



META ANALYSIS ARTICLE

Antibiotic Resistance Conferred by Class 1 Integron in *Vibrio cholerae* Strains: A Meta-analysis

Zavuga Zuberi, Albert Joseph Sillo..... 119

ORIGINAL ARTICLES

Clinical and Epidemiology Characteristics of COVID-19 Cases Detected During Mass Screening Campaign from July to October 2020 in Bujumbura, Burundi

Edouard Nkuzimana, Jean Claude Bizimana, Adolphe Ndoreroaho et al.....127

Factors Associated with Uptake of Intermittent Preventive Treatment for Malaria During Pregnancy. Analysis of Data from the Tanzania 2015-2016 Demographic Health Survey and Malaria Indicator Survey

Theresia J. Masoi, Fabiola V. Moshi, Maximilian B. Tungaraza..... 134

Placental Parasitic Infections and Pregnancy Outcomes Among Women Delivering at a Tertiary Hospital in Northern Tanzania

Eustadius Kamugisha Felician, Octavian Aron Ngoda, Ola Farid Jahanpour et al.....141

The Influence of Fear During Pregnancy, Labour and Delivery on Birth Outcome Among Post-Delivery Women: A Case Control Study in Zanzibar

Mwanaali H. Ali, Saada A. Seif, Stephen M. Kibusi.....147

Determinants of Antenatal Healthcare Services Utilization: A Case of Dodoma, Tanzania

Saraphina J Kibesa, Yona W Kitua, Daniel W Kitua.....155

Factors Influencing Formal Mental Treatment - Seeking Behaviour among Caretakers of Mentally Ill patients in Zanzibar Zanzibar

Said S. Bakar, Fabiola M. Moshi.....162

Characterisation of Malaria Diagnosis Data in High and Low Endemic Areas of Tanzania

Martina Mariki, Neema Mduma, Elizabeth Mkoba.....171

Intellectual Property Management Capacity in Tanzania: Perception of Researchers in Academia and Research Institutions of Health and Allied Sciences

Kijakazi Obed Mashoto.....180

Lived Experiences of Adults with Sickle Cell Disease: A Qualitative Study, Dar es Salaam, Tanzania

Dickson Ally Mkoka, Rehema Nkingi.....189

Diabetic foot risk assessment among patients with type 2 diabetes in Kenya

James Ngoyo Nduati, Samwel Maina Gatimu, Yeri Kombe.....196

Correlation of Malaria Rapid Test and Peripheral Blood Smear Microscopy among Patients attending Byumba Health Centre

Cedrick Izere, Joyce Niyigena, Jean de Dieu Tuyishime et al.....203



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Antibiotic Resistance Conferred by Class 1 Integron in *Vibrio Cholerae* Strains: A Meta-analysis

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ABSTRACT

Background: Class 1 integron is the most ubiquitous platform among antibiotic resistance bacterial populations, including *Vibrio cholerae* strains. This meta-analysis aimed to determine the antibiotic resistance conferred by class 1 integron conserved segments (CS); 3'-qacEΔ1 and sul1, and 5'-int1 in *V. cholerae* strains.

Methods: An intensive literature search of electronic databases for relevant studies from their starting dates up to April 2019 was conducted by two independent investigators. The electronic databases included; PubMed, Ovid Medline and Google Scholar databases. Only studies that determined antibiotic resistance conferred by class 1 integron in *V. cholerae* strains isolated from clinical and/or environmental samples using Polymerase Chain Reaction (PCR) assay were included in this study.

Results: The random-effects model was selected and performed for all the studies included in this meta-analysis. Fourteen studies consisting of both qacEΔ1 and sul1, and int1 in the class 1 integron of *V. cholerae* strains were included. The proportions of class 1 integron 3'-CS and 5'-CS were 70.4 % (95%CI: 37.5–94.4) and 52 % (95% CI: 6.3–95.7) respectively.

Conclusions: The proportions of class 1 integron in *V. cholerae* strains significantly contributed to the antibiotic resistances, which are comparable to other gram-negative bacteria clinical isolates. Moreover, the 3'-CS qacEΔ1 and sul1 are highly involved in the antibiotic resistance in comparison to 5'-CS int1. Generally, the study findings provide a general view on antibiotic resistance conferred by class 1 integron in *Vibrio cholerae* strains.

BACKGROUND

Cholera is a disease with the most rapidly devastating effects, accounting for morbidity, mortality, and antibiotic drug resistance in people's life.¹ *Vibrio cholerae* are environmental organisms that can acquire antibiotic-resistant genes through intimate contact with fundamentally resistant environmental bacteria using mobile genetic elements that share resistant traits with other enteric pathogens.^{2,3} This results in antibiotic resistance of *V. cholerae* strains to drugs, thus leading to the high burden of cholera disease in different parts of the world.^{4,5}

Antibiotic-resistant genes are carried in class 1 integron elements capable of moving resistant genes and integrating them into chromosomes of the bacteria by site-specific recombination.⁹ Class 1 integron has two conserved segments (CS); 3'-CS and 5'-CS with variable region possessing antibiotic resistance gene cassettes.¹⁰ The 3'-CS segment contains the qacEΔ1 and sul1 genes possessing 800 bp amplicon size while 5'-CS, an integrase (*intI*), and its attachment site (*attI*) are located together with gene promoter with about 900 bp amplicon size.³ The molecular variation in amplicon size for 5'-CS *intI* can be due to several

factors, including primer degradation, primer slippage, polymerase dissociation, and mis-priming due to the secondary structure accounting for the differences.^{11,12} About 200 O-serogroups of *Vibrio cholerae* strains exist but only serogroup O1 is associated with antibiotic resistance. The serogroup O1 is classified into classical and E1 Tor biotypes.⁵ The classical biotype is further classified into O1-Inaba, and O1-Ogawa biotypes (Figure 1). The O1-Inaba, O1-Ogawa, and E1 Tor biotypes share genomic properties between their biotype strains. The most apparent difference between O1 serogroup and non-serogroups (non-O1 and non-O139) relies on the possession of a capsule.^{6,7} Serogroups other than O1 and O139 are generally named *V. cholerae* non-O1, non-O139, or non-agglutinating Vibrios (NAGs).⁸

Different molecular characterization techniques have been reported for determining the *V. cholerae* serogroup 1 from clinical and environmental samples. These include multi-locus enzyme electrophoresis, ribotyping, polymerase chain reaction (PCR) assays, and pulsed-field gel electrophoresis.⁶ However, other molecular techniques such as simplex and multiplex PCRs can be used for non-O1, and non-O139 *V. cholerae*.⁸

Despite the diversity of molecular techniques, all studies included in this meta-analysis used PCR assay in studying antibiotic resistance in *V. cholerae* strains as it can detect CS amplicons of smaller-size ranging between 800 and 900 bp.

Resistant serogroup O1 of *V. cholerae* has been disseminated globally, which threatens the effective treatment and control of cholera mostly in low- and middle-income countries.¹³ However, there are limited data available about the nature and extent of antibiotic resistance caused by the serogroup O1 strains.¹⁴ Although most of the studies about the intervention of Cholera and its antibiotic resistance were done in other parts of the world like India, Iran, and China. Africa is also known to be affected by this pandemic. Cholera was imported to Africa through West Africa and then spread to East, Central, and later South Africa in the 1970s during the seventh pandemic.²⁸ Most prominently El Tor and classical biotypes were later identified in clinical and environmental samples in different parts of Africa. This necessitates the need to conduct in-depth studies of antibiotic resistance for these biotypes as one of the management strategies for Cholera intervention in Africa. Moreover, Mohammed et al.²⁸ reported in their systematic review done in sub-Saharan African countries that among the antibiotics resisted by *V. Cholerae* the most reported includes in their order of Trimethoprim, Sulphamethoxazole, Ampicillin, Chloramphenicol, and Streptomycin. However, very little information is known concerning the magnitude of antibiotic resistance conferred by class 1 integron in *Vibrio cholerae* strains. Therefore, this study determined the antibiotic resistance conferred by class 1 integron conserved segments (CS); 3'-*qacEA1* and *sul1*, and 5'-*int1* in *V. cholerae* strains.

METHODS

Overview of the Modus Operandi for the Study

This meta-analysis was performed following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.³⁰ A comprehensive literature search of studies that meet the inclusion criteria was conducted in the 3 electronic databases.

Search Strategy

The intensive literature searches of the relevant studies from their starting dates to April 2019 were conducted in PubMed, Ovid Medline, and Google Scholar databases. The terms 'class 1 integron' 'antibiotic resistance', and '*Vibrio cholerae*' were used in the searching. These searches were supplemented by scanning citations for the relevant studies. All identified study abstracts were independently reviewed for their eligibility by two investigators.

Inclusion and Exclusion Criteria

Studies which were included in the meta-analysis met the following criteria: (1) conducted on either clinical or environmental samples of *V. cholerae* strains; (2) used PCR assay to identify antibiotic resistance conferred by class 1 integron in *V. cholerae* strains studies; (3) full-text articles accessed; and (4) article written in English language. Studies which used phenotypic methods instead of PCR assay, reported review, systematic reviews or meta-analyses of other studies, congress abstracts and those written in languages other than English were excluded.

Selection Procedure

The titles and abstracts of all searched records were reviewed to identify the full-text articles for eligibility and determine their relevance for inclusion in the meta-analysis.

Data extraction

Reviewers used a standardized data extraction form to extract data from studies which met the inclusion criteria.²⁹ Where there was disagreement, a discussion between the two reviewers was conducted so as to reach a consensus. The extracted information included author's name, publication year, country, the total number of *V. cholerae* strains studied, type of *V. cholerae* strains, study period, number of strains with antibiotic resistance, and the relative frequency of *V. cholerae* strains.

Minimizing Biases

To minimize bias, two authors reviewed the articles independently and the retrieved records were double-checked. Publication biases are presented in funnel plots in Figure 4.

Statistical Analysis

All statistical analyses were performed using MedCalc Statistical Software (18.11.6; MedCalc Software bvba, Ostend, Belgium). The weighted random-effects model for each study sample size was considered statistically significant at $p < 0.05$. In addition, the pooled proportions and 95% confidence intervals (CIs) for positive *V. cholerae* strains per class 1 integron CS were computed using proportions presented in the full-text report of each study. Heterogeneities among studies were evaluated using the I^2 statistic with 95% CI. For publication bias, funnel plots were derived for each class 1 integron CS (Figure 4).

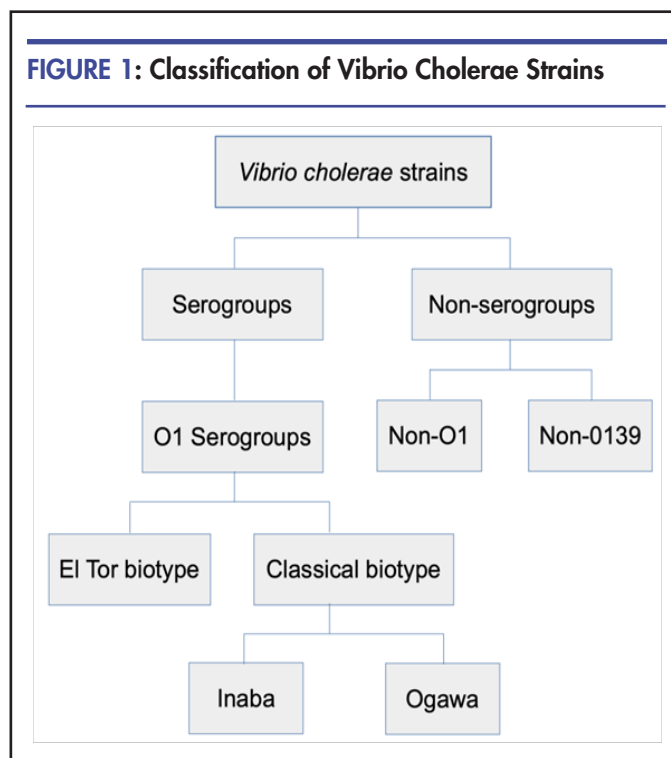
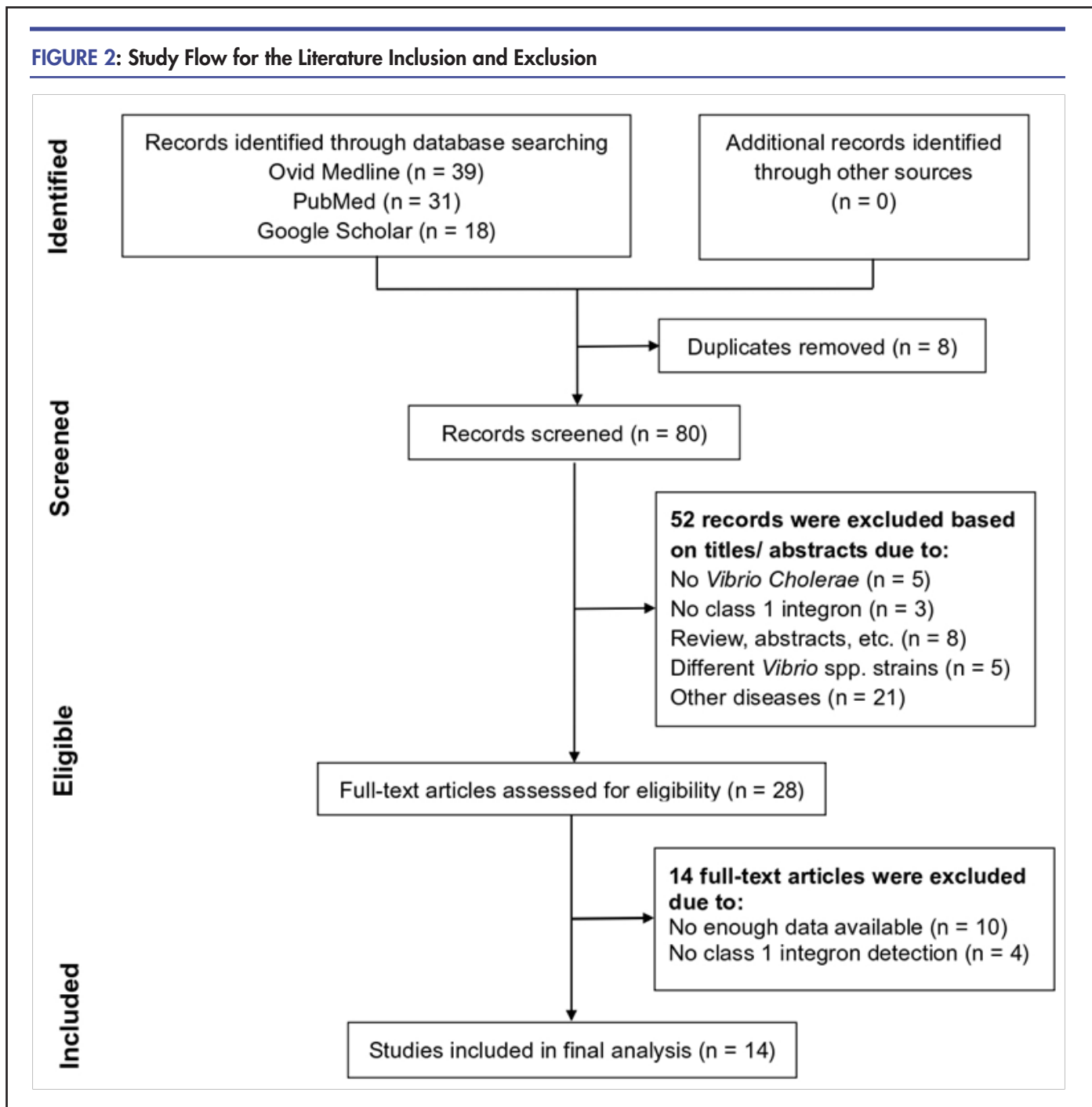


FIGURE 2: Study Flow for the Literature Inclusion and Exclusion



RESULTS

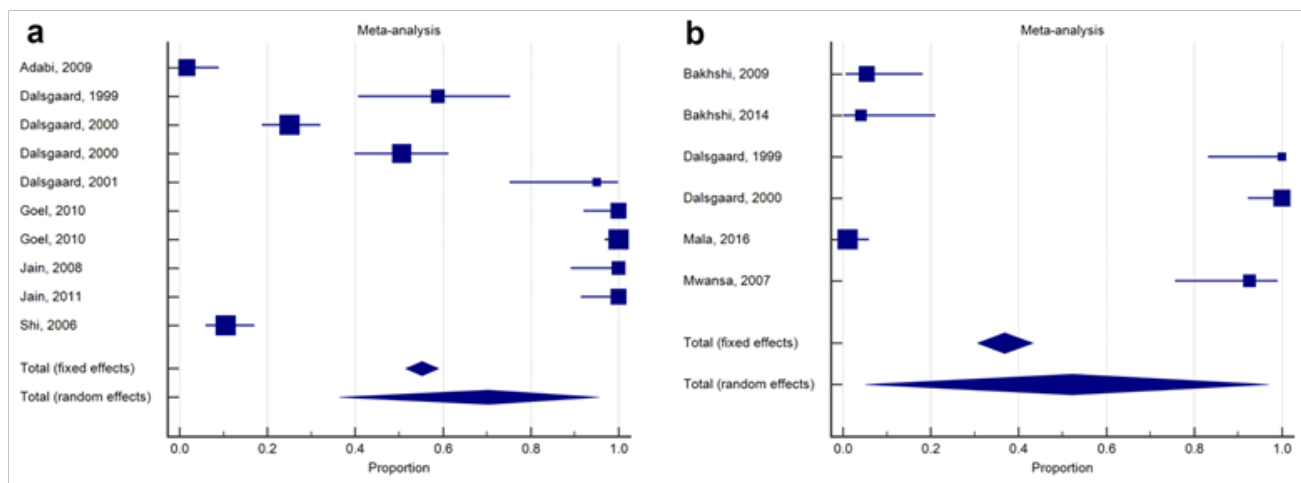
General Characteristics of Studies Involved in the Analysis

Using three electronic databases and manual searches yielded 88 references. However, 8 references were excluded as they were duplicate publications. Based on titles and /or abstracts, we excluded 52 references and reviewed 28 references for full-text articles. After the application of the study inclusion criteria,

14 studies of antibiotic resistance in *V. cholerae* in the years between 1996 and 2016 were included in the meta-analysis (Figure 2). The pooled studies that were included in our meta-analysis involved O1-Inaba, O1-Ogawa, El Tor, non-O1, and non-O139 of *V. cholerae* strains and were studied to determine the antibiotic resistance conferred by class 1 integron.

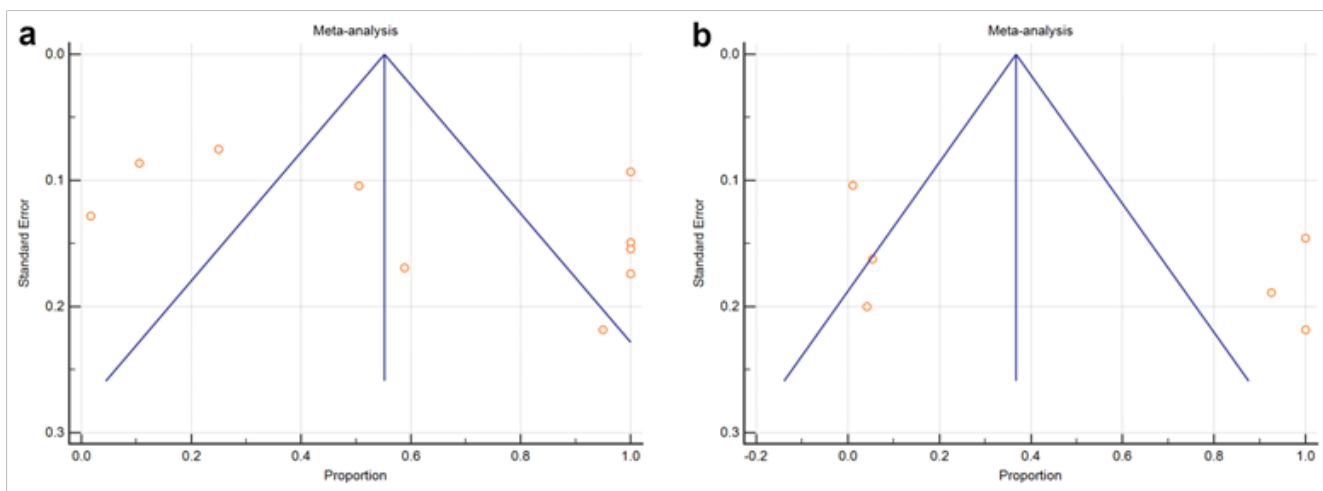
Number of *V. Cholerae* Strains with Antibiotic Resistance

FIGURE 3: Forest plot for the antibiotic resistance conferred by (a) class 1 integron *qacEΔ1* and *sul1* 3'-CS (b) class 1 integron *int1* 5'-CS in *Vibrio cholerae* strains



Each square is proportional to the percentage weight of each study in the meta-analysis. The diamond represents the overall summary estimate, with the confidence interval given by its width.

FIGURE 4: The funnel plot for the antibiotic resistance was conferred by (a) class 1 integron *qacEΔ1* and *sul1* 3'-CS (b) class 1 integron *int1* 5'-CS in *Vibrio cholerae*



The vertical line in the middle represents the estimate of summary effect size and the two stands sidlined show the spread of the 95% CIs. Each point represents a separate study.

Moreover, 10 articles studied *qacEΔ1* and *sul1*^{9, 10, 14-21}, 6 articles studied *int1*^{4, 10, 16, 22-24}, and 2 articles studied both *qacEΔ1* and *sul1*; and gene cassette *int1*^{10, 16} in the class 1 integron of *V. cholerae* strains. The amplicon sizes reported in the studies were 800 bp for *qacEΔ1* and *sul1*, while

int1 varied between 900-1800 bp (Table 1). All studies involved clinical *V. cholerae* strains; except one study that included only environmental *V. cholerae* strains.²²

Heterogeneity and Publication Bias

TABLE 1: Studies Included in Meta-Analysis

Study [ref]	Publication Year	Study period	Country	<i>V. cholerae</i> strains studied	Number of <i>V. cholerae</i> strains	Number of antibiotic resistant strains	Class 1 integron probes	Amplicon size (bp)
Adabi et al. [9]	2009	2004-2006	Iran	O1-Inaba, O1-Ogawa, non-O1, non-O139	60	1	qacEAI-F and sul1-R	800
Bakhshi et al. [22]	*2009	2006	Iran	Non-O1, non-O139	37	2	int1-F, int1-R	ns
Bakhshi et al. [23]	2014	3 years duration	Iran	Ns	24	1	int1-F, int1-R	900
Dalsgaard et al. [16]	1999	1979-1990	Vietnam	O1-Ogawa ^a	34	20	qacEAI-F, sul1-B	800
Dalsgaard et al. [15]	2000	1982-1995	Thailand	O1-Inaba ^b	20	20	int1-F, int1-B	1,000
Dalsgaard et al. [16]	2000	1996-1997	Guinea-Bissau	O-Serotype	176	44	qacEAI-F, sul1-B	800
Dalsgaard et al. [14]	2001	1997-1998	Mozambique	O1-Serotype	91	46	qacEAI-F, sul1-B	800
			5- South Africa		46	16	int1-F, int1-B	1,800
				O1-Ogawa	20	19	qacEAI-F, sul1-B	800
Goel et al. [17]	2010	2004	India	O1-Ogawa	44	44	qacEAI-F, sul1-B	800
Goel et al. [18]	2010	2004-2007	India	O1-Ogawa	114	114	qacEAI-F, sul1-B	800
Jain et al. [20]	2008	2007	India	O1-El Tor	32	32	qacEAI-F, sul1-B	800
Jain et al. [19]	2011	2010	India	O1-Ogawa	41	41	qacEAI-F, sul1-B	800
Mala et al. [4]**	2016	2004-2012	Thailand	O1, non-O1, non-O139	92	1	int1-F and int1-R	923
Mwansa et al. [24]	2007	1990-2004	Zambia	O1-El Tor	69	22/23 ^c	int1-F and int1-R	923
Shi et al. [21]	2006	1992-2000	India	O1, O139, non-O1, non-O139	133	3/4 ^d 14	qacEAI-F, sul1-B	800

* study involved *V. cholerae* strains from environmental samples
 ** study involved 67 *V. cholerae* strains from clinical samples and 25 *V. cholerae* strains from environmental samples
 a strains isolated between 1979-1981
 b strains isolated between 1982-1999
 c and d strains isolated in the year 1996 and 1997 respectively
 AR: Antibiotic resistance
 ns not stated

TABLE 2: Meta-analysis of Antibiotic Resistance and Heterogeneity Test For Class 1 Integron Conserved Segments

Study [ref.]	Number of <i>V. cholerae</i> strains	Number of antibiotic resistant strains	Percent antibiotic resistance	95% CI	Weight (%)	I ² (95% CI)
Meta-analysis: % antibiotic resistance by qacEA1 and sul1 3'-CS						
Adabi, 2009 [9]	60	1	1.7	0.04-8.9	10.0	98.8% (98.5-99.1)
Dalsgaard, 1999 [16]	34	20	58.8	40.7-75.3	9.9	
Dalsgaard, 2000 [15]	176	44	25.0	18.8-32.1	10.1	
Dalsgaard, 2000 [10]	91	46	50.5	39.9-61.2	10.1	
Dalsgaard, 2001 [14]	20	19	95.0	75.1-99.9	9.8	
Goel, 2010 [17]	44	44	100.0	91.9-100.0	9.9	
Goel, 2010 [18]	114	114	100.0	96.8-100.0	10.1	
Jain, 2008 [20]	32	32	100.0	89.1-100.0	9.9	
Jain, 2011 [19]	41	41	100.0	91.4-100.0	9.9	
Shi, 2006 [21]	133	14	10.5	5.9-17.0	10.1	
Total (random effects)	745	375	70.4	37.5-94.4	100.0	
Meta-analysis: % antibiotic resistance by int1 5'-CS						
Bakshi, 2009 [22]	37	2	5.4	0.7-18.2	98.7%	(98.1-99.1%)
Bakshi, 2014 [23]	24	1	4.2	0.1-21.1	16.58	
Dalsgaard, 1999 [16]	20	20	100.0	83.1-100.0	16.52	
Dalsgaard, 2000 [10]	46	46	100.0	92.3-100.0	16.74	
Mala, 2016 [4]	92	1	1.1	0.03-5.9	16.84	
Mwansa, 2007 [24]	27	25	92.6	75.7-99.1	16.62	
Total (random effects)	246	95	52.2	6.3-95.7	100.00	

On average proportions of class 1 integron 3'-CS and 5'-CS were (70.4 %; 95% CI: 37.5–94.4), and (52 %; 95% CI: 6.3–95.7), respectively (Figure 3a, Table 2). Heterogeneities between studies were high for the class 1 integron *qacEΔ1* and *sul1* (I^2 : 98.8 %; 95% CI: 98.5–99.1, $P < 0.0001$); while for *int1* (I^2 : 98.7 %; 95% CI: 98.1–99.1, $P < 0.0001$) (Figure 3b, Table 2). Concerning publication bias, the funnel plots of *qacEΔ1* and *sul1* 3'-CS, and *int1* 5'-CS of class 1 integron in *V. cholerae* strains indicate the symmetrical distribution in the absence of bias (Figure 4).

DISCUSSION

Cholera outbreaks are seasonally ongoing in some developing countries. For decades, antibiotic resistance patterns have not been well studied and elucidated.²⁵ This consequently affects the treatments for disease, leading to high mortality rates during outbreaks. Our study aimed at demonstrating the current perspectives of antibiotic resistance for class 1 integron in *Vibrio cholerae*. Most studies were conducted in India⁵, Iran³, Thailand², Vietnam¹, Guinea-Bissau¹, Mozambique & South Africa¹ and Zambia¹.

Published information on the meta-analysis of antibiotic resistance conferred by class 1 integron in *Vibrio cholerae* strains are limited. Only one meta-analysis was published generally on gram-negative bacteria clinical isolates.²⁶ It included 29 studies which were conducted in Iran, and evaluated the prevalence of integron classes and different gram-negative bacterial strains. Our meta-analysis determined the effects of antibiotic resistance conferred by class 1 integron CS 3'-*qacEΔ1* and *sul1*, and 5'-*int1* in *V. cholerae* strains among countries that had cholera outbreaks. There was a significant presence of integrons in clinical isolates with a pooled prevalence of (79%; 95% CI 73.6–83.7) of class 1 integrons in multidrug resistance (MDR) isolates which is comparable to the pooled proportion of 70.4% in class 1 integron 3'-CS reported herein.²⁶ In addition, this showed independent effects of antibiotic resistance of conserved segments in class 1 integron in *V. cholerae* strains.

Moreover, of all the pooled studies, 71.4% antibiotic resistance was highly contributed by the conserved segment 3'-CS *qacEΔ1* and *sul1* as compared to the 42.9 % antibiotic resistance outcomes in the conserved segment *int1* 5'-CS (Table 2). In addition, the majority of the O1 serogroups identified by this study are supported by another meta-analysis study that reported 80.0% of the predominating cholera toxigenic *V. cholerae* isolates of the serogroup O1 were the El Tor biotype with Ogawa and Inaba serotypes.²⁸ There are several factors that might have contributed to the antibiotic resistance caused by class 1 integron in *V. cholerae* across different countries. Some of the potential factors may include the exportation of drugs via efflux pumps, chromosomal mutations or the exchange of conjugative plasmids, conjugative transposons, integrons, or self-transmissible chromosomally integrating SXT elements.²⁷

Limitations of the Study

Some possible limitations should be considered for this meta-analysis. First, the limited literature search to only studies published in the English language. This may be associated with some systematic bias in our meta-analysis

Second, heterogeneities exist among studies included in this meta-analysis. Although the random-effects model allows the presence of heterogeneity, there may still be disagreement regarding the pooled estimates proportions in the presence of heterogeneity among studies. Finally, the limited number of studies that met eligibility criteria could have possibly affected the statistical analyses in detecting funnel plot symmetry in reporting biases.

CONCLUSION

This meta-analysis study has provided a general view on antibiotic resistance conferred by class 1 integron of *Vibrio cholerae*. Our study highlights the proportions of antibiotic resistance determined by conserved regions (3'-CS and 5'-CS) that can be used for monitoring and developing control strategies. However, a very limited number of studies have focused on antibiotic resistance against *Vibrio cholerae* strains. Therefore, more research on the detection of class 1 integron as a remarkable genetic platform is highly recommended. There is also a need for developing new control strategies and involvement of experts in the relevant field in the management of antibiotic resistance among *V. cholerae* strains.

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Clinical and Epidemiology Characteristics of COVID-19 Cases Detected During Mass Screening Campaign from July to October 2020 in Bujumbura, Burundi

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ABSTRACT

Background: Coronavirus disease of 2019 (COVID-19) is an infectious disease caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-COV-2 Virus). It was reported for the first time in Wuhan city, Hubei province of China. The first cases of COVID-19 in Burundi were identified on 31st March 2020. Several signs and symptoms, including mainly; fever, dry cough, fatigue, myalgia, and dyspnea are the most prominent characteristics of the disease. The aim of this study was to provide description of the clinical and epidemiological characteristics of COVID-19 cases identified during the mass screening campaign conducted between July and October, 2020 in Burundi.

Methods: We conducted a retrospective secondary analysis of data of clients to the mass screening campaign in Bujumbura city that was run between July and October 2020. Clients with complete data and tested for COVID-19 with Reverse Transcription Polymerase Chain Reaction (RT-PCR) were included in the study. Epi-Info 7.2.2.6 was used to perform descriptive and analytical statistics and Quantum Geographic Information System (QGIS) was used for cases mapping. Association between positive cases and independent variables such as sex, history of contact with confirmed COVID-19 case was measured using chi-square statistical test at a *p-value* of .05.

Results: The study included 20,114 participants. 243 (1.2%) were tested positive for COVID-19. The mean age for confirmed cases was 33 (± 15) years. The majority of cases (72.8%) were between 20 and 59 years of age and they were predominantly males (67.9%). 164 (67.5%) were symptomatic and cough was the most frequent symptom observed 109 (66.5%), followed by rhinorrhea 69 (42.1%). Fever was present in only 18 (11.0%) of symptomatic patients. Participants with a history of contact with a COVID-19 confirmed case (aOR=2.2; 95%CI [1.6-3.0]; *p-value* <.001), were more likely to be positive for COVID-19. Also, those who were coughing (aOR=1.47; 95%CI [1.06-2.05]; *p-value*=.023) and having sore throat (aOR=2.4; 95%CI [1.1-4.9]; *p-value*=.02) were more likely to test positive for COVID-19.

Conclusion: This study revealed that a significant proportion (32.5%) of COVID-19 patients were silent carriers of the virus. Data highlighted that high proportion of cases were among the active age group and contacts with confirmed cases, and noted high proportion of asymptomatic cases at diagnosis. Measures including routine testing of asymptomatic contacts could contribute to tackling corona virus in Burundi.

BACKGROUND

On 31st December 2019, the World Health Organization (WHO), China Country Office was informed of cases of pneumonia with unknown aetiology detected in Wuhan City, Hubei Province of China. The Chinese authorities identified a new type of coronavirus, which was isolated on 7 January 2020.¹ The WHO named this new coronavirus pneumonia COVID-19.² The disease is highly infectious, and its main clinical symptoms include; fever, dry cough, fatigue, myalgia and dyspnea.³ Since the initial detection of COVID-19, the disease has spread globally and was declared a pandemic on March 11, 2020, by the WHO.⁴ Its main route of transmission

in humans is through direct contact or air droplets, the transmission risk is higher within a span of one metre from the infected person.⁵ The case fatality rate is reported to be around 2.2%⁶, which is far lower than the rates for the previous two coronavirus epidemics that occurred in the 21st century – namely; Severe Acute Respiratory Syndrome (SARS)-CoV in 2003 (10%) and Middle East Respiratory Syndrome (MERS)-CoV in 2012 (37%).⁷

In the initial stage of the pandemic, sub-Saharan Africa reported some of the lowest infection rates of COVID-19. Numbers began to rise in late March 2020, with confirmed cases increasing across the continent,

however, this number may reflect a shortage of tests and testing facilities.⁸

The first cases of COVID-19 in Burundi were identified on 31st March 2020 from 2 Burundians from Dubai and Kigali.⁹ Since then, the epidemic has resulted in 515 cases with 1 death (case fatality rate of 0.2%) as of October 6th, 2020 and more than three-thirds (75.9%) of the cases in Burundi were recorded in Bujumbura City.¹⁰ Different studies have shown scarcity of information on the description of clinical characteristics of COVID-19 patients. To the best of our knowledge, no study describing the clinical and epidemiological characteristics of COVID-19 patients was conducted in Burundi. This study was designed to provide description of the clinical and epidemiological characteristics of cases presenting to mass screening sites in Bujumbura City (ETS Kamenge, Source du Nil Hotel and Paroisse Kanyosha), and confirmed to be infected with SARS-CoV-2 by real time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR).

METHODS

Study Design

We conducted a retrospective secondary analysis of data from patients presented at screening sites in Bujumbura city between July and October 2020. Socio-demographic and clinical data was collected using Open Data Kit (ODK) collect v1.29.2 and transferred to CARP platform.

Laboratory Methods

Sample Collection, Transport, and Storage

Oropharyngeal swab specimens were transported in viral transport medium from screening sites to the National Reference Laboratory. The specimen were refrigerated (2 to 8°C) before testing was performed on Abbott Instrument Systems.

Sample Processing

Sample testing was performed with the Abbott Real Time SARS-CoV-2 assay developed by Abbott Molecular. Abbott Real Time SARS-CoV-2 assay is a real-time reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in respiratory specimens collected by a healthcare worker, from individuals suspected of COVID-19.

Qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures performed the Abbott Real-time SARS-CoV-2 assay.

Study Variables and Measurements

In this study, we considered the RT-PCR result for COVID-19 as the dependent variable. The independent variables were socio-demographic information (age, sex), history of contact with COVID-19 confirmed patient, and clinical presentation (symptomatic or asymptomatic).

Data Management and Analysis

We received data in Microsoft Excel 2016 from the emergency unit of Burundi Ministry of Health and AIDS control. Data was cleaned and transferred into Epi-Info 7.2.2.6 for re-coding and analysis of the variables

to suit the study objectives. Descriptive statistics were used to summarise the data and results were presented as frequency and proportions in tables and charts. QGIS was used to perform the distribution of cases by district of residence. Descriptive statistics were generated for explanatory variables and chi-square test was used to determine the independent predictors of a positive test for COVID-19. Multivariable logistic models were developed to assess the association between explanatory variables and the outcome variable. Explanatory variables that were significant in the bivariate analysis at $p < .20$ were considered candidates for the multivariable logistic models. The final multivariable logistic models were developed using backwards elimination of the explanatory variables with p values $< .05$.

Ethical Consideration

Permission to carry out the study was sought and obtained from Burundi Ministry of Health and Fight against AIDS. Ethical clearance was obtained from Burundi National Ethical committee (reference number: CNE/32/2021). To ensure confidentiality, participants' identifying information was not included in the dataset used in statistical analyses. This analysis was based on secondary data collected during screening campaigns, therefore, participants consent was not sought.

RESULTS

Socio-demographic Characteristics of Screened Patients and Confirmed Cases

A total of 20,114 participants were included in the analysis. Their mean age was 34 (± 14) years. The Majority were males (14,605, 72.6%). A total of 7,636 (38.0%) participants were screened at Source du Nil Hotel which is located in the Centre District of Bujumbura City. About 17,882 (88.9%) participants were residents of Bujumbura City while 2,232 (11.1%) were residents of other provinces especially around Bujumbura City (Bujumbura-4.6%, Bubanza-4.5%). Health professionals constituted 420 (2.1%) of the participants. Among those screened, 10,364 (51.5%) participants were symptomatic while 3,134 (15.6%) had had contact with COVID-19 confirmed cases.

Two hundred and forty-three (243) cases were confirmed by laboratory RT-PCR test, which gives a positivity rate of 1.2%. The mean age for confirmed cases was 33 (± 15) years. The prevalence of COVID-19 among male participants was 1.1% and 1.4% among females. Among health care workers, the prevalence of COVID-19 was 1.7%. Majority cases were from residents of Northern Health District with 101 (41.6%), followed by Southern District 70 (28.8%) and Central District 55 (22.6%) of Bujumbura City (Figure 2).

Clinical Characteristics of Confirmed COVID-19 Cases

About 164 (67.5%) were symptomatic. Cough was the most common symptom 109 (66.5%), followed by rhinorrhea, 69 (42.1%), headache 45 (27.4%), fatigue 36 (22.0%), fever 18 (11.0%), shortness of breath-dyspnea 16 (10.4%), sore throat 8 (4.9%), loss of smell-anosmia 2 (1.2%) and lack of the sense of taste-ageusia 1 (0.6%) (Figure 1). Eleven patients (4.5%) had chronic diseases such as hypertension, diabetes and Human Immunodeficiency Virus (HIV). Contact with

FIGURE 1: Clinical Characteristics of Confirmed Cases

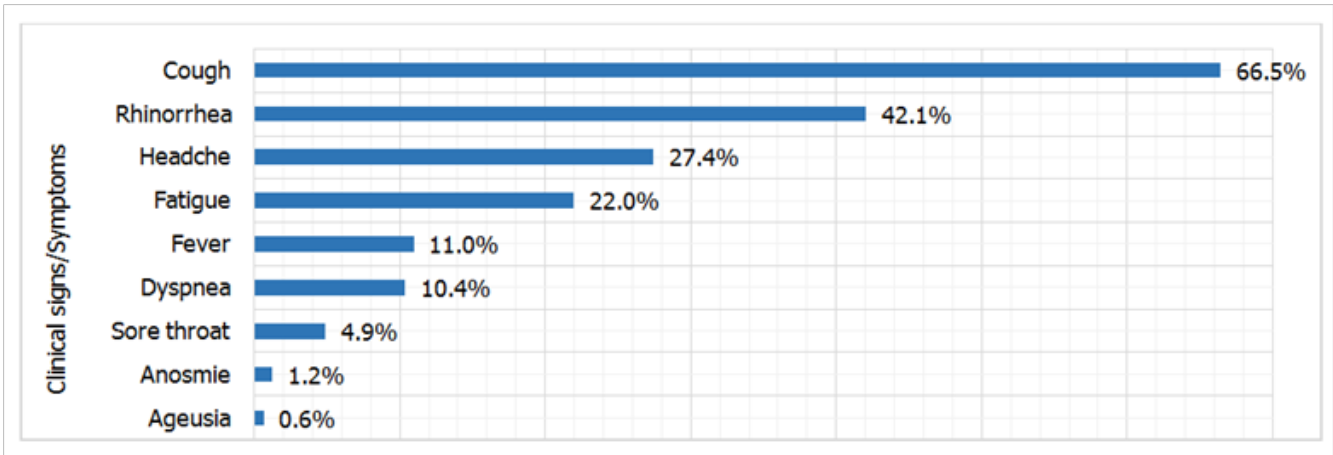
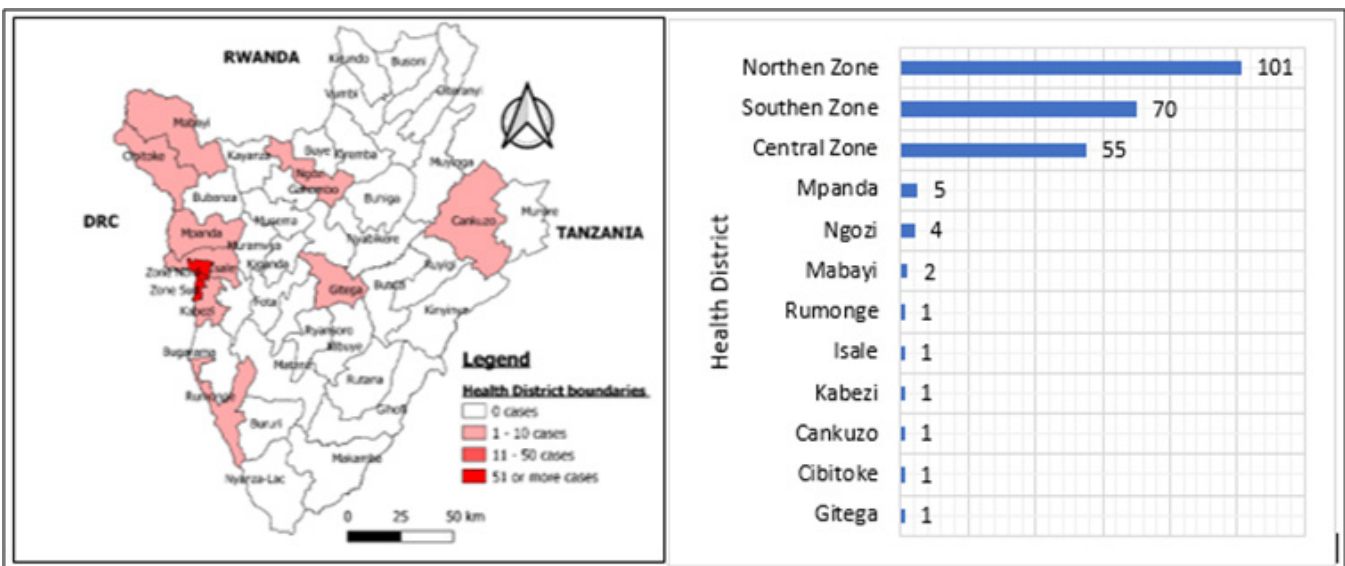


FIGURE 2: Distribution of Confirmed Cases by Health District of Residence, Bujumbura, July to October 2020



COVID-19 confirmed case was declared in 24.3% of confirmed cases (Table 1).

Factors affecting the COVID-19 RT-PCR Results among Screened Persons

This section presents factors found to be independently associated with RT-PCR positive results after adjustment of factors that were significant at *p-value* <.2 in bivariate analysis (Table 2). Persons who had contact with a COVID-19 confirmed case (aOR=2.20; 95%CI [1.62-

2.98]; *p-value* <.001) were two times more likely to be positive for COVID-19 compared to those with no history of contact. Also, coughing (aOR=1.47; 95%CI [1.06-2.05]; *p-value*=.023) and having sore throat (aOR=2.35; 95%CI [1.14-4.85]; *p-value*=.021) were statistically associated with COVID-19 RT-PCR positive result (Table 3).

DISCUSSION

The results from this study highlighted the COVID-19 RT-PCR positivity rate of 1.2% from July to October 2020.

TABLE 1: Characteristics of screened persons from July to October 2020, Bujumbura, Burundi

Characteristics	All screened persons		Confirmed cases	
	Number	(%)	Number	%
Site of screening				
ETS Kamenge	7608	37.8	100	41.2
Hôtel Source du Nil	7636	38.0	78	32.1
Paroisse Kanyosha	4870	24.2	65	26.7
Sex				
Male	14605	72.6	165	67.9
Female	5509	27.4	78	32.1
Age				
Mean (SD)	34	(14)	33	(15)
<5	269	1.3	7	2.9
5-9	407	2.0	4	1.6
10-19	2237	11.1	35	14.4
20-29	5295	26.3	63	25.9
30-39	5121	25.5	54	22.2
40-49	3793	18.9	46	18.9
50-59	2921	14.5	14	5.8
≥60	71	0.4	20	8.2
Province of residence				
Bujumbura Mairie	17882	88.9	226	93.3
Bujumbura	931	4.6	2	0.8
Bubanza	896	4.5	5	2.1
Other provinces	405	2.0	10	4.1
Health professional				
Yes	420	2.1	7	2.9
No	19694	97.9	236	97.1
Contact history				
Yes	3134	15.6	59	24.3
No or unknown	16980	84.4	184	75.7
Symptomatic				
Yes	10364	51.5	164	67.5
No	9750	48.5	79	32.5

TABLE 2: Association between some Selected Variables and the Covid-19 RT-PCR Positive Results, Bujumbura, July to October 2020

Variables	Covid-19 status				OR	[95% CI]	P-Value
	Positive n	(%)	Negative n	(%)			
Age group							
<10	11	(1.6)	665	(98.4)	Ref.		
10-19	35	(1.6)	2202	(98.4)	1.0	[0.5-2.0]	.999
20-29	63	(1.2)	5232	(98.8)	0.7	[0.4-1.5]	.433
30-39	54	(1.1)	5067	(98.9)	0.6	[0.3-1.3]	.256
40-49	46	(1.2)	3747	(98.8)	0.7	[0.4-1.5]	.485
≥50	34	(1.1)	2958	(98.9)	0.6	[0.4-1.4]	.393
Sex							
Female	78	(1.4)	5431	(98.6)	1.3	[0.9-1.6]	.113
Male	165	(1.1)	14440	(98.9)			

Continued

TABLE 1: Continued

Variables	Covid-19 status		OR	[95% CI]	P-Value		
	Positive n	(%)				Negative n	(%)
Contact history							
Yes	59	(1.9)	3075	(98.1)	1.8	[1.3-2.3]	<.001†
No/unknown	184	(1.1)	16796	(98.9)			
Symptomatic							
Yes	164	(1.6)	10200	(98.4)	2.0	[1.5-2.6]	<.001†
No	79	(0.8)	9671	(99.2)			
Fever							
Yes	18	(2.3)	759	(97.7)	2.0	[1.2-3.2]	.007 †
No	225	(1.2)	19112	(98.8)			
Cough							
Yes	109	(1.7)	6161	(98.3)	1.8	[1.4-2.3]	<.001 †
No	134	(1.0)	13710	(99.0)			
General weakness/ fatigue							
Yes	36	(2.0)	1746	(98.0)	1.8	[1.3-2.6]	.002 †
No	207	(1.1)	18125	(98.9)			
Headache							
Yes	45	(1.8)	2508	(98.2)	1.6	[1.1-2.2]	.008 †
No	198	(1.1)	17363	(98.9)			
Sore throat							
Yes	8	(3.2)	244	(96.8)	2.74	[1.25-5.35]	.010 †
No	235	(1.2)	19627	(98.8)			
Dyspnea							
Yes	17	(1.7)	960	(98.3)	1.5	[0.9-2.4]	.159
No	226	(1.2)	18911	(98.8)			
Runny nose							
Yes	69	(1.4)	4834	(98.6)	1.2	[0.9-1.6]	.164
No	174	(1.1)	15037	(98.9)			
Anosmia							
Yes	2	(3.3)	58	(96.7)	2.8	[0.7-11.7]	.359
No	241	(1.2)	19813	(98.8)			
Comorbidity							
Yes	11	(1.4)	787	(98.6)	1.2	[0.6-2.1]	.756
No	230	(1.2)	19084	(98.8)			

This rate is lower than what is recorded in WHO African Region (9.0%).¹¹ The prevalence (1.7%) of COVID-19 among health care workers in this study is lower than what was observed among health care workers in a University Teaching Hospital in Central Italy (2.7%).⁵ This difference may be explained by the fact that this study's participants voluntarily reported to the screening site. The mean age of COVID-19 confirmed cases was 33 (\pm 15) years which is higher than that of the general population (21.3 years).¹⁴ Comparing to other studies, this mean age was lower than the mean age of patients in Lagos, Nigeria (46.2 years)¹⁵ and in Liaocheng, China (42 years).⁷ Children under 5 years of age and those aged 5 to 10 years, respectively, accounted for 2.9% and 1.6% of confirmed COVID-19 cases in this study. This shows that children are at low risk of getting infected by COVID-19 considering that the proportion of less than 5 years of age in general population is 17.9%.¹⁴ However, it remains unclear why children are less affected by COVID-19 than

older individuals, evidence suggests that this could be due to differences in their immune system function.¹⁷ Majority (72.8%) of cases were among participants aged between 20 to 59 years which is similar to findings from studies conducted in Nigeria and Jordan.^{15,18} The higher proportion of COVID-19 cases recorded among economically active age groups suggests potential impact of socio-economic or work-related activities.

Clinically, 67.5% of confirmed cases were symptomatic. Our finding is different from the findings of a study conducted in Kuwait where only 41.0% of the participants were symptomatic.¹⁹ Another study conducted in Nigeria reported that 33.0% of COVID-19 confirmed cases between the month February and June were symptomatic²⁰, this is lower than this study's findings. However, a descriptive study conducted in Lagos, Nigeria found out that nearly all their study's participants (89.6%) were symptomatic¹⁵, this observed difference could be due to the fact our study was a health centre based study.

A study conducted on COVID-19 patients admitted in the quarantine centre at King Abdullah University Hospital in Jordan between March 16 and May 21, 2020 showed that 58.0% of the participants were symptomatic.¹⁸ According to WHO, the main clinical presentation of COVID-19 cases are; fever, cough, general weakness/fatigue, headache, myalgia, sore throat, coryza, dyspnoea, anorexia/nausea/vomiting, diarrhoea and altered mental status.²¹ In our study, cough was the most frequent symptom, accounting for 109 (66.5%) cases, followed by rhinorrhoea, (42.1%), headache (27.4%), fatigue (22.0%), fever (11.0%), dyspnea (10.4%), sore throat (4.9%), anosmia (1.2%) and ageusia (0.6%). The common clinical features observed in our study are similar to features observed by other related studies.^{15,20} Although fever was found to be the 5th most observed symptom in our study, numerous other studies reported fever as the most prevalent symptom.^{7,17,19,20,22}

This may be explained by the fact that public messages inviting people for early screening were sent and those who responded to the invite were not necessarily sick. Similarly to our findings, cough was found to be the most common symptom in a study conducted in Jordan between March 16 and May 21, 2020.¹⁸ Our study also showed that patients presented at screening sites with cough were more likely to test positive for COVID-19 (aOR=1.47; 95% CI [1.06-2.05]; *p-value*=.023). Although relatively small in proportion, patients with sore throat were also more likely to test positive for COVID-19 and this is consistent with available evidence.^{15,18-20}

Eleven patients (4.5%) had chronic diseases such as hypertension, diabetes and HIV. This was low compared with other studies conducted elsewhere.^{7,15,19} For example, hypertension (17.6%) and type II diabetes mellitus (10.2%) were the most common comorbidities experienced at King Abdullah University Hospital in Jordan.¹⁸ Our study noted that patients with a history of contact with a COVID-19 confirmed case were more likely to be positive for COVID-19 compared to those with no history of contact. This is consistent with scientific evidence from studies conducted elsewhere.^{5,15,23} This explains that there was an active human to human transmission during that period. Then, although only 24.3% of the study participants were asymptomatic, it is known that they can be infective.²³ Hence, it is important to identify asymptomatic cases as quickly as possible through testing of the contacts of each confirmed case, so that the spread of the virus can be controlled.

CONCLUSION

In conclusion, this study revealed that a large proportion of COVID-19 patients (32.5%) were silent carriers of the virus. Economically active age groups were more likely to be infected with COVID-19, and the most occurring symptoms were; cough, rhinorrhoea, and headache, which are similar to seasonal flu symptoms. The study also highlighted the high proportion of asymptomatic cases at diagnosis and among contacts with confirmed cases. Evidence from this study will be useful by policymakers and stakeholders in the health and other sectors in contextualising public health planning, policy and response as well as facilitating scientific activities in the country. Following the study's findings, measures such as case finding protocols should include routine testing of

asymptomatic contacts.

Study Limitations

The study has several limitations which are mainly related to the methodology used. Part of this research, should be considered. First, the external validity of the study to the community of Bujumbura cannot be retained since the data used was obtained from volunteers who visited the mass screening sites and these probably were suspecting themselves to be infected with COVID-19 and thus their willingness to test for the disease. Secondly, we were unable to determine the exact period of infection, since patients were discovered during the mass screening campaign, it is possible that they acquired the infection several days before the detection test.

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Factors Associated with Uptake of Intermittent Preventive Treatment for Malaria During Pregnancy. Analysis of Data from the Tanzania 2015-2016 Demographic Health Survey and Malaria Indicator Survey

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ABSTRACT

Background: Malaria is a life-threatening disease caused by parasites that are transmitted to people through bites of infected female Anopheles mosquitoes. Africa is the home to over 90% of malaria burden when compared to other regions of the world. The region is estimated to have a dominance of 94% of maternal deaths occurring in the world. The purpose of this study was to identify factors associated with the uptake of IPTp-SP among pregnant women in Tanzania.

Method: The study used data from the 2015-16 Tanzania Demographic and Health Survey and Malaria Indicators Survey (2015-16 TDHS-MIS). A total of 6,885 women of active reproductive age from 15 to 49 were included in the analysis. Both univariate and multiple regression analyses were performed to determine factors associated with uptake of IPTp-SP during pregnancy in Tanzania.

Results: A total of 4764 (68.6%) of pregnant women took at least one dose of IPTp-SP during Antenatal Care (ANC) visits. After adjusting for confounders, factors which were associated with uptake of IPTp-SP were; early antenatal booking (AOR=1.495, $p<.001$); age group of pregnant woman [20 to 34 years (AOR=1.446, $p=.001$), more than 34 years (AOR=1.648, $p<.001$)]; wealth index [middle (AOR=1.418, $p<.001$), rich (AOR=1.589, $p<.001$)], education level [primary education (AOR=1.457, $p<.001$), secondary education (AOR=1.653, $p<.001$); parity [para 2 to 4 (AOR=1.213, $p=.014$), para 5 and above (AOR=1.226, $p=.043$)] and zone [Mainland rural (AOR=0.647, $p=.019$), Unguja (AOR=0.172, $p<.001$) and Pemba (AOR=0.310, $p<.001$)].

Conclusion: Factors associated with uptake of IPTp-SP during pregnancy were; timing for ANC booking, age of pregnant woman, parity, level of education, and place of residence.

BACKGROUND

Malaria is a life-threatening disease caused by parasites that are transmitted to people through bites of infected female Anopheles mosquitoes.¹ Malaria is a preventable and curable disease.² Africa is the home to over 90% of malaria burden when compared to other regions of the world.² The region is estimated to have a dominance of 94% of maternal deaths occurring in the World.⁴

Malaria is one of the indirect causes of maternal deaths, accounting for about 15% of all reported maternal deaths in the world. In 2015, malaria was considered the third cause of deaths among women of child bearing age in the world. About 24 million pregnant women in the sub-Saharan Africa are affected with malaria every year. In endemic areas, events of maternal deaths due to malaria accounts for about 25%.⁶ A study that used District Health Information System (DHIS) data of 2014 and 2017 in Tanzania, reported malaria prevalence of 8.1% and

6.7% respectively, indicating an absolute difference of 1.4%.⁷

Primigravidae, adolescents, and pregnant women co-infected with Human Immunodeficiency Virus (HIV)/ Acquired Immunodeficiency Syndrome (AIDS) are usually accompanied with adverse complication.⁶ Commonly reported complications of malaria in pregnancy include; placental malaria, maternal anaemia, abortions, premature labour, intrauterine growth retardation and low birth weight.⁸ Asymptomatic malaria is also common among primigravidae especially among those from malaria-endemic areas.⁹ Maternal decline of immunity pronounced during the first and second pregnancies predispose them to high vulnerability to malaria¹⁰.

The World Health Organization (WHO) and the Global Malaria Community targets a malaria free world by 2030.² Nurses should routinely administer Intermittent Preventive Treatment of Malaria in Pregnancy Sulfadoxine-Pyrimethamine

(IPTp-SP) to all pregnant women attending antenatal care services as one of the strategies to preventing malaria in pregnancy. Administration of IPTp-SP is based on the assumption that every pregnant woman living in malaria-endemic areas has malaria parasites in her blood or placenta, regardless of whether she is symptomatic or asymptomatic.¹⁰ The appropriate time to administer the first IPTp-SP dose is during the early second trimester. Subsequent doses are scheduled at 4 weeks apart while the last dose can be administered during late pregnancy, i.e. after 36 weeks of gestation, up to the time of delivery. Frontline antenatal care providers should ensure that pregnant women receive not less than 3 doses of IPTp-SP before delivery.¹¹

According to Tanzania Demographic and Health Survey and Malaria Indicator Survey (TDHS-MIS) (2015/2016), 71% of pregnant women who attended antenatal care services in Tanzania received IPTp-SP.¹² The *2019 World Malaria Report* indicated that Tanzania and Burkina Faso had over two-third of their pregnant women receive 3 doses of Intermittent Preventive Treatment of Malaria in Pregnancy (IPTp3) in 2018. The report also showed low coverage (31%) of IPTp-SP across sub-Saharan Africa.¹³

Several factors have been raised as enablers and/or barriers to IPTp-SP uptake. A study conducted in Korogwe District, Tanzania showed that nurses do not provide IPTp-SP as Direct Observed Therapy (DOT) due to reasons such as shortage of clean drinking water; therefore, it is not clear whether the provided anti-malaria drugs are taken as intended¹⁴. Having knowledge on when to start and stop IPTp-SP can also be a challenge to IPTp-SP uptake.^{15,16} Studies have also revealed that factors such as education level of up to college level, early booking and having at least 4 ANC visits contribute to adequate uptake.^{16,17} Moreover, having parity of at least 4, being single and self-employment have been reported to impede the uptake.¹⁸ The nurse's limited knowledge on IPTp-SP protocol was a barrier to adequate uptake of the service as it was reported in Ghana.¹⁹ Similarly, IPTp-SP uptake can be determined by the age of the woman. Several studies from elsewhere showed that as the woman's age increases, the likelihood to IPTp-SP uptake also increases.^{17,20,21}

The Tanzanian government has invested in ensuring that all pregnant women access IPTp-SP services during their visit for Antenatal Care Services. The government not only expanded health facilities to each village but also deployed adequate number of nurse/midwives to ensure pregnant women receive skilled services. However, according to TDHS-MIS (2015/2016), 24% and 49% of pregnant women book ANC services late and had inadequate ANC visits respectively.¹² This can impede the pregnant women to receive IPTp-SP timely. Therefore, this study aimed at analysing factors associated with uptake of intermittent preventive treatment for malaria dose at least once during pregnancy using data from TDHS-MIS.

METHOD

Study Area and Period

The study was conducted in the United Republic of Tanzania from August 22, 2015, through February 14, 2016. Tanzania is among the countries found in East

covers 940,000 square kilometres with 60,000 square kilometres of inland water. The country lies south of the equator and shares borders with 8 countries: Kenya and Uganda to the North; Rwanda, Burundi, the Democratic Republic of Congo, and Zambia to the West; and Malawi and Mozambique to the South.

Study Design

This was a national-based cross-sectional study utilising the 2015/2016 Tanzania Demographic and Health Survey and Malaria Indicator Survey (TDHS-MIS) dataset.

Study Population

All women of reproductive age (15 to 49 years) were eligible to participate in the study. The study used Individual file recode (TZIR7BFL) with a total of 13,266 women who responded to the survey (97% response rate). The study included only women who responded to the question on if they have ever taken anti-malaria medication during pregnancy. Those who were not able to recall the timing and those who did not respond to the question were excluded from the analysis. A total of 6,885 women who had given birth within 5 years preceding the survey were included in the study.

Two stages of sampling were used to obtain sample data for urban and rural areas in Tanzania Mainland and Zanzibar. In the first stage, a total of 608 clusters were selected and in the second stage, a systematic selection of households was adopted. A total of 22 households were systematically selected from each cluster, yielding a representative probability sample of 13,376 households for the 2015-16 TDHS-MIS. To enhance representativeness, Tanzania was divided into 9 geographic zones. Regions were grouped into zones so as to reduce sampling error by way of increasing the number of people in the denominator. The zones were; western zone (Tabora and Kigoma regions), Northern zone (Kilimanjaro, Tanga, and Arusha), Central zone (Dodoma, Singida and Manyara), Southern Highland zone (Iringa, Njombe, and Iringa), Southern zone (Lindi and Mtwara), South West Highland zone (Mbeya Rukwa and Katavi), Lake zone (Kagera, Mwanza, Geita, Mara, Simiyu, and Shinyanga), Eastern zone (Dar es Salaam, Pwani, and Morogoro) and Zanzibar zone (Kaskazini Unguja, Kusini Unguja, Mjini Magharibi, Kaskazini Pemba and Kusini Pemba).

Study Variables

Literature review was done and a conceptual framework was developed to guide the data review process. The conceptual framework defined the independent variables (socio-demographic and obstetric characteristics of a woman) and the dependent variables (having ever taken anti-malaria drugs during pregnancy), coded 1 for those who have ever taken anti-malaria drugs during pregnancy and 0 for those who had never.

Data Collection Tools

The 2015-16 TDHS-MIS used household and individual questionnaires. These questionnaires were based on the Demographic and Health Surveys (DHS) standard AIDS Indicator Survey and Malaria Indicator Survey questionnaires standards. They were adapted and modified to reflect the Tanzanian population. They were

The data presented in this study is from the individual questionnaires.

Data Analysis

Data was analysed using IBM SPSS version 20. Women who took anti malaria drugs at least once were coded as 1 and those who never took anti malaria drugs during pregnancy were coded 0. Data analysis started by describing all study variables using frequencies and percentages. The association between dependent and independent variables was assessed using the chi-squared test. Univariate, binary and multivariable analysis was performed for descriptive and significant predictors of uptake of IPTp-SP. All analyses were based at a 5% level of significance.

Ethics Approval and Consent to Participate

Data collection and the survey content and protocol were approved by Tanzania's National Institute for Medical Research (NIMR), the Zanzibar Medical Ethics and Research Committee (ZAMREC), the Institutional Review Board of ICF International, and the Centres for Disease Control and Prevention in Atlanta, USA. Participants provided verbal consents and the household interviews took place privately. For participants under the age of 18, written consent was requested from their parent or guardian.

RESULTS

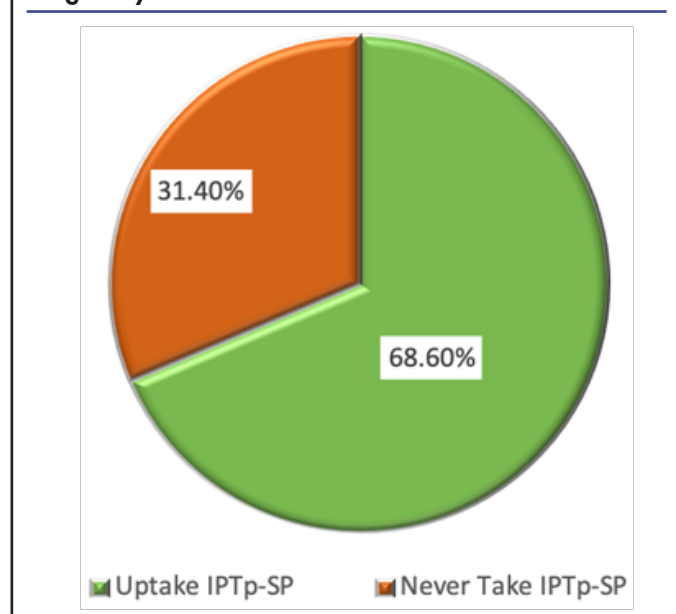
Socio-demographic Characteristics

The study included 6,885 women of reproductive age who had given birth within 5 years preceding the survey. Majority of study respondents 5,113(73.8%) resided in the rural setting of Tanzania, 4,557(65.8%) were aged 20 to 34 years. 4,209(60.8%) had primary education, and 5,650(86.1%) were married (Table 1).

TABLE 1: Socio-Demographic Characteristics of Respondents

Variables	Frequency	Percent (%)
Place of residence		
Urban	1811	26.2
Rural	5113	73.8
Age group		
Less than 20 years	541	7.8
20 to 34 years	4557	65.8
More than 34 years	1826	26.4
Educational level		
No education	1329	19.2
Primary education	4209	60.8
Secondary	1326	19.2
Higher	60	0.9
Parity		
Para one	1595	23
Para 2-4	3154	45.6
Para 5+	2175	31.4
Wealth index		
Poor	2734	39.5
Middle	1363	19.7
Rich	2827	40.8
Marital Status		
Never in union	441	6.4
Married	5650	86.1
Widow	119	1.7
Separated	714	10.3
Respondent currently working		
Not working	1498	21.6
Working	5426	78.4
Mainland/Zanzibar		
Mainland urban	1618	23.4
Mainland rural	4357	62.9
Unguja (Zanzibar Island)	594	8.6
Pemba (Pemba Island)	355	5.1

FIGURE 1: Uptake of SP/ Fansidar Atleast Once During Pregnancy



Uptake of anti-malaria at list once during pregnancy
 A total of 4,725(68.6%) took anti malaria prophylaxis at least once during their pregnancy while a total of 2,160 (31.4%) never took (Figure 1).

The Relationship between Women's Characteristics and Uptake of Malaria Drugs for Intermittent Treatment of Malaria during Pregnancy

Variables which showed significant relationship were; place of residence ($X^2=70.107$ and $p<.001$), age group ($X^2=33.932$ and $p<.001$), education level ($X^2=70.342$ and $p<.001$), parity ($X^2=8.395$ and $p=.015$), timing for ANC visits ($X^2=66.16$ and $p<.001$), Number of ANC visits ($X^2=78.962$ and $p<.001$), wealth index ($X^2=70.107$ and $p<.001$) and zones ($X^2=330.254$ and $p<.001$) (Table 2).

Factors Associated with Uptake of Malaria Drugs for Intermittent Treatment of Malaria during Pregnancy

After adjusted for confounders, factors which were

TABLE 2: The Relationship between Women's Characteristics and uptake of Malaria drugs for Intermittent Treatment of Malaria during Pregnancy

Variable	Uptake of anti-malaria		X ²	p-value
	Never n(%)	at least once n(%)		
Age categories of respondents			33.932	<0.001
15years -24years	778(35.9)	1389(64.1)		
25years-29years	476(29.6)	1133(70.4)		
30years-34years	354(27.3)	945(72.7)		
35years-49years	552(30.5)	1258(69.5)		
Type of place of residence			128.4	<0.001
Urban	373(20.7)	1427(79.3)		
Rural	1787(35.1)	3298(64.9)		
Wealth Index			70.107	<0.001
Poor	1007(37)	1716(63)		
Middle	405(29.8)	952(70.2)		
Rich	748(26.7)	2057(73.3)		
Marital Status			6.586	0.086
Never in union	118(26.9)	321(73.1)		
Living with partner	1799(32)	3824(68)		
Widowed	37(31.1)	82(68.9)		
Divorced	206(29.3)	498(70.7)		
ANC Visits			78.962	<0.001
Adequate	916(26.4)	2549(73.6)		
Inadequate	1244(36.4)	2176(63.6)		
Parity of the respondent			8.395	0.015
Para one	524(33)	1064(67)		
2 to 4	929(29.6)	2209(70.4)		
Para 5+	707(32.7)	1452(67.3)		
Timing for ANC Booking			66.16	<0.001
Late booking	1796(33.9)	3509(66.1)		
Early booking	364(23)	1216(77)		
Highest educational level			70.342	<0.001
No education	537(40.7)	783(59.3)		
Primary	1195(28.5)	2998(71.5)		
Secondary	413(31.5)	899(68.5)		
Higher	15(25)	45(75)		
Mainland/Zanzibar			330.254	<0.001
Mainland urban	279(17.3)	1333(82.7)		
Mainland rural	1404(32.3)	2937(67.7)		
Unguja (Zanzibar Island)	318(55)	260(45)		
Pemba (Pemba Island)	159(44.9)	195(55.1)		

TABLE 3: Factors Associated with Uptake of Anti-Malarial Dose atleast Once During Pregnancy

Variable	OR	95%CI		p-value	AOR	95%CI		p-value
		Lower	Upper			Lower	Upper	
ANC Booking								
Late booking	1				1			
Early booking	1.702	1.495	1.939	<0.001	1.495	1.306	1.712	<0.001

Continued

TABLE 3: Continued

Variable	OR	95%CI Lower	Upper	p-value	AOR	95%CI Lower	Upper	p-value
Age groups								
Less than 20 years	1				1			
20 to 34 years	1.62	1.35	1.944	<0.001	1.446	1.169	1.787	<0.001
More than 34 years	1.631	1.338	1.988	<0.001	1.648	1.27	2.137	<0.001
Place of residence								
Urban	1				1			
Rural	0.483	0.425	0.548	<0.001	0.956	0.688	1.328	0.788
Wealth index								
Poor	1			1				
Middle	1.379	1.199	1.586	<0.001	1.418	1.226	1.641	<0.001
Rich	1.621	1.446	1.817	<0.001	1.589	1.352	1.866	<0.001
Educational level								
No education	1			1				
Primary education	1.71	1.504	1.944	<0.001	1.457	1.271	1.67	<0.001
Secondary	1.499	1.278	1.758	<0.001	1.653	1.354	2.018	<0.001
Higher	2.034	1.122	3.686	0.019	1.456	0.758	2.796	0.260
Parity								
Para one	1				1			
Para 2-4	1.172	1.029	1.334	0.016	1.213	1.04	1.414	0.014
Para 5+	1.016	0.885	1.166	0.822	1.226	1.006	1.493	0.043
Mainland/Zanzibar								
Mainland urban	1				1			
Mainland rural	0.438	0.38	0.506	<0.001	0.647	0.45	0.93	0.019
Unguja (Zanzibar Island)	0.181	0.147	0.222	<0.001	0.172	0.123	0.241	<0.001
Pemba (Pemba Island)	0.257	0.201	0.328	<0.001	0.31	0.211	0.456	<0.001

booking, (AOR=1.495 at 95% CI=1.306-1.712, $p<.001$); age group of pregnant woman [20 - 34 years (AOR=1.446 at 95% CI= 1.1690-1.787, $p=.001$), above 34 years (AOR=1.648 at 95% CI=1.270-2.137, $p<.001$)] less than 20 years was a reference population; wealth index [middle (AOR=1.418 at 95% CI=1.226-1.641, $p<.001$), rich (AOR=1.589 at 95% CI=1.352 -1.866, $p<.001$)] poor was a reference population, education level [primary education (AOR=1.457 at 95% CI=1.271-1.670, $p<.001$), secondary education AOR=1.653 at 95% CI=1.354-1.866, $p<.001$], no formal education was a reference population; parity [para 2 to 4 (AOR=1.213 at 95% CI=1.04-1.414, $p=.014$), para 5 and above (AOR=1.226 at 95% CI=1.006-1.493, $p=0.043$)], para one was a reference population and zone [Mainland rural (AOR=0.647 at 95% CI=0.45-0.93, $p=0.019$), Unguja (AOR=0.172 at 95% CI=0.123-0.241, $p<.001$) and Pemba (AOR=0.310 at 95% CI=0.211-0.456, $p<.001$)] (Table 3).

DISCUSSION

A national-based cross-sectional study utilising the 2015-16 TDHS-MIS dataset was carried out among women of reproductive age (aged 15 to 49 years) to investigate factors associated with uptake of IPTp-SP in Tanzania. The outcome of the survey revealed that early ANC booking increased the odds of IPTp-SP uptake to more than one-fold compared to reference category. This finding mirrors the findings of a study conducted in Ghana, which also revealed early ANC booking being among the factor which

influenced IPTp-SP uptake.¹⁹ Significance similarity was also reported in a study conducted in Arusha, Tanzania which revealed that early booking increased the odds of IPTp-SP uptake to almost two-folds.¹⁶ Early booking provides the pregnant women with ample chance to have adequate ANC visits and hence increasing the chance of IPTp-SP uptake. The research evidence support the premise that increased ANC visits increased the probability to IPTp-SP uptake.¹⁷⁻²⁰

This study revealed that maternal age had a positive influence to IPTp-SP uptake. The uptake of IPTp-SP increases with increasing maternal age. This results echoed the DHS of 2013 which indicated that women with greater than or equal to 30 years had increased odds to IPTp-SP uptake.²¹ Contrary to this, a demographic health survey (UDHS-2015/2016) conducted in Uganda indicated that maternal age did not contribute to IPTp-SP uptake among pregnant women.¹⁷ Similarly, the results of a systematic and meta-analysis study conducted in sub-Saharan Africa demonstrated insignificant association between maternal age and IPTp-SP uptake.²⁰ Differing socio-demographic characteristics of the respondents could be the reason for the demonstrated conflicting results.

The analysis also reported wealth index of the respondents to be a significant determinant of IPTp-SP uptake. The likelihood for IPTp-SP use increased based on the woman's wealth index. Middle class and richer women were more than one-fold likely to have adequate IPTp-SP

associated with uptake of IPTp-SP were; early ANC uptake compared to the poor group. This observation is in line with what was revealed from a data analysis study conducted in Nigeria.²⁰ Being wealthy implies that the pregnant woman has the ability to cater for costs relating to access and utilisation of ANC services, and hence, promoting IPTp-SP uptake. There is a positive relationship between increasing wealth quintile and receiving ANC services which increases the chance of pregnant women to received IPTp-SP services.

The uptake of IPTp-SP was also found to increase with increasing education level of the woman. Pregnant women with primary education were one-fold versus those with secondary education or above whose odds were almost two-folds likely to have adequate IPTp-SP uptake compared to the reference category. This observation is supported by several other studies conducted in sub-Saharan Africa.^{17,20} Educated women tend to have greater awareness and knowledge of the existence of IPTp-SP services and the benefits of using such services.²²

This study showed that multi-parity and grand-multi-parity increased the likelihood of uptake of IPTp-SP compared to primiparity. However, this observation is contradicted by a cross-sectional study conducted in Ghana at Winneba, Trauma and Orthopedic Hospital, which revealed that women with 4 and above parities had the least likelihood to use IPTp-SP during pregnancy.¹⁸ The difference in the findings can be attributed to the different sample sizes used, 6,885 and 391. A similar study conducted in Ethiopia reported the significant association maternal parity and health services utilisation including IPTp-SP uptake.²³

It was further revealed that being a resident of Mainland rural, Unguja and Pemba was negatively associated with IPTp-SP uptake compared to urban Mainland residency. The observed results could be due to socio-cultural differences especially with reference to residents of Unguja and Pemba Islands. Research evidence have linked rural residency with illiteracy, inadequate access to health services, inaccessible to health information updates, poverty etc., and all these attribute to inadequate IPTp-SP uptake.^{24,25}

CONCLUSION

Although IPTp-SP is a recommended routine measure against malaria infection during pregnancy, a considerable percentage of pregnant women do not receive the service. Based on this study, women who are most likely not to receive IPTp-SP are; those who book late for their ANC, below 20 years of age, with no formal education, low parity and reside in Mainland rural, Island Unguja and Pemba. Innovative strategies are recommended to address the challenge of low uptake of IPTp-SP during pregnancy.

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Placental Parasitic Infections and Pregnancy Outcomes Among Women Delivering at a Tertiary Hospital in Northern Tanzania

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ABSTRACT

Background: Placental parasitic infections continue to be a public health problem despite numerous interventions put in place. Placental parasitic infections reported are *Toxoplasma*, *Trypanosome*, *Borrelia*, *Schistosoma*, Hookworm and *Plasmodia*. The infections persist to cause poor pregnancy outcomes such as maternal anaemia, low birth weight and stillbirth. This study aimed to determine the prevalence and pregnancy outcomes associated with placental parasitic infections at a tertiary hospital in northern Tanzania.

Methods: A cross sectional study was conducted at Kilimanjaro Christian Medical Centre between June and July 2016. Pregnant women were interviewed before delivery and additional information obtained from their medical files. Blood samples as well as placental material were collected from each mother. Malaria was tested using a malaria rapid diagnostic test (mRDT). A total of 80 placental slide sections were made following histological protocols. After staining, slide sections were examined for the presence of parasites microscopically. Pearson's Chi-square and Fisher's exact tests were used to test for differences between groups.

Results: Placental malaria parasites were found on histological examination of 8(10%) mothers' placental sections, none of whom had a positive mRDT. Education status was significantly associated with placental malaria ($p=0.035$). Stillbirth, maternal anaemia and pre-eclampsia were significantly associated with placenta malaria ($p<0.05$).

Conclusion: Placental malaria was found to be prevalent in the studied population and was associated with stillbirth, maternal anaemia and pre-eclampsia. Efforts for developing malaria tests that will detect subclinical infections are needed in order to identify infections early and offer prompt treatment to prevent poor pregnant outcomes.

BACKGROUND

Placental parasites infect millions of pregnant women in the world each year, and either directly or indirectly lead to fetal complications like intrauterine growth retardation, congenital malformations and fetal loss.¹ There is a regional variability in the prevalence of placental parasites affecting pregnant women. In Latin America 1, 1250,000 women are infected annually with *Trypanosomacruzi*.² Each year, 25 million pregnant women in sub-Saharan countries are at risk of placental infections, the majority reported are from *Plasmodium falciparum*.³ In Tanzania, the prevalence of placental parasitemia has been reported to range from 8%⁴ to 63.5%.⁵ In Kilimanjaro, the Malaria Survey conducted in 2017 reported the maximum monthly prevalence of placental infection in antenatal care to be $\geq 2\%$ to $< 5\%$.⁶ The reported placental infections include; *Toxoplasma*, *Trypanosome*, *Borrelia*, *Schistosoma*, *Hookworm* and *Plasmodia*.⁵

Placental infections have been associated with maternal and neonatal mortality⁷⁻⁹ as well as

morbidity.⁷⁻¹¹ It is estimated that up to 200,000 deaths per year in sub-Saharan Africa result directly from placental parasitic infections.⁷ Maternal anemia,⁸⁻¹⁰ stillbirth,^{8,11} premature delivery, intrauterine growth retardation and low birth weight^{7,8,11} are among the outcomes of placental parasites.

Malaria incidence fell by 37% from 2000 to 2015 and one of the targets of the Sustainable Development Goal (SDG) number 3.3 is to end the epidemics of Acquired Immune Deficiency Syndrome (AIDS), tuberculosis, malaria and neglected tropical diseases by 2030.¹² Successful control of placental parasites especially malaria in pregnant women is a major step towards reducing the disease burden in Africa. Control of these parasites in pregnancy involves preventing infection as well as clearing parasitemia when it occurs.¹³ Preventive measures put in place by the World Health Organization (WHO) include keeping a clean environment, use of Insecticide Treated Nets (ITN), intermittent preventive treatment in pregnancy and effective case management.¹⁴ The use of preventive

treatment like Sulfadoxine Pyrimethamine (SP) has been shown to be effective in pregnancy.¹⁴

The Ministry of Health (MOH) of the Government of United Republic of Tanzania adopted SP as the preferred chemo preventive method in pregnancy with set guidelines for its use. Despite these interventions, placental parasitic infections, especially malaria, may still occur. The presence of placental receptors for parasites may enable their sequestration, which may then cause re-infections or ultimately lead to maternal and neonatal complications.¹⁵ However, there are limited studies in Tanzania to quantify these infections especially after the introduction of various interventions. The majority of researchers would use daily routine (eosin and hematoxylin) or Giemsa stain to investigate placental parasite infections.¹⁶ The use of both stains may provide more accurate findings, whereby Giemsa stain would reveal parasites like *Leishmania*,¹⁷ while eosin and hematoxylin would reveal malaria parasites.¹⁸ This study was carried out to determine the prevalence, risk factors and peripartum maternal outcomes associated with placental parasitic infections among women who delivered at Kilimanjaro Christian Medical Centre (KCMC). This information can be used to plan effective measures for reducing maternal and fetal risk factors and outcomes resulting from parasitic infections.

METHODS

A hospital based cross sectional study recruited delivering mothers from June to July 2016 at the KCMC referral and consultant hospital serving the northern zone in Tanzania. Pregnant women aged 18 to 40 years who delivered and were admitted to the labour ward were invited to participate in this study after providing written, informed consent. Pregnant women who did not consent, had planned abortion and those that experienced miscarriage were excluded from this study. A total of 80 pregnant women met the inclusion criteria and consented to participate in this study. A non-probability convenient sampling technique was used to select study participants. A hemoglobin test using Haemoglobinometer HemoCue 201+ machine and the rapid malaria detection test (mRDT) using SD BIOLINE Malaria Antigen P.F HRP2/PLDH, followed by microscopic examination of blood slides on positive samples using Olympus CX31 Binocular Microscope, was done for each participant at enrollment. Hemoglobin test, rapid malaria detection test and microscopic examination of blood slides were performed the clinical laboratory. After delivery, the maternal surface of the placenta was washed with normal saline and then incised with a scalpel and specimens fixed in 10% neutral buffered formalin. One full placental block with 4-5µm thickness was prepared by dehydration using acetone for two hours using Semi-Automated Rotary Microtome M-240, clearing by using Xylene for two hours, and paraffin infiltration with paraffin wax. Two slides' sections were made and stained differently; one slide stained with Hematoxylin and Eosin (H&E) as the routine stain and other slide stained with Giemsa stain as the special stain. The slides were then examined by light microscopy. Placental parasites were recorded during examination and all diagnoses confirmed by an experienced pathologist at Bugando Medical Centre

(BMC) pathology laboratory for External Quality Control (EQC). Pre-tested questionnaires were used to collect socio demographic information where examination record files and clinic card were used to collect clinical characteristics.

Maternal anemia, stillbirth, low birth weight and preeclampsia were the main outcomes assessed. Low birth weight was defined as an infant born with a weight of less than 2.5kg while maternal anemia as a pregnant mother with hemoglobin level less than 11g/dl. This was further categorized into mild anemia 10.0-10.9g/dl, moderate anemia 7.0-9.9 g/dl, and severe anemia <7.0 g/dl as adapted from a study conducted in Jordan.¹⁹ Preeclampsia was defined as a blood pressure of greater than 140/90 and protein in urine. Stillbirth, the death of an infant before delivery in a term pregnancy, was based on the first day after the mother's last menstrual period. The exposures for placental parasitic infections included maternal age, maternal occupation, marital status, area of residence; types of diet often used (nutrition), consumption of soil, education status and gravidity. Analysis was conducted using SPSS Inc. Released 2009. PASW Statistics for Windows, Version 18.0. Chicago: SPSS Inc. Pearson's Chi-square test was used to determine the association between the exposures and outcomes of interest. A *p* value of less than 0.05 was considered statistically significant.

Ethics Approval and Consent to Participate

Approval to conduct this study was obtained from the Kilimanjaro Christian Medical College Research and Ethical Review Committee (CRERC) with ethical clearance certificate code number 2103, an independent review board for the medical college. Pregnant women aged 18-40 years who were admitted to the labor ward and delivered were invited to participate in this study after providing written, informed consent. Individual level medical information obtained from those mothers before and after delivery was kept strictly confidential.

RESULTS

The socio-demographic characteristics of the pregnant mothers are summarized in Table 1. The median age of the 80 participants was 32 years (IQR 24-36). Most mothers had secondary or higher education 53(66.2%) and were multigravida 51(63.8%). Proportion of anemia cases was 23(28.7%).

Histopathological examination revealed that 8(10%) of placenta were infected with malaria parasites, despite the fact all mothers had negative mRDTs test results. Placental malaria infection was significantly associated with level of education of the mother (Table 2).

Prevalence of placental malaria infection was associated with low hemoglobin levels ($\chi^2=14.978$, $p<0.01$), preeclampsia ($\chi^2=7.485$, $p=0.048$), and stillbirth ($\chi^2 =14.815$, $p=.006$) (Table 3).

TABLE 2: Association Between Socio-demographic Characteristics and Parasitic Infections

Characteristics	Number	Parasitic Infections		χ^2 (p-value)
		Seen (%)	Not seen (%)	
Occupational				2.956 (0.135)
Employed	43	2 (4.7)	41 (95.3)	
Self employed	37	6 (16.2)	31 (83.8)	
Pica habit				1.455 (0.424)
Yes	55	7 (12.7)	48 (87.3)	
No	25	1 (4.0)	24 (96.0)	
Education				6.960 (0.035)
Primary education	27	6 (22.2)	21 (77.8)	
Secondary education	43	2 (4.7)	41 (95.3)	
Higher education	10	0 (0.0)	10 (100.0)	
Gravidity				2.170 (0.247)
Primigravida	29	1 (3.4)	28 (96.6)	
Multigravida	51	7 (13.7)	44 (86.3)	
Gestation Age (Week)				1.437 (0.284)
28-36	36	2 (5.6)	34 (94.4)	
37-43	44	6 (13.6)	38 (86.4)	
Marital status				1.725 (0.341)
Union	67	8 (11.9)	59 (88.1)	
Non union	13	0 (0.0)	13 (100.0)	

TABLE 3: Association Between Placental Malaria Parasitic Infection and Pregnancy Outcomes

Adverse pregnancy outcomes	N	Placenta malaria parasites		χ^2 (p-value)
		Yes n (%)	No n(%)	
Still birth				14.815 (0.006)
Yes	5	3(60.0)	2 (40.0)	
No	75	5 (6.7)	70(93.3)	
Birth weight (Kg)				0.969 (0.459)
< 2.5	47	6(12.8)	41(87.2)	
≥ 2.5	33	2 (6.1)	31(93.9)	
Hemoglobin level (g/dl)				14.978(<0.0001)
Normal	57	1 (1.8)	56(98.2)	
Anemia	23	7(30.4)	16(69.6)	
Pre-eclampsia				7.485 (0.048)
Yes	4	2(50.0)	2 (50.0)	
No	76	6 (7.9)	70(92.1)	

Key: Kg – Kilogram; g/dl – grams/deciliter; χ^2 – Chi-square

TABLE 1: Socio-Demographic Characteristics of Women whose Placenta were Examined for Parasitic Infections (N=80)

Characteristics	Frequency	Percentage
Education		
Primary education	27	33.8
Secondary education	43	53.7
Higher education	10	12.5
Age(year)		
≤24	22	27.5
>24	58	72.5
Gravidity		
Primigravida	29	6.2
Multigravida	51	63.8
Birth weight (Kg)		
<2.5	20	25.0
≥2.5	60	75.0
Gestation age (Week)		
28-36	36	45.0
37-42	44	55.0
Hemoglobin level/anemia (g/dl)		
Normal (> 11)	57	71.3
Moderate (9.0 - 10.9)	9	11.2
Mild (7.0 - < 9.0)	14	17.5
Severe (< 7.0)	0	0
Occupation		
Employed	43	53.8
Self-employed	37	46.2
Soil Consumption		
Yes	55	68.8
No	25	31.2

Key: Kg – Kilogram; g/dl – grams/deciliter; χ^2 – Chi-square

DISCUSSION

Malaria was the only placental parasitic infection observed among delivering mothers in this study population. Malaria positivity among women who delivered at KCMC referral hospital was significantly associated with level of education, stillbirth, anemia and pre-eclampsia.

The prevalence observed in this study is higher than the 8% prevalence reported in the previous study²⁰ and lower than 16.4% reported in another study conducted in Tanzania.⁵ Variations in community acquired immunity, sociodemographic characteristics of the study population, as well as endemicity of parasitemia which can be attributed to behavioral and environmental exposure to malaria may explain the observed differences.²¹

Additionally, geographical location, stage of pregnancy and the methods used to determine presence of parasites in the placenta may have also contribute to the observed difference between the current and previous studies. Dar es Salaam and Mwanza (high endemic area) are hotter than Kilimanjaro (low endemic area). Hotter weather has been found to favor the sporulation of Oocyst.²² A study

in Dar es Salaam used immunosorbent agglutination assay, in Mwanza ELISA²³ was used and in this study, manual histological staining was used.

Furthermore, the presence of placental malaria infections among participants was different based on their level of education while this difference was not seen with other socio-demographic characteristics. This revealed that pregnant women who are in the primary level of education were more likely than those with secondary and higher education to have placental malaria infection.

In this study, placental malaria was associated with anemia. Anemia is the most common consequence of *P. falciparum* malaria infection. A study conducted in Tanzania found that malaria infection during pregnancy contributed 15% of maternal anemia.²⁴ The result of this outcome also corresponds with previous studies conducted in Sub-Saharan Africa.²⁵ The pathogenesis of anemia by malaria parasites (*P. falciparum*) includes the hemolysis of the infected red blood cells. This is thought to be due to the reduced production of red blood cells, rupture of infected red blood cells and the destruction of uninfected cells due to antibody sensitization and with the resulting pathological effects. Marrow hypoplasia occurs in acute infections of malaria which may reduce the production of red blood cells.^{21,26} The mentioned processes may also explain how placenta malaria is significantly associated with anemia in this study.

The study also showed an association between placental malaria and stillbirth. Eight (8) percent of stillbirths worldwide (208,906) were estimated to be contributed by malaria parasites especially *P. falciparum* in pregnancy.²⁷ Most stillbirths, however, occur where malaria transmission is low³ and the effect of malaria on stillbirth is likely to be greater in areas of low transmission where there is little or no maternal immunity.²⁸ In Moshi, falciparum malaria detected at delivery, even at sub-microscopic levels may increase the risk of stillbirth. These findings suggest that even low-level, asymptomatic and/or sub-microscopic infections that might easily be missed during routine antenatal care could be detrimental to the developing fetus.²⁸

Placental malaria also was significantly associated with pre-eclampsia. Seasonal changes in the incidence of pre-eclampsia have been described in tropics, which are consistent with malaria transmission periods. Placental malaria is likely to impair placental development and cause maternal hypertension and placental vascular dysfunction.^{29–32}

Strength and limitations of the study

This study used a standard histological examination, where this method can diagnose parasites which could not be detected by the rapid test (mRDT). Information was collected with the help of midwives who interviewed the women using a standardized questionnaire. To ensure data completeness and accuracy, information obtained from clinic cards was triangulated with responses from the questionnaire.

This study also had some limitations which are important to be taken into account while interpreting the results. Firstly, the sample size was small and therefore limits the power of the inference being made. Secondly, the method

used, although highly specific, can miss some other parasite as compared with more sensitive techniques like immunosorbent assay e.g. ELISA.

CONCLUSION

These findings add to the evidence of adverse the health outcomes of placental parasitic infections among delivering mothers. Malaria in pregnancy was found to be significant associated with anemia, stillbirth as well as contributing to increased risk of pre-eclampsia. There is a need for more sensitive tests for early diagnosis and adequate treatment during pregnancy to prevent adverse pregnancy outcomes caused by submicroscopic malaria infection.

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The Influence of Fear During Pregnancy, Labour and Delivery on Birth Outcome Among Post-Delivery Women: A Case Control Study in Zanzibar

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ABSTRACT

Background: Assessing the influence of fear during pregnancy, labour, and delivery on birth outcomes among women is very important. Normally, women experience happiness during pregnancy, but some may develop fear which may cause maternal and neonatal complications. The aim of this study was to determine the influence of fear during pregnancy, labour and delivery on birth outcome among post-delivery women in Zanzibar.

Methodology: This was a matched case-control study involving 204 post-delivery women who were randomly selected from 4 hospitals in Zanzibar. Cases (n=68) were those who experienced a negative birth outcome, whether maternal, fetal, or both. The control group (n=136) had normal birth outcomes. A self-administered questionnaire was used to collect data and was analyzed using SPSS whereby percentages, chi-square test, and odds ratio results were reported.

Results: Among cases, 27(39.7%) had high level of fear during pregnancy compared to the control group, 75(40.4%). During labour, 29(42.6%) of cases had high level of fear, and in control, 55(42.4%). And during delivery 35(51.4%) of cases had highest level of fear, while only 47(34.5%) of control had high level of fear. The chi-square test showed only fear during delivery was significantly associated with undesirable birth outcomes. Women who experienced a high level of fear during delivery were 2 times more likely to have undesirable birth outcomes (AOR=1.941, $p=.051$) after adjusting for other variables.

Conclusion: This study established that most women experience high level of fear during pregnancy, labour and delivery. A high level of fear during delivery is associated with having negative birth outcomes, but not during pregnancy and labour. The findings are of clinical importance as they highlight the need to integrate a universal screening intervention into antenatal care services for early management.

BACKGROUND

Having a new life developing inside a woman's body during pregnancy creates a new state of emotions. Pregnancy has been termed as an emotional crisis^{1,2} since it is associated with many different physical and social changes.³ Normally, women experience happiness, satisfaction, and self-fulfilment during pregnancy, but may also develop pregnancy-related anxiety which includes fears and worries about, but not limited to, the health and survival of the unborn child, having an abnormal baby, the delivery process, developing medical problems during pregnancy, and the ability to parent and care for the infant following birth.⁴

Pregnancy-related anxiety has attracted considerable research attention and fear is one of its dimensions.⁵ The high maternal and neonatal morbidity and mortality rates in sub-Saharan African countries, poverty, and shortage of resources in hospital settings may lead to a high prevalence of fear related to

pregnancy and its effects may be more prominent among post-delivery women. Tanzania has a maternal mortality ratio of 556/100,000 live births⁶ while Zanzibar has a ratio of 276/100,000 live births⁷, a fertility rate of 5.1 children⁸, and 65,688 women of expectant reproductive age.⁶ However, not much is known in many sub-Saharan African countries, Tanzania included, about the fear in pregnancy and its influence on birth outcome.

The worldwide prevalence of pregnancy-related fear of childbirth has been estimated at around 14%. In developed and developing countries, the prevalence of fear is about 10% and 25%, respectively. Pregnancy-related fear is estimated to be around 23% in Alberta, Canada, 15.6% in Germany, and 49% in Pakistan.⁹

Studies have shown a correlation between fear and undesirable birth outcomes. Fear can end up with fetal distress, premature delivery, and the possibility of a ruptured uterus.¹⁰ Fear has also been linked to preterm labour, low birth weight, Caesarean Section

(C/S) and instrumental deliveries¹¹ as well as prolonged labour, post-partum haemorrhage, birth asphyxia and even death.¹² Fear in early pregnancy may result in fetal loss, and fear in the second and third trimesters leads to a decrease in birth weight.¹³ However, there is not enough information to support the correlation between fear during pregnancy, labour and delivery and birth outcome in low-income countries.

In Tanzania, there is a paucity of information about pregnancy-related anxiety. The only qualitative study conducted in Mwanza-Tanzania showed that women acknowledged experiencing a state of worry and concern during pregnancy, often causing physical symptoms and disrupting their personal sense of peace.⁴ Another is a quantitative study also conducted in Mwanza which showed that about 25% of the study participants scored higher in pregnancy-related anxiety scale and it was predicted by the perceived stress, active depression and number of people living in the home.¹⁴ There is still a need to explore more about the pregnancy-related anxiety in Tanzania and how much it is associated with undesirable birth outcomes. Therefore, this study intended to assess the influence of fear during pregnancy, labour, and during delivery on maternal and neonatal birth outcome.

METHODOLOGY

Study Design and Setting

The study design was a matched case-control. This was a hospital-based study conducted in postnatal wards in Unguja, Zanzibar-Tanzania in national and district hospitals. Unguja has one national referral hospital (Mnazi Mmoja hospital) and two district hospitals (Kivunge and Makunduchi hospitals), all of which offer birth delivery services.

Study Population, Sample Size, and Sampling

The study involved all post-delivery women admitted and had delivery at the health facilities. Participants in the case and control groups were matched based on age and parity. Cases and controls were defined according to the status of birth outcome.

Cases definition: Having undesirable/negative birth outcome for either mother or infant or both. The undesirable birth outcomes considered in this study were birth asphyxia, caesarean section, fetal distress, instrumental delivery, intrauterine fetal demise, low birth weight, postpartum haemorrhage, premature delivery, prolonged labour, ruptured uterus and severe pre-eclampsia.

Controls definition: are defined as having a normal birth outcome for both the mother and the infant.

The exposure status, which was determined retrospectively, was having a high level of fear during pregnancy, labour, and delivery.

Non-exposure status was having a low level of fear during pregnancy, labour, and delivery.

The study included all who agreed to participate and excluded all known cases of diabetes, renal, and heart diseases among both cases and controls.

The sample size was estimated with a hypothesis of two-sided equality.¹⁵ The prevalence of fear among women

with undesirable birth outcomes of 30% in developing countries was used.¹³

$$n_{pairs} = \frac{[Z_{\alpha/2} + 2 * Z_{1-\beta} * \sqrt{P_A(1 - P_A)}]^2}{4 * (P_A - 0.5)^2 * P_D}$$

Variation Notation

n_{pairs} = Sample size pair for case control study

α = Probability of margin error of cases of 5%

β = Probability of margin error of control 5%

P_A = Population proportion of cases with characteristic of (30%)

P_D = Population proportion of control with characteristic of (21%)

Z = Constant, Standard normal deviance (1.96 for 95%)

Therefore, the sample size obtained was 90 pairs. Adding 13% attrition rate, the sample size obtained per group was 102, and this made a total sample enrolled for this study 204 women. Using a ratio of 1 case to 2 controls, there were a total of 68 cases and 136 controls in this study.

The stratified proportionate sampling method was initially used to obtain a representative sample from each hospital using the formula $n_i = (N_i/N_t) * n$ ¹⁶ where N_i = The average number of post-delivery mothers in each hospital for one week (Kivunge 138, Makunduchi 138 and Mnazi-mmoja hospital 352) N_t = The total number of post-delivery mothers in all the selected three hospitals for one week (628), n = The sample size for this study and n_i = The number of a sample from each hospital which are (Kivunge= 45, Makunduchi =45, Mnazi Mmoja 114). Within the hospital, a group of cases and controls were identified, and simple random sampling by lottery with replacement method was used to select the required number of cases and the controls.

Data Collection

An interviewer-administered questionnaire was used to collect data. Three nurse-midwives with advanced diploma levels were selected as research assistants. Prior to data collection, these assistants were trained on the data collection method and tool, as well as how to ask questions and complete the questionnaire. Each research assistant and the principal investigator were assigned to a single hospital at a time, and they collected data separately. The data collection was conducted at the post-delivery ward on a daily basis during the morning and evening hours whereby, immediately after delivery, the birth outcome was assessed to identify the cases and the controls, and then mothers in both groups were interviewed within the first 4 hours for their fears experienced during pregnancy, labour and delivery.

Measurement of Level of Fear

The tool used to measure fear was the 'Childbirth Attitude Questionnaire' which was adopted and modified from Dönmez et al.¹⁷ Fear was measured using an index score, which was computed based on 19 items on a Likert scale with Strongly Disagree (SD=1), Disagree (D=2), Agree

(A=3), and Strongly Agree (SA=4). Fear during pregnancy consisted of 7 items (fear of abortion, morning sickness, loss of appetite, change in body shape, thinking of date of delivery, change in partner behaviour, and fear of death). Fear during labour had 5 items (fear of pushing, fear of labour pain, fear of having baby with abnormalities, fear of heavy bleeding, and fear of death), while fear during delivery was measured using seven items (fear of pushing, fear of tears, fear of severe bleeding, fear of C/S, fear of the kind of baby that should have, fear of touching a baby, and fear of death). Strongly disagree and disagree were combined to form disagree while agree and strongly agree were combined to form agree. The fear index was derived using principal component analysis (PCA) in order to reduce a larger set of a variable into a smaller set if the variable is highly correlated and measuring the same underlying construct that does not sufficiently represent the construct of interest. During the PCA analysis, all items had a commonality of 0.3 and a factor loading of 0.5 hence were retained. The distribution of the fear index score was then divided into five categories (quintiles), each with approximately 20% of the population. The quintiles were named as the lowest, low, middle, high, and highest levels of fear.

Data Analysis

Data was analysed using the Statistical Package for Social Sciences (SPSS) version 20.0. Descriptive statistics were used to describe the demographic characteristics of the respondents using percentage and frequency. A chi-square test was used to determine the relationship between fear experienced during pregnancy, labour and delivery, and birth outcomes. Inferential statistics using a logistic regression model were used to assess the association between fear during pregnancy, labour and delivery and birth outcomes. The odds ratio (OR) with its 95% CI was reported and the significance level was set at *p-value* < .05.

Ethics Approval and Consent to Participate

The University of Dodoma (UDOM) Research Ethical Committee provided ethical clearance for this study with a reference number UDOM/DRP/134/VOL VII/36 and the ethical clearance for conducting research in Zanzibar was approved by the Zanzibar Medical Research Committee with reference number OMPR/M.95/C.6/2/VOL.XVII/92. A research permit was given by the Zanzibar Research Committee from the Office of Chief Government Statistician. The purpose of the study was explained to the participants and a written informed consent was obtained. Participants were allowed to withdraw from the study and be assured that obtained information was considered confidential and no harm associated with the study or means of data collection. Participants that were willing to participate were included. The participants that were found with health issues like diabetes and heart diseases were excluded. The undesirable outcome was managed according to the guideline and hospital protocol.

RESULTS

Characteristic of the Study Participants

A total of 204 post-delivery women participated in this study, which is equivalent to 100% of the response. Out of 204 participants, a majority 157(76.96%) were in the

age group of 25 to 35 years which is the prominent age group among cases 51(75.0%) and among controls 106 (77.94%). All participants were married and the majority of all cases 49(72.06%) and all control 92(67.65%) were less than para 4. Most participants in all cases 47(69.1%) and all controls 69(50.7%) completed secondary school, and slightly more than half of all cases 38(55.9%) and controls 74(54.4%) were unemployed. There was no statistical difference between cases and controls in all of the demographic characteristics (Table 1). The following birth outcomes were observed: Postpartum Hemorrhage (PPH) 14(21%), prolonged labour 12(18%), and ruptured uterus 1(1%). More details are shown in Table 2.

Fear During Pregnancy, Labour and Delivery

On a Likert scale, respondents were asked what they feared during pregnancy, labour, and delivery. Strongly disagree and disagree were combined to form disagree, and agree and strongly agree were combined to form agree. The results showed that, during pregnancy, the majority of women 155(75.98%) feared for death, a little less than half 86(42.16%) feared for thinking of the date of delivery, and only 29(14.21%) feared for change of body shape. The majority of 172(84.31%) feared death during labor, 136(66.66%) feared pushing the baby, and only 41(20.10%) feared having a baby with an abnormality. And during delivery majority 165(80.88%) feared for death, 109(53.43%) feared for tears and 100(49.02%) feared for undergoing caesarean section (Table 3).

Level of Fear During Pregnancy, Labour and Delivery among Cases and Control

Figures 1, 2 and 3 show the distribution of fear levels among cases and control during pregnancy, labour, and delivery. The fifth quintiles were combined, lowest and low to form low, high and highest to form high and medium remained the same. The findings showed that during pregnancy, among cases, 27(39.7%) had a high level of fear during pregnancy compared to the controls, 75(40.4%). During labour, equal proportions of cases 29(42.6%) and of controls 55(42.4%) had a high level of fear, and during delivery, 35(51.4%) of cases had a high level of fear, while only 47(34.5%) of controls had a high level of fear. (Figure 1, 2 and 3).

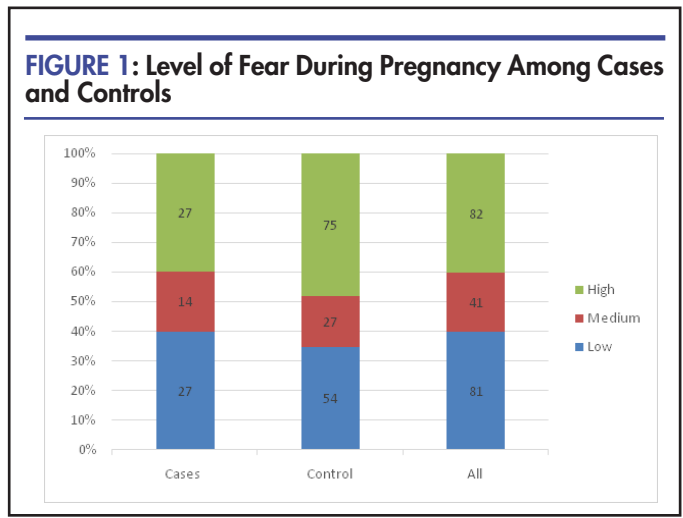


FIGURE 2: Level of Fear During Labour among Cases and Controls

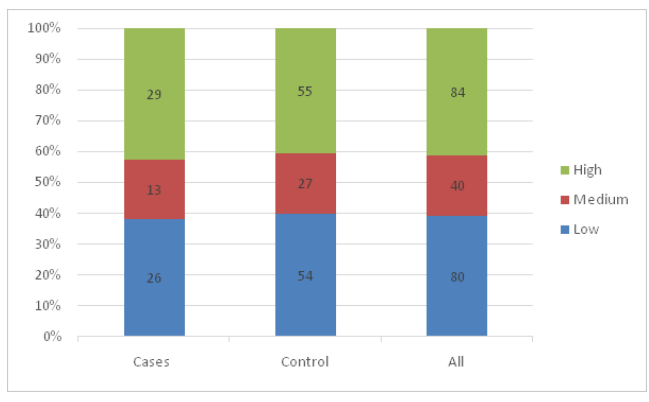
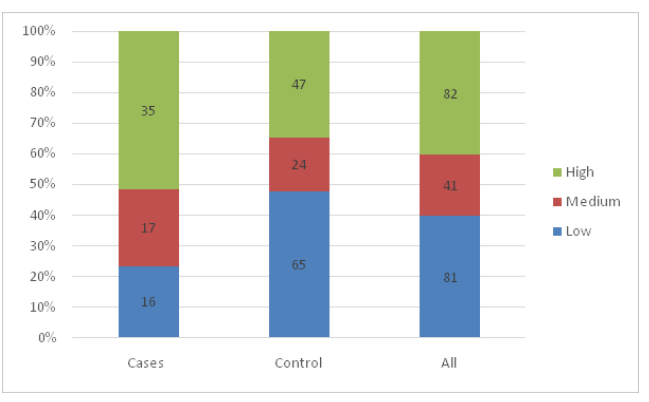


FIGURE 3: Level of Fear During Delivery among Cases and Controls



The above-mentioned comparative graphical analysis of patterns of fear among cases and controls may provide a clear indication of the premise that there is association between them. To validate that premise, the chi-square test with a significance level of 5% was conducted, and the results showed that only fear during delivery was statistically significantly associated with having undesirable birth outcomes ($\chi^2 = 11.17, p = .003$). The study showed no significant relationship between fear experienced during pregnancy ($\chi^2 = 0.02, p = .9909$) and during labour ($\chi^2 = 0.09, p = .9555$) with the birth outcome. Furthermore, the chi-square test was conducted to confirm if there are covariates other than fear that can significantly provoke undesirable birth outcomes, and the results showed none of the covariates (demographic variables) showed a significant association with birth outcomes (Table 4).

Simple and multiple logistic regression analysis were then conducted to determine the sole effect of fear during delivery on birth outcomes. The results of the models showed that women who experienced a high level of

TABLE 2: Frequency Distribution of Birth Outcomes Observed (N= 68)

Birth outcome	n(%)
Birth asphyxia	11 (16.1)
Cesarean section	8 (11.7)
Fetal distress	4 (5.8)
Instrumental delivery	2 (2.9)
Intrauterine fetal demise	1 (1.4)
Low birth weight	5 (7.3)
Postpartum hemorrhage	14 (20.5)
Premature delivery	9 (13.2)
Prolonged labour	12 (17.6)
Ruptured uterus	1 (1.4)
Pre/eclampsia	1 (1.4)
Normal birth outcomes	136 (66.6)

fear during delivery were two times more likely to have undesirable birth outcomes than those who experienced a low level of fear (AOR = 1.941, $p = .051$) after adjusting for fear during labour and during pregnancy (Table 5).

DISCUSSION

Fear as one of the dimensions of pregnancy-related anxiety reported to negatively affect women’s and infants’ health. This study therefore determined the influence of fear during pregnancy, labour and delivery on birth outcomes in Unguja Zanzibar.

This study shows that all women experience some degree of fear at varying levels during pregnancy, labour, and delivery. The reason for having fear was not explored in this study. However, it has been observed in the qualitative study done in Mwanza –Tanzania that a lack of knowledge or understanding of what was normal was one among the reasons for many of the worries participants had about pregnancy.⁴ Fear of death was the most popular type of fear experienced during pregnancy, labour, and delivery. This was expected considering the high maternal mortality rates accompanied by a shortage of resources in this setting which may impair the quality of pregnancy-related services.¹⁸

This study has found that only having fear during delivery is associated with having undesirable birth outcomes assessed in this study, which includes birth asphyxia, C/S, fetal distress, low birth weight, PPH, premature delivery, prolonged labour, ruptured uterus, and severe pre/eclampsia. Evidence shows that fear results in increases in cortisol and norepinephrine, which are known to be associated with abnormal uterine contractions and subsequent obstetric complications.¹⁹ Despite the fact that this study did not specify the type of birth outcome related to fear experienced during pregnancy, labour, and or delivery, previous research has shown that fear during delivery is associated with elective C/S and emergency C/S.²⁰

This study, however, did not find a significant association between fear during pregnancy and labour with birth outcomes. However, evidence suggests that severely

TABLE 1: Characteristics of the Study Participants (N=204)

Variable	Total (n= 204) n(%)	Case (n=68) n(%)	Control (n=136) n(%)	Chi-square (P-value)
Age				0.228(.8924)
<25	19(9.31)	7(10.29)	12(8.82)	
25-35	157(76.47)	51(75.00)	106(77.94)	
>35	28(27.95)	10(14.71)	18(13.24)	
Para				1.628(.6531)
<4	142(69.85)	49(72.06)	92(67.65)	
4-6	54(50.74)	15(22.06)	39(28.68)	
7-9	6(6.62)	3(4.41)	3(2.21)	
10-12	3(2.94)	1(1.47)	2(1.47)	
>12	0(0.00)	0(0.00)	0(0.00)	
Education				8.732(.0682)
Illiterate	29(28.68)	10(14.71)	19(13.97)	
Primary	39(34.55)	8(11.76)	31(22.79)	
Secondary	116(59.93)	47(69.12)	69(50.74)	
High school	11(9.56)	2(2.94)	9(6.62)	
College/University	9(7.35)	1(1.47)	8(5.88)	
Job				2.237(.5248)
Employed	20(8.38)	5(7.35)	15(11.03)	
Not employed	112(55.14)	38(55.88)	74(54.41)	
Peasant	24(22.06)	6(8.82)	18(13.24)	
Small business	48(49.26)	19(27.94)	29(21.32)	

TABLE 3: Frequency Distribution of Constructs of Fear during Pregnancy, Labour and Delivery (N=204)

Variable	Strongly Disagree n(%)	Disagree n(%)	Agree n(%)	Strongly Agree n(%)
During Pregnancy				
Abortion	121(59.31)	24(11.76)	33(16.18)	26(12.75)
Morning sickness	98(48.04)	23(11.27)	67(32.84)	16(7.84)
Loss of appetite	99(48.53)	22(10.78)	65(31.86)	18(8.82)
Change of body shape	116(56.86)	59(28.92)	17(8.33)	12(5.88)
Date of delivery	85(41.67)	33(16.18)	42(20.59)	44(21.57)
Change of partner behaviour	119(58.33)	40(19.61)	22(10.78)	23(11.27)
Death	46(22.55)	3(1.47)	17(8.33)	138(67.65)
During labour				
Pushing	60(29.41)	8(3.92)	64(31.37)	72(35.29)
Labour pain	64(31.37)	11(5.39)	67(32.84)	62(30.39)
Abnormalities of baby	111(54.41)	52(25.49)	24(11.76)	17(8.33)
Heavy bleeding	81(39.71)	44(21.57)	46(22.55)	33(16.18)
Death	30(14.71)	2(0.98)	16(7.84)	156(76.47)
During delivery				
Pushing	56(27.45)	21(10.29)	69(33.82)	58(28.43)
Tear	60(29.41)	35(17.16)	53(25.98)	56(27.45)
Severe bleeding	95(46.57)	42(20.59)	46(22.55)	21(10.29)
Fear of C/S	75(36.76)	29(14.22)	56(27.45)	44(21.57)
Abnormalities of baby	110(53.92)	69(33.82)	9(4.41)	16(7.84)
Touching of the baby	113(55.39)	32(15.69)	43(21.08)	16(7.84)
Death	36(17.65)	3(1.47)	13(6.37)	152(74.51)

TABLE 4: Relationship between factor and birth outcome (N=204)

Variable	Level of fear		Chi-square	p-Value
	Case n(%)	Control n(%)		
Age			0.228	.8924
<25	7(10.29)	12(8.82)		
25-35	51(75.00)	106(77.94)		
>35	10(14.71)	18(13.24)		
Parity			0.4134	.5203
<4	49(72.06)	92(67.65)		
4+	19(27.94)	44(32.35)		
Job			2.237	.5248
Employed	5(7.35)	15(11.03)		
Not employed	38(55.88)	74(54.41)		
Peasant	6(8.82)	18(13.24)		
Small business	19(27.94)	29(21.32)		
Education level			3.6224	.1635
No formal education	10(14.71)	19(13.97)		
Primary	8(11.76)	31(22.79)		
Level of fear in Pregnancy			0.018	.9909
Low	27(39.71)	54(39.71)		
Medium	14(20.59)	27(19.85)		
High	27(39.71)	55(40.44)		
Fear during Labour			0.091	.9555
Low	26(38.24)	54(39.71)		
Medium	13(19.12)	27(19.85)		
High	29(42.65)	55(40.44)		
Fear during Delivery			11.167	.0038
Low	16(23.53)	65(47.79)		
Medium	17(25.00)	24(17.65)		
High	35(51.47)	47(34.56)		

TABLE 5: Logistic Regression Model for Association between Fear and Birth Outcome (N=204)

Variable	Un adjusted logistic model		Adjusted logistic model	
	OR(95%CI)	p-value	AOR(95%CI)	p-value
Fear in Pregnancy				
Low	Reference	1.000	Reference	
Medium/ High	1.0(0.55- 1.81)			
Fear during Labour				
Low	Reference	.839	Reference	
Medium/ High	1.0(0.58-1.93)			
Fear during Delivery				
Low	Reference	.001	Reference	.051
Medium/ High	2.9(1.54-5.72)		1.94(1.19- 4.1)	

anxious mothers may feel overwhelmed and fatigued during pregnancy, which may impact their consistency of prenatal care, diet, and sleep habits, potentially contributing to poor birth outcomes.¹³ This study's findings are consistent with what has been reported in several studies that maternal fear or anxiety during pregnancy has effects on the length of labour,²¹ pre-eclampsia, prolonged labour and forceps delivery,²² use of anaesthesia during delivery,²³ and preterm delivery.²⁴ Furthermore, literature shows that severe anxiety during pregnancy has a significant long term impact on newborns such as height, head circumference, and weight²⁵ and an increased risk of giving birth to low birth weight babies and preterm births.²⁶ The effect of fear on newborn might be due to changes in the blood flow to the baby, making it difficult to carry oxygen and other important nutrients to the baby's developing organs.^{27,28}

The inconsistent findings in this study can be due to lack of specificity. That is the specific dimensions of fear (eg, fear of pain, coping, or safety) may interact with specific birth outcomes (e.g., duration of labour or fetal heart rate deceleration). Therefore, the broad definition of fear and birth outcome in this study may be the reason for the inconsistent results. Moreover, the results of this study should be interpreted with caution as there are some limitations that are worth mentioning. The assumption used to calculate the sample size may have underestimated the sample, thus reducing the power of this study. Results are also limited by a failure to control for confounding variables, such as the kind of healthcare services received during pregnancy, labour, and delivery, which may have an influence on birth outcome and level of fear, or women's knowledge of the possibility of complications. Finally, the timing of the measurement of fear in this study may not be possible to distinguish whether the fear was present before delivery or whether the fear came as a result of adverse birth outcomes. The ideal design would have been to assess the presence of fear before labour or delivery and then briefly follow up the mothers to determine whether they developed adverse birth outcomes or not. Therefore, future studies should take these suggestions into consideration.

CONCLUSION

This study established that, most women experience high level of fear during pregnancy, labour, and delivery. A high level of fear during delivery is associated with having undesirable birth outcomes but not during pregnancy and labour. The findings are of clinical importance as they highlight the need to integrate a universal screening intervention into the antenatal care services for early management.

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Determinants of Antenatal Healthcare Services Utilisation: A Case of Dodoma, Tanzania

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ABSTRACT

Background: Antenatal Care (ANC) coverage is a key determinant of maternal and perinatal morbidity and mortality. Low utilization of ANC services and high Maternal Mortality Ratio (MMR) have been reported in the East African Region. Due to the paucity of information on the determinants of ANC utilization in this region, we conducted the study aiming at exploring factors influencing the utilization of ANC services. We further sought opinions that will aid the improvement of utilization of ANC services.

Methods: A triangulation mixed-method study was conducted in August 2021 among forty-five women and ten healthcare providers in a selected health center located in Dodoma Urban District, Tanzania. Information was gathered using semi-structured questionnaires and in-depth interviews. Quantitative data were analysed using IBM SPSS Statistics. The relationship between the outcome variable and the predictor variables was assessed by either the Chi-square test or Fisher's exact test and a p value $< .05$ was considered statistically significant. Manual thematic analysis was used for qualitative data after thorough transcript and documentary reviews.

Results: Almost half (48.9%) of the interviewed women attended ANC services at least once during their last pregnancy. Women who reported having a low income and those who spent more than an hour reaching the health facility had poor ANC attendance (p value $< .05$). The main themed factors that negatively impacted ANC utilization included cultural practices and gender norms, poor communication between partners, and long waiting time at the ANC clinics.

Conclusion: Utilization of ANC services was found to be low among women living in Dodoma Urban District. ANC attendance varied with the level of income and the time women spent reaching the health facility. Cultural practices and gender norms, communication between spouses, and service waiting time were mentioned to influence ANC attendance.

Recommendations: Public and private sectors should invest in maternal health, provide affordable services and formulate strategies to improve the accessibility of ANC services. Interventions should target women of low socio-economic class and those living in remote areas. Moreover, schemes to address the sociocultural barriers to ANC utilization need to be formulated.

BACKGROUND

Despite the average annual decline (2.9%) in the Maternal Mortality Ratio (MMR) in the Sub-Saharan Africa region through the years 2000 to 2015, the region reported the highest estimates (987 maternal deaths per 100,000 live births) among all the 'Sustainable Development Goals (SDGs)' Regions.¹ The trend has been more or less similar for the East African Community (EAC) member States (Figure 1) with the highest MMR (1,150 maternal deaths per 100,000 live births) reported in South Sudan as of the year 2017.² A 10-year retrospective study by Bwana et al³ conducted across 34 public hospitals in Tanzania reported a rising trend of the in-hospital MMR; from 40.2 to 57.9 per 100,000 live births from the years 2006 to 2015 respectively. Majority of deaths (83.8%) were attributed to direct causes such as eclampsia, obstetric hemorrhage, and maternal sepsis; whereas,

anemia and cardiovascular disorders were the main indirect causes.³

Antenatal Care (ANC) coverage is vital in reducing potential risks for maternal and perinatal mortality and remains integral for the well-being of the mother and the newborn.⁴ Receiving at least 8 antenatal visits as recommended by the World Health Organization (WHO) increases the chances of detecting and managing potential pregnancy complications as well as enhancing birth preparedness and complication readiness.⁵ Although numerous initiatives have been implemented to improve maternal healthcare coverage, there is still less than average coverage and low utilization of these services, especially in developing countries where approximately 99% of maternal deaths occur.^{6,7}

About 59% of pregnant women in Sub-Saharan

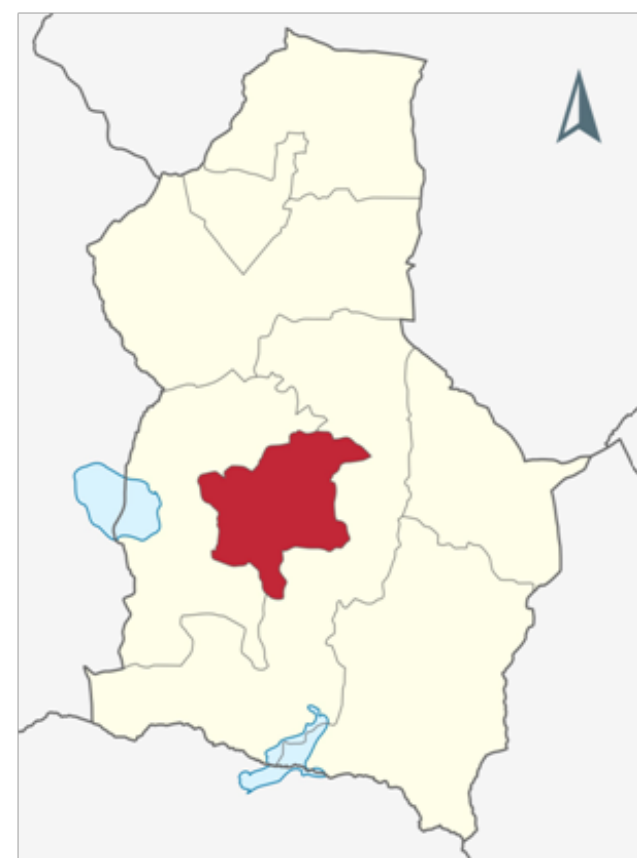
African countries who attended ANC services met the previous minimum recommendation of four visits; with the highest attendance reported in the Southern Region (78.9%) and the lowest in the Eastern Region (53.4%).⁸ In Tanzania, the utilization of ANC services has been similar to the East Africa regional estimates (56.4%) with relatively lesser utilization reported in rural areas (39.1%) as compared to the urban areas (54.8%).^{9,10} Diverse factors influencing the utilization of ANC services in sub-Saharan Africa have been identified. These include religion, residency, literacy level, economic status, occupation, women’s healthcare decision autonomy, media exposure, access to healthcare, and birth order.^{9,11–13}

An increase in demand for Maternal and Child Health (MCH) services has been observed following the shift of capital functions from Dar es Salaam to Dodoma at the end of the year 2020. Moreover, Dodoma region has one of the country’s highest MMR (417 deaths per 100,000 live births)¹⁴, and information on the determinants of ANC services utilization in this region is limited. Identifying the determinants of ANC utilization will be essential in informing strategic interventions which will contribute to the reduction of MMR in the region. This study therefore aimed at determining factors that influence the utilization of ANC services in Dodoma, Tanzania, and provides recommendations for improving the utilization of ANC services.

derived from the sets of data and provided a detailed elaboration on the patterns of relationship within the sets of data.

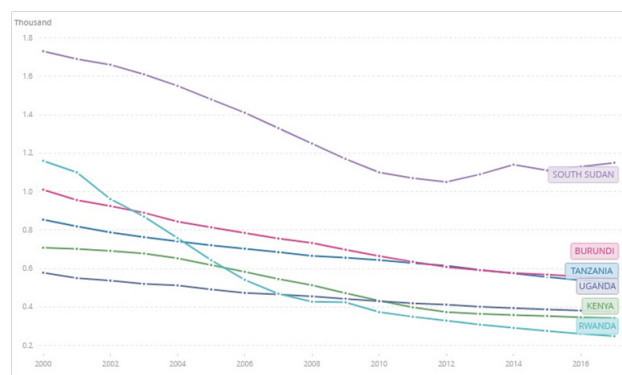
In Tanzania, majority of the ANC services including hospital deliveries take place in dispensaries and health centers.¹⁵ Health centers are equipped to provide services within a catchment of up to 50,000 people and attend referral cases from dispensaries within the respective catchment area.¹⁶

FIGURE 2: The Map Indicating the Study Area (Dodoma Urban District) in Dodoma Region, Tanzania



Adopted from: Nord NordWest (2022)¹⁷

FIGURE 1: Figure 1. Maternal mortality ratio (modeled estimate, per 100,000 live births) for Tanzania, Kenya, Uganda, Burundi, Rwanda, and South Sudan



Adapted from WHO et al.²

METHODOLOGY

Study Area, Period and Design

This study was conducted in a randomly selected health center located in Dodoma Urban District (Figure 2), one of the 8 districts of Dodoma Region in Tanzania. A cross-sectional study design that employed a triangulation mixed-method approach of data collection was used. The method allowed us to compare and interlink findings from quantitative and qualitative data. Furthermore, the design allowed us to examine the major attributes

Selection of Participants

A purposive sampling technique was employed in selecting 55 respondents that included 10 healthcare providers (3 doctors, 4 nurses, and 3 medical attendants), and 45 women who resided in Dodoma Region during their antenatal period and gave birth in facilities located in Dodoma. The ‘45 women’ were selected from those attending postnatal care at the selected center during the data collection period. A document review was performed to confirm the aforementioned inclusion criteria. The involvement of healthcare providers and

postpartum women allowed an in-depth and multi-faceted understanding of the factors which influence the utilization of ANC in the selected health facility.

Data Collection and Management

Semi-structured questionnaires were used to collect quantitative data, whereas in-depth interview guides were used to collect qualitative data. Both quantitative and qualitative information on the determinants of ANC utilization were collected from the enrolled postpartum women. Saturation of information from the in-depth interview was reached after interviewing 31 women. Opinions on improving ANC utilization were sought from both the healthcare providers and the postpartum women so as to generate care provider- and patient-centered methodological solutions.

Verbatim transcription and translation into English language from the local language were performed for the collected qualitative information. Each questionnaire and transcript was reviewed for content and completeness. All data was securely stored electronically.

Data Analysis

Quantitative data were analyzed using IBM SPSS Statistics, Version 26.0. Armonk, NY. Descriptive data were presented as frequencies and proportions. Chi-square test or Fisher's exact where applicable was used to assess the relationship between the outcome variable and the predictor variables. A p value $< .05$ was considered significant.

Manual thematic analysis approach as proposed by Nowell et al.¹⁸ was used in qualitative analysis. This included a thorough review of the data followed by thematic coding using the emergent coding approach. Themes were then reviewed and defined prior to the production of the final results.

Ethical Considerations

Permission to conduct the study was obtained from The Institute of Rural Development Planning (Ref: T40/6 CHRO 33), and the permit to collect data was obtained from Dodoma City Council (Ref: HMD/I.10/6/40). Written informed consent was sought from all the study participants. Information was collected in a secured room and the database was anonymized by coding the participants' identities to ensure confidentiality.

RESULTS

Socio-demographic characteristics

A total of 45 women were enrolled in our study. Table 1 shows that majority (60%) of the participants were aged between 18 and 30 years. About two-thirds (60%) of the participants were not married, whereas 8.9% were divorced/separated. Among the respondents, 48.9% and 42.2% were Muslims and Christians respectively. Majority of the participants self-reported a low (51.1%) and middle (46.7%) level of income. The assessment of income was done subjectively (self-reported levels) thus limiting the determination of the cut-point values. Nonetheless, there has been a significant incongruence in the subjective and objective adequacy levels in terms of income making this assessment acceptable.¹⁹ Among the interviewed women, ANC attendance during the last

pregnancy was reported by 48.9%.

Quantitative results of factors influencing utilization of ANC services

As depicted in Table 1, about half (48.9%) of respondents spent between 30 minutes and 1 hour to reach the health facility. However, a third of the respondents (31%) spent more than an hour reaching the health facility. The commonest means of transport to the health facilities were public buses. Despite high awareness of ANC services (91%), utilization of the services was low.

Self-reported level of income and time taken to reach the health facility significantly influenced the ANC attendance (Table 1). Women who reported having a low income had a relatively low attendance (26.1%) as compared to those who reported a middle (71.4%) and high (100%) income. Moreover, women who spent less than 30 minutes to reach the health facility had relatively better attendance (88.9%) as compared to those who spent more than 30 minutes. Age, marital status, education level, religion, means of transport to the health facility, and awareness of ANC services did not have an influence on ANC attendance (p value $> .05$).

Qualitative results of factors influencing utilization of ANC services

Thirty-one women were interviewed, and three main themes of factors affecting ANC attendance emerged as summarised in Table 2. These factors include cultural practices and gender norms, poor communication between partners, and long waiting time at the ANC clinics. In quantitative analysis, none of these themed factors significantly influenced ANC attendance (Table 2).

Slightly over half of the women (54.8%) reported that cultural practices and gender norms contributed to poor ANC attendance as exemplified by the following responses:

"In our community men barely get involved in issues concerning pregnancy... even when we try to convince them, they refuse to accompany us to the clinic because they feel embarrassed."

"According to my culture, my mother-in-law is the person responsible to care for my pregnancies... I did not have the opportunity to attend the clinic quite often during my pregnancy because my mother-in-law attended to most of my concerns, sometimes by using traditional means."

Twelve (38.7%) participants reported poor communication between partners as a reason for poor ANC attendance. One respondent mentioned that:

"We barely talked with the father of my children about my pregnancy. Perhaps that is the reason he used to assign me a lot of duties to perform... If he was an understanding person and assisted in performing some of the household chores at least once in a while, then I think I could have time to attend the clinic"

Only two participants (6.5%) reported that long waiting time at the ANC clinics was the reason for poor ANC clinic attendance. An interviewee mentioned that:

"I engage in small-scale businesses as an entrepreneur. Long waiting time at the clinic consume the valuable time I could

TABLE 1: Demographics and determinants of ANC Clinic Attendance

Variables	Frequency (%)	Attended ANC		P value
		Yes	No	
Age				
18-30	27 (60.0)	13	14	0.364
31-40	16 (35.6)	8	8	
41-50	2 (4.4)	2	0	
Marital status				
Married	14 (31.1)	9	5	0.293
Not married	27 (60.0)	12	15	
Separated/Divorced	4 (8.9)	1	3	
Education level				
Primary	11 (24.4)	4	7	0.271
Secondary	22 (48.9)	11	11	
Technical/vocational training	9 (20.0)	4	5	
University/college	3 (6.7)	3	0	
Religion				
Christian	19 (42.2)	13	6	0.074
Muslim	22 (48.9)	8	14	
No Religion	4 (8.9)	1	3	
Self-reported level of income				
Low income	23 (51.1)	6	17	0.006
Middle income	21 (46.7)	15	6	
High income	1(2.2)	1	0	
Time to reach the health facility				
< 30 minutes	9 (20.0)	8	1	0.026
30 minutes - 1 hour	22 (48.9)	9	13	
> 1 hour	14 (31.1)	5	9	
Means of transport				
Public buses	22 (48.9)	8	14	0.136
Motorbike	11 (24.4)	7	4	
Three-wheelers	9 (20.0)	4	5	
On foot	3 (6.7)	3	0	
Awareness of ANC services				
Aware	41 (91.1)	21	20	0.608
Not aware	4 (8.9)	1	3	

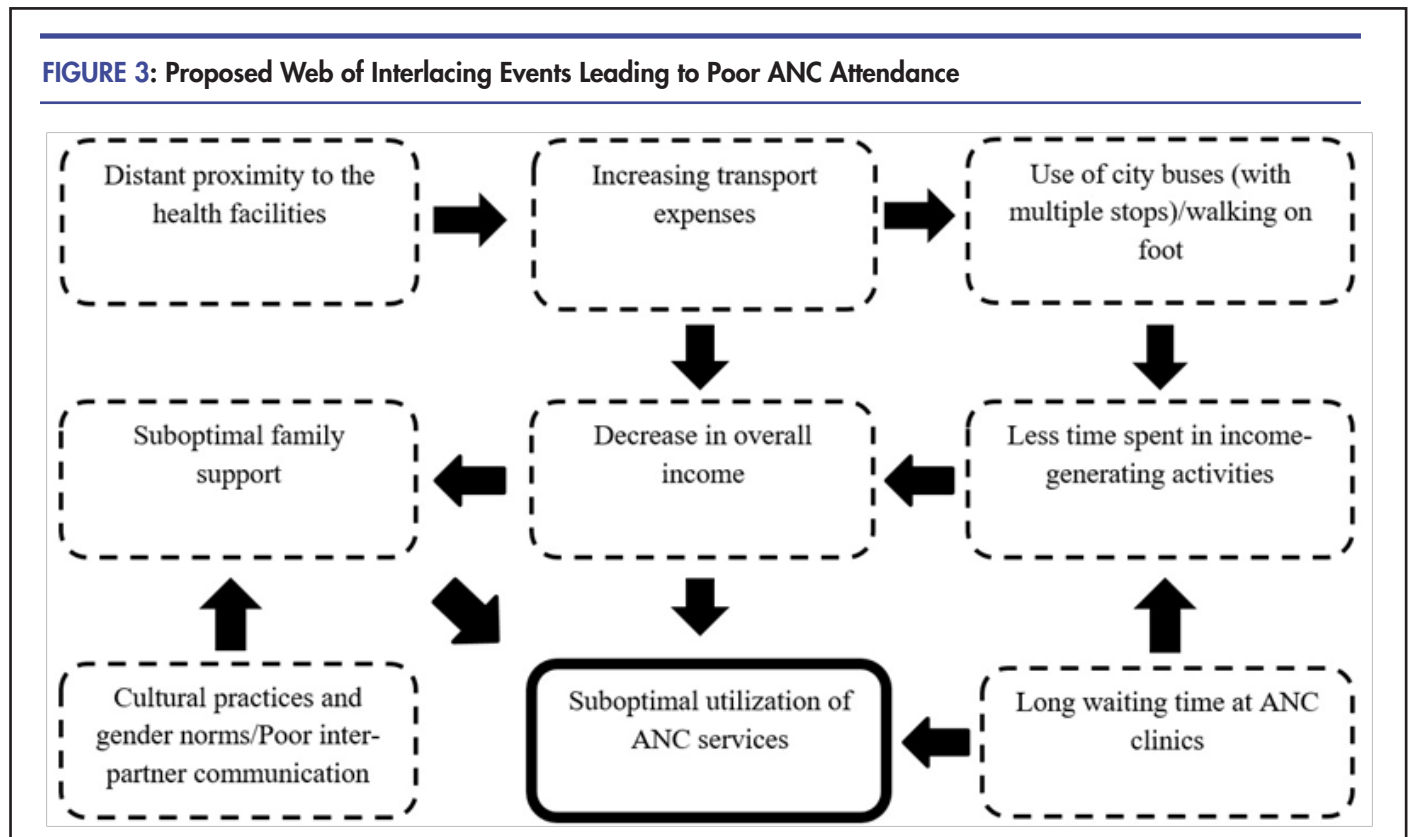
ANC = Antenatal Care

TABLE 2: Themed Factors Contributing to Poor ANC Clinic Attendance

Factors	Total (%)	Attended ANC		P value
		Yes	No	
Cultural practices and gender norms	17 (54.8)	5	12	0.103
Poor communication between spouses	12 (38.7)	3	9	
Long waiting time at the ANC clinics	2 (6.5)	2	0	

ANC = Antenatal Care

FIGURE 3: Proposed Web of Interlacing Events Leading to Poor ANC Attendance



spend in generating income for my children.”

Participants’ Opinions on Improving Utilization of ANC Services Investing in Maternal Healthcare

The government should establish a platform of collective responsibility with other partners in order to reach a satisfactory level of antenatal healthcare utilization. An interviewee mentioned that:

“The government should encourage non-governmental health-based organizations to support antenatal healthcare programs by creating suitable regulations that will enable them to create well-planned and coordinated programs that support antenatal care with full community participation.”

Providing Affordable Services

Private sectors ought to make ANC services affordable so as to curtail the workload in public centers which provide services at a relatively cheaper cost. An interviewee mentioned that:

“Private facilities also have to provide services at an affordable cost in order to reduce the overwhelming number of women attending public facilities.”

Improving Accessibility of Services

Equipped medical facilities should be increased in order to ease the accessibility of services. Moreover, increasing the number of health facilities should conform to the standard package of services to be provided by ANC

facilities. A healthcare provider mentioned that:

“We are often overloaded in the antenatal clinic because many women depend on this center for antenatal services, some of whom reside out of this administrative ward. Most of them spend a long time waiting for their turn to be attended to. In some cases, some become impatient and decide to leave. The government has to increase medical facilities and encourage investment so that all clients can have easy and equal access to quality antenatal services.”

DISCUSSION

Despite starting antenatal care at a later gestational age and having fewer than the recommended ANC visits, about 90% of pregnant women in Tanzania attend ANC clinics at least once during their pregnancies.²⁰ This is low compared to 98% of women who receive ANC in developed countries.²¹ Although a significant proportion of the participants in this study were aware of ANC services provided at the health facilities, utilisation of the services remained low. The disproportionate attendance could be explained by low income and distant proximity to the healthcare facilities as presented in the current results.

Income has a significant bearing in healthcare-seeking behavior (HSB) with members of low-income communities being up to 6 times more likely to have inappropriate HSB as compared to members of high-income communities.^{22,23} In sub-Saharan Africa, low income has been linked to poor ANC attendance.²⁴

Similarly, in this study, self-reported income status emerged as a significant determinant of ANC attendance, whereas women who reported having a low income had poor ANC clinic attendance. Furthermore, long waiting time at the ANC clinics was mentioned as a reason for low ANC utilization due to the impression of wasting valuable time in the case of women who engaged in income-generating activities. However, ANC services are relatively cheap in the current study setting²⁵ thus, the lack of the concepts and practices of scientific medicine, and differences in beliefs and values within low-income communities might be an alternative explanation to the poor attendance.²⁶ Concurring with the later argument, about 38% of the interviewees mentioned cultural practices and gender norms as the underlying contributors to poor ANC clinic attendance. Respondents revealed that there has been poor support and involvement of men in matters regarding reproductive health despite the ongoing campaigns encouraging the engagement of men in ANC.²⁷ They also argued that some social-cultural practices and gender norms exempt men from supporting and accompanying their spouses to the ANC clinics. This is based on the belief among several tribes that experienced elderly women within the clan are the ones responsible for monitoring the health of young pregnant women; a strategy which has currently not been feasible due to rapid westernization in the urban communities. This subjects pregnant women to poor social support on matters of reproductive health.

Despite the increase in the number of health facilities across the country²⁸ universal access to healthcare for those requiring MCH services is still limited. Partly, due to uneven distribution of health facilities, shortage of staff, and lack of equipment. Findings from this study revealed that 31.1% of the women spent over an hour reaching the ANC clinic. Moreover, longer durations taken to reach the health facility was linked to poor ANC attendance, with similar findings reported in other Sub-Saharan countries.²⁴ Acceptable suppositions of the former finding could be a search for quality and cheap services. Evidence shows that women often bypass the closest facilities due to the poor quality of the services and are willing to travel a long distance in search of free services available in public hospitals.²⁹ Corresponding to the later findings, Herman²⁶ argued that living close to a health facility increased the probability of seeking health care.

Poor communication between spouses was mentioned as a contributor to poor ANC clinic attendance. In a patrilineal society as in the settings of our study, majority of household decisions are made mainly by husbands; and women are hardly the main decision-makers. Moreover, only 15% of wives are the main decision-makers regarding their health.⁹ Respondents argued that poor communication between partners on reproductive health matters caused men to be unaware of the women's health-seeking intentions, thus causing men to pause a tone of household duties on women while giving less priority to their health.

A proposed relationship of the discussed findings has been illustrated in the web of events seen in [Figure 3](#). Further studies will be needed to confirm or disprove this proposed hypothetical inter-relationship.

Limitations

The purposive sampling technique that was employed limits the generalization of the findings to the subpopulation from which the sample was drawn. Furthermore, the small sample size limited by the study's inclusion criteria makes the quantitative component of the study findings prone to type II statistical error. Due to these limitations, we recommend additional studies that will address the aforementioned setbacks and extensively examine other variables that were not included in this study.

CONCLUSION

Findings from this study demonstrate low utilization of ANC services among women living in Dodoma Urban District. Moreover, qualitative and quantitative evidence shows that self-reported income status, proximity to the health facility, cultural practices and gender norms, communication between partners, and service waiting time at the ANC clinics influence the utilization of ANC services. The study findings should guide policy formulation and interventions, targeting groups of women with low utilization of ANC services.

RECOMMENDATIONS

The government and other stakeholders should focus on improving the coverage of ANC services in order to minimize the time spent reaching the health facilities. Furthermore, policies that govern the ANC user fees in both public and private sectors should be reviewed and refined by the respective authorities in order to suit women of low socioeconomic class. Policies should also focus on harmoniously addressing the sociocultural barriers to ANC utilization.

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Factors Influencing Formal Mental Treatment - Seeking Behaviour among Caretakers of Mentally Ill Patients in Zanzibar

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ABSTRACT

Background: Mental illnesses are health conditions which are associated with changes in emotion, thinking, or behaviour (or a combination of these). Healthcare-seeking behaviour for formal mental health treatment is lacking all over the world, particularly in low and middle-income countries. Inappropriate health-seeking behaviours are reported to result in delays in seeking appropriate care and thus increase the risk of complications in mentally ill patients. The study aimed to assess factors influencing formal mental treatment-seeking behaviour among caretakers of mentally ill patients in Zanzibar

Methods: A community-based cross-sectional study design was conducted from January to June, 2021. A total of 246 caretakers of mentally ill patients were recruited for the study using multi-stage sampling technique. An interviewer-administered semi-structured questionnaire was used to collect information from caretakers. Bivariate and multivariable logistic regression models were applied to determine the factors influencing formal mental treatment-seeking behaviour.

Results: Majority of caretakers 187(76%) were aware of formal mental treatment. Also, majority of the participants 145(58.9%) had appropriate healthcare-seeking behaviour toward formal mental treatment. Factors influencing formal mental treatment-seeking behaviour were; perceived severity (AOR 4.651 at 95% CI 2.397-9.021 $p < .001$) and being aware (AOR 2.907 at 95% CI 2.349-2.326 $p = .004$).

Conclusion: Majority of caretakers were aware of formal mental illness treatment. Also, more than half of the caretakers had appropriate healthcare-seeking behaviour. Factors associated with formal mental treatment-seeking behaviour were awareness of formal mental treatment and perceived severity of mental illness. The study recommends a community sensitisation campaign to raise community awareness and perception towards formal mental treatment. Community sensitisation is crucial for improving formal mental treatment-seeking behaviour.

BACKGROUND

Mental illnesses remains among the top 10 leading cause of burden worldwide with no sign of reduction since 1990.¹ The statistics have estimated that there were 970¹ million people around the globe who were diagnosed with mental illnesses in 2019.² The number drastically increased in 2020 due to the coronavirus disease of 2019 (COVID-19) pandemic.¹ Sub-Saharan Africa is reported to have at least 10% of the global mentally ill patients.² East African countries form part of the sub-Saharan African countries with high proportion of people living with mental illness. In Kenya, 1 in 10 people is suffering from a common mental illness and the country ranks 5th among African countries with the highest number of depression cases.² Depression and anxiety are the main mental health illness in Uganda affecting 1 in 4 people.³ In Tanzania, mental illness contributed to disability-adjusted life years at 2,727.86 per 100,000 population in 2017.² The prevalence of participants who had previously been diagnosed with mental illness in Zanzibar was found to be at 1.6% (CI 0.9-2.9) with more than half (25 out of 39 diagnosed) of

them being diagnosed with anxiety.⁴ This big number of affected people and the associated impacts of mental illness motivate intervention. Empirical evidence shows that mental illness results in tremendous mortality, morbidity, and impairment.² The World Health Organization (WHO) has estimated that 25% of the global population will suffer from at least one type of mental illness in their lifetime.¹

It is recognised that effective prevention and treatment of mental illness options do exist.⁵ In recognising this, the Government of Tanzania intentionally provides mental illness treatment services free of charge. Contrarily, there are many people with serious mental illnesses in the country but they do not attend treatment. It is argued that the associated stigma and irrelevant controls are contributing factors to the withdrawal of seeking mental illness treatments.⁶

Mental health policy is an important tool to improving the country's mental healthcare services. Mental health policy is a written policy document by the government's Ministry of Health that stipulates the goals for improving mental health in the country,

priorities, and the directions to attain them.⁷ The policy may also include; advocacy for mental health goals, promotion of mental well-being, prevention of mental disorders, treatment of mental disorders, and rehabilitation mechanisms to help mentally ill clients to achieve optimum social and psychological functioning.⁸ Zanzibar introduced its first mental health policy in 1999. The implementation of the policy has improved mental health services for over 10 years.⁹

Most studies conducted within African communities revealed that mental illness is associated with supernatural causes, such as; curses, witchcraft, demons and God's will, and that the first point for seeking help is through traditional and religious healers.¹⁰⁻¹² Formal treatment is usually considered the last option.¹⁰ The reported factors which influence formal mental health-seeking behaviour include; knowledge regarding mental illness; traditional beliefs; stigma and discrimination, knowledge about how to access treatment, and the perceived side effects of antipsychotic medication.^{10,13} People of Zanzibar, like other African communities seek alternative treatment for mental illness (traditional and spiritual healers) first and turns to formal treatment when the health status of their patients worsen.¹⁴ Delayed seeking of formal treatment has negative consequences for the individual, their family, the community, and the health system.

Mental illness affects the individual's ability to make an informed choice regarding his/her health. Place for treatment is mostly decided by a close relative. In this study, these close relatives are termed as informal caretakers. An informal caretaker is a person who provides healthcare or assistance to a friend or family member with a health problem or disability without payment and has no specialised training. Family support is a key predictor for formal mental health treatment among mentally ill patients.¹⁵

Formal treatments are treatments offered by trained professionals who utilise available resources to provide evidence-based treatments to people with mental illness.⁵ Being unaware of mental illness is the leading reason for disconnection between actual treatment and care-seeking tendency which, consequently makes people withdraw from seeking mental health services or drop out the mental health service.³

The perception that mental illness is caused by supernatural powers is not the only barrier to formal mental health utilisation in Zanzibar, accessibility of mental health services in the region is also a contributing factor.¹⁴ Studies indicate that negative perception of mental illness, such as; fear of stigma influence mentally ill patients and their caretakers' decision to withdraw from seeking health services.⁶

Health service physiognomies are illustrative factors related to the performance of proper and effective healthcare program. Among others, these are reliability, availability, and accessibility of drugs, quality medical care, and the attitude towards people with mental illness. Educational qualifications are categorised by the person's level of education accomplishment.⁴ The healthcare-seeking tendency is any action or inaction done by people who consider themselves to be having a health problem.⁴

The most barriers to care-seeking and service participation in mental illness are behaviours and perceptions that hinder health decisions. They involve stigma which contributes to avoidance of treatment or dropping out prematurely, poor understanding of mental illness issues, misinformation about the effectiveness of treatment, and lack of support networks that promote care-seeking and perceived cultural irrelevance of many treatments.³

Mental health services in Zanzibar are provided at Primary Health Care level (PHC) units in areas such as; Nungwi, Jambiani, Matemwe, Pwani Mchangani, Kitogani, Donge, Kiwengwa, Chaani, and Kikobweni. Secondary-level mental health services are provided in the district hospitals, these have a psychiatric clinic. There is one tertiary hospital, Kidongochekundu Mental Hospital, this provides outpatients and admission psychiatric services. The ultimate goal for this study was to determine factors associated with formal mental health-seeking behaviour among caretakers of mentally ill patients.

METHODS

Study Design and Setting

The study was a community-based analytical cross-section study conducted in Zanzibar. Zanzibar lies 25 miles off the East African coast. It is part of the United Republic of Tanzania and is comprised of 2 main islands, Unguja (1,464km²) and Pemba (868km²). The 2 islands are surrounded by numerous other islands along the East African coast. Zanzibar has 5 regions; Urban West, North and South Unguja, and North and South in Pemba. Zanzibar has one Mental hospital known as Kidongochekundu hospital located in Urban West region in Unguja island, and other psychiatric clinics in Unguja are Kivunge and Makunduchi District Hospitals, Komben, Kitogani, Upenja, and Donge PHC units.

Pemba Island has three District hospitals; Abdallah Mzee Hospital located in Mkoani District, Chake Chake hospital located in ChakeChake District (both in the South Region) and Wete hospital located in Wete District, North Region. The Island also has 2 Primary Health Care Centres (PHCC), located in Vitongoji-South Region and in Micheweni-North Region. The hospitals and health centres have more number of admitted psychiatric cases (outpatient departments in Kidongo Chekundu and the Psychiatric Units).

Study Population

The study included caretakers of mentally ill patients in Zanzibar. Inclusion criteria was all caretakers above 18 years old who are caring for registered mentally ill patients in the Zanzibar community who were willing to participate, with no history of mental illness and having provided care to a mental illness patient for at least 6 months. Caretakers with history of progressive chronic physical illness and those who refused to participate in the study were excluded.

Sample Size Estimation

Sample size of 246 respondents was obtained from a total study population of 5,298 using the formula:

$$n = Z^2 p (1-p) / E^2$$

Whereby:

n = sample size required

p = proportion 20% of people who use appropriate health-seeking behavior (17).

Z = Z-Score (1.96)

E = Marginal Error (5% = 0.05)

$n = 1.96 \times 1.96 \times (1-0.2)/0.05 \times 0.05 = 246$

Therefore, a total of 246 respondents were recruited for the study.

Sample Technique

Multistage random sampling procedure was used to select areas for data collection and study participants. Determining sample size was obtained by using multistage sampling involving several stages as shown in the figure (Adam Hayes, 2020).

The first stage was used to select a region; whereby 3 regions (1 in Pemba and 2 in Unguja) were involved in the study. Purposive sampling technique was utilised for selection of the regions. The second and third stages utilised Simple Random Sampling lottery technique to select Districts and Shehias within the 3 regions that were nominated for the study's data collection process. Caretakers were drawn from the register of mental illness patients at the respective unit that offers mental health services in Zanzibar. Patients' files were traced at the mental health unit to get the location of their homes and the contact of the responsible caretaker.

Systematic random sampling procedure was used to select Shehias in 2 regions of Unguja. The name of each Shehia was listed on a piece of paper and categorised into 5 groups of 24 names in each group. This gives chances for each district and Shehias to be picked randomly after getting a random number through the lottery method. The Shehias names used for data collection in Unguja were; Mlandege, Amani, Kwabinthamrani, Mtopepo and Nyamaz. For Northern region of Unguja and Southern region of Pemba, each has two districts. The lottery procedure was done separately for each region. This enabled mechanism for establishing a random number that allowed the selection of 5 Shehias per region. A systematic sampling procedure was used as mentioned above. Data was collected from the two regions in Shehias; Ole, Mkoroshoni, Shungi, Mfikiwa, Kengeja, and Uweleni, of the south region of Pemba and Kidoti, Nungwi, Mkokotoni, Kivunge, and Donge of the north region in Unguja as shown in Figure 1.

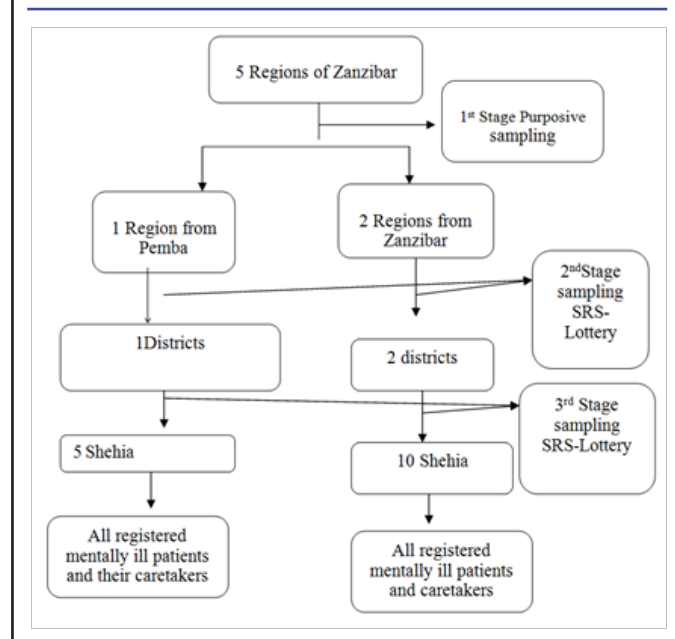
Data Collection Methods, Tools and Procedures

Data was collected using semi-structured interview technique. The principal researcher and research assistants interviewed respondents and filled in the questionnaire appropriately as per response received. Collected data covered to answer all specific objectives, requirements and social demographic characteristics of caretakers. Research assistants were trained about the research aim, confidentiality, the data collection process, and on how to fill out the questionnaire. Questionnaires were standardised with a structure of closed-ended questions. Questions were translated into Kiswahili language for easy understanding by those who wished to read the questionnaire by themselves.

Documentary review was used to assess the outpatient mental ill registration register. Relevant information

was collected. This included; demographical data, such as; sex, age, tribe, level of education, mental status, and occupation.

FIGURE 1: Represent summary of Sampling procedure and Technique



Questions on healthcare-seeking behaviour consisted of 8 Likert questions with a 5-point scale namely; never 1, rarely 2, sometimes 3, most times 4, and every time 5. Perceived severity and Perceived benefit consisted of 8 items. Perceived benefit was structured by 9 items on a Likert scale of 5 points; strongly disagree 1, disagree 2, neutral 3, agree 4, strongly agree 5). A tool to measure awareness about formal mental treatment consisted of 11 items of multiple-choice questions. The tool was adopted from Pierce.⁸

Data collection was conducted from October 2020 to November 2020. Three (3) research assistants were recruited and trained by the principal researcher.

Research assistants team consisted 2 qualified nurses working in the mental hospital and psychiatric clinic with experience in providing care for patients with mental problems.

Research Variables and Measurements

The dependent variable of the study was formal mental treatment-seeking behaviour. The Independent Variables were; Caretaker's Social Demographic Characteristics, Patients' Social Demographic Characteristics, Awareness of the caretakers, Perception of the caretakers.

To make variables measurable (operational sing) and meaningful, variables were made operational with precise definitions, scale, and indicators (measurement) to ensure that everyone understands exactly what has been measured for consistency in measurement. For

this study, only 3 variables were operational. These were dichotomised or easy two-by-two analysis (Table 1).

Data Analysis Plan

Data processing and analysis was performed using Statistical Package for the Social Sciences (SPSS) software, version 20. Both descriptive and inferential analysis was worn. Data analysis process started with data cleaning to eliminate unusual information, followed by findings on whether the variables were normally distributed or not by use of mutual measures of central tendency and dispersion. To justify the distribution of variables, a normality test of the skew value of the histogram was established. Numerical data was summarised by use of mean and standard deviation while categorical data was summarised by use of frequency and proportions. Categorical variables for baseline characteristics were compared using the Chi-square or Fisher’s exact tests. Logistic regression analysis was conducted for the odds ratio to measure the determinants for health-seeking behaviour as well as control identifiable confounders. All variables with a 95% confidence interval which do not contain or cross one or with $p < 0.05$ were regarded as statistically significant. Findings were presented by using tables and figures.

Ethical Approval and Consent to participate

Ethical clearance was obtained from the University of Dodoma after being approved by The University of Dodoma Research Ethical Committee with reference number Re: No. MA.84/261/02/208. Permission to conduct this research in the Zanzibar Islands was granted by the office of Second Vice President of Zanzibar. Written informed consent was obtained from each participant.

RESULTS

Background Characteristics of Caretakers of Mental Ill Patients

A total of 246 Caretakers were included in the study, 116 (47.2%) had 46 years and above, the lowest age being 19 years and the highest age was 80 years with mean age of 46 ± 11 years. Majority of the study participants 152(61.8%) were female. On the side of Educational Status, majority of the participants 118(48%) had Secondary Education. On the side of marital status, majority of the study participants 164(66.7%) were married. Moreover, majority of the participants (85.4%) were self-employed (Table 2).

Background Characteristics of the Mentally Ill Patients

A total of 246 mentally ill patients were included in the study, out of which 145(58.9%) were in the age group of 21 to 40 years. Majority of the participants 149(66.6%) had primary education and (Table 3).

Health Care-seeking Behaviour among Caretakers of Mentally Ill Patients

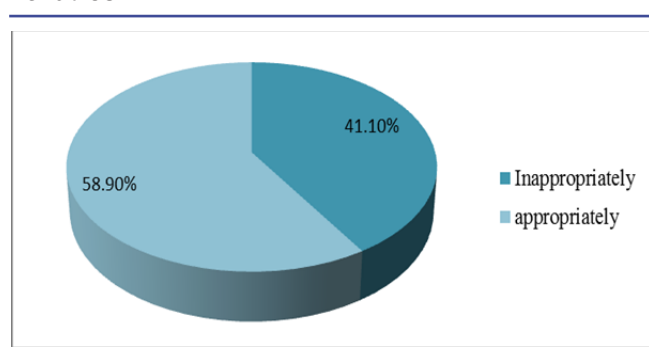
Majority of the study respondents 145(58.9%) had appropriate health-seeking behaviour towards formal mental treatment while 101(41.1%) of caretakers had inappropriately health-seeking behaviour toward formal mental treatment (Figure 2).

The findings of this study revealed that majority of study participants 187(76%) had ever heard about formal

TABLE 2: Socio-Demographic Characteristics of Care Takers (N=246)

Variable	Frequency (n)	Percent (%)
Age Groups		
19-35	65	26.4
36-45	65	26.4
46+	116	47.2
Sex		
Male	94	38.2
Female	152	61.8
Religion of Respondents		
Christian	2	0.8
Muslim	244	99.2
Level of Education		
No Formal Education	55	22.4
Primary Education	62	25.2
Secondary Education	118	48
University/ College	11	4.5
Marital Status		
Single	24	9.8
Marriage	164	66.7
Divorced	18	7.3
Widow	40	16.3
Employment Status		
Government Employment	19	7.7
Private Employment	17	6.9
Self-Employment	210	85.4

FIGURE 2: Proportional of Health Care Seeking Behaviour



mental illness treatment while 59(24%) of participants had never heard about formal treatment of mental illness (Figure 3).

Proportional Distribution of Perceived benefit towards Formal Mental Illness Treatment

The study findings revealed that most of the study respondents 139(56.5%) had perceived benefit towards formal mental illness treatment on mental illness while 107(43.5%) of caretakers had perceived low benefit towards formal mental illness treatment.

TABLE 1: Measurement of Variable

Research Variables	Measurement Level of Measurement	Indicator
Health care seeking behaviour	Scale	1-3 Points =Inappropriately 4-5Points =Appropriately
Perceived severity	Scale	1-3Points=Low Severity 4-5points =Severity
Perceived benefit	Scale	1-3Points=Low Benefit 4-5points = Benefit
Perceived barrier	Scale	1-3Points=Low Barrier 4-5points =Barrier
Awareness	Ordinal	1-3Points=Un aware 4-5points =Aware

TABLE 4: The Relationship between the Predictors of HBM and Health Care Seeking Behaviour

Variable	Health care Seeking Behaviour		χ^2	p-value
	Appropriately (%)	In appropriately n(%)		
Perceived Barrier				
No barrier	132 (66.7)	66 (33.3)	25.014	(< 0.001)
Barrier	13 (27.1)	35 (72.9.1)		
Perceived Benefit				
No benefit	53 (49.50)	54 (50.5)	6.929	(< 0.008)
Benefit	92 (66.2)	47 (33.8)		
Age				
19-35	38 (58.5)	27 (41.5)	666	0.0717
36-45	41 (63.1)	24 (36.9)		
46 Above	66 (56.9)	50 (43.1)		
Sex of Participate				
Male	53 (56.4)	41 (43.6)	412	0.521
Female	92 (60.5)	39.5		
Religion of Respondent				
Christian	0 (0.0)	2 (100)	2.895	0.089
Muslim	145 (59.4)	99 (40.6)		
Level of Education				
No School	33 (60.0)	22 (40.0)	4.436	0.218
Primary Education	30 (48.4)	32 (51.6)		
Secondary Education	74 (62.7)	44 (37.3)		
University or College	8 (72.7)	3 (27.3)		
Marital Status				
Single	13 (54.2)	11 (45.8)	3.709	0.295
Marriage	101 (61.61)	63 (38.4)		
Divorce	7 (38.9)	11 (61.1)		
Widow	24 (60.0)	16 (40.0)		
Awareness				
Aware	126(86.9)	61(60.4)	22.932	0.001
Not aware	19(13.1)	40(39.6)		
Perceived Severity				
Perceived severity	122(84.1)	46(45.5)	40.949	0.001
perceived not severity	23(15.9)	55(54.5)		

TABLE 5: The Association Between the Predictors of HBM and Health Care Seeking Behaviour among Caretakers of Mental Ill Patients’ Simple Binary Logistic Regression

Variable	OR	Lower	95% CI	Upper	p-value
Perceived Benefit	1				
low benefit	1.994	1.189		3.344	.009
Benefit					
Perceived Barrier	1				
Barrier	5.385	2.669		10.863	<.001
Low barrier					
Perceived Severity	1				
Perceived low severity	6.342	3.504		11.478	<.001
Perceived severity					
Awareness	1				
Low aware	4.349	2.326		8.131	<.001
Aware					
Age Group	1				
19-35	1.066	.576		1.972	.838
36-45	1.294	.694		2.414	.418
46+					
Sex	1				
male	0.843	0.500		1.420	.521
Female					
Level of Education	1				
No School	0.563	0.134		2.356	.431
Primary Education	0.352	0.085		1.451	.148
Secondary Education	0.631	0.159		2.503	.512
University or College					
Marital Status	1				
Single	0.788	0.283		2.190	.648
Marriage	1.068	0.527		2.166	.854
Divorce	0.424	0.136		1.326	.140
Widow					
Employment Status	1				
Self Employment	1.039	0.2750		3.919	.955
Private Employment	1.049	0.405		2.715	.922
Government Employment					

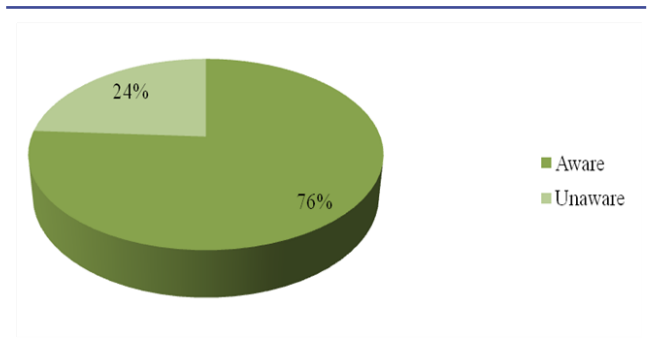
TABLE 6: The Association between the Predictors of HBM and Health-care Seeking Behaviour with Multivariate Logistic Regression

Variable	AOR	Lower	95% CI	Upper	p-value
Perceived Benefit	1				
No benefit	1.251	0.691		2.267	.46
Benefit					
Perceived Barrier	1				
Barrier	1.589	0.668		3.784	.295
No barrier					
Perceived Severity	1				
Perceived no severity	4.6	2.397		9.021	.000
perceived severity					
Awareness	1				
Not aware	2.9	1.406		6.009	.004
Aware					

TABLE 3: Socio-Demographic Characteristics of Mentally Ill Patients (N=246)

Variable	Frequency (n)	Percent (%)
Age Group		
1 - 20 years	47	19.1
21 - 40 years	145	58.9
41 - 60 years	50	20.3
61+ years	4	1.6
Sex of the Patient		
Male	117	47.6
Female	129	52.4
Religions of Respondents		
Christian	2	0.8
Muslim	244	99.2
Level of Educational		
No formal education	29	11.8
Primary Education	149	60.6
Secondary Education	68	27.6
Marital Status of the Patient		
Single	83	33.3
Married	46	18.7
Divorced	106	43.1
Widow	11	4.5

FIGURE 3: Proportional of Awareness on Formal Mental Health Treatment (N=246)



Proportional Distribution of Perceived Barriers toward Formal Mental Illness Treatment

The current study observed that majority of study respondents 198(80.5%) had perceived a low barrier toward formal mental illness treatment while 48(19.5%) of caretakers had perceived a barrier toward formal mental treatment.

Proportional Perceived severity towards mental illness on health-seeking care behaviour among caretakers of mental illness

Most of the respondents 168(68.3%) had perceived severity towards mental illness on health care seeking behaviour among caretakers of mentally ill patients while

78(31.7%) of caretakers had perceived low severity toward mental illness on healthcare-seeking behaviour among caretakers of a mentally ill patient.

Relationship between Socio-Demographic characteristics and formal Mental Treatment-Seeking Behaviour among Caretakers of Mentally Ill Patients

Socio-demographic Characteristics of Caretakers were assessed to determine their relationship with healthcare-seeking behaviour. A Chi-Square test was performed to find the relationship. Results show that 4 items exhibits a relationship with healthcare-seeking behaviour. The items include; Perceived low barrier $p < .001$, perceived benefit $p < .008$, perceived severity $p < .001$, and awareness $p < .001$ (Table 4).

Factors Influencing Formal Mental Treatment - Seeking Behaviour

Binary logistic regression analysis was performed to determine factors influencing formal mental treatment-seeking behaviour. The results show that only four variables are associated with healthcare-seeking behaviour. The items are; perceived barriers with health care seeking behaviour OR 5.385 $p < 0.00$ and perceived severity with health care seeking behaviour OR 6.342 $p < 0.00$, awareness of health care seeking behaviour OR 4.349 $p < 0.00$ and perceived benefit (OR 1.994 $p < 0.009$) was statistically significant while all social demographical characteristic of caretakers were not statistically significantly (Table 5).

Multivariate logistic analysis was performed to confounders and result revealed that awareness (AOR 2.907 at 95% CI 2.349-2.326 $p = 0.004$) and perceived severity (AOR 4.651 at 95% CI 2,397-9.021 $p < 0.000$) were statistically significantly associated with health care seeking behaviour while perceived benefit (AOR 1.25 at 95% C I 0.691-2.267 $p = 0.46$) and perceived barrier (AOR 1.589 at 95% CI 2.669-10.863 $p = 0.295$) were not statistically significantly associated with the health-seeking behaviour (Table 6).

DISCUSSION

The study was conducted to determine the influence of awareness and perception on formal mental treatment seeking behaviour, among caretakers of mentally ill patients in the community of Zanzibar. The study findings revealed that majority of caretakers were aware of formal mental treatment. Despite being aware, majority of them reported having a history of seeking traditional treatments for their patients before seeking for formal mental treatment. A previous study done by Iseselo et al.,⁹ reported that attitude towards psychotropic medication is one of the challenges of formal mental health treatment seeking behaviour. A study conducted in Bangladesh reported that majority of the study respondents were not aware of formal mental health treatment.²⁴ This finding is contrary to the findings of this study. The possible reasons for the different findings could be differences in the study respondents’ characteristics. This study studied caretakers of mentally ill patients while the study in Bangladesh recruited its respondents from the general population.

Further, the findings from this study showed that patients with chronic mental illness are more likely to

be aware of formal treatment compared to patients with acute mental illness. The possible reasons could be due to the prolonged mental illness treatment process. The current finding is contrary to the study conducted by Holden et al²¹, who found that majority of the respondents were not aware of mental illness problems. The difference among respondent it may be due to mass mental health education companies, for example, outreach program, TV and Radio program, school health program and hospital visiting services.

The current study observed that most caretakers had perceived benefits towards formal mental illness treatment but the results reveal that there is no statistical significance between perceived benefit and health care seeking behaviour. This could be due to the fact that caretakers have sufficient knowledge about mentally illness. Similar to the study done by Latunji and Akinyemi¹⁷ who found that 62% of the respondents perceived mental illness as a chronic disease that can be cured by modern treatment. Also another similar study conducted by Girma and Tesfaye²², shows that 98.7% of the respondents believed that mental illness can be cured with modern treatment. This is a bit contrary to what was reported by O'Connor et al.,²³ where the majority of the respondents perceived mental illness cannot be cured by modern treatment as a long-term treatment. This distinction might be due to differences in study design used and sample size.

In this study, it was found that majority of caretakers had perceived low barrier toward formal mental treatment. This means that caretakers were ready to take responsibility for their patients no matter the consequences and this could probably be due to the reason that they had become aware of the importance of formal mental treatment which made them have the appropriate healthcare seeking behaviour. Similar results from a study conducted in Tanzania¹² reported that majority of the respondent reported low barriers and had a positive belief about treatment. The current results differ greatly from what was found by a previous study conducted in Zanzibar⁹ which reported that therapeutic could not bring any changes to patient when they failed to see the changes immediately, and thus they were likely to seek alternative treatment, especially from a traditional healer, this finding shows that poor prognosis may lead to barrier on formal treatment. Moreover, the study was contrary to what was reported by Henderson et al¹³ who found that the most common barrier to formal treatment is a belief that mental illness would go away or would be solved on its own without treatment. Meanwhile, a study by Iyiola¹⁴ showed strong agreement of the respondent on the perceived barrier to accessing formal treatment.

The current study found that majority of caretakers had perceived severity towards mental illness on healthcare-seeking behaviour. This could be because the caretakers were already having experiences on recurrence and relapse conditions of their patients, that is why they were taking immediate action of use of formal treatment to avoid complications. Similar results were reported from a study conducted by Asfaw et al.,²⁷ who found that caretakers had high perceived severity toward mental illness. The finding is similar to the study conducted by Henderson et al.¹³ The same to the study conducted by Girma and Tesfaye²² who found that the majority of the

respondents perceived that mental illness is a chronic mental disease that can be cured by modern treatment. The current results differ greatly from what was found by a study conducted in Uganda¹¹ where respondents' perceived severity was not a significant predictor of the intention to seek help. This difference might be due to variations in study location, sample size, study design and sample method.

CONCLUSION

Majority of caretakers of mentally ill patients were aware of formal mental illness treatment. Also, more than half of the caretakers had appropriate healthcare-seeking behaviour. Factors influencing formal mental treatment-seeking behaviour were awareness of formal mental treatment and perceived severity of mental illness. The study recommends a community sensitization campaign to raise awareness and perception towards formal mental health treatment. Community sensitization is crucial for improving formal mental health seeking behaviour.

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Characterisation of Malaria Diagnosis Data in High and Low Endemic Areas of Tanzania

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ABSTRACT

Background: Malaria remains a significant cause of morbidity and mortality, especially in the sub-Saharan African region. Malaria is considered preventable and treatable, but in recent years, it has increased outpatient visits, hospitalisation, and deaths worldwide, reaching a 9% prevalence in Tanzania. With the massive number of patient records in the health facilities, this study aims to understand the key characteristics and trends of malaria diagnostic symptoms, testing and treatment data in Tanzania's high and low endemic regions.

Methods: This study had retrospective and cross-sectional designs. The data were collected from four facilities in two regions in Tanzania, i.e., Morogoro Region (high endemicity) and Kilimanjaro Region (low endemicity). Firstly, malaria patient records were extracted from malaria patients' files from 2015 to 2018. Data collected include (i) the patient's demographic information, (ii) the symptoms presented by the patient when consulting a doctor, (iii) the tests taken and results, (iv) diagnosis based on the laboratory results and (v) the treatment provided. Apart from that, we surveyed patients who visited the health facility with malaria-related symptoms to collect extra information such as travel history and the use of malaria control initiatives such as insecticide-treated nets. A descriptive analysis was generated to identify the frequency of responses. Correlation analysis random effects logistic regression was performed to determine the association between malaria-related symptoms and positivity. Significant differences of $p < 0.05$ (i.e., a Confidence Interval of 95%) were accepted.

Results: Of the 2556 records collected, 1527(60%) were from the high endemic area, while 1029(40%) were from the low endemic area. The most observed symptoms were the following: for facilities in high endemic regions was fever followed by headache, vomiting and body pain; for facilities in the low endemic region was high fever, sweating, fatigue and headache. The results showed that males with malaria symptoms had a higher chance of being diagnosed with malaria than females. Most patients with fever had a high probability of being diagnosed with malaria. From the interview, 68% of patients with malaria-related symptoms treated themselves without proper diagnosis.

Conclusions: Our data indicate that proper malaria diagnosis is a significant concern. The majority still self-medicate with anti-malaria drugs once they experience any malaria-related symptoms. Therefore, future studies should explore this challenge and investigate the potentiality of using malaria diagnosis records to diagnose the disease.

BACKGROUND

Globally, according to World Health Organization (WHO) malaria report of 2021, malaria cases increased from 227 million in 2019 to 241 million in 2020, mostly in sub-Saharan Africa.¹⁻³ Likewise, in 2020, malaria deaths were reported to have increased by 12% to approximately 627,000 from about 558,000 deaths in 2019.^{3,4} In Tanzania, more than 6 million malaria cases were confirmed in 2019, and the disease continues to be one of the leading health concerns in the country.^{3,5} According to the source estimates, Tanzania accounted for 3% of the global malaria cases that year.⁶ Moreover, there were more than 2,500 malaria deaths in the country in 2021 compared to 1,171 deaths in 2019.³ Malaria is considered preventable and treatable. Hence the global priority is to reduce the burden of disease and

death while retaining the long-term vision of malaria eradication.⁷⁻¹⁰ Nevertheless, the growing number of malaria cases worldwide can be attributed to increasing transmission risk in areas where malaria control has declined, the increasing prevalence of drug-resistant strains of parasites, and in relatively few cases, massive increases in international travel and migration.^{11,12} In Tanzania malaria burden is still unacceptably high, with an overall prevalence of around 9% in mainland Tanzania.¹³ This is further compounded by the practice of self-medication which has been described as a significant hindrance to proper disease management in many developing countries.¹⁴⁻¹⁷ Recently, in Tanzania, the "not every fever is Malaria" campaign aims to educate people that not every fever episode experienced requires an antimalarial.¹⁸ Other diseases such as typhoid,

dengue, chikungunya, and urinary tract infections present the same symptoms as malaria.^{19–25} Therefore, proper management of malaria requires prompt and accurate diagnosis and treatment.²⁶

Understanding the critical characteristics of malaria symptoms, testing and treatment are essential to controlling the disease that continues to pose a significant risk of morbidity and mortality in the country, with evidence of its resurgence in recent years.^{27,28} Understanding the malaria diagnostic process will be essential to inform future case management strategies and guide programmes to improve adherence to national guidelines. Medical records track disease management history and offer information on diagnoses, laboratory test results, and treatment.^{28–30} In addition, medical records help us measure and analyse trends in healthcare use, patient characteristics, and quality of care.³⁰ Understanding malaria cases' elements are critical for evaluating the disease state. Therefore, this study aims to investigate the features of malaria diagnosis records and explore different variables that can influence malaria diagnosis.

METHODS

Study Design

This was a mixed-methods study with a retrospective chart review and a cross-sectional survey. The first phase included retrieving malaria patient records from the health facilities to curate the malaria diagnosis dataset. The second phase engaged a semi-structured questionnaire to collect relevant data that showed the current malaria diagnosis process to gain insight into malaria diagnosis and treatment practices.

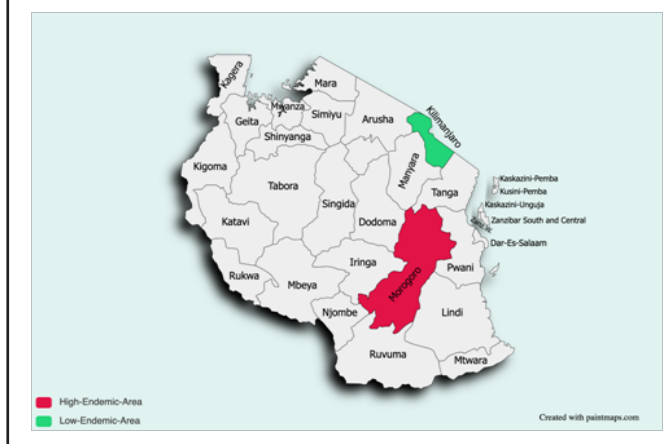
Study Area and Scope of the Study

The present study was undertaken in 2 regions in Tanzania, Morogoro and Kilimanjaro, as illustrated in Figure 1. Morogoro Region, with a malaria prevalence of 15.0%, represented the regions in Tanzania with a high Malaria prevalence. The region is situated in the coastal zone of Tanzania (6°49'S and 37°40'E) with a population of approximately 2.3 million at an average altitude of 522 m above mean sea level. The study site on the lower slopes of Uluguru Mountains experiences heavy rainfall from February to June with a total average annual precipitation of 783.5 mm, mean relative humidity of 72%, minimum temperature of 22 °C, and maximum temperature of 33°C during wet seasons.³¹ On the other hand, Kilimanjaro, alongside Arusha, with a malaria prevalence of 1%, represented the regions with a low malaria prevalence in the country. The region is located in the northern zone of Tanzania with a population of approximately 1.6 million with an altitude range of roughly 600–1,800m, including the significant municipality of Moshi at about 900 m above sea level. The area receives between 900 and 1,200 mm of rainfall per year with two rainy seasons, the long rains from March to May and the short rainy season from November to December.

Four health facilities were selected, two each for Morogoro Region and Kilimanjaro Region. The chosen health facilities for each region included one highest level of healthcare regional hospital and one randomly selected primary health centre. Those selected in Kilimanjaro regi-

ion were Mawenzi regional hospital and Majengo health centre, while in Morogoro Region, Morogoro regional hospital and Mzumbe health centre were chosen. These health facilities were selected to represent patients of all levels.

FIGURE 1: Study Area



Study Population

The study population for the secondary data retrospective chart review included routinely collected malaria data of the patients treated for malaria from 2015 to 2018 in the four selected health facilities in the two chosen regions. Therefore, only records of malaria case data diagnosed with either microscopy or mRDT and existed at the time of the study were accessed for review. As for the survey, the patients over 5 years old who visited the health facilities for treatment with malaria-related symptoms were selected and interviewed to gain more insight into malaria treatment and diagnosis.

Inclusion Criteria

For retrospective chart review, records of malaria cases considered included those diagnosed by either microscopy or mRDT, reported patients' symptoms, and the type of treatment given. All eligible positive and negative diagnosis records of patients over 5 years were included in the study. For the survey, only patients aged over five years who had visited the health facility with malaria-related symptoms were included in the study.

Exclusion Criteria

Any record that did not have complete treatment data was excluded from the study. Patients below 5 years of age were excluded since they could not explain their symptoms when sick.

Ethical Clearance

The study was approved by the National Institute for Medical Research (NIMR/HQ/R.8.c/Vol.I/1352). Before the malaria patients' records were collected and participants were recruited for the survey, permission to conduct the research was sought and granted by the medical officers in charge at the Regional, District, and

health facility levels. Informed consent was obtained from all the patients (or accompanying parents/guardians of minors) who willingly signed the consent form after they were provided with information about the study's objectives. In addition, children over 7 years verbally assented to that purpose. The study was of no greater than minimal risk and had no direct impact on patients' rights, welfare, or clinical care. Measures implemented to minimise the risk of confidentiality breaches during the study include anonymising data records and keeping data secured and accessible only to authorised persons.

Data Collection

The primary data collected for this study were (1) malaria patients' records from patients' treatment files and (2) a survey of patients who visited the health facility with malaria-related symptoms. Two data collection tools were developed to collect data from the two groups. Firstly, the patient's records extraction form was designed based on the summary of the Ministry of Health (MoH) patient's file and the information collected when the patient visits the selected health facilities. The records were retrieved from the files of the patients who had been treated for malaria from the year 2015 to 2018. Data collected from the patient's files were: (i) the patient's demographic information, (ii) the symptoms presented by the patient when consulting a doctor, (iii) the tests taken and results, (iv) diagnosis based on the laboratory results and (v) the treatment provided. Two trained nurses administered data collection in each health facility.

Secondly, a questionnaire-based exit interview was administered to patients with malaria-related symptoms in the health facility. The survey aimed to supplement information on the malaria patients' characteristics that was not captured in the patients' files, such as the significance of travel history. Also, the survey acted as a validation point of the common symptoms observed by the patients against symptoms recorded in the file.

Data Analysis

The collected data were entered in Redcap and obtained into a comma-separated values (CSV) file analysed in Anaconda (Jupyter Notebook) using Python 3.6. First, the data were coded and cleaned; then, descriptive analysis was generated to identify the frequency of responses to the question items. The investigation was grouped into patients' demographic information and malaria diagnosis procedures. Initial tabulations and univariate analysis examined the distribution of malaria symptoms, diagnosis and treatment overall and within categories.

We computed the association between observed malaria-related symptoms from the patient's records against malaria positivity. The aim was to learn the significance of each symptom and patient demographic information on malaria diagnosis. In addition, observe the likelihood of being malaria positive in a high or low endemic area. Correlation analysis was performed to determine the association between variables such as the age of the patient, the residence area, and age and travel history and signify the degree to which changes in the importance of a dependent variable (Y) increased or decreased in parallel with changes in the values of an independent variable (X). Random effects logistic regression assessed the adjusted

impact of covariates on malaria-related symptoms and positivity and adjusted for correlation within hospitals. Significant differences between the dependent and independent variables were accepted at $p < 0.05$, i.e., a confidence level of 95%. A simple linear regression model was used to determine how the number of malaria cases varied with years, season, age and sex.

RESULTS

Documentary Review

The documentary analysis method was used to identify, select, interpret, and synthesise information contained in the files of patients who suffered from malaria or presented with malaria-related symptoms. The documentary analysis identified 2,556 patient records, of which 60% were from the Morogoro Region and 40% were from the Kilimanjaro Region. The results also indicated that 61% and 39% of the selected records were female and male, respectively. These patients were of different age distributions, whereby 49.22% were aged between 5 to 24 years, 32.98% were between 25 to 44 years, and 17.78% were aged 45 years and above, as shown in Table 1.

TABLE 1: Reviewed Malaria Patients Records Preliminary Information

Category	Frequency	Percentage (%)
Malaria Diagnosis		
Positive		
Morogoro	495	69
Kilimanjaro	227	31
Negative		
Morogoro	1024	56
Kilimanjaro	802	44
Health Facility Visited		
Majengo Health Centre	651	25
MawenziRH	378	16
Morogoro RH	981	38
Mzumbe Health Centre	546	22
Visit Month (the Year 2015 -2018)		
January	188	7
February	211	8
April	359	14
July	40	2
August	335	13
September	148	6
October	115	4
December	47	2
July	172	7
June	239	9
March	252	10
May	295	12
November	155	6
Sex		
Female	1561	61
Male	995	39
Patient's Age		
05-14	641	25
15-24	742	29
25-34	420	16
35-44	320	12
45-54	220	0.09
55-64	130	0.05
65+	93	0.04

TABLE 2: Reported Malaria Symptom among Interviewed Patients

Symptoms Reported	Document Reviewed (N= 2556)	Percentage (%)
Fever	1531	59.9
Headache	1114	43.6
Vomiting	573	22.4
General Body Malaise	552	21.6
Abdominal Pain	518	20.3
Coughing	336	13.1
Muscle Pain	245	9.6
Joint Pain	216	8.5
Dizziness	199	7.8
Confusion	153	6.0
Chest Pain	142	5.6
Backache	90	3.5
Fatigue	85	3.3
Nausea	72	2.8
Appetite Loss	70	2.7
Problem Breathing	49	1.9
Running Nose	32	1.3
Shaking Chills	29	1.1
Flue	25	1.0
Yellow Skin	24	0.9
Sweating	15	0.6
Diarrhoea	9	0.4
Conversion	8	0.3
Restless	7	0.3
Anaemia	5	0.2
Pale	5	0.2
Pain In Urination	4	0.2
Blurred Vision	4	0.2

compared to those presenting the sign of body malaise. The difference in the two proportions has shown statistical significance ($p=.015$). The magnitude of malaria among those with general body malaise is 36.1%, and the extent of malaria among those without general body malaise is 63.8%.

Location and Malaria Positivity

Malaria prevalence is different from one location to the other one in Tanzania. Some regions have high malaria prevalence, and some have low malaria prevalence. The two regions selected in this study represent both; Morogoro represents regions with low malaria prevalence, and Kilimanjaro represents regions with high malaria prevalence.

Comparison between Morogoro and Kilimanjaro Region

As shown in Table 1, 69% of the patients diagnosed with malaria are from Morogoro, while 31% are from Kilimanjaro. This means that patients from Morogoro have a 9.8 chance of having malaria compared to those from Kilimanjaro. The difference in the two relationships has statistical significance.

Health Facilities

The results in Table 3 show a 6% risk of malaria for the patients in the Majengo health facility, and this association

TABLE 6: Respondents’ Demographics Information

Category	Frequency	Percentage (%)
Residence Area		
Morogoro	173	55.8
Kilimanjaro	138	44.2
Patients Education Level		
Primary School Education	150	48.2
Secondary School Education	105	33.7
College Education	53	16.8
None	4	1.3
Patients Gender		
Female	204	65.6
Male	108	34.4

TABLE 7: Symptoms Observed from the Face-to-Face Interview

Symptoms Observed	Patients Survey (N=312)	Percentage
	Frequency	
High fever (from 40 °C)	137	3.9%
Shaking chills	23	7.4%
Profuse sweating	8	2.6%
Fatigue	110	35.2%
Headache	210	67.3%
Muscle aches/pain	90	28.8%
Abdominal discomfort	45	14.4%
Nausea	42	14.4%
Vomiting	33	10.6%
Dizziness	36	11.5%
Delirium and confusion	1	0.32%
Problem breathing	1	0.32%
Severe anaemia	2	0.6%
Seizure	1	0.32%

is statistically significant. Of all patients with malaria positivity, 8% are from Mawenzi regional hospital, and they have a 50% risk of having malaria. Also, the analysis shows that 31% of the patients diagnosed with malaria are from Morogoro regional hospital and have 3.7 times the chance of malaria. The differences in the two relationships have statistical significance. As for Mzumbe Health Centre, 54% of the patients diagnosed with malaria are from this health facility, and there is three times the chance of having malaria when from this facility.

Significant Malaria Symptoms

As shown in Tables 3, 4, and 5, the significant symptoms of malaria diagnosis were shown.

High Fever from 40°c

It was found that the magnitude of malaria among patients with a high fever of 40°c and above was significantly higher at 70.8% than that found among patients without

TABLE 3: Malaria Symptoms Observed with Malaria Positivity in Documentary Review

Symptoms Observed	Checked with Malaria	Checked with No Malaria	Unchecked with Malaria	Unchecked with No Malaria	p-Value for the symptom
High fever ($\geq 40^{\circ}\text{C}$)	51(70.8%)	149(50.3%)	21(29.2%)	147(49.6%)	.002
Shaking chills	1(1.39%)	0(0%)	71(98.6%)	296(100%)	.042
Profuse sweating	0(0%)	1(0.34%)	72(100%)	296(100%)	.621
Fatigue	1(1.39%)	6(2.03%)	71(98.6%)	290(97.9%)	.722
Headache	48(66.6%)	195(65.5)	24(33.3%)	101(34.1%)	.899
Muscle aches/pain	2(2.7%)	8(2.7%)	70(97.2%)	288(97.3%)	.972
Abdominal discomfort	16(22.2%)	102(34.4%)	56(77.7%)	194(65.5%)	.046
Vomiting	31(43.0%)	69(23.3%)	41(56.9%)	227(76.6%)	.001
Dizziness	7(9.7%)	33(11.5%)	65(90.2%)	263(88.8%)	.727
Problem breathing	0(0%)	5(1.6%)	72(100%)	291(98.3%)	.267
Seizure	0(0%)	1(0.3%)	72(100%)	295(99.6%)	.621
Nausea	3(4.1%)	8(2.7%)	69(95.8%)	288(97.3%)	.513
Joint pain	12(16.6%)	26(8.7%)	60(83.3%)	270(91.2%)	.049
General body malaise	26(36.1%)	66(22.3%)	46(63.8%)	230(77.7%)	.015
Chest pain	2(2.7%)	34(11.4%)	70(97.2%)	262(88.5%)	.026
Coughing	7(9.7%)	40(13.5%)	65(90.2%)	256(86.4%)	.387
Backache	2(2.7%)	43(14.5%)	70(97.2%)	253(85.4%)	.006
Loss of consciousness	0(0%)	2(0.68%)	72(100%)	294(99.3%)	.484

TABLE 4: Multivariate Analysis of the Significant Factors to Malaria Positivity Results (b)

Malaria diagnosis factors	Odds Ratio	Std. Err.	z	P> z	Interval
Majengo Health Facility	13.6054	6.911744	5.14	.000	5.026762 - 36.82428
Mzumbe Health Facility	7.641262	3.386888	4.59	.000	3.205393 - 18.21582
Sex_(M)	1.065771	.3500778	0.19	.846	.5598429 - 2.028903
Age					
25-44	.9478376	.3332518	-0.15	.879	.4758374 - 1.888032
45+	7296848	.3896629	-0.59	.555	.2562008 - 2.078213
Symptoms Observed					
High fever	.2761818	.0957055	-3.71	.000	.1400321 - .5447065
Abdominal discomfort	1.646044	.6146237	1.33	.182	.7917858 - 3.421964
Nausea	.5845159	.1916728	-1.64	.102	.307378 - 1.111527
Joint pain	.2416235	.1119603	-3.07	.002	.0974363 .5991805
Body malaise	.5119071	.1828989	-1.87	.061	.2541358 1.031137
Chest pain	2.280418	1.788837	1.05	.293	.4901211 10.61025
Back pain	1.872374	1.528118	0.77	.442	.3781757 9.270254
Cons	.1396885	.1867649	-1.47	.141	.0101647 1.919665

high fever at 29.2% ($P=.002$). Patients with a high fever of 40°C and above had a 40% risk of malaria, while those without a high fever of 40°C were 60% less likely to have malaria.

Abdominal Pain

The magnitude of malaria among those with abdominal pain is 22.2%, and the extent of malaria among those without abdominal pain who have malaria is 77.7%. The difference in the two proportions is statistically significant with ($p=.046$). Patients without abdominal pain had twice the risk compared to those with abdominal pain.

Vomiting

The patients with vomiting symptoms have a 100% risk of having malaria, while those who have not demonstrated vomiting symptoms have a 40% risk of having malaria. The magnitude of malaria among those with vomiting symptoms is 43.0%, and the extent of malaria among those without abdominal pain is 56.9%. The difference in the two proportions is statistically significant, with a p -value of .001.

Joint Pain

Patients with joint pain symptoms have a 100% risk of

TABLE 5: Multivariate Analysis of the Significant Factors to Malaria Positivity Results (b)

Malaria diagnosis factors	Odds Ratio	Std. Err.	z	P> z	95% Conf. Interval	
Majengo Health Facility	17.6626	8.62072	5.88	0.000	6.785819	45.97345
Mzumbe Health Facility	10.49589	4.305658	5.73	0.000	4.697174	23.45319
Symptoms observed						
High fever	.2440872	.0822909	-4.18	0.000	.1260588	.4726252
Nausea	.5809043	.1855332	-1.70	0.089	.310629	1.086344
Joint pain	.2268551	.1025172	-3.28	0.001	.0935589	.5500621
Body malaise	.4657251	.1559291	-2.28	0.022	.2416237	.8976764
Cons	.728074	.4287537	-0.54	0.590	.2295691	2.309072

TABLE 8: Interviewed Patients’ Malaria Treatment History and Control Initiative Use

S/N	Questions	Feedback	n(%)
1	Being diagnosed with malaria in the past three months (N=312)	Yes No	192 (61.5%) 120(38.5%)
2	Observed malaria related symptoms in the past three months (N=120)	Yes No	80(66.6%) 40(33.4%)
4	The number of times you have been diagnosed with malaria or observed malaria-related symptoms in the past three months N=192	Once (One time) More than once	60(31.3%) 132 (68.7%)
5	Did you get any treatment for such self-observation of malaria-related symptoms?	Yes No	186 (68.3%) 86(31.7%)
6	Use of malaria control initiatives	<ul style="list-style-type: none"> • Treated Nets 275(88%) • Insecticides Spray 19 (6.5%) • Malaria Vaccination 2 (0.64%) • Non-use of Malaria Control Initiative (MCI) 16 (5.12%) 	
7	Reason for not using any MCI	<ul style="list-style-type: none"> • Minimal amount of mosquitos 10 (62%) • Tear and wear of the current Net 6 (38%) 	

having malaria, while those who have not shown any sign of joint pain have a 48% risk of having malaria. The difference in the two proportions is statistically significant, with a *p-value* of .049. The magnitude of malaria among those with joint pain is equal to 16.6%, and the extent of malaria among those without joint pain is equal to 83.3%

General Body Malaise

The analysis also observed that patients who have not observed body malaise have a 50% risk of having malaria

Sex/Gender and Age

The analysis in Tables 3 and 4 shows that male patients have twice the chance of having malaria compared to females. Also, the research shows that age has no statistical significance in malaria positivity. However, general observation after the odds ratio analysis was done on different variables against malaria positivity is that patients that are from the facilities in Morogoro, male, with ages between 25 to 44 years and those who come with high fever, headache, abdominal pain, joint pain,

body malaise, vomiting as symptoms have a statistical significance.

Malaria Patients Survey

The overall observation from the patient survey was that of the 312 malaria patients questioned, 44.24% were from the Kilimanjaro region, and 55.76% were from the Morogoro region. Among the 312 respondents, 65.58% were female, 34.42% were male, and 54.54% were between 15 -and 35 years. The results also indicated that 48.22% of the respondents have only primary school education, 33.65% have a secondary school education, 16.8% have a college education, and only 1.29% are uneducated, as shown in Table 6.

Survey Patients Symptoms

Symptoms observed from the malaria patients survey of 312 participants found that headache 210(67.3%), high fever (up to 40°C) 137(43.9%), fatigue (feeling tired) 110(35.2%), muscle aches/pain 90(28.8%) and abdominal

discomfort 45(14.42%) and nausea 42(14.42%) were highly observed symptoms in both the regions. Other symptoms are indicated in table 7.

Malaria Diagnosis and Treatment History

The survey in Table 8 revealed that 192(61.5%) were formally diagnosed with malaria in three months of 2018, and among that, Kilimanjaro 105(54.5%) and Morogoro 85(45.5%) while 120(38.5%) were not diagnosed with malaria. Amongst the 38.5% who were not diagnosed with malaria Kilimanjaro 37(31%), and Morogoro value 83(69%). Also, the analysis showed that among the 120 patients who were not diagnosed with malaria, 80(66.7%) observed malaria symptoms. Among them, 45(56%), mainly from Morogoro, self-medicated with anti-malaria drugs. In addition, 75(40%) patients diagnosed with malaria have a travel history to high-endemic areas in the past three months.

The use of malaria Control Initiatives

As illustrated in Table 2, most respondents (88%) used Treated Nets, followed by Insecticides Spray 6.57%. Malaria vaccination shows an inferior adaptation was only 0.64%. A few respondents (5.12%) did not use any malaria control initiative. The reasons were that the area has few or no mosquitoes and the current Insecticides Treated Nets are worn out.

DISCUSSION

This study aimed to explore different variables that can influence malaria diagnosis from the malaria diagnosis records. Overall, it was found that half of the patients who observed malaria-related symptoms treated themselves with anti-malaria drugs without any proper diagnosis from the health facility. This signifies that self-medication is still a challenge. Similar findings were also observed in the studies done in Kenya, Benin and Ghana, where self-medication is still practised in these counties and Tanzania is no different.^{32,33} Furthermore, we found that patients from high endemic facilities, who are male, and those who come with high fever, headache, abdominal pain, joint pain, general body malaise, and vomiting symptoms have a high chance of being diagnosed with malaria. This finding aligns with the Tanzania malaria diagnosis guideline, where the guideline also identifies the symptoms observed in this study.³⁴ As for the male gender, the 2022 study by Okiringin Uganda also found that males had a higher probability than females of testing positive for malaria, and this makes the general lifestyle and economic activities of male to be in question.³⁵ Also, the same study observed that those aged between 15 and 39 are at risk of being diagnosed with malaria, as found in this study, where ages between 25 and 44 years are more likely to have malaria than other age ranges.

The findings also revealed that the risk of malaria among males is high due to the high participation rate in social activities at night and some economic activities such as agriculture. Supporting these findings is the study done in East Africa under the Gates Foundation, where it was noted that men often face the risk of exposure through their occupations, such as fishing, mining, forestry, or agriculture, when these activities are conducted during peak biting times.³⁶

Apart from that, it was found that a lack of awareness of the effects of self-medication was described as a significant source of self-medication, as supported by Bria's study.³⁷ Mboera et al. described self-medication as contributing to drug resistance, developing chronic diseases, and even death, sometimes to untreated infections, assuming they have malaria.³⁸ There are several reasons why self-medication is more practised; the study by Ngasala et al. has shown that even though over 80% of Tanzanians live within 5 km of a health facility providing malaria treatment, treatment is often inadequate due to a lack of standard malaria treatment guidelines.³⁹ Another study by Yeka et al. has shown that inappropriate drug usage has been caused by financial constraints to seek the full treatment procedure and sometimes inherited behaviour among community members.⁴⁰ Apart from that, it was also found that residence area, high fever, nausea, joint pain, and body malaise had the strongest correlation with malaria positivity compared with the other symptoms. This indicates that kin observation of both non-symptoms, such as where the patients live and their sex, are significant in observing the patient malaria diagnosis and raising awareness in the community.³⁷

With all that has been observed developing a tool that can give patients the probability of being malaria positive when observing any malaria-related symptoms might be a possible solution to reduce the rate of self-medication.³⁷ Prediction models are among those tools that can improve the diagnosis and awareness of the patient's state before buying over-the-counter medication.⁴¹ The model can relate patients' history of the diseases and integrate symptoms and signs presented to physicians.^{37,41}

The limitations of this study are the following: firstly, our study population was based only in two regions which cannot generalise our findings to the entire country. Secondly, this study only described the dataset without demonstrating the development and implementation of machine learning models in Tanzania. The study's strength is comparing the data from two regions representing the country's higher endemic and low endemic areas. In addition, we analysed both medical history records and recent data obtained through the survey.

CONCLUSION

Our data indicate that proper diagnosis of malaria is a significant concern. As the majority still self-medicate with anti-malaria drugs once they experience any malaria-related symptoms, future studies should explore this challenge and investigate the potentiality of using malaria diagnosis records to diagnose the disease. Furthermore, although microscopic blood slides and rapid diagnostic tests are widely available, several challenges were identified, including self-medication with anti-malaria drugs and presumptive treatment of malaria. Therefore, it is recommended that better methods of malaria diagnosis should be imposed in society to reduce the effects of malaria drug resistance and misuse of drugs.

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Intellectual Property Management Capacity in Tanzania: Perception of Researchers in Academia and Research Institutions of Health and Allied Sciences

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ABSTRACT

Background: Intellectual Property (IP) management is a fundamental element in putting intellectual property to work for the public good. This study aimed at assessing the perception of the research community on intellectual Property Management (IPM) capacity in universities of health and allied sciences, and health research institutions in Tanzania.

Methods: A total of 148 respondents which included scientists, researchers and postgraduate students from 18 institutions in Tanzania returned the filled in self-administered online questionnaire (59.4% response rate).

Results: Most respondents (76.5%) were of the view that social and economic development are the priorities of their institutions but not intellectual property (IP) commercialisation as only a few (18%) reported that their institutions have arrangement with local industries and 22% said that their institutions have functioning intellectual Property Management Office (IPMO). About 30% of the respondents reported that IP policies exist in their institutions. In most cases, respondents were of the view that the need for effective management of IP (86.7%) triggered the institution's decision to have IP policy. Among the respondents who stated that their institutions have IP policy, slightly over one third to a half acknowledged that their institutions' IP policies intend to regulate mechanisms for benefit sharing and IP ownership.

Among those who reported that their institutions had IP policies, only 12.8% indicated that the policies were being implemented. Majority of respondents (80.4%) knew the existence of employment contracts but, only 28.4% signed the contract and 12.8% were well informed that they had been employed to invent. Over 20% of respondents said that their institutions had the capacity to exploit and manage IP and only a quarter of respondents reported to have capacity for IP management. Less than 40% of respondents admitted that their institutions had entrepreneurship capacity and 30% affirmed that their institutions were capable of establishing IPMO.

Conclusion: Opinions of the respondents indicate that universities and health research institutions in Tanzania have inadequate capacity for IPM due to inadequate or lack of frameworks, mechanisms, structures and resources for protection of generated IP. Technical and financial support are needed to strengthen capacity for IPM in universities and health research institutions in Tanzania.

BACKGROUND

The importance of research undertaken within universities and research institutions is widely recognized by governments, industries and diverse stakeholders. However, in Tanzania, the contribution of universities and research institutions in the generation of new ideas and knowledge as an economic driver, has never been higher.¹⁻³ At the same time, universities are faced with a rapidly changing environment shaped by pressure on funding, an emphasis on quality assurance and the increasing impact of globalization, marketization and new technology.⁴ Such pressures for change have placed a particular emphasis on the need for effective intellectual property management (IPM) in higher learning and research institutions.⁵⁻⁹ Intellectual property rights (IPRs) play an essential role in the safety and protection of the knowledge produced

and thus IPM is a fundamental element in putting intellectual property (IP) to work for the public good. The IP strategy consists of a set of measures, formulated and implemented by an institution. These measures encourage and facilitate the effective creation, development, management, and protection of IP¹⁰⁻¹¹.

Industrial context and institutional setting matter tremendously when it comes to how IP is constructed, used and deployed. In other words, the impact of IP depends on how it is used, who uses it, and for what purpose. The rewards from successful IPM can be enormous, but without effective IPM skills, universities and research institutions risk squandering the rights, powers, and opportunities that the IP system provides. Thus, it is important to invest in the tools, people and processes in order to improve and maximise IPM, revenue generation activities and

increase the IP value within the organisation.¹²

The IP strategies can serve to either restrict or expand access to innovations, research results and data. Failure of the organization to obtain and maintain rights for the generated IP may result in other entities appropriating elements of the value without major regard to the mission of institution in question, or it could lead to the intellectual assets becoming useless due to lack of further investment and development.¹³ The aim of this study was to assess research communities' perception on the capacity for IPM in academia and research institutions of health and allied sciences in Tanzania.

METHODS

Study Population and Sample Size

Study population included researchers, scientists, academicians and post graduate students from health and allied science universities and research institutions in Tanzania. With the population of 3,083 researchers and scientists in the targeted health and allied sciences institutions¹⁴⁻¹⁵ and assumption that 50% of targeted population perceive that universities and research institutions have capacity for IPM, provided that the level of confidence is 90% and accepted margin of error is 5%, the calculated sample size was 249.¹⁶

Sampling Procedures

Three research institutions (1 public and 2 private), 6 out of 12 public universities and 4 out of 18 private universities were purposively selected because they are institutions of health and allied sciences. In each selected university and research institute, all researchers including postgraduate students were eligible for the survey, and hence administrators of the selected institutions were asked to share the survey link to their researchers and postgraduate students through email, WhatsApp and Twitter. Potential study participants were requested to respond to the questionnaire within the allocated time. Therefore, study participants were self-selected.

Study Design

A cross section survey was conducted to assess IP capacity in health research institutions and universities in Tanzania. All researchers, scientists, academia and postgraduate students from health research institutions and universities in Tanzania were eligible to participate in this study.

Data Collection

Administrators of the selected health and allied sciences institutions were asked to share the questionnaire link with their researchers and postgraduate students. The targeted health and allied sciences institutions included 3 research institutions (1 public and 2 private), 6 out of 12 public universities and 4 out of 18 private universities. The online self-administered questionnaire was distributed to all researchers and postgraduate students in the targeted academic and research communities in Tanzania through emails, WhatsApp and Twitter. However, the link was active from the 2nd to the 4th week of May 2021. Thus, analysis was based on individuals who responded to the questionnaire within the allocated time. Data collection tool was designed to collect information on IP existence of IP policy, agreements and guidelines,

reasons for developing IP policy and implementation status, institutions' commercialization strategies, types of commercialized and granted IPRs, institutions' capacity and individuals' skills and knowledge for IPM, and entrepreneurial environments and capacity. For each question, respondent was required to select one of the three pre-determined responses (agreed, disagreed or not sure).

Data Analysis

Descriptive and cross tabulation analysis were conducted using IBM SPSS Statistics for Windows version 21 (IBM Corp, Armonk, NY, USA) data management software. Chi-Square tests were used to measure significance of association or differences between two variables or groups. Score for institutions' entrepreneurship capacity was constructed by summing up 9 items which assessed institution's resources for IPM, ability for commercialisation, involvement of external community partners, support for innovation and creation of new business and entrepreneurship, linkage or engagement with industry and entrepreneurial climate. The generated variable was categorized into comprehensive entrepreneurship capacity and limited entrepreneurship capacity.

Institution's capacity to exploit generated IP was assessed by 5 items which included availability of the following: resources for creation of spin off company, government or regional fund to support IP commercialization, budget for IP protection, licences for ongoing use of digital publications or digital databases, and institution's accessibility to relevant physical and digital information via networking/partnership. After summation of the 5 items, the resulted variable was categorized into comprehensive capacity for IP exploitation and limited capacity for IP exploitation.

Score for institution's IPM capacity was constructed using 7 items which included availability of resources for legal support, fund for operationalization of IP management office (IPMO), unit responsible for evaluating invention's economic prospects and deciding whether to protect and commercialize IP, staff with skills for evaluation of economic prospectus of the invention, staff with business skills, and that institution's strategy align with commercialization goal. The final score was categorized into comprehensive IPM and limited IPM.

Readiness for IPM score was generated by summation of 3 items: scope and volume of research results justify establishment of IPMO, institution's consideration to pool resources with other institutions to manage IP, and reported institution's ability to set up IPMO. For analysis purposes, the score was categorised into comprehensive IPM readiness and limited IPM readiness.

Individual IP capacity was assessed by 6 items which included respondent knowing his/her role in protection and commercialization of IP and where to get IP information, respondent's capacity for protection and commercialization institution's IP, exposure to IP training in the past 5 years, involvement in developing IP policy and entrepreneurship skills. The final individual IP capacity score was constructed by summation of all 6 items and then categorized into comprehensive capacity

and limited capacity.

Study participants were skewed towards 2 major institutions of health and allied sciences in Tanzania, and therefore decided to group participants into 3 categories which included 46 participants from National Institute for Medical Research (NIMR), 46 participants from Muhimbili University of Health and Allied Sciences (MUHAS) and 56 respondents from 16 other institutions.

Ethical Consideration

Data used in this paper were collected through needs assessment study aimed at generating information to inform IP policy developing process for universities and research institutions. The study was granted ethical approval waiver (Ref number NIMR/HQ/R.8a/Vol II of 2020/122) from Medical Research Coordination Committee (MRCC).

RESULTS

Respondents' Profile

A total of 148 individuals from health research institutions and universities in Tanzania responded to the distributed online questionnaire, giving a response rate of 59.4%. The majority of respondents per institution were males (78.3%) from Muhimbili University of Health and Allied Sciences (Table 1). Over 70% of respondents have been working with their current institutions for over 6 years.

Perceived Drivers of Institutions' Mission, Priority and Orientation

Most respondents (76.5%) were of the view that social and economic development werethe priorities of their institutions but IP commercialization (29.4%) including databases and software, and meeting local industrial needs didnot form part of the institutions' missions (Table 2). These findings are supported by lack of institutions' strategic direction for IP regulation as only 18% of the respondents reported that their institutions had arrangement with local industries. Furthermore, only 22% of the respondents said that their institutions had functioning IPMOs (Table 3).

Awareness on Intellectual Property Management Policies and Related Agreements

As shown in Figure 1 and Table 4, approximately 30% of the respondents reported that IP policies existed in their institutions. The frequently mentioned main reason (86.7%) for the institutions to have IP policies in place is to ensureeffective management of created IP (Figure 2). Among respondents who asserted that their institutions had IP policy, 72% reported to have signed employment contract (data not shown in Table or Figure). Over one third to a half acknowledged that their institutions' IP policies intended to regulate mechanisms for benefit sharing and IP ownership (Table 4). Few respondents were aware of the existence of institutions' IP related agreements such as licensing (31.8%) and technology transfer agreement (29.7%).

Dissemination and Utilization of IP Management Policies and Related Documents

Among those who reported that their institutions had IP policies, only 12.8% affirmed that the policies were being implemented: 13.3% (MUHAS), 18.2% (NIMR), and 9.5%

other institutions. The majority of respondents (80.4%) knew the existence of employment contracts, but only 28.4% had signed the contract, and 12.8% were well informed that they had been employed to invent (Table 5). According to respondents, the form of IPRs most granted to their institutions included certification, copyrights and patents (Figure 3), and that commercialization was through establishment of joint ventures, exclusive licensing and assignment (Figure 4).

TABLE 2: Respondents' Perception of Drivers of Institutions' Mission, Priority and Orientation (N=148)

Drivers of institutions' mission	n	%
Academic Research	96	64.7
IP commercialization	113	76.5
Academic and research	44	29.4
Research and commercialization	113	76.5
Academic, research & commercialization	44	29.4
Institutions' priority	26	17.6
Humanitarian & philanthropic	61	41.2
Social & economic development	113	76.5
Institution orientation		
Society needs	113	76.5
Academic needs	122	82.4
Local industry needs	44	29.4
Developing & use of databases	87	58.8
Commercialization of databases	44	29.4
Commercialization of software	44	29.4

TABLE 3: Institution's Strategic Direction for IP Regulation (N=148)

	n	%
Regulate precise type of IP	55	37.0
Have arrangement with commodity group or industry	27	18.5
Have access to research infrastructure	71	48.1
Have functioning IPMO	33	22.2
Employee responsible for research records and laboratory books	71	44.4

Capacity and Environment for Intellectual Property Management in Universities and Health Research Institutions

Respondents were of the opinions that universities and health research institutions had inadequate capacity for IP management as only over 20% of respondents said that their institutions had the capacity to exploit and manage IP, and only a quarter of respondents reported to have capacity for IP management (Figure 5).

TABLE 1 : Profile of Respondents

	Others n (%)	MUHAS n (%)	NIMR n (%)	ALL n (%)	P value
Sex					<.001
Female	20 (36.7)	10 (21.7)	15 (32.6)	45 (30.4)	
Male	36 (64.3)	36 (78.3)	31 (67.4)	103 (69.6)	
All	56 (37.8)	46 (31.1)	46 (31.1)	148 (100.0)	
Age group					<.001
29 – 41 years	27 (48.2)	31 (70.5)	10 (21.7)	68 (46.6)	
42 – 72 years	29 (51.8)	15 (29.5)	36 (78.3)	80 (53.4)	
All	56 (37.8)	46 (31.1)	46 (31.1)	148 (100.0)	

TABLE 4: Presence of Institutional Intellectual Property Policy and regulations (N=148)

	Others n (%)	MUHAS n (%)	NIMR n (%)	ALL n (%)	P Value
Existence of IP policy	21 (37.5)	10 (21.7)	13 (28.3)	44 (29.7)	.001
IP ownership regulation	37 (66.1)	29 (63.0)	23 (50.0)	89 (60.1)	.201
IP use regulation	33 (58.9)	30 (65.2)	23 (50.0)	86 (58.1)	.122
IP commercialization regulation	29 (51.8)	24 (52.2)	19 (41.3)	72 (48.6)	.451
Benefit sharing mechanisms	34 (60.7)	21 (45.7)	17 (37.0)	72 (48.6)	.017
Default legal regime for employee's invention	26 (46.4)	17 (37.0)	8 (17.0)	51 (34.5)	.004
IP ownership of publicly sponsored research regulation	38 (67.9)	25 (54.3)	22 (47.8)	85 (57.4)	.005
IP ownership of privately sponsored research regulation	26 (45.4)	20 (43.5)	21 (45.7)	67 (45.3)	.634
Student's or visiting researcher's IP ownership regulation	27 (48.2)	23 (50.0)	15 (32.6)	65 (43.9)	.462
IP policy implementation	21 (37.5)	15 (32.6)	11 (23.9)	47 (31.7)	.004
Research collaboration policy	52 (92.9)	36 (78.3)	35 (76.1)	123 (83.1)	.534

TABLE 5: Existence of IP Related Contracts and Agreements(N=148)

	Others n (%)	MUHAS n (%)	NIMR n (%)	ALL n (%)	P Value
Licensing agreement	16 (28.6)	22 (47.8)	9 (19.0)	49 (31.8)	.005
Technology transfer agreement	20 (35.7)	6 (19.6)	15 (32.6)	44 (29.7)	<.001
Employment contract	46 (82.1)	31 (67.4)	42 (91.3)	119 (80.4)	.046
Staff employed to invent	5 (8.9)	6 (13.0)	6 (17.4)	19 (12.8)	.014
Signed employment contract	17 (30.4)	10 (21.7)	15 (32.6)	42 (28.4)	.761

FIGURE 1: Awareness on Existence of Institutions's Tools For Intellectual Property Management

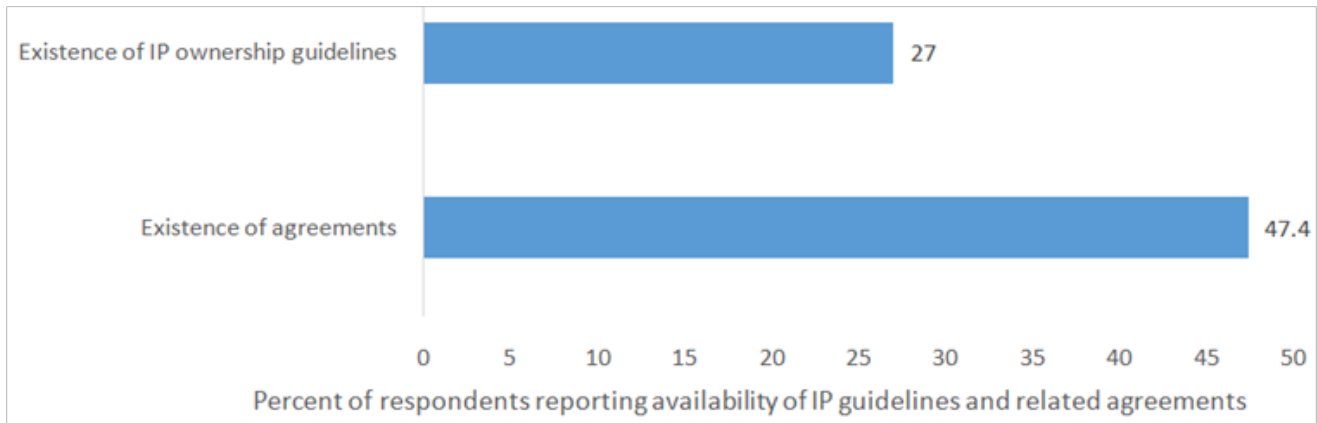
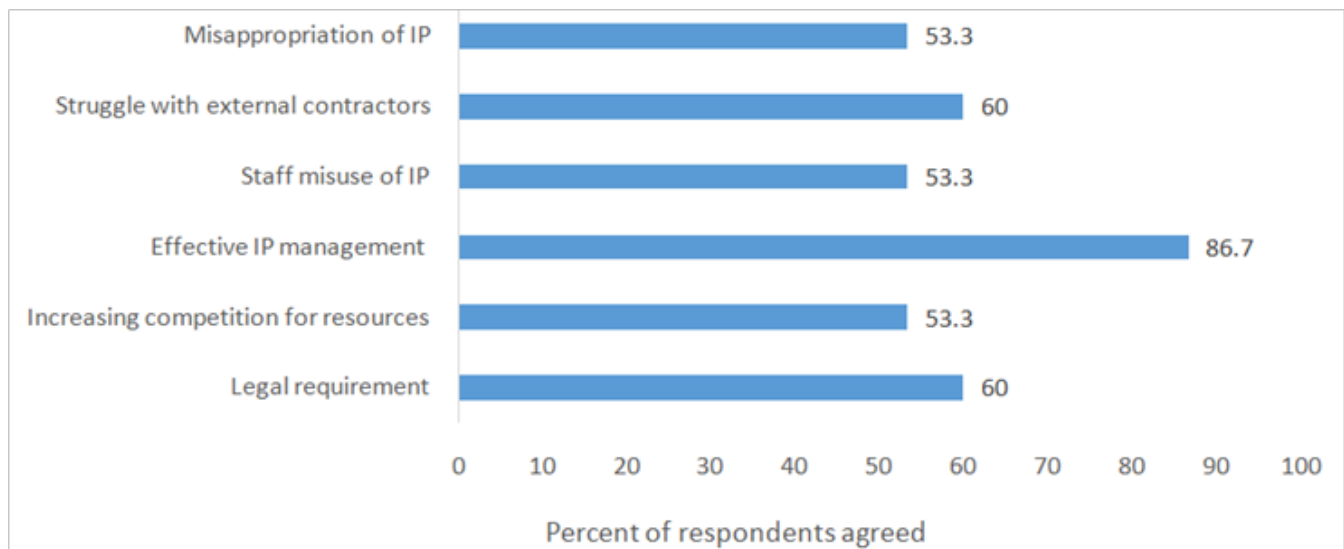


FIGURE 2: Respondents' Perceived Reasons for Institution to Have Intellectual Property Policy in Place



In addition, respondents indicated that their institutions do not have conducive environment for IPM. For instance, less than 40% of respondents said that their institutions had entrepreneurship capacity and 30% affirmed that their institutions were capable of establishing IPMO (Figure 5). Only 5.9% of respondents had ever been incentivized for creation of IP and among those, 67.7% expressed dissatisfaction with the incentives provided by their institutions following commercialization of IP they created.

DISCUSSION

IP policies and related regulations, guidelines and agreements are usually designed to consider the ownership rights, profit sharing and other related rights.¹⁷ These policies, regulations, agreements and guidelines are important to establish proper management of IPRs, safeguard the process of IP and to provide framework to incentivize researchers in order to promote productivity.¹⁸ Views of the respondents indicated that there are either gaps in the IP policies of the universities

FIGURE 3: Types of Intellectual Property Rights Granted to the Respondents' Institutions

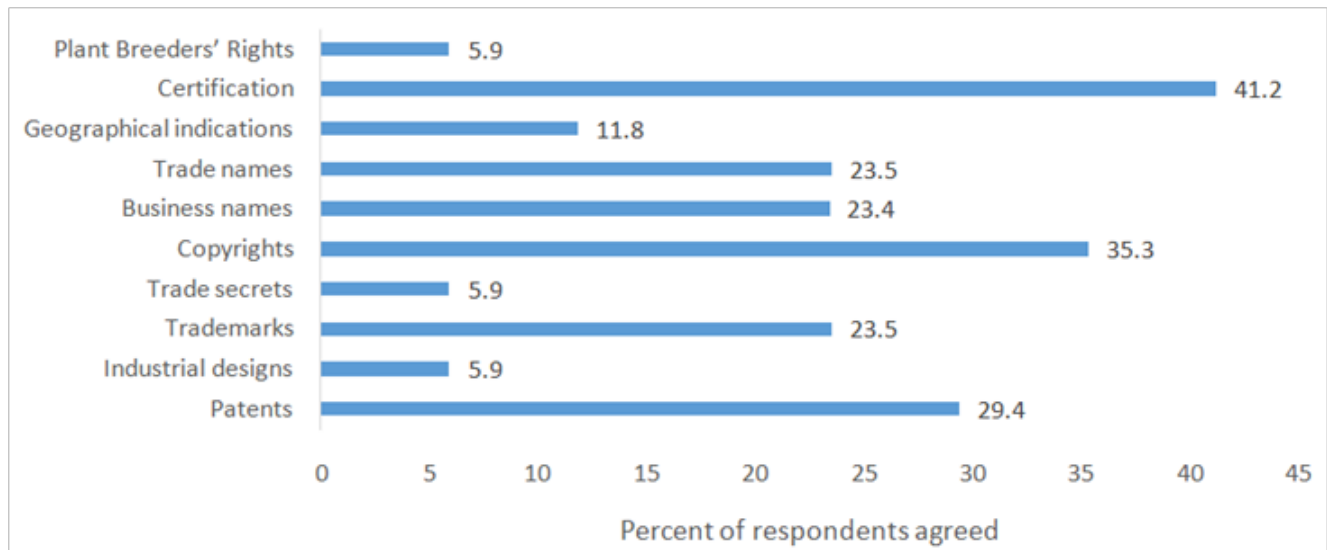
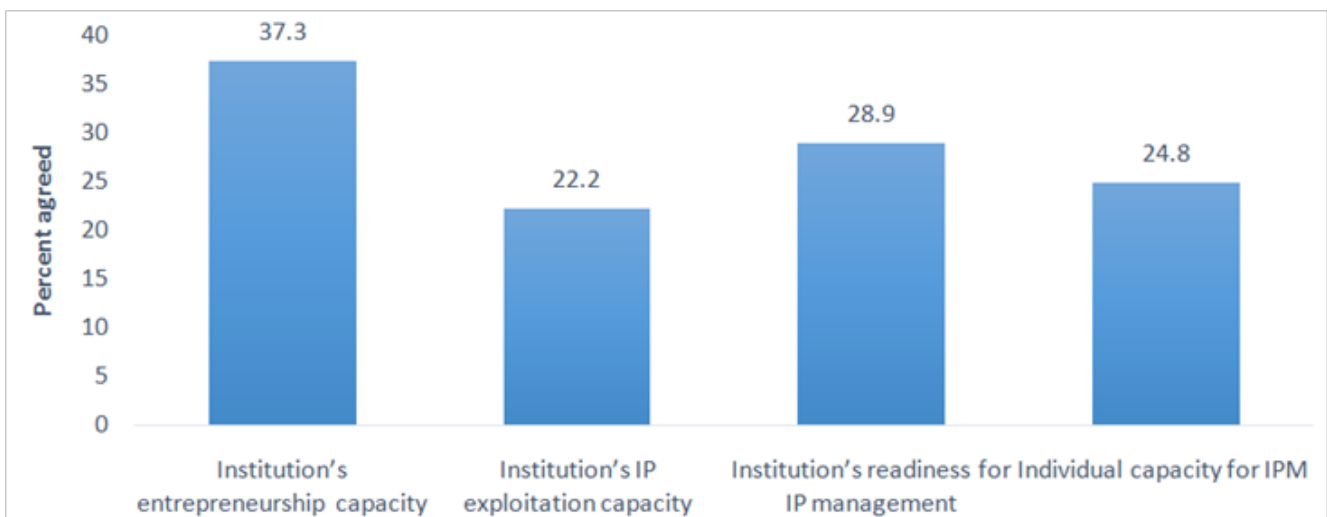
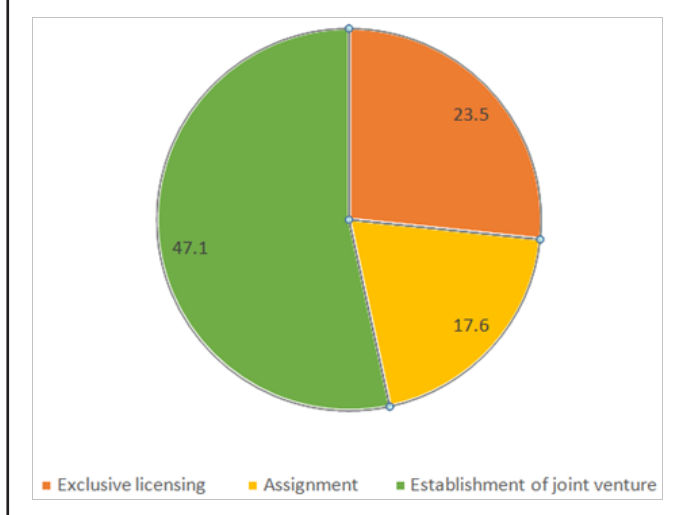


FIGURE 5: Opinions of Respondents on Universities' and Research Institutions' Capacity for Intellectual Property Management and Entrepreneurship



and research institutions in Tanzania or respondents have limited knowledge on the contents of their institutional IP policies. These explanations regarding respondents' views are in line with the gaps which were identified in the review of IP policies in academia and research institutions in Tanzania.¹⁹

FIGURE 4: Institutions' Intellectual Property Commercialisation Strategies



Universities and research institutions are perceived as an engine for economic growth through commercialisation of IP.²⁰ However, environments for accelerating protection and commercialization of research products are not conducive in most academic and research communities in Tanzania. Commercialization is the process of turning a new idea into a marketable product or service²¹ and depends to a large extent on the availability of enabling legislative and policy frameworks that support the effective identification, protection, and management of any intellectual property associated with the R&D results. Commercialisation activities are more valued, if incentives and rewards are provided to researchers in academia and research institutions.¹⁹

Licensing involve an agreement by the owner of a patent (*licensor*) to allow another party (*licensee*) to make, sell and use the patented invention on an exclusive or non-exclusive basis, without transferring ownership of the patent; hence licensing can be used to generate revenue.¹² Respondents in the current study indicated that their universities and research institutions rarely use this type of commercialization strategy. Respondents' awareness on existence of institutional IP policies and related regulations, guidelines and agreements is low, even in institutions which have such documents. Lack of dissemination of such information may have contributed to the observed low awareness. Different means of communication channels such as print media, bulletins, internet, videos and WhatsApp should be adopted by universities and research institutions if the goal of raising IP awareness is to be fulfilled. Offering IP awareness and instill a culture of IPM among staff of universities and research institutions. It should be noted that awareness by itself is of little use if institutions do not create and provide suitable systems to enable research communities to protect their rights.¹⁴ Therefore, it is of little value to raise scientists' awareness on the importance of novelty for getting a patent without supplying them

with adequate tools to determine if their inventions are novel or not.

Majority of the respondents were of the views that universities and research institutions in Tanzania lack clear IP policies, regulations, guidelines and agreements that provide guidance on IP ownership, benefit sharing and commercialization. Incentives are rarely provided and in most cases those who received the incentives were dissatisfied. The findings conform with the view that provisions of incentives and rewards for innovators or inventors in academia and research institutions are not systematically organised.²³

Study findings revealed that respondents perceived their knowledge and skills for IPM are inadequate. Respondents' opinions also indicated that commercialization of IP generated in academia and research institutions in Tanzania is low. The respondents were of the views that negligible proportion of created IP is protected and commercialised. The findings of this study are in line with what have been reported in a study which assessed implementation of IP policy in universities and research institutions in Tanzania.¹⁸ However, creation of value from IP commercialisation depends very much on what happens before the product is developed²⁴ and collaboration between universities, research centres and other organisations.²² From respondents' perspective, universities and research institutions in Tanzania have inadequate resources and weak or lack of linkages with industries which may hinder effective commercialization of IP as demonstrated by other studies.^{25,26}

Despite the fact that research management centre or technology transfer office plays an important role in developing, coordinating and facilitating commercialisation of IP,^{27,28} respondents in the current study were of the views that their institutions are not well prepared to establish IPMO due to lack of resources and expertise in the relevant field. For universities and research institutions to sustain commercialization of IP, it is crucial to increase IP knowledge and skills among academia and research communities, and improve IPM by nurturing healthy relationship with business partners and facilities.²⁹

The ability to leverage IP may require specialised business and/or industry knowledge. Hence, to make the most of the institution's IP holdings, prior knowledge and skills on industry and IPM is required. The industry context and institutional setting matter when it comes to how IP is constructed, used, and deployed. Universities and research institutions in Tanzania are faced with the challenge of realising how knowledge generated through their research base can best be utilized as an asset that can provide maximum value to society, economic and the institution.

Limitation

Response rate was low, and individuals who responded to the questionnaire may have not been in a position to know the details of the institutions' strategic plans and direction for managing IP and therefore their views may not necessarily reflect the institutions'. Nevertheless, the results of the in-depth interviews and reviews of IP policy documents from various institutions¹⁸ supported the

findings of the online survey in terms of low IP awareness, lack or inadequate implementation of IP policy and limited capacity to manage IP.

CONCLUSION

Perceptions and views of researchers indicate that universities and health research institutions in Tanzania have inadequate capacity for IPM. According to the respondents, universities and research institutions in Tanzania do not have mechanisms, structures, frameworks and human resource with skills for effective management of IP. Interventions are required for improving institutions' and individuals' capacity to manage IP in Tanzanian health research institutions and universities. In order to create the best environment for IP to be produced and transferred to practical use, universities and research institutions in Tanzania must have a suite of IP policies and practices that reflect their missions, and at the very least ensure that there are arrangements for sharing benefits arising from commercialisation of IP. However, different institutions may put a difference emphasis on the voices of students, research, academic and administrative communities in their policies. Once IP policies are developed, they should be effectively communicated both inside and outside the institution.

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Lived Experiences of Adults with Sickle Cell Disease: A Qualitative Study, Dar es Salaam, Tanzania

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ABSTRACT

Background: Sickle Cell Disease (SCD) is most common genetic disorder and its prevalence in sub-Saharan Africa is increasing. Despite increased survival rates, experiences of adults living with SCD in Tanzania is not well explored. This article provides perceived causes of pain crisis, pain self-management approaches and psychosocial implication of SCD.

Aim: This study aimed at exploring experiences of adults living with SCD regarding pain triggering or aggravating factors; self-management for pain; psychosocial-economical implication of SCD and coping mechanism used by individuals living with SCD

Methods: A qualitative study design was chosen using in-depth interviews with adults living with SCD to explore their experience of living with SCD. Fifteen adults aged 18 years and above living with SCD were interviewed. Data were analyzed by using content analysis approach.

Findings: Four categories emerged that described experiences of individuals with SCD. The four categories are; "Pain Triggering and Aggravating Factors" describing participants' perceived factors causing pain in SCD; "Self-care remedies for the pain" referring to participants' methods for self-management of pain; "Psychosocial-economic impact of illness" referring to participants' experience of implication of illness on social and economic life and "Dealing and coping with illness" referring to experience of participants on management and coping strategies used to live with the illness.

Conclusion: Individuals with SCD experiences several episodes of pain that affect their quality of life. Pain episode can be triggered or aggravated by various factors. Several approaches are used by individuals with SCD to self-manage the pain including taking rest, drinking plenty of water or using pain relieving medication. Care for individuals with SCD should be comprehensive and include proper management of pain, health education on home-based intervention for sickle cell pain, supportive services to deal with psychosocial implications of SCD and improving coping strategies to live with the illness.

BACKGROUND

Sickle Cell Disease (SCD) is a potentially overwhelming genetic disorder accompanied by episodes of painful attacks that affect quality of patient's life. The disease is due to genetic defect of hemoglobin, a molecule in red blood cells that carries and delivers oxygen to cells throughout the body. People with this disease have abnormal hemoglobin known as Hemoglobin S (HbS) which alter the shape of red blood cells to sickle shaped or crescent. SCD is prevalent in many countries including Africa and is the most common genetic disorder.¹⁻⁴ It is estimated that 16% of the population in Africa has a sickle hemoglobinopathy which is the highest proportion worldwide.⁴ The symptoms for the disease usually begin in early childhood and most present with low number of red blood cells, repeated infections and periodic episodes of pain.

Despite high mortality during childhood, several

others survive to adulthood. However, living with the SCD has been a challenge to many adults with the disease. The effects of SCD are multi-dimensional, ranging from causing high morbidity, and reducing the quality of life, to imposing a high socio-economic burden on individuals, and families.⁵⁻⁷

Pain is one of the major problems of SCD. SCD pain occurs when red blood cells with the abnormal form of hemoglobin become sickling (deforming), preventing blood flow, and thus producing ischemia, hypoxia, and possible tissue damage. Pain is gradual in SCD, affecting all aspects of life.⁸⁻¹² Management of SCD pain has to be holistic (take into account all aspects of patient's life) without forgetting mental and social factors and not just the physical symptoms of the disease, but this has not been the case among health care providers in hospitals.

Poor painful crises management can lead to increase in frequencies of crises, and later to chronic pain that

may result in recurrent hospital admissions, frustration, and loss of precious time for adult's daily activities. This can have direct consequences on economy and implicate social life. Little is known about experience of adults living with SCD in Tanzania. This study is therefore set to explore the experience of adults living with SCD and in particular, how they perceive factors triggering SCD related pain episodes, how they self-manage such pain; their understanding of psychosocial-economic implications of SCD and their coping mechanisms that help them to live with the illness. Such understanding is useful in developing comprehensive intervention including preparation of educative sessions on self-care management, prevention or reduction of crisis occurrences programs and counseling targeting reduction of psychosocial impact of the disease as well as improving their coping mechanism.

METHODS

Study Design and Setting

A qualitative study design was used. The study conducted in-depth interview of adults living with SCD to explore their perceptions regarding causes of the pain they experience, how they manage pain, psychosocial and economic effects of the illness.

This study was done at Muhimbili National Hospital (MNH), in Dar-es-Salaam, Tanzania. The hospital is a tertiary, referral and teaching hospital that serves the whole country. It is the largest hospital with 1,500 bed facility, admitting 1,000 to 1,200 inpatients per week. The hospital has 2700 employees of whom 300 are doctors and specialists, while 900 are registered and enrolled nurses. It has a General Haematology Clinic that enrolled over 6000 individuals with SCD since 2006.

Study Participants

This study included participants who have been living with SCD for more than 18 years, confirmed to have SCD screened at the Hematology Unit and consented to be enrolled in the study.

Sample Size and Sampling Technique

A total of fifteen (15) participants were interviewed in this study. The sample size was not predetermined. However, the researchers stopped with 15th interview after noting repetition of information with little or no new insight in relation to our research questions. Selection of participants was purposely done to include those who has been living with SCD for more than 18 years and attending the General Hematology Clinic.

Data Collection

Interviews were conducted between March and May 2017. The authors in collaboration with nurses at the hematology unit identified participants who met inclusion criteria and requested to participate in the study. All interviews were conducted in a convenient room to avoid interruption during interview sessions. Interviews were conducted in Kiswahili language by RCN, who is a nurse, a Kiswahili native speaker with prolonged experience of working in Haematology Unit at the Hospital. Interviews were conducted using semi-structured interview guide with open-ended questions on issues regarding causes of pain; self-management of pain, psychosocial and econom-

ic effects of the illness. However, the interviewer remained open to other new emerging issues with regard to participants' experience of living with SCD. The interviews were recorded using digital recorder with permission from study participants to ensure that all information was captured. Field notes were also taken and preliminary analysis of data was done following initial data collection. This enabled the researchers to gain an insight of emerging issues which were followed up in subsequent interviews.

Ethical Consideration

Ethical approval to conduct this study was obtained from the Senate Research and Publications Committee, which is the Institutional Review Board of Muhimbili University of Health and Allied Sciences. The permission to conduct the study was given by MNH. Before interview, researchers obtained written informed consent from the participants.

Data Analysis

To ensure accuracy and completeness of data, interviews were reviewed daily. Recorded interviews were transcribed verbatim and then translated into English. Translation was done in by two authors (DAM & RCN) who use Kiswahili language as their mother tongue. Qualitative content analysis as described by Graneheim and Lundman¹³ was employed in analyzing the data. Transcripts were then read and re-read by all authors to familiarize with the data and generate insight on the contents. Each transcript was then analyzed for identification of text (meaning units) related to causes of pain, self-management of pain at home, perceived effect of the illness in social and economic life and the management and coping methods developed to live with the illness. The meaning units were condensed and codes were then extracted. Similar codes were sorted to form categories reflecting the manifest content of the text and similar categories were organised into themes reflecting the latent content of the text. Data from field notes were used as supportive information in clarifying concepts that emerged during analysis of the transcripts.

RESULTS

The age of participants ranged from 18 to 45 years. Nine participants were females and 6 were males. All participants were not married except 6 females who were divorced. Seven participants had primary school education, four secondary school education and 4 had college education. Only 2 participants were employed and the rest were not employed. Only 4 out of the 15 participants owned health insurance treatment cards.

Lived Experience of Individuals with SCD

During analysis of the interviews, four categories emerged that described the experiences of participants living with SCD. Categories and selected codes are presented in Table 2.

Pain Triggering and Aggravating Factors

Pain was mentioned as a common symptom experienced by participants in the course of their illness. The frequency and severity of pain experienced varied among participants. It was noted that some participants

TABLE 1: Demographic Information of Participants (N=15)

Demographic characteristics	Numbers (%)
Age range (Years)	
18-20	2 (13.3%)
21-30	8 (53.3%)
31-40	4 (26.7%)
41-50	1 (6.7%)
Gender	
Male	7
Female	8
Marital status	
Married	0
Single	13
Divorced	2
Occupation	
Employed	0
Self-employed	13
Student	2
Pain experienced in the past six months	
No pain	1
Moderate pain	4
Severe pain	10
Possession of National Health Insurance Fund (NHIF) card	
Have NHIF card	3
Have no HHIF card	12

experience severe pain daily while others experience pain intermittently and that the pain can either be moderate or severe.

Participants in this study, shared their experiences on what they view as factors that trigger or aggravate pain. Although some participants reported to experience pain spontaneous without any obvious cause, several others reported to experience severe pain after being wet from rain or during cold weather. Some participants reported to experience pain whenever they go through stressful situations. It was noted that having an infected wound could trigger pain among patients living with SCD. One participant shared on how she started to experience severe pain after having an infected ulcer in one of her legs.

Some participants reported that when they drink little amount of water and became dehydrated, they end up getting severe pain. Others mentioned that involvement in energy demanding work like strenuous physical exercise or other activities that demand more energy was mentioned to trigger severe pain as attested by one of the participants.

“I feel severe pain when I do excessive exercise. Another thing is that I get pain when I drink little water or if I don’t drink water at all.” (Participant 15)

Self-care Remedies for Pain

Participants reported various modalities they use to alleviate pain or get relief from pain. Some reported that when they get pain, they sleep or sit without doing any-

hing and the pain disappear or get reduced. Some reported that drinking plenty of water or fluids helped to alleviate pain crisis once it occurs. Though participants are normally advised to drink about 3 liters per day, some participants reported to have been drinking more or less than what is recommended. However, other participants reported to get difficulty to achieve the required amount of water per day and mentioned that, achieving that goal need some extra effort as mentioned by one participant below.

“I drink that amount because I don’t like water. I try my best to drink but I cannot finish two liters in a day. I don’t like water like others do, so, drinking that amount needs some effort”. (Participant 6)

Wearing warm clothes during cold weather was also mentioned as one of the approaches that helps to alleviate pain or prevent painful crisis. Others preferred to be massaged or take bath with hot water to alleviate pain. However, some participants tried to distract pains by continuing with their normal activities.

All participants reported self-treatment by using analgesic tablets as a way of alleviating pain. However, it was noted from the interview that, the medication taken are not necessarily prescribed and that amount of drugs taken depends on their effectiveness in relieving the pain, exposing them to drug toxicity.

Psychosocial-Economic Implication of Illness

Almost all participants reported to have missed classes and examinations in schools due to frequent sickness from SCD. Some participants dropped out of school completely due to sickness.

Other participants shared their concerns about financial status, some mentioned that they lost their jobs because of SCD illnesses. Few reported to have been fired from work by their employers due to frequent sickness. Other participants reported to have been stigmatized in their working place after disclosing their disease status. One participant narrated on how he was terminated from work after his employer discovered that he was suffering from SCD.

Participants also shared the challenges they are experiencing when want to establish family life. Some confirmed to have been in relationship or marriage that ended into breakdown or divorce. One female participant described how her fiancée broke the relationship after she disclosed her SCD status. Other participants expressed that, due to frequent illnesses and sickle cell crises, or miscarriages, their in-laws become intolerant and convinced their sons to divorce. A participant who was divorced due to frequent sickness and miscarriages stated as follows:

“Yes, my husband knew, but after the marriage the problems started again, I was attending hospital frequently, sometimes admitted, sometimes this, till when I had my first child. After the delivery, the frequency of sickness declined, but he knew this would happen again and so I was divorced and went back home”. (Participant 7)

Managing and Coping with Illness

Participants in this study shared different approaches they use to self-manage pain. However, once pain become

TABLE 2: Categories and Selected Codes Describing Experiences of Adults Living with SCD

Experience of Adults with SCD	Selected Codes	Category
What causes and exacerbates pain	<ul style="list-style-type: none"> -Pain varies with frequency, intensity and severity -Pain can start by itself -Getting wet and cold from rain -Stressing events -Having infected wounds -Energy demanding work -Decreased water intake 	Pain triggering and aggravating factors
How to deal with pain at home	<ul style="list-style-type: none"> -Rest by sitting or sleeping -Distracting pain with other activities -Massaging using hot water -Self-medicating with pain killers -Drinking plenty of water 	Self-care remedies for pain
Psychosocial and economic effect of illness	<ul style="list-style-type: none"> -Poor school attendance due to frequent hospital admission -School dropout caused by chronic illness -Lost job due to chronic illness -Stigmatized once disclosing the illness -Difficulty in getting life partner -Altered family process due to frequent admission -Divorced due to illness induced infertility 	Psychosocial-economic implication of illness
How to manage and live with illness	<ul style="list-style-type: none"> -Seeking hospital care if pain persist - Attending hospital for health checkup -Knowing and receiving right treatment -Seeking healing from tradition healers -Praying daily for divine healing - Hoping and believing in God for healing 	Managing and coping with illness

severe or persistent almost all participants reported going to hospital for further management. Several participants mentioned that once in hospital, they were treated by injectable Diclofenac or Tramadol and IV fluids. It was noted from the interviews that, most of the participants are known by health care providers and often given right management.

Some participants were concerned of the high cost for treatment. Others narrated how some hospitals denied treatment and referred them to MNH for only pain management. Lack of patients’ involvement in care was another concern as narrated by one participant below:

“I once went to the hospital and I had very severe pain! The doctor forced me to take tablets only saying that it would help while I knew that the tablets at that time would not help me at all”. (Participant 11)

Some participants confirmed attendance to traditional healers, taken by their relatives after associating the disease with witchcraft. Other participants acknowledged to practice religious practices such as prayers and considered it to be helpful in promoting hope and inner strength to face the challenges emanating from living with SCD. Some confirmed to pray whenever they are in pain or very sick and had faith that one day they will experience divine healing from God.

“We pray every day. I pray daily for a relief from the disease. I pray daily, I believe, I believe in God and He will heal me”. (Participants 1)

DISCUSSION

This study explored the experience of adults living with SCD. The study found several factors that trigger or aggravate pain crisis and approaches that individuals living with SCD use to self-manage the pain at home. Furthermore, the study found several psychosocial and economic implications resulting from living with SCD and various strategies used by such individuals to cope with the illness.

Pain Triggering or Aggravating Factors and Self-care Remedies for Sickle cell related Pain

Individuals with SCD experience episodes of pain that can be very severe and result in multidimensional problems that affect their quality of life. However, the study found variation on how individuals with SCD experience such pain. Most participants in this study reported to experience intense and continuous pain, however, for others, the pain just occurred occasionally and moderately. This variation could better be described by genomic variability, whose exploration can be used for identification of susceptibility to chronic pain experienced

by individuals living with SCD.^{9,13–20}

Several studies have demonstrated how genomic information is crucial determinant of chronic pain and hence recommend the need for evaluation of genomic variables for predicting pain chronicity in individuals with SCD.^{9,17}

This study found several factors that trigger or aggravate pain in SCD. Cold weather or becoming wet was found to be the main triggering factor for painful episodes in individuals with SCD. The study in Ghana by Tewari and his colleagues^{9,17,21} showed that extreme cold weather coincided with the rainy season precipitate severe pains in patients with SCD. However, it was noted in this study that, in most cases, patients with SCD were not aware of this and recommend routine advice to avoid getting cold or being wet.²¹

It has been reported in other studies that, hospital admission with sickle pain increases in cold winter months even when episodes with overt infection were excluded, and speculated that this may be due to increased blood viscosity and cold diuresis.^{20,22,23} Also, dehydration, infection and other life stressors were found to either trigger or aggravate pain in individuals with SCD in this study. Apart from this, energy-demanding activities such as running exercise were revealed in this study to be among pain aggravating factors. Several other studies demonstrated the pathophysiological link between physiological or emotional stress and the occurrence of vaso-occlusive crisis among patients with SCD.^{19,23–27} It is now known that mental stress decreases microvascular blood flow, which may trigger episodes of vaso-occlusive crisis among patients with SCD.²⁵ Also dehydration in SCD, makes blood more viscous and hence increasing risk for vaso-occlusive crisis leading to severe pain.^{27,28}

The study revealed several approaches by which individuals with SCD use to deal with sickle cell pain. Most of these approaches are non-pharmacological including resting once pain arises, massaging using hot water and drinking plenty of water. Also, distraction was also found to be an effective intervention that some patient use to relieve themselves from pain. Non-pharmacological approaches are considered to be preferred methods for pain relief among individuals with SCD.^{29–31} Other non-pharmacological pain relief approaches that are used elsewhere by SCD patients are acupuncture, aromatherapy, relaxation, massage, music, vibration, therapeutic exercises and self-hypnosis.^{30,31}

Exploring the usefulness of these approaches and their effectiveness in relieving pain among patients with SCD is recommended. Introduction of these approaches could widen patients' choice for non-pharmacological approaches for pain relief which are considered to have fewer side effects.^{30,31} However, similar to other studies^{32–34} self-medication with non-steroid inflammatory drugs such as diclofenac, acetylsalicylic acid (aspirin), and acetaminophen was found in this study to be common among patient living with SCD. While this could risk users with irrational use of these drugs, the study recommends thorough assessment and individualization of therapy coupled with the use of non-pharmacologic and pharmacologic approaches.

Psychosocial-economic Implication of SCD and Coping Mechanism Utilised by SCD Patients

Findings in this study reveal that, individuals with SCD encounter psychological, sociological and economic challenges affecting their quality of life. Frequent illnesses and admissions to hospitals was found to be major cause of poor academic achievements for some participants in this study. Frequent school absence in children with SCD was found to be a predictor of poor academic performance in other countries.^{35–37} This poor academic performance has implication later in adult life, as most of them end up with low level of education hence getting difficulties in securing well-paid jobs.

Those who managed to advance in school still faced difficulties in securing stable employment due to stigmatisation or being terminated from their jobs due to frequent illness. Furthermore, physical disabilities, frequent acute and chronic pain episodes or other complications are major reasons leading to SCD patients being fired from work and leaving them economically unstable.^{12,38,39} Additionally, this study shows that, individuals living with SCD fail to establish strong courtship, experience difficulties in getting married and establish stable family life. Some female participants shared how they went through unstable relationship with their sexual partners; experienced break up of relationship and living single life after being divorced because of frequent illness or miscarriage. Other findings show how SCD individuals experience marital dysfunctions or difficulties with interpersonal relationship with sexual life partners.^{12,40} Hospital facilities should include genetic counselling and other social services targeting provision of psychosocial support for adults with SCD.

Despite the challenges implicated by the diseases, this study found a number of adoptive coping mechanisms utilised by individuals with SCD to live with the illness. The study revealed the use of religious practice such as prayers as useful means utilised by some patients as a source of hope and inner strength to cope with the disease. A study done in Nigeria found that people living with SCD commonly used religious practices as an affective coping strategy.³⁸ Religious practices such as prayer meetings are considered as effective supportive mechanism for individuals with SCD and their close families to cope with the illness.^{41–44} Religious and spiritual practices have been associated with positive health outcomes in many chronically ill adults.^{43–46} There should be a strategy to find integration of spiritual care in medical setting and this can start by assessing patients' preference of discussing religious and spiritual care during their clinical visits.

Study Limitation

This study did not involve service providers whose information could have added different perspectives particularly on the home-based self-management of pain crisis and integration of psychosocial care in medical settings. Further researches should include their views and experiences. Few individuals with SCD were selected purposively, hence limit generalization of the findings.

However, findings from this study might provide an insight that can be used to improve comprehensive care given to individuals living with SCD.

CONCLUSION

Individuals living with SCD experience several episodes of pain that affect their quality of life. Several approaches are used by individuals with SCD to self-manage the pain including taking rest, drinking plenty of water or using pain relieving medication. Care for patients with SCD should be comprehensive and should include proper management of pain, health education on home-based intervention for sickle cell pain crisis prevention, supportive services to deal with psychosocial implications of SCD and improve coping strategies to live with the illness.

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Diabetic Foot Risk Assessment among Patients with Type 2 Diabetes in Kenya

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ABSTRACT

Background: Screening for diabetic foot complications is often neglected, especially during routine and/or annual diabetes check-ups. We assessed the risk of diabetic foot complications among patients with type 2 diabetes in Kenya using the International Working Group on Diabetic Foot risk stratification guidelines to highlight the need for improved foot care.

Methods: We conducted a descriptive cross-sectional study in Mathari National Teaching and Referral Hospital in Kenya between July and October 2015. Seven hundred patients with type 2 diabetes were identified and 147 were systematically sampled. A trained podiatrist examined patients, and urine and blood samples were taken for biochemical tests and assessed by the investigating team.

Results: In total, 44(29.9%) men and 103(70.1%) women were sampled; 75(51.0%) were aged over 55 years, 113(76.9%) were overweight/obese, 117(79.6%) had poor glycaemic control and 125(85%) had never had their feet screened for complications. Thirty participants (20.4%) were categorised as being at high risk for developing diabetic foot complications while 54(36.7%) had moderate risk, 53(36.1%) had low risk and 10(6.8%) had no risk. Compared to other risk groups, those with moderate risk for developing diabetic foot problems had higher mean levels of glycosylated haemoglobin (9.4%), albumin-creatinine ratio (50.3) and high-density lipoprotein cholesterol (1.4 mmol/L) at presentation. No other differences in clinical and laboratory profiles were noted.

Conclusion: Our results show high rates of obesity, and poor glycaemic control in patients with type 2 diabetes and 56.5% of patients are categorised as being a moderate-to-high risk for foot problems. This highlights the need for healthcare professionals and patients in Kenya to be sensitised regarding the importance of foot screening to prevent lower-extremity complications.

BACKGROUND

Sub-Saharan Africa is experiencing an increase in the prevalence of non-communicable diseases, including diabetes. Specifically, the prevalence of diabetes has rapidly increased over recent decades.¹ Unmet need for diabetes care among 77% of diabetes patients² results in 80% to 90% of patients with diabetes having poor glycaemic control^{3,4} and complications including diabetic foot disease with a lifetime risk of developing foot ulcer estimated at 19% to 34%.⁵ Kenya with an age-standardized prevalence of diabetes at 2.4%,⁶ has between 27.1%⁷ and 63.4%⁸ of diabetes patients having poor glycaemic control.

Diabetic foot is often a neglected chronic complication,⁹ despite being a preventable complication,¹⁰ with an estimated rate of foot ulcers of 4% to 61% in Africa.¹¹⁻¹³ From a global perspective, complications contribute to 25% of all hospital admissions, 84% of lower limb amputations, early mortality,¹⁴ a huge cost burden^{15,16} and long-term detrimental effects on the quality of life of patients with diabetes.¹⁷ In

Africa, the complication of the diabetic foot includes a 3% to 61% rate of amputation, 55% mortality rate and 0% to 77% rate of peripheral arterial disease.^{11,12} Besides, treatment of diabetic foot is also expensive costing about USD 70 annually¹⁸ excluding the cost of managing diabetes, which ranges between USD 528.5 to USD 684.^{19,20}

Diabetic foot complications are associated with poor glycaemic control,²¹ longer diabetes duration and insulin use,²² combined with high blood pressure.²³ Whilst the presence of calluses on the feet,²³ presence of infection,²⁴ and the presence of peripheral vascular disease or peripheral neuropathy in patients with diabetes increases risk.²⁵ However, screening and foot care including regular inspection and examination of the at-risk foot; of patients, families and healthcare providers; appropriate footwear; and treatment of non-ulcerative pathology can help prevent amputation.²⁶

Currently, various studies from low- and middle-income countries, including Nigeria, Iran and Kenya,

still show poor awareness of foot care among patients with diabetes.^{27,28} For instance, in Embu and Meru Counties in Kenya, 45.1% to 51.2% of diabetes patients had poor levels of foot self-care practices which were associated with a high prevalence of diabetic foot ulcers.^{29,30} In addition, a qualitative study highlighted that delay in the presentation of diabetic foot complications is associated with a low level of knowledge and awareness of foot problems, poor health-seeking behaviours and competing for personal priorities.³¹ Importantly, even when the patient visits the hospital early, only 58% of health facilities in Kenya offer diabetes care services, of which only 74% can test blood glucose.³² Health education provided by healthcare providers is also biased towards blood glucose control and diet with very minimal or no messages on foot care practices.³³

The optimal management of diabetic foot requires a multidisciplinary team approach,³⁴ with the patients taking a key role in self-care. All diabetes patients are recommended to undergo an annual foot review or a three-month foot review for those with a history of diabetic foot infection.³⁵ Moreover, healthcare providers should provide comprehensive diabetes education, and advise patients on their risk status to effectively support self-care practices³⁶ while also screening the patients early for risk of foot ulceration.³⁷ We, therefore, aimed to assess the risk of diabetic foot complications among patients with type 2 diabetes in Kenya. The findings contribute to evidence on the risk for diabetic foot among patients with diabetes and provide an overview of the state of diabetes care at a tertiary referral hospital in Kenya.

METHODS

Study Design and Setting

We conducted a descriptive cross-sectional study involving patients with type 2 diabetes attending the Mathari National Teaching and Referral Hospital (MNTRH) between July and October 2015 following institutional review board and ethics approval. The MNTRH is one of four national teaching and referral hospitals in Kenya offering specialised inpatient and outpatient care. It is located in Nairobi, Kenya's capital city, and runs its diabetes outpatient clinic once a week. At the time of the study, the clinic had 700 registered patients with diabetes who were reviewed regularly by a diabetes nurse and consultant endocrinologist.

Sample Size

A sample size for a single proportion was calculated based on the estimated 12% prevalence (p) rate of diabetes in an urban setting in Kenya,³⁸ with a 5% precision level (e) and 95% confidence level ($z=1.96$ standard deviation correspondence to 95% confidence level). Thus, the minimum sample size (n) was calculated as follows: minimum sample size (n) = $z^2 p(1-p)/e^2 = 1.96^2(0.12)(1-0.12)/0.05^2 = 163$. The sample (nf) was adjusted for the finite study population of 700 as follows:

$nf = (N \times n) / (N + n) = (700 \times 163) / (700 + 163) = 133$. The sample was adjusted by 10% for non-response resulting in 147 participants.

Participants Selection

All the type 2 diabetes patients attending the MNTRH

diabetes clinic were eligible to participate. Upon ethical approval, patients' file numbers were entered into a computer program, which generated a random sample of 147 patients. Sampled patients were invited to participate and provided with information about this study. All sampled patients consented to the study.

Data Collection

A semi-structured questionnaire was used to collect data on participants' demographic characteristics. One trained foot care specialist performed foot examinations. This included assessing for foot ulcers, dryness, deformities, amputations, previous ulcers, calluses, and neuropathies. Peripheral sensory neuropathy was assessed using 10 monofilaments, with insensitivity at four of the 10 sites considered to indicate peripheral sensory neuropathy. Posterior tibial and dorsalis pedis artery pulses were evaluated on the same limb using a hand-held Doppler ultrasound to assess for peripheral vascular disease. Data were collected daily in English and Swahili by the researchers at the hospital's diabetes outpatient clinic until the final sampled patients were examined.

Sample Collection Method

Urine samples for kidney function tests and blood samples for blood glucose, glycated haemoglobin (HbA1c) and lipid profile tests were collected by a trained laboratory technologist. The samples were tested within 3 hours by an accredited laboratory service provider in Kenya. Participants' blood pressure was measured on two separate occasions in a sitting position, and the average value was calculated and recorded. Weight and height were measured using a Seca® weighing scale and stadiometer, respectively, and participants' body mass index (BMI; kg/m^2) was calculated.

Diabetic Foot Risk Categorisation

Diabetic foot risk was categorised according to the International Working Group on the Diabetic Foot (IWGDF) consensus guidelines. The IWGDF categorises diabetic foot risk using four groups: risk category (RC) 0 = normal foot with no neuropathy; RC 1 = loss of protective sensation; RC 2 = loss of protective sensation, deformity and peripheral arterial disease; and RC 3 = previous history of ulceration or amputation.³⁹ (Supplementary Table 1).

Statistical Analysis

Statistical analyses were conducted using STATA version 15,⁴⁰ with the level of statistical significance set at $p < 0.05$. Descriptive statistics were used to evaluate participants' demographic, clinical and laboratory characteristics and diabetic foot risk categories. A one-way analysis of variance was performed to assess the differences between the means of diabetic foot risk categories against demographic, clinical and laboratory profiles. Post-hoc analyses were performed using Bonferroni correction to assess the differences between pairs of diabetic foot risk groups.

Ethics

The Kenyatta National Hospital and the University of Nairobi Ethical Review Board approved this study (Ref: KNH-UON/A/303). The MNTRH hospital administration

granted permission to conduct this study at the hospital. Participants provided written informed consent after all study processes and procedures had been explained to them. Serial numbers were used to ensure participants were anonymous, and the data were encrypted. Access to the data was limited to maintain privacy and confidentiality following institutional and national guidelines. Study participants benefitted from this study by receiving basic screening tests and contributing to highlighting gaps in diabetes care and management.

RESULTS

Participants' Characteristics

The participants were 147 patients with diabetes: 44(29.9%) men and 103(70.1%) women. The average age was 55.1 years (range 35–81 years), and the mean duration since diabetes diagnosis was 8.1 years (range 1–28 years). One hundred and five participants (59%) had HbA1c $\geq 7.0\%$, and the mean HbA1c was 9.2% (95% confidence interval [CI]: 7.7%–8.7%). The mean low-density lipoprotein cholesterol was 3.6 mmol/L (95% CI: 2.9–4.3 mmol/L)(Table 1).

TABLE 2: Diabetic Foot Clinical Characteristics

Diabetic Foot Clinical Characteristics	n	%	95% CI
Skin moist	120	81.6	75.2–88.0
Callus/corns	69	46.9	38.8–55.1
Previous ulcers	30	20.4	13.8–27.0
Dry and cracked skin	27	18.4	12.0–24.7
Ulcers	21	14.3	8.6–20.0
Oedema	20	13.6	8.0–19.2
Vibrations	18	12.2	6.9–17.6
Peripheral sensory neuropathy	15	10.2	5.3–15.2
Discoloured skin	12	8.2	3.7–12.6
Loss of distal posterior artery pulse	12	8.2	3.7–12.6
Deformity	11	7.5	3.2–11.8
Loss of posterior tibial artery pulse	11	7.5	3.2–11.8

Diabetic Foot Risk Characterisation

Out of 147 participants, 30(20.4%) were at high risk (RC 3) for developing diabetic foot, 54(36.7%) were at low risk (RC 1) and 53(36.1%) were at moderate risk (RC 2). Only 10(6.8%) participants had no risk for diabetic foot (Table 1).

Participants' feet were characterised by calluses/corns (46.9%), dry and cracked skin (18.4%), oedema (13.6%) or discoloured skin (8.2%). Neurological examination revealed loss of vibration (12.2%) and peripheral sensory neuropathy (10.2%). Importantly, a vascular examination revealed a loss of distal posterior artery (8.2%) and posterior tibial artery (7.5%) pulses and deformity (7.5%). A minority of participants reported previous ulcers (20.4%) (Table 2).

Association between Diabetic Foot Risk and Clinical Variables for Diabetes Control

Participants in RC 2 and 3 had a high average fasting blood sugar (12.2 mmol/L and 11.3 mmol/L, respectively) and HbA1c (9.4 g% and 9.2 g%, respectively). Participants in RC 2 had the highest mean levels of serum high-density lipoprotein cholesterol (1.4 mmol/L) and urine albumin-creatinine ratio (50.3), and those in RC 3 had the lowest level of serum low-density lipoprotein (2.8 mmol/L). However, there were no significant differences between and within the means of the diabetic foot risk groups and demographic, clinical and laboratory variables (Table 3 and Supplementary Table 2).

DISCUSSION

The findings demonstrate that the majority of the sampled population with diabetes had an increased risk of developing diabetic foot complications. One-fifth of participants were at high risk for developing diabetic foot, 36.7% had low risk and 36.1% had moderate risk. The proportion of patients with diabetes that had a high risk for developing diabetic foot was similar to a previous study conducted at the largest teaching and referral hospital in Kenya.⁴¹ However, we report higher numbers of patients with low (36.7%) and moderate (36.1%) risk for diabetic foot were higher than reported in other studies.^{37,41,42} For example, the proportion of participants with no risk of developing diabetic foot in our study was much lower than observed in comparative studies in other low-resourced countries e.g., 37.3% in Egypt,⁴² 57% in Kenyatta National Hospital,⁴¹ and 72.7% in Tunisia.³⁷ The high proportion of patients with diabetes at high risk of developing diabetic foot in our study may be explained by several local reasons. These include a low awareness and poor knowledge of diabetes management and complications amongst patients and healthcare workers;^{30,43} inadequate or lack of proper foot care among patients with diabetes;^{29,33,44,45} and low levels of diabetic foot screening and foot self-care.^{29,30,33} The poor foot screening practice may be because tools and equipment in diabetes clinics for diabetic foot screening (e.g. Doppler ultrasound machines) are not universally available.³² Thus, highlighting the fact that foot care is possibly a neglected part of diabetes management. The diabetic foot risk classification has been proposed as an effective tool to prevent lower-extremity complications of diabetes and can form part of a screening system.^{42,46}

The proportion of participants with previous ulcers in our study was higher than in a recent study in Kenya where only 1.6% and 3.8% of patients had a history of or active foot ulcers, respectively.⁸ This was, however, similar to previous studies in sub-Saharan Africa that reported 16%⁴¹ and 4% to 61%^{11,12} rates of previous foot ulceration. The high rate in our study may be explained by the high risk of developing diabetic foot among our participants, most of whom also had calluses/corns and infections that are associated with diabetic foot complications.^{23,36,46} However, in our study, we noted fewer foot deformities compared with a previous study in Tunisia where 43.6% of the participants had foot deformities.³⁷

Previous studies identified several risk factors for developing diabetic foot ulceration, including longer duration of diabetes, poor glycaemic control, diastolic hypertension and poor self-care.^{44,47} Our study found that most patients with diabetes had poor glycaemic control,

TABLE 1: Participants' Demographic, Clinical and Laboratory Characteristics

Demographic variables (N=147)	n	%	95% CI
Sex			
Male	44	29.9	23.0–37.9
Female	103	70.1	62.1–77.0
Age, years			
<45	20	13.6	8.9–20.2
45–54	52	35.4	28.0–43.5
55–64	47	32.0	24.9–40.0
>65	28	19.1	13.4–26.3
Marital status			
Single	15	10.2	6.2–16.3
Married	102	69.4	61.4–76.4
Widowed	18	12.2	7.8–18.7
Divorced/separated	12	8.2	4.7–13.9
Education			
No formal education	19	12.9	8.4–19.5
Primary school	58	39.5	31.8–47.7
Secondary school	58	39.5	31.8–47.7
Tertiary	12	8.2	4.7–13.9
Occupation			
Formal employee	23	15.7	10.6–22.5
Self-employed	78	53.1	44.9–61.1
Casual	12	8.2	4.7–13.9
Unemployed	34	23.1	17.0–30.7
Diabetic foot risk category*			
0 – No risk	10	6.8	2.7–10.9
1 – Low	54	36.7	28.9–44.6
2 – Moderate	53	36.1	28.2–43.9
3 – High	30	20.4	13.8–27.0
Clinical and laboratory variables	Mean	SD	Range
HbA1c, g/dL	9.2	2.2	5–15
Cholesterol, mmol/L	5.1	1.2	1.9–10
Low-density lipoprotein cholesterol, mmol/L	3.1	1.1	0.8–6.1
High-density lipoprotein cholesterol, mmol/L	1.3	0.5	0.1–4
Triglyceride, mmol/L	1.9	1.5	0–13.2
Urine albumin creatinine ratio	47.2	29.5	1–106
Fasting blood sugar	11.4	4.8	4.9–25
Body mass index, kg/m ²	27.7	5.2	2–41

CI: confidence interval; HbA1c: glycated haemoglobin; SD, standard deviation. * Risk categorisation from the IWGDF (2015), utilised in diabetic foot screening – RC 0: Normal foot with no neuropathy; RC 1: Loss of protective sensation; RC 2: Loss of protective sensation, deformity and peripheral arterial disease and RC 3: Previous history of ulceration or amputation

which increased the likelihood of developing diabetes complications and a mean duration of 8.1 years. However, similar to studies in Botswana and Saudi Arabia,^{48,49} we found no significant association between poor glycaemic control and diabetic foot risk groups; though intensive glycaemic control, which significantly decreases the risk of amputation among patients with type 2 diabetes is needed.⁵⁰ In addition, there is a need for enhanced training of healthcare providers on comprehensive management of diabetes, health education among patients on diabetic foot prevention and management and a multidisciplinary approach to preserve limbs in low-resourced settings.⁵¹

Already, the Ministry of Health in Kenya through funding from the World Diabetes Foundation is investing in equipping at least 350 health centres, establishing 52 diabetic foot care centres, establishing a mobile foot care clinic for hard-to-reach areas, and training 1000 healthcare professionals at primary level and 3000 community health workers on diabetic foot care and education to strengthen prevention and management of diabetes and diabetic foot in Kenya.⁵² Moreover, at least in the capital city, evidence shows that most healthcare professionals are trained in the management of diabetes.⁵³ While these efforts are being implemented, Kenya

TABLE 3: Differences in Diabetic Foot Risk Categories by Demographic and Clinical Variables

Variables	Diabetic Foot Risk Category, Mean (SD)				p-value ¹
	0	1	2	3	
Age, years	57 (8.89)	55.30 (11.10)	54.58 (9.82)	54.8 (9.65)	0.8674
Glycated haemoglobin, g%	9.21 (2.31)	8.90 (2.11)	9.43 (2.23)	9.21 (2.06)	0.7734
Cholesterol	5.76 (0.68)	5.15 (1.44)	5.21 (1.22)	4.74 (0.91)	0.0664
Low-density lipoprotein cholesterol, mmol/L	3.68 (0.98)	3.02 (0.98)	3.25 (1.21)	2.77 (0.85)	0.1154
High-density lipoprotein cholesterol, mmol/L	1.24 (0.36)	1.27 (0.43)	1.41 (0.63)	1.18 (0.39)	0.2142
Triglyceride, mmol/L	1.94 (1.04)	1.91 (2.00)	1.82 (1.04)	1.86 (1.02)	0.7231
Urine albumin creatinine ratio	39 (26.16)	47.04 (32.4)	50.30 (27.3)	44.7 (29.16)	0.3864
Fasting blood sugar	10.53 (4.86)	10.98 (4.92)	12.17 (4.71)	11.25 (4.87)	0.8181
Body mass index, kg/m ²	29.3 (6.15)	27.46 (4.16)	27.74 (6.48)	27.76 (3.99)	0.5874

¹ Differences in average clinical characteristics between diabetic foot risk was assessed using one-way analysis of variance rank test. SD, standard deviation.

remains with a significant shortage of foot specialists resulting in untrained healthcare professionals to provide foot care, which may sometimes not be comprehensive to preserve patients' limbs.

Strengths and Limitations

The present study was limited to one referral hospital and included a small sample; therefore, the results cannot be used to generalise the current risk of diabetic foot in Kenya. However, this study indicates the magnitude of the risk of diabetic foot in Kenya, especially considering that foot examination is not routine practice in most health facilities. Moreover, we lacked some equipment such as a Doppler ultrasound machine to measure the absence of vibratory perception (neuropathy) and a blood pressure machine to measure the ankle-brachial index. Our study did not also assess the potential confounders to developing diabetic foot including the duration of seeking care at the clinic. Despite these limitations, the study provides evidence of the possibility of using the diabetic foot risk classification system in Kenya and forms a basis for further studies on clinical outcomes after diabetic foot risk assessment.

Implications for Practice and Health Policy

These findings highlight a need for diabetic care facilities to strengthen the provision of comprehensive diabetes care including foot examination and diabetes education. Routine management of patients with diabetes should include foot examination and risk stratification to improve the quality of care provided to this population. Healthcare providers should also undergo foot examination training to be able to screen patients with diabetes for risk of developing diabetic foot, and investment should continue to be made in foot examination tools and equipment to help detect early signs of foot ulcers. The findings also highlight that a large number of patients with mild to moderate risk of diabetic foot disease exist indicating a need for comprehensive diabetes care including foot

examination and diabetes education and ongoing risk stratification to improve the quality of care provided to this population. Therefore, investment in foot examination and risk assessment training and a screening program with the availability of foot examination tools and equipment to help detect early signs of foot ulcers is essential and reduces the rate of unnecessary amputations.

CONCLUSION

The observations in this study provide a direct assessment of diabetic foot disease and risk and foot care in Kenya among patients with diabetes receiving care at an urban referral hospital. The practice of diabetic foot screening is poor in our study setting, and efforts should be made to routinely screen patients for diabetic foot complications. Healthcare professionals, providers and patients should be sensitised about the importance of foot screening to prevent lower-extremity complications. Moreover, even in a large institution like ours, the lack of some equipment prevents accurate assessment and the extent of neuropathy and vascular supply. Notwithstanding these limitations, the study provides evidence of the high incidence of patients with moderate foot risk in Kenya and forms a basis for further studies to identify foot disease and improve clinical outcomes. As this is among the first studies in Kenya on this topic, more research is needed to explore the feasibility of diabetic foot risk stratification and the needs of this population.

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Correlation of Malaria Rapid Test and Peripheral Blood Smear Microscopy among Patients attending Byumba Health Centre

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ABSTRACT

Background: Malaria presents a diagnostic challenge in most tropical countries including Rwanda. Microscopy remains the gold standard for diagnosing malaria, however, it is labour intensive and depends upon the skill of the examiner. Malaria rapid diagnostic tests (MRDTs) have been developed as an easy, convenient alternative to microscopy.

Methods: A cross sectional study was conducted from October to November 2019 on 130 febrile patients who were directed to the laboratory department for blood screening for malaria parasites at Byumba Health centre. The main objective of this study was to correlate Microscopy and MRDTs in diagnosis of malaria.

Results: After signing a consent form, blood samples were collected and screened for malaria parasites microscopically and by using MRDTs. Data collection forms were filled with relevant information and obtained results for MRDTs and for peripheral blood smear were recorded. The collected data were statistically analyzed using GraphPad Prism 9 software. The mean age found to be 16 years old. In this study peripheral blood smear microscopy was considered as a reference method. The sensitivity and specificity of RDT Histidine-Rich Protein 2 (HRP-2) were calculated and found to be 96.6% and 60% respectively. The negative predictive value was found to be 92.85% where positive predictive value was 73.3%.

Conclusion: MRDTs should be used along with microscopy to avert complications associated with delayed diagnosis and similar studies are required to identify alternative techniques with high specificity for the diagnosis of malaria.

BACKGROUND

Malaria is one of the highest killer diseases affecting people in tropical countries especially in Africa. The 2019 World Health Organization (WHO) Malaria Report estimates that there were 228 million malaria cases and 405,000 deaths in 2018. According to WHO, the first priority for all countries where transmission rates of malaria are high or moderate is to ensure maximal reduction of morbidity and mortality through sustained provision of universal access to quality-assured and appropriate vector control measures, diagnostics and antimalarial medicines, while retaining the long-term vision of malaria eradication.¹ Of all the human malaria parasites, *Plasmodium falciparum* (*P. falciparum*) is the most common pathogenic and is frequently fatal if untreated in time.² Traditionally, in sub-Saharan Africa, outpatients presumptively treat malaria based on patient's history of fever, however, different studies report that a significant proportion of patients treated

this way may not be infected with malaria causing parasites (over 50% in many settings) and hence resulting into wastage of considerable amounts of drugs.³ However, this old clinical based practice is still relevant today especially, in cases involving infants where the time spent on getting a confirmatory laboratory diagnosis could lead to increased fatality.⁴ WHO currently makes the tentative recommendation that parasite-based diagnosis should be used in all cases of suspected malaria with the possible exception of children in high-prevalence areas and certain other situations.⁵ For this recommendation to be adhered to obviously, rapid and accurate laboratory finding or demonstration of malaria parasite should be established. The traditional method of microscopic identification of parasite however, is not only daunting in poor power setting, but also time consuming and requiring a lot of expertise/training. Thus, the peripheral blood smear examination technique is generally used, however, it is limited to large clinics/tertiary centres. This conventional

staining of peripheral blood smears/microscopy still remains the gold standard in laboratory diagnosis of malaria.⁴ Malaria Rapid Diagnostic Tests (MRDTs) are commercially available in kit forms with all necessary reagents and the ease of performance of the procedures does not require extensive training or equipment to perform or to interpret the results. Results are read in 12 to 15 minutes. MRDT mainly come in two forms. One is antigen based and normally requires the use of haemolysed red blood cells while the other is antibody based and normally requires the use of extracted serum. Generally speaking, antibodies are better expressed in serum otherwise plasma could also stand in place of serum for antibody-based method.⁶ This study aimed to correlate Microscopy and MRDT (Histidine – rich protein 2 (HRP-2), Ag of *plasmodium falciparum*) in diagnosis of malaria at Byumba Health centre.

METHODS

Study Area

This study was conducted out in the laboratory department of Byumba Health Centre, located in Northern Province, Byumba Sector, Gicumbi District, Rwanda. The city lies about 60 kilometres (37 mi), north of the capital Kigali. This location lies approximately 30 kilometres (19 mi), south of the International border with Uganda at Gatuna.

Study Design and Period

A cross sectional study design was conducted among patients of Byumba Health Centre. Data was collected from October to November 2019.

Study population and Sample Size

130 Samples that tested for Malaria were used. The samples were taken from patients who attended Byumba Health Centre between October and November 2019.

Inclusion and Exclusion Criteria

All male and female patients attending Byumba Health Centre between October and November 2019 with clinical suspicion of malaria based on fever and or history of fever within the previous 48 hours were eligible for inclusion in the study. Lack of consent and incomplete data constituted the exclusion criteria.

Ethical Consideration

The study was approved by the research committee of Byumba Health Centre, accredited by Byumba District Hospital. The objectives and procedure were carefully controlled according to set Standard Operating Procedures (SOPs). Written consent was sought for from study participants or study participant's caretaker for minors. To ensure confidentiality, numbers were used as study participants' ID instead of names on patient's data extraction forms.

Sample Collection and Processing

After filling the consent form, Blood sample was collected from the middle or ring finger of the patient by using lancet. 5ul of whole blood from the finger was added into MRDT, then 4 drops of assay diluents were added into MRDT according to the manufacture's protocol and test to detect malaria parasite/ antibody detection method. The results were read after 15 min. Similarly, peripheral

blood smears were made on a clean slide and allowed to air dry before being sent to the Parasitology laboratory. 10% Giemsa stain was used to stain thick smear for 15 minutes and tested with right microscopy. The results from both MRDT and microscopy were reported qualitatively (Positive or Negative). MRDT results and thick smear results were recorded on the data collection sheet. This was done within one hour from the collection time. Materials were consisted of Giemsa stain, microscopic slides, and light microscopy with good 100X objectives, MRDTs kits and lancets.

Data Collection and Analysis

Collected data was checked and analysed using GraphPad Prism 9 software. The validity of diagnostic test was used in calculation and then the measurements were reported in number and percentage.

RESULTS

Demographic Characteristics of Study Subjects

The study considered a total of 130 participants; 70(54%) females and 60(46.1%) males. The mean age of the participants was found to be 16 years. The demographic characteristics of the study subjects are shown in Table 1;

TABLE 1: Demographic characteristics of the study participants

Characteristics	Gender		Total
	Female	Male	
Age (Years)			
1-24	47	28	75 (57.6%)
25-34	10	18	28 (21.5%)
35-44	7	4	11 (8.4%)
45-54	4	6	10 (7.6%)
55-77	2	4	6 (4.6%)
Total	70 (53.8%)	60 (46.2%)	130 (100%)

Proportions of malaria by MRDT and peripheral blood smear microscopy are presented in table 2. True positive and true negative results were 44.6% and 40 % respectively while false positive and false negative results were 12.3% and 3.07% respectively.

TABLE 2: Malaria Status by MRDT and Peripheral Blood Smear's Microscopy

Positive for mRDTs & for microscopy	True positive=58 (44.6%)
Negative for mRDTs & for microscopy	True negative=52 (40%)
Positive for mRDTs & negative for microscopy	False positive=16 (12.3%)
Negative for mRDTs & Positive for microscopy	False negative=4 (3.07%)

Sensitivity of MRDTs in Diagnosis of Malaria

In this study, microscopy was considered as a method of reference. The sensitivity of MRDTs HRP2 in diagnosis of malaria is reported at 96.6%, this is presented in Table 3. Therefore, 44.6% of the patients who tested positive with

both methods (peripheral bold smear microscopy and MRDTs) were considered true positives. Patients who tested negative with MRDT and positive to peripheral blood smear microscopy were 3.07% and these were considered false negative. This high sensitivity (96.6%) may be due to factors relating to how health community workers transported the MRDTs, thus being damaged by extreme temperature or humidity during transportation, and storage. These results are in contradiction with what was reported by a study elsewhere, where the sensitivity was 76.9%.¹⁵

TABLE 3: Sensitivity of MRDTs (HRP-2) in Diagnosis of Malaria

Variables & Formula	Values
True positive	44.60%
False negative	3.07%
$\text{Sensitivity} = \frac{44.6}{(44.6 + 3.07)} \times 100$	96.60%

Specificity of MRDTs in Diagnosis of Malaria

Table 4 shows the specificity of MRDT (HRP-2) at 76.4% in diagnosis of malaria. True negative was 20.45% (patients who tested negative by both MRDT and peripheral blood smear microscopy), whereas the false positive was 12.3%, (patients who tested positive with MRDTs but tested negative with peripheral blood smear microscopy). Transportation of MRDTs, sample correction, storage and humidity could be the factors responsible for the low specificity and this result is in contradiction with what was reported in a similar study elsewhere where the specificity was 94.2%.¹⁶

TABLE 4: Specificity of MRDTs (HRP-2) in Diagnosis of Malaria

Variables & Formula	Values
True Negative	40.0%
False Positive	12.3%
$\text{Specificity} = \frac{40}{(40 + 12.3)} \times 100$	76.4%

Predictive Values of MRDTs in Diagnosis of Malaria

Predictive values of MRDT (HRP-2), positive and negative were calculated as shown in Table 5. Negative predictive value was found to be 92.87% whereas positive predictive value was 78.38%. The negative predictive values of MRDTs were high compared to the positive predictive values and were in contradiction to the study conducted in Egypt which was 96.2%.¹³ These results mean that if you tested negative for Malaria by MRDT (HRP-2), you would have 92.85% chances of not having the disease. When you tested positive for Malaria with MRDT (HRP-2), you

would have a chance of 73.3% of truly having the disease.

TABLE 5: Positive and Negative Predictive Values of MRDT in Diagnosis of Malaria

Variables & Formula	Values
True negative	40.00%
False negative	3.07%
True positive	44.60%
False positive	12.30%
$\text{PPV} = \frac{44.6}{(44.6 + 12.3)} \times 100$	78.38%
$\text{NPV} = \frac{40}{(40 + 3.07)} \times 100$	92.87%

PPV: Positive predictive values NPV: Negative predictive values

DISCUSSION

Malaria affects a significant number of people across the world each year and is the most wide-spread parasitic disease encountered.⁷ The disease has a worldwide distribution and is found throughout the tropics, sub-Saharan Africa, South East Asia, the Pacific islands, India, Central and South America. Malaria caused by *Plasmodium falciparum* predominates in Africa where the mortality attributed to it approaches 1 million annually, and accounts for 90% of the global malaria burden.⁸ Majority of these deaths are of children under the age of 5 years. Thus, one child dies of malaria in Africa every 30 seconds, which translates into a tragic 3000 children each day. Many of the children who survive an episode of severe malaria suffer from brain damage and cognitive disability, consequently crippling these families with its debilitating aftermath.⁹ Malaria presents a diagnostic challenge in most tropical countries like Rwanda. Microscopy remains the gold standard for diagnosing malaria, but it is labour intensive and depends upon the skill of the examiner. RDTs have been developed as an easy, convenient alternative to microscopy.¹⁰ Poor diagnosis of malaria implies under diagnosis and inappropriate treatment procedures.³ MRDTs are known to capture at least 3 target antigens: lactate dehydrogenase (LDH), *Plasmodium falciparum* histidine-rich protein 2 (PfHRP2) and pan-plasmodial aldolase. HRP-2 MRDTs are the most sensitive for parasite detection and are heat-stable under field conditions compared to the other antigen tests.¹² However, HRP-2 MRDTs have limitations, as their performance has been shown to be affected by product quality and parasite-related factors such as *pfhrp2/3* gene deletion, non-*P.falciparum* species and prozone effects that may lead to false-negative MRDTs.¹³ Microscopy is the most widely tool used to diagnose malaria at peripheral levels. In capable hands it is very sensitive for parasitaemia $\leq 50/\mu\text{L}$ (0.001%)¹⁹ and it can give important information to the clinician like species, parasites stages and parasite density.

The observed high sensitivity (96.6%) and specificity in

this study is similar to reports of other studies conducted elsewhere.^{17, 18} The study also observed high negative predictive values of MRDTs compared to the positive predictive values. This finding is in contradiction with findings of a similar study conducted in Egypt.¹³ Several studies conducted elsewhere have shown varying degree of false negative result for MRDT because of hyperparasitaemia, deletion or mutation of *HRP-2* gene and the prozone effect (which is defined as false-negative or falsely low results in immunological reactions because of excess of either antigens or antibodies).^{20,21}

CONCLUSION AND RECOMMENDATIONS

This research on the correlation of malaria rapid test and peripheral blood smear microscopy has been carried out on patients who attended Byumba Health Centre, suspected to have malaria. The sensitivity of HRP-2 based Rapid diagnostic test for malaria was (96.6%) and high to the specificity of this type of MRDT with 76.4%. The negative predictive values of MRDTs were high compared to the positive predictive values. If you tested negative for Malaria by MRDT (HRP-2), you would have 92.87% chances of not having the disease. When you tested positive for Malaria with MRDT (HRP-2), you would have a chance of 78.38% of truly having the disease. In this study, there are tests that were considered as false positive (positive for MRDTs and negative for peripheral blood smear microscopy) while Other tests were reported as false negative (negative for MRDTs and positive for peripheral blood smear microscopy). The results obtained by MRDT (HRP-2), for malaria parasites should be confirmed with other Tests of high specificity such as microscopy and Polymerase Chain Reaction. Health professionals are recommended to confirm MRDTs results with microscopy before administering treatment and precautions on the uses of MRDTs, transportation of kits and samples correction should be taken into consideration. Further studies should determine the most appropriate type of malaria diagnostic test to be used in combination with microscopy and MRDTs.

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