive hermeneutics phenomenology was utilized for the thematic analysis, where there was continual review and analysis between the parts and the whole text (Polit & Beck, 2005). With the researchers applying their understanding and knowledge of the participants' cultural context and the subject under study, statements that were seen to illuminate the researched phenomenon were extracted. With the list of non-redundant units of meaning, clusters of themes were typically formed by grouping units of meaning together. Supporting verbatim quotes were lifted from the scripts to evidence the experiences.

Results

Participants' demographics

The participants were aged 31-72 (*M* = 50.43 years, *SD* = 11.38). Most (85.7%) were married, with an average of 5 children per woman. The majority (80.9%) were from the Igbo ethnic group, with the rest from the neighbouring Yala ethnic group. Farmers constituted the largest occupational group (Table 1).

Table 1: Socio-demographic characteristics of the participants

N	Age	Job	Marital Status	Number of Children	Edn	Type of Hysterectomy	Awareness of loss of womb
1	40	Trader	Married	7	None	total abdominal	Yes
2	39	Teacher	Married	7	HND	total abdominal	Yes
3	55	Farmer	Married	8	None	total abdominal	Yes
4	45	Baker	Married	5	FSLC	sub-total abdominal	Yes
5	62	Frying akara	Married	5	FSLC	total abdominal	Yes
6	69	Civil servant	Married	2	HND	sub-total abdominal	Yes
7	72	Farmer	Married	12	None	total vaginal	Vague
8	70	Farmer	Married	5	None	total vaginal	Yes
9	45	Civil servant	Married	2	BSc	sub-total abdominal	Yes
10	40	Farmer	Married	8	SSCE	total abdominal	Yes
11	31	Farmer	Married	6	SSCE	total abdominal	Yes
12	60	Farmer	Married	7	FSLC	total abdominal	Yes
13	59	Farmer	Married	8	FSLC	total vaginal	Yes
14	53	Farmer	Divorced	0	FSLC	total vaginal	Yes
15	39	Hair dresser	Single	9	FSLC	sub-total abdominal	Yes
16	40	Farmer	Married	3	FSLC	total vaginal	Yes
17	48	Farmer	Married	7	SSCE	total vaginal	Yes
18	50	Civil servant	Divorced	5	SSCE	total abdominal	Yes
19	50	Farmer	Married	6	SSCE	total abdominal	Yes
20	47	Trader	Married	2	SSCE	total abdominal	Yes
21	45	Radiographer	Married	4	BSc	sub-total abdominal	Yes

Note: *N:* Participant code number; Edn: Educational level; FSLC: First School Leaving Certificate; SSCE: Senior Secondary Certificate of Education; HND: Higher National Diploma; BSc: Bachelor of Science degree

Lived experiences after hysterectomy

The overarching theme in the women's post-hysterectomy experiences is the "experience of living with no uterus" due to its prominence in their responses. Figure 1 shows the subthemes.

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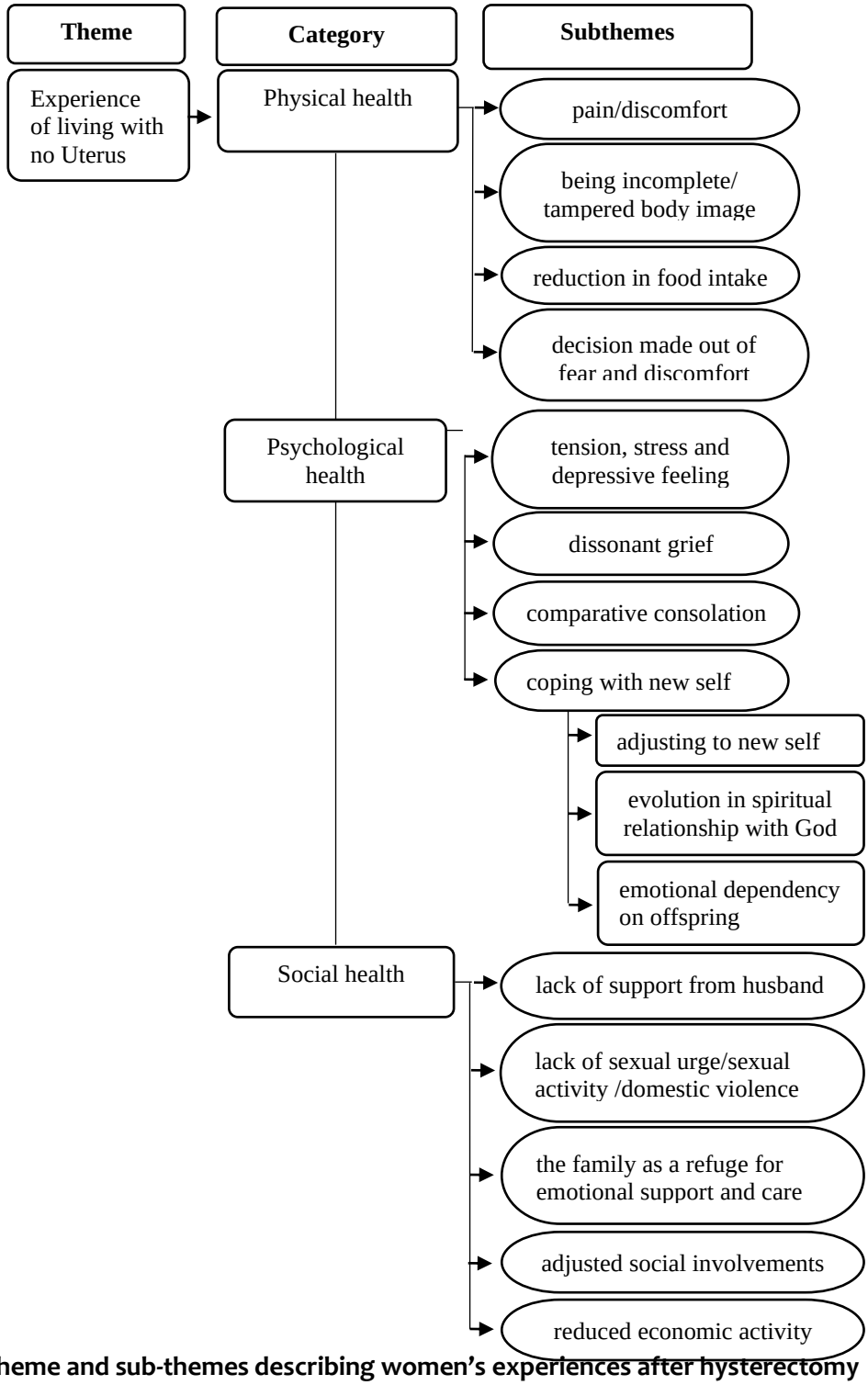

Figure 1: Theme and sub-themes describing women's experiences after hysterectomy

Their narratives fit into three categories: physical health, psychological health, and social health. These categories are reflected in subthemes, as shown in Figure 1. Economic issues emerged as outcomes of experiences in the physical, psychological, and social domains.

Physical health

The women's physical health experiences appeared under the subthemes of pain/discomfort, incomplete/ tampered body image, reduction in food intake, and decisions made of fear and discomfort.

Pain /discomfort

Pain was mainly reported as backache, lower abdominal pain, burning sensation at the surgery site, and general body pain. The pain made it difficult for some of them to perform daily activities. Many of them experienced delays in the achievement of pre-morbid capacities. A 40-year-old woman with a third-degree prolapse who had a hysterectomy described her experience as:

> *I think that after the operation, the pain that comes with that thing coming out from my body will stop. Pain came over my body; I was disturbed and thought of how I would be without a womb.* (P1)

The women used different coping mechanisms to reduce the pain. P2, a 39-year-old teacher, married with 7 children, explained:

> *I feel tired; sometimes I feel dizzy, and everything becomes dark. I wash my face and sit, then get myself.* (P2)

P5, P8, and P16 reported unexplained fatigue, soreness, and pain months after the surgery. Each of them observed that the first three months were particularly difficult for them. They indicated that the area of incision had continued to hurt, even at the time of the interview. P1, P12, P15, and P17 noted that their sleep patterns were disrupted and that they lost the desire to eat anything, even to swallow food.

Being incomplete/ tampered body image

Many of the participants recalled how they were initially distressed at the recommendation of a hysterectomy and struggled to come to terms with the implications of being without a uterus. Some of them seemed to find it difficult to align their pre- and post-surgery self-image and believed that their body had been essentially tampered with. P9, a 45-year-old married with 2 children, showed her awe*:*

> *I did not believe that a woman could stay with no womb. Now that I have no womb, I am not complete as a woman and just there … (sighs).*
>
> *I feel as if I lack something in my body. I see myself as someone lacking a big thing, and it disturbs me a lot.*

P6, a 69-year-old married with 2 children, was more definite in her concern:

> *I have started infertility in my lineage, as any child that is my reincarnate will come to the world without a womb since I removed it in my first world.* (P6)

Reduction in food intake

It seems that because of the stress they experienced after the surgery, most of the women reported a decreased appetite. Reduced food intake and anxiety may partly account for their complaint of persistent physical weakness. One of the women indicated that trying to eat puts pressure on the stomach muscles and hurts her tummy.

Decisions made from fear and discomfort

The women were afraid of developing cancer and complications after hysterectomy. Fear of the invasiveness and removal of the uterus was a matter of stress for the women.

Psychological health

How hysterectomy affected the women's psychological health is summarized under the sub-themes of tension, stress and depressive feeling, dissonant grief, comparative consolation, and coping with a new self.

Tension, stress and depressive feelings

Many of the women were tensed months after hysterectomy. Some felt depressed and guilty and blamed themselves and their fate for suffering uterine prolapse. They recounted sadness, fatigue and loss of interest in everyday living. Their responses also show that even after the surgery, the women were concerned about the limited information they had about hysterectomy and its implications. They seemed to lack professional social support beyond medical care. P19 presented the issues thus:

> *I worry about other problems coming up. I have no peace of mind due to what I am seeing in my body: heat all over my body, weakness in my bones, night heat, etc.* (P19)

Dissonant grief and comparative consolation

Some of the women narrated the inner pain and anguish that they were experiencing. They were torn between a justification of the hysterectomy and a perceived perpetual loss of reproductive viability. They compared themselves with others who had cancer in terms of how much money and years they had spent awaiting a cure or death. They considered that their disease had a cure, although they did not like the cure.

Coping with the new self

Most of the participants reported experiencing a sense of loss after the hysterectomy that affected their emotional state and changed their relationship with significant others. These changes ranged from increasing to decreasing relationships with persons. Some of them explained that a new self in capacity, social reputation and rating emerged after the surgery, which they were adjusting to. Coping with a new self-appeared in three domains: adjusting to a new self, evolution in spiritual relation, and emotional dependency on offspring.

> *I see myself as someone who has come to the end of my womanhood. It means that I am inferior to other women because I can no longer do what they can do as a woman, like bearing children.* (P6, 69-year-old, married, 2 children)

P4, a 45-year-old married with 5 children, cried while stating:

> *I am nothing but an empty sack. I can't feel like a woman any longer. Look, now. Look at me. What use am I for?* P4

Evolution in spiritual relation and emotional dependency on offspring

Most of the women experienced fear and uncertainty after hysterectomy and sought refuge in their spiritual relationship with God as absolute power. P19, a 50-year-old married with 6 children, was an exception. She instead reduced her spiritual relationship. Hysterectomy also made them more sensitive and emotionally attached to their children and increased their dependence on them.

Social health

Social health experiences included four sub-themes on how hysterectomy affected the women's spousal relationship, seeking emotional support and care, adjusted social involvements, and economic activity.

Spousal relationship

Some of the participants stated that hysterectomy introduced fresh problems in their relationship with their spouse. The loss of the uterus made them feel deficient, and they were

concerned about their spouse's reaction to their condition. They lacked sexual urges. Some women concluded that they did not receive enough support from their husbands after hysterectomy. They felt lonely and abandoned. Lack of support from their spouses harmed the women's emotional relationships with them. They were, therefore, reluctant to discuss their issues or have sexual intercourse with their spouses and did not accompany them in work and leisure. Their spouses became aggressive.

> *The only relationship problem is my husband because I refuse sex with him. I am afraid the sperm will enter my stomach and may cause a problem.* (P3)

> *The operation has affected my husband seriously. He now beats me. He is easily angry towards me and threatens to get another wife.* (P8)

P18, a 50-year-old with five children, was subsequently divorced:

> *There is division in my family, and he tells my children that I am trying to kill him. Our children are against me, seeing that he only caters to their needs. This operation has changed the peace we used to enjoy; my husband is always irritated. I also feel bad; I feel guilty that I caused all the problems, and even my children are affected. With time, I hope we will make up.* (P18)

Seeking emotional support and care from parental family and adjusted social involvement

The parental family served as a refuge for emotional support and care for most participants, especially when they felt lonely and found their spouse non-supportive. They trusted to receive support from their family. They were reluctant to attend public gatherings but attended family gatherings. They sometimes received emotional support and care from friends, especially those who have had hysterectomy. Many of the women reported reduced social involvement, with some basing their decision on fear of being the subject of gossip, and some feared being stigmatized and accused of envying other women with intact wombs.

Economic activity

The women reported economic deprivation and reduced ability to contribute to the financial needs of their families due to their poor health. Farming constituted a significant activity for a large proportion of the participants. Despite their dissatisfaction with their health condition after surgery, they still needed to go to the farm. Some had to change their economic engagements:

> *I had to change to a zobo (a local beverage) business, but it was not like my farm work, which produces food for me and my children, and most times, I sell the extra for money. I lacked food because Zobo's money was not enough for our upkeep.* (P2)

Discussion

The findings of this study show that although the women were aware that the surgery would involve the removal of their uterus, the loss of the uterus was particularly distressing to them due to the significance they attached to the uterus as a symbol of womanhood. Their recovery periods seem to be longer than were reported for European women (Dedden et al., 2022; Shehmar, 2016). Their post-surgery experiences were marked by tension and loss. The women in this study still complained about pain and fatigue months after the surgery. The pre-and post-surgery tension experienced by the women probably exacerbated their physical symptoms and delayed recovery.

Their apprehension about the loss of the womb seems to be peculiar and rarely observed in studies in other cultures (e.g., Li et al., 2023; Shehmar, 2016), although a more general concern with reproduction for those still seeking a child and resumption of sexual activity has been reported among European, Asian and African women (Afiyah et al., 2020; Alshawish et al., 2020;

Li et al., 2023; Pilli et al., 2020; Schmidt et al., 2019; Solbrække & Bondevik, 2015). They feared that the removal of their uterus would introduce infertility into their lineage by reincarnation.

African women seem to highly value childbearing and attach much importance to the uterus as a symbol of viability. The efficacy of the womb seemed to persist beyond menopause. The experience of body pain and discomfort related to the surgery, feeling incomplete due to the loss of the uterus, perceived poor spousal support and depressive feelings seem to have contributed to their aversion to the resumption of sexual intercourse with their spouses (one of them was apprehensive about where the sperm from her spouse would enter). After the surgery, these women seem to have suffered from low self-esteem and fear of losing their femininity and charm in front of their husbands due to their loss of fertility.

The women seemed to attempt to cope with the physical changes in their bodies and the pain/discomfort they experienced by avoiding friends and refusing to participate in social activities. They may have considered that being unable to relate or work as usual would elicit concern and inquisitiveness from others. Thus, the women preferred to keep their condition to themselves and limited their social interactions because they expected stigmatization.

Hysterectomy affected the women's economic lives, although this was not as prominent as their physical, psychological and social life experiences. It seems that their economic difficulties can be accounted for by their physical, psychological and social life experiences and that their economic problems would be significantly reduced if their challenges in these other domains are addressed. Most of the women were married, and the cultural norm in the area of the present study places the burden of responsibility for the economic maintenance of the family on the male spouse (Onwuatuegwu, 2020).

Hysterectomy seems to be situated in a culture of contradictions. It is almost impossible to shield the women who had hysterectomies from observing and comparing themselves to other women either within or outside the hospital who they assume have intact wombs. Many of the participants were also concerned about the limited information they had on hysterectomy and its complications. Professional support in providing critical information to enlighten them on their concerns might help. This seemed to be lacking, inadequate or ineffective.

Previous studies (e.g., Hoga et al., 2012; Richter et al., 2000) reported that women who had hysterectomies believed that most husbands lacked basic knowledge or even had negative perceptions of hysterectomy and were unable to provide adequate emotional support to their spouses. The women in the present study also complained that they did not receive adequate information about hysterectomy and that their spouses did not provide adequate emotional support and care. Some of the women sought assistance from other women who had previously had a hysterectomy. This context portrays the tension the women experienced. Psychological intervention could reduce the length of stay and anxiety among women who underwent surgery (Xie et al., 2022).

The concern for healing and improvement of the life experiences of women who underwent hysterectomy for uterine prolapse, at least in Southeast Nigeria, seems to require both medical and psychological care that would impact their peculiar care needs. The psychological care component seems to be lacking among the participants in this study. This could be a deficiency in the management of patients who had hysterectomy. Further research is therefore required in this area, and the attention of concerned medical teams is also drawn to this.

Notwithstanding the findings, this study has probable limitations. The percentage of potential participants who did not meet the inclusion criteria for this study is extensive. They might differ in yet unknown ways from those who participated. In addition, the interviews in this study were conducted some months after the women had the surgery. It is possible that time-related changes in their post-surgery experiences were missed in this study. Future studies may consider a longitudinal design.

Conclusion

Removal of the uterus to manage uterine prolapse was very problematic among women in Southeast Nigeria. They considered the uterus to be central to womanhood. The women expected more empathy from their spouses about hysterectomy, although the women themselves had limited knowledge about the treatment. Clinical nurses and other health team members, therefore, need to provide more apparent knowledge about hysterectomy to the patients and include psychologists to target psychological care guidance that personalizes health education based on the women's individual needs and concerns and work with their families to help them cope with life without a uterus. Pre- and post-hysterectomy counselling by competent professionals would be beneficial to them. There is also a need to create self-help groups for women who underwent hysterectomy and improve public awareness about hysterectomy.

Availability of data and materials

The study dataset is available from the corresponding author following institutional approval.

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Conflict of interest

The authors report no potential conflict of interest.

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Authors' contributions

PNE, ILO, **JEO**, **PNI**, and **JEE** designed the study; **JEO** selected the participants; **PNE** interviewed them; ILO, PNI, CHU, and AOA interpreted the interview transcripts; PNE, JEE, and EWO analyzed the data; and PNE, ILO, JEO, PNI, JEE, and **CHU** prepared the initial draft of the manuscript.

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Sub-chronic Toxicological evaluation of extract of *Lavandula stoechas* on Liver, haematological parameters, and feed consumption of Wistar rats

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Abstract
Introduction: *Lavandula stoechas*are commonly used to treat various medical ailments. This study aims to determine its toxicological impact on Wistar rats' meal consumption, liver, and haematological markers.
Method: Animals of either sex were selected. Group 1 received normal saline (10 ml/kg), while groups 2, 3, and 4 received 50, 100, and 200 mg/kg, respectively, of Lavandula stoechas. The animals were kept in standard cages and given oral access to the extract for 28 days before being weighed and killed. A cardiac puncture was utilized to get blood, which was then immediately tested. The haematoxylin and eosin (H&E) staining technique evaluated the plant's histological hepatotoxic potential.
Result: Compared to the control, ethanol leaf extract of *Lavandula stoechas* generated a substantial ($P<0.05$) increase in body weight in the first, third, and fourth weeks but not in the second. There was a significant ($P<0.05$) drop in RBC, HGB, and MCV but no change in neutrophils, basophils, eosinophils, or platelets. At 100 mg/kg dose, *Lavandula stoechas* generated a substantial ($P<0.05$) rise in ALP and BILD. Other metrics did not differ substantially ($P<0.05$) across doses delivered. A histological examination revealed minor tubular deformation.
Conclusion: Though the plant is primarily safe, the study results show that it may have a minor effect on the liver, implying that it should be used cautiously for an extended period. A histological examination revealed minor tubular deformation.

Key: *Lavandula stoechas*, blood, rats, liver

Introduction

The liver is a significant metabolic organ found solely in vertebrates that performs several vital biological tasks, such as detoxification and the formation of proteins and biochemicals required for digestion and growth (Nosek 2016). It is positioned in the right upper quadrant of the belly, below the diaphragm, and is primarily protected by the lower right rib cage in humans. Other metabolic functions include carbohydrate metabolism, hormone generation, food conversion and storage (such as glucose to glycogen), and red blood cell disintegration. The liver also functions as an accessory digestive organ, producing bile, an alkaline fluid containing cholesterol and bile acids that emulsifies and assists in the digestion of dietary fat. In many mammals, including humans but not rats, is the gallbladder, a small hollow pouch located directly beneath the right lobe of the liver, which stores and concentrates bile produced by the liver, which is then discharged to the duodenum to aid digestion (Molina *et al.*, 2012).

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The liver, primarily through its hepatocytes, regulates a wide range of high-volume biochemical activities, including the creation and breakdown of tiny and complex organic compounds, many of which are required for proper essential functions. The overall number of functions performed by the organ is estimated to be around 500 (Molina *et al.,* 2012).

Long-term compensation for the absence of liver function is unknown, while liver dialysis techniques can be utilized in the short term. Without the liver, artificial livers have not been produced to promote long-term replacement. Liver transplantation is the only treatment for total liver failure as of 2018 (Nguyen-Lefebvre *et al.,* 2015). However, long-term clinical experience has often supported therapeutic plants, with little to no scientific evidence of their safety and efficacy (Pathan *et al.,* 2003). Many medicinal herbs are used as medicine based only on a long-standing, widespread traditional folk practice. With the upsurge in the use of herbal drugs, a thorough scientific investigation of these plants is imperative based on the need to validate their folkloric usage (Younossi*et al.,* 2023). Although herbs are generally assumed to be safe, many unsafe and fatal side effects have been reported. These could be direct toxic effects, allergic reactions, effects from contaminants and/or interactions with drugs and other herbs (Younossi*et al.,* 2023). Phytotherapeutic products are often mistakenly regarded as less toxic because they are 'natural'. Nevertheless, those products contain bioactive principles that can potentially cause adverse effects (Schweitzer *et al.,* 2015).

Lavender (*Lavandula stoechas*), a member of the Labiatae family, is utilized in herbal medicine for various cosmetic and medicinal uses (Aviram, 2000). Inhaling lavender essential oils reduced cholesterol plaques in rabbits with atherosclerotic disease but did not affect serum cholesterol levels (Huxley & Neil 2003). In rats, lavander has a hypolipidemic impact (Sesso *et al.,* 2003). Furthermore, lavender aromatherapy has been shown to have vasodilatory effects and to increase coronary blood flow in humans (Fuhrman & Aviram, 2001). A lavender flower extract protected Isolated rat hearts from ischemia-reperfusion (IR) injury. In our recent study, lavender oil showed neuroprotective activity and antioxidant properties in an experimental stroke model (Cavanagh & Wilkinson, 2002). In a just-completed study, therapy with lavender essential oil after MI decreased ischemia injury in rats. This research sought to evaluate the sub-chronic effect of the extract of Lavandula stoechas on feed consumption and the liver and haematological parameters of Wistar rats.

Methods

Study design: This experimental study used laboratory animals (Winstar rats in a confined and controlled environment) as subjects. The study was conducted in the Animal House of Bringham University in Nigeria, West Africa.

Figure: Location of the study site

Study animals: 198 male and 239 female Wistar rats were acquired from Bingham University's Animal House. They were fed standard animal pellets purchased from Grand Cereals Limited and given unlimited water. The Animal Ethics Committee of Bingham University College of Health Sciences issued rights and approval for the studies (BU/2021/1132). The rats were randomized to treatment groups with six animals (n = 6). The care and handling of the animals followed established public health guidelines in the Guide for Care and Use of Laboratory Animals (2011).

Plant collection: Fresh leaves of *Lavandula stoechas*were were taken from its natural habitat in the adjacent Karu village, Nasarawa State, Nigeria. The Department of Botany at Bingham University validated the plant and assigned it a voucher number (BU1177).

Plant extraction: The *Lavandula stoechas*leaves were shade-dried for two weeks. The dried plant material was then crushed and reduced to little pieces. Extraction was carried out with 70% ethanol at a ratio of 200g of extract per litre of ethanol by percolation at room temperature. The liquid filtrates were concentrated and evaporated to dryness in a vacuum at 40°C using a rotary evaporator. The ethanol extract was kept at -4°C until it was needed.

Animal study: The Organization for Economic Development (OECD) guideline no. 425 for analysis of Chemicals was employed for this study (OECD 2008). Twenty-four (24) rats of either sex (weighing between 190 and 289g) were randomly chosen. The extract was given to rats in groups 2, 3, and 4 at doses of 50, 100, and 200 mg/kg, respectively, while group 1 served as the control group and received normal saline (10 ml/kg). The weights of the rats were recorded at the start of the experiment and once a week thereafter. The day of sacrifice was designated as D29, whereas the initial day of dosing was defined as D0.

Haematological analysis: The rats were sacrificed using diethyl-etherbythe protocol on the 29th day of the trial. Blood samples were slowly obtained through cardiac puncture. Blood was drawn into sample bottles containing EDTA for haematological analysis, including haemoglobin concentration, white blood cell counts (WBC), differentials (neutrophils, eosinophils, basophils, lymphocytes, and monocytes), red blood cell counts (RBC), platelets, and haemoglobin (Hb) concentration. This was accomplished with the help of an automated haematology machine (Cell-Dyn, Abbott, USA).

Food and water consumption: The difference between the daily supply of feed and water and the amount still available after 24 hours was used to compute the daily feed and water consumption. The rats were sacrificed on the 29th day of the experiment, and their organs were removed for further gross and histo-pathological investigation.

Biochemistry analysis: The second portion of the blood was collected into a plain bottle, allowed to clot, and centrifuged at 300rpm for 10 minutes. The serum collected was used to estimate biochemical parameters.
Histological study: The liver of the animals was surgically removed and weighed, and a part of each was fixed in 10% formaldehyde for histological processes.
Statistical analysis: Data were expressed as the Mean, standard Error of the Mean (SEM). Data were analyzed statistically using one-way Analysis of Variance (ANOVA) followed by Dunnett's post hoc test for multiple comparisons between the control and treated groups. Values of $P \leq 0.05$ were considered significant.

Results

Effect of 28 days oral administration of *Lavandula stoechas* on body weight (g) in rats: At 100 mg/kg dose level, ethanol leaf extract of *Lavandula stoechas* caused a significant ($P<0.05$) increase in body weight in the first, third, and fourth weeks, but not in the second week when compared to the control (Table 1).

Effect of 28 days oral administration of *Lavandula stoechas*on haematological parametersin rats *Lavandula stoechas* induced a substantial ($P<0.05$) drop in red blood cell, hemoglobin, and platelet levels at 100 mg/kg dose and a significant ($P<0.05$) rise in mean corpuscular hemoglobin concentration in rats at 50 mg/kg dose compared to the control. However, mean corpuscular hemoglobin concentration did not affect basophiles, neutrophils, eosinophils, or lymphocytes ($P<0.05$). (Table 2).

Effect of 28 days oral administration of *Lavandula stoechas*on hepatic indices in rats: *Lavandula stoechas* significantly ($p<0.05$) increased ALP and BILD at 100 mg/kg dose. The other parameters' level was not significantly affected across doses administered ($p<0.05$).

Effect of 28 days oral administration of ethanol leaf extract of *Lavandula stonemason* histology Liver of rats: The liver showed vascular congestion, slight hepatic necrosis with slight sinusoidal congestion and lymphocyte hyperplasia at 100 mg/kg and 200 mg/kg, Sinusoidal congestion at 100 mg/kg and Moderate hepatic necrosis and vascular congestion at the control (10ml/kg normal saline) (Fig. 4).

Table 1: Effect of 28 days of oral administration of *Lavandula stoechas* on body weight (g) in rats

Treatment (mg/kg)	Week 1	Week 2	Week 3	Week 4
DW (10ml/kg)	195.11±6.7	197.10±6.3	194.61±5.3	195.72±9.1
50 mg/kg	199.13±10.7	197.65±15.8	197.58±3.1	172.60±5.8
100 mg/kg	206.26±19.5*	215.61±22.5	210.83±13.5*	212.10±20.40*
200 mg/kg	200.64±11.3	201.08±8.1	197.47±6.1	203.54±8.1

*Significantly different from the distilled water (DW) control at p<0.05. DW = distilled water

Table 2: Effect of 28 days oral administration of ethanol leaf extract of *Lavandula stoechas* on haematological parameters in Wistar rats

			Treatment (mg/kg)	
Haematological parameters	DW(10ml/kg)	LS (50)	LS (100)	LS (200)
WBC (×10^9/L)	8.17±0.77	6.74±1.42	3.70±0.67*	7.20±1.85
RBC (×10^12/L)	8.30±0.35	8.65±0.664	6.17±0.55*	7.74±0.25
HGB (g/dL)	15.90±0.56	15.24±0.66	11.36±0.87*	14.58±0.36
HCT (g/dL)	55.2±2.02	56.6±3.7	34.7±3.1*	53.4±1.8
MCV (fL)	66.7±0.94	65.4±1.45	57.1±0.3*	69.6±1.7
MCH (pg)	19.1±0.2	17.8±1.9	18.8±0.7	18.80±0.2
MCHC (g/dL)	29.1±0.2	27.4±1.3	32.1±0.6*	27.1±0.7
PLT (×10^9/L)	620.8±52.8	567.0±96.8	252.0±50.4*	670.4±55.8*
LYM (%)	86.8±4.6	85.0±4.3	82.8±5.8	86.41±3.1
NEUT (×10^9/L)	10.8±3.6	10.8±3.7	15.4±5.6	11.0±3.2
EOSI (×10^9/L)	1.5±0.3	2.4±0.8	1.8±0.44	1.2±0.2
BASO (×10^9/L)	1.0±0.28	2.0±0.5	2.5±1.5	3.3±2.2

Data presented as Mean ± SEM: n = 6, One way ANOVA, followed by Dunnett's post hoc for multiple comparison
*significantly different from the distilled water (DW) control at p<0.05. DW = distilled water (WBC = white blood cells, RBC = red blood cells, HGB = hemoglobin, HCT = hematocrit, MCV = mean corpuscular volume, MCH = mean corpuscular hemoglobin, MCHC = mean corpuscular hemoglobin concentration, PLT = platelet, LYM = lymphocyte, NEUT = neutrophils, EOSI = eosinophils, BASO = basophils).

Table 3: Effect of 28 days of oral administration of *Lavandula stoechas*on hepatic indices in wistar rats

		Treatment (mg/kg)		
Hepatic indices	DW(10ml/kg)	LS (50)	LS (100)	LS (200)
ALB (g/L)	38.5±1.7	44.2±1.0	35.2±1.7	43.2±1.3
ALP (IU/L)	113.2±6.7	152.0±8.2	370.0±43.7*	125.5±6.3
ALT (IU/L)	62.8±3.4	70.0±10.2	94.2±10.4	87.5±1.9
AST (IU/L)	299.4±9.9	297.3±7.6	175.2±3.8	233.0±1.7
BILD (mol/L)	0.32.1±0.1	0.3±0.7*	0.6±0.2*	0.6±0.1
BILT (mol/L)	2.3±0.5	2.9±0.2	3.4±0.2*	2.8±0.2
TP (g/L)	69.6±3.1	66.1±2.7	61.3±5.1	82.2±2.1

Data presented as Mean ± SEM: n = 6, One Way ANOVA, followed by Dunnett's post hoc for multiple comparison *significantly different from the distilled water (DW) control at p <0.05. DW = distilled water (ALB = albumin, ALP = alanine phosphatase, ALT = alanine transaminase, BILD = unconjugated bilirubin, BILT = conjugated bilirubin, TP = total protein).

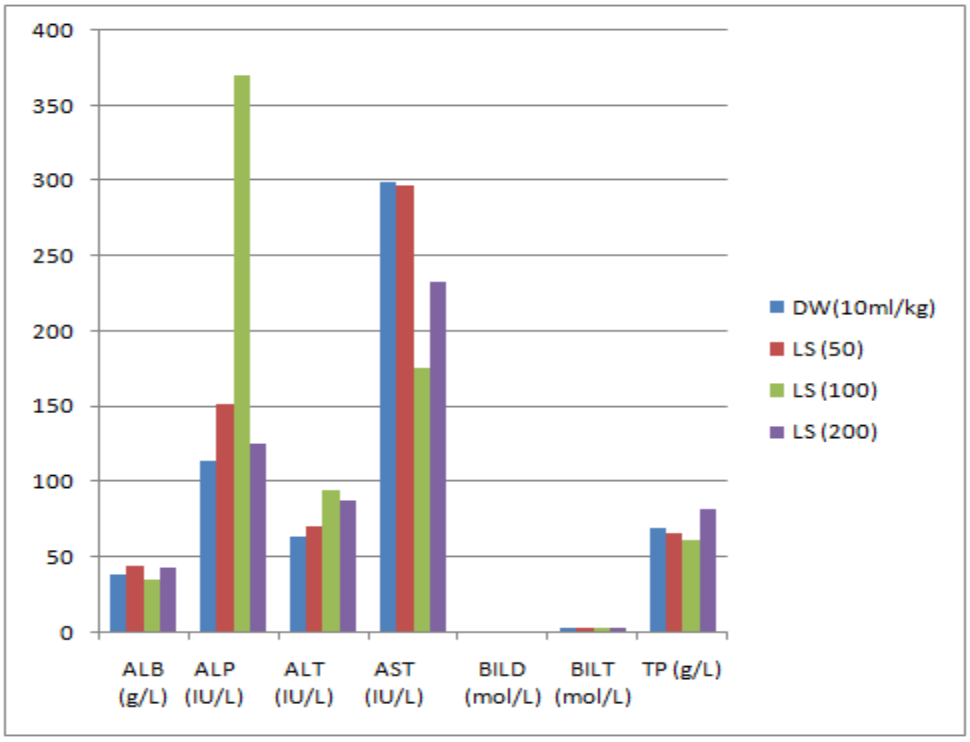

Figure 2: Effect of 28 days oral administration of *Lavandula stoechas*on hepatic indices in Wistar rats

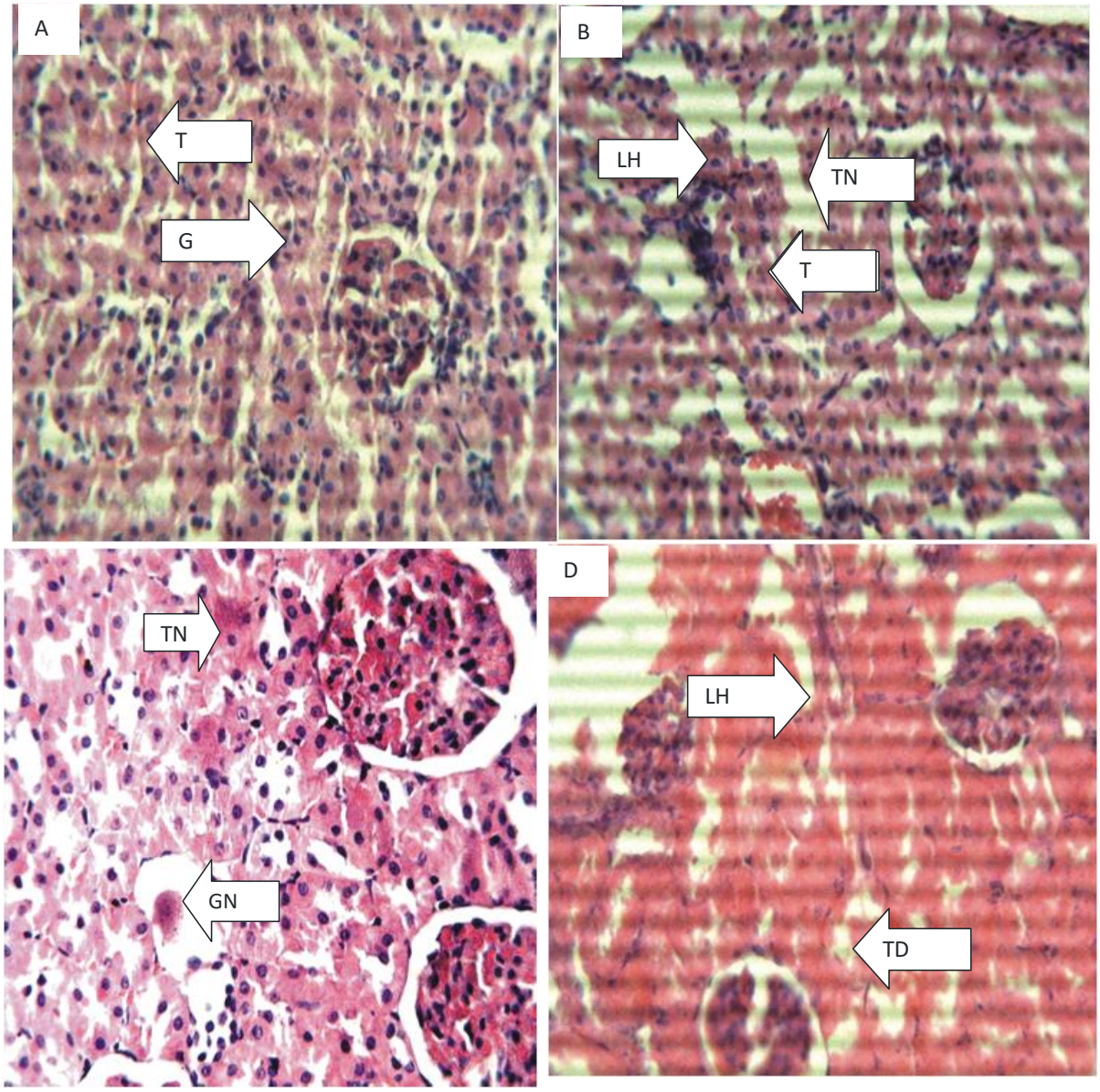

Figure 3: figure of the liver (Hematoxylin and eosin. H and E ×100). (a) Control group, shows normal hepatocyte (H). (b) LS 50 mg/kg, (c) LS 100 mg/kg, (d) LS 200 mg/kg.

Discussion

Herbal medicines are essential in Oriental medicine (OM), which has been practised for over 2000 years (El-Hilaly*et al.,* 2003). Herbal remedies include dietary supplements containing herbs, either alone or in combination. They are sometimes called botanicals because of their fragrances, flavors, and/or therapeutic properties (Furman 2015). Herbal drugs are widely used worldwide and available in health food stores without a prescription (Toygar *et al.*, 2020). Over the past decade, there has been an increased global interest in traditional systems of medicine and herbal medicinal products. This surge has partly been due to the rare or non-existent access to modern medicine in developing countries and large populations' acceptance of herbal medicines in developed nations (Setacci*et al.*, 2020).

Haematological parameters are functional indices that can be employed to assess the toxic potentials of plant extracts in living systems (Hüser*et al.,* 2020). They can also explain the related functions of chemical compounds/plant extracts. Herbal plants have been used for various medicinal and health benefits. Medicinal plants are often consumed locally without a graded dose or expected duration of use (Liamis*et al.*, 2014). This can precipitate unexpected side effects on the tissue, organ or body system. In this study, the impact of the plant on the liver and vascular parameters was evaluated (Maric *et al.*, 2022).

Ethanol extract of *Lavandula stoechas*resulted in a significant decrease in the red blood cells, haemoglobin and platelet compared to the control group of rats. This indicated that the plant may either suppress the production of red blood cells, decrease the lifespan of red blood cells or cause problems with how the body uses iron. Anemia, or decreased red blood cell count, can induce weariness and weakness. When a person's red blood cell count is lower than expected, their body needs to work harder to get enough oxygen to the cells. A low RBC count can result in some symptoms and health concerns. Hemoglobin is required for oxygen transmission in the blood from the lungs to the tissues. In muscle cells, myoglobin receives stores, transports, and releases oxygen (Archer *et al.,* 2003). The extract did not affect the levels of basophiles, neutrophils, eosinophils, or lymphocytes. This suggests that the plant does not affect the body's immune system. It could also imply that the plant has immunomodulatory properties.

To determine liver function, the activity and concentrations of serum ALT, AST, ALP, bilirubin (total and direct), total cholesterol, total protein, and albumin, all of which originate in the cytoplasm, were measured (Spampinato *et al.,* 2020). When there is hepatopathy, these enzymes and chemicals leak into the bloodstream, acting as a marker for liver disease (Spampinato *et al.,* 2020). Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) are the most often utilized indicators of liver (hepatocellular) injury. Because AST is detected in various organs, such as the heart and skeletal muscle, ALT is thought to be a more specific sign of liver inflammation (Algieri *et al.,* 2016).

Normal serum ALT, AST, total protein, and albumin levels in extract-administered rats indicate that the plant has little to no effect on inducing liver injury. The most common test for detecting biliary blockage is alkaline phosphatase estimate. Bilirubin is the primary bile pigment in humans, and when it is increased, it causes the yellow colouring of the skin, known as jaundice. Bilirubin is formed primarily from the breakdown of a substance called heme found in red blood cells. It is taken up from the blood, processed, and then secreted into the bile by the liver. Healthy individuals usually have a small amount of bilirubin in the blood (<17µmol/L). Conditions that produce increased bilirubin synthesis, such as red blood cell death, or decreased bilirubin removal from the bloodstream, such as liver failure, may result in a modest increase in bilirubin levels in the blood (Spampinato *et al.,* 2020). The study found that ALP, BILD, and BILT levels increased dramatically. These findings imply that the plant extract may damage red blood cells, mildly block the bile duct, and/or limit the evacuation of RBC from the bloodstream. A histological examination that reveals minor hepatic necrosis and other typical liver features agrees with other measures.

Conclusion

Although the *Lavandula stoechas* plant is generally safe, the study's findings reveal that it may have a minor impact on the liver, implying that it should be used cautiously over an extended period. A histology examination reveals only minor tubular distortion.

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