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# From Preparedness to Recovery: Learning Lessons Of COVID-19 Outbreak from China

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## SUMMARY

At the end of December 2019, the Chinese public health authorities reported several cases of acute respiratory syndrome in Wuhan City, Hubei province, China. Chinese scientists soon identified a novel coronavirus as the main causative agent. The disease is now referred to as coronavirus disease 2019 (COVID-19), and the causative virus is called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The COVID-19 outbreak was declared a pandemic by the World Health Organization on March 12th, 2020. COVID-19 propagates quickly and threatens the population at large; around 20% of affected populations have presented severe forms of the diseases. In China approximately ~5% cases became critical patients in need of admission to intensive-care units. The need for intensive care has led to unprecedented overcrowding in hospitals, with catastrophic situations witnessed in Italy and other countries. The highest mortality rates have been witnessed amongst the elderly with several comorbidities. In this viewpoint we draw lessons from the implementation of population containment measures, vulnerable people protection and relevant public health pillars in China. We then discuss how these lessons can or cannot be applied to other settings.

## BACKGROUND

COVID-19 is a severe acute respiratory syndrome (SARS) with pandemic characteristics that was first reported in Hubei province, Wuhan City in central China in December 2019.<sup>1</sup> It is caused by novel coronavirus 2019 (nCoV-2019), one of the coronaviruses family. In 2002 another SARS coronavirus (SARS-CoV) first infected humans in the Guangdong province of southern China – By 2003 (when it was formerly identified) the epidemic had affected 26 countries and resulted in more than 8,000 cases.<sup>1,2</sup> Another coronavirus disease known as the Middle East respiratory syndrome (MERS) was first identified in 2012 and caused 858 deaths across 27 countries.<sup>3</sup> Although COVID-19 is known to have a lower mortality rate than MERS, its quick propagation makes it very dangerous. Some estimates suggest that half of the world's population will be infected and around 100 million will die.<sup>2</sup> International outbreaks and pandemics of infectious diseases have been present throughout history. In the mid-13th century, the Black Death killed more than 50 million in Europe and the Mediterranean region and 20 million people in India. In 1918-1919 Spanish influenza killed between 50-100 million people.<sup>4,5</sup> Measles killed 630,000 people in 1990, and Cholera has killed numerous people in seven known historical large outbreaks and continues to have a devastating impact in sporadic cases around the world.<sup>6</sup> By the end of May 2020, COVID-19 had already spread across the World infecting 5.2 million people and had claimed 337,687 lives. At the time of writing, the United States had the highest

number of cases (1,568,448 cases) and the largest death toll of 94,011.<sup>7</sup> Alarming, high case numbers were also reported in the Russian Federation with 344,481 cases at the time of writing. In Europe, the United Kingdom had registered the highest death toll (36,675).<sup>7</sup> In addition to the mortality and case numbers, the impact of the COVID-19 pandemic has manifested in significant psycho-social and economic burdens, especially in the most affected countries. Such impacts have been caused by restrictions of movement and social gatherings.<sup>8</sup> China had the earliest experiences of living within this pandemic disease, and important lessons can be learned from their experiences. Currently, China's preventive measures of COVID-19 like wearing masks, hand wash with soap/sanitizers, social distancing, and social gathering avoidance, and isolation, confinement provided promising results.<sup>9</sup> Africa ranked the last continent and at the time of writing had significantly fewer cases (77,295) and fewer deaths (2,073) where Americas ranked first with 2.3 million cases and 138,116 deaths. Within Africa, South Africa ranked first with 2,343 cases and followed by Egypt with 16,513 cases but with elevated COVID-19 mortality in Africa (735 deaths).<sup>7</sup> The total cases within the East African Community countries was 2,943 with 78 deaths. At the time of writing, Kenya had registered the most COVID-19 cases (1,192) and deaths (50) compared to other countries of the East African community.<sup>7</sup>

### Case Fatality Rate and ICU Admissions

In February of 2020, the COVID-19 case fatality rate (CFR) in China was 2.3%. In March of the same year, the CFR in Italy

was 7.2% mainly due to the high aged population. There was no death recorded in those under 9 years of age, however, the older aged group mortality increased where the group of 70-79 years case fatalities was 12.5% in Italy and 8.0% in China. The group of 80 years and above was 20.2% in Italy and 14.8% in China.<sup>3,10</sup> The CFR increased to 49.0% (1023 of 2087) in critical cases. It was also elevated for patients with comorbidities among other cardiovascular diseases with CFR of 10.5%, diabetes with CFR of 7.3%; chronic respiratory diseases with CFR of 6.3%, high blood pressure with CFR of 6.0%, Cancer with CFR of 5.6%.

In total, 1,716 of health workers were infected by COVID-19 in China where 14.8% were classified in severe or critical cases, and 5 deaths were recorded.<sup>3,11,12</sup> In Italy, 16% of all patients were critically ill and required to be taken care of in ICU while only 5% was admitted to ICU in China. The increase of critical status patients in Italy immediately suffocated their health care system especially their intensive-care units. This has emphasised the application of population containment strategies such as lockdown to slow down COVID-19 spreading.<sup>13</sup>

In this viewpoint, we considered the application of COVID-19 prevention, mitigation, and control in low-income countries, especially in Africa. The aim is to assist country response teams in their choice of which evidence-based strategies they could adopt to proactively prevent the exponential growth of the COVID-19 pandemic.

### The Journey from Preparedness to Recovery

This may have speeded the recovery as per the International Health Regulation (IHR) 2005 for minimising multi-sectoral pandemic negative effects.<sup>14,15</sup> The adaptation of the World Health Organization road map to professional and surge logistic requirement capacity would be oriented to a planned recovery.<sup>16</sup> Succeeding over the COVID-19 outbreak requires planning, organization, implementation, evidence-based monitoring, and evaluation. The World Health Organization created 7 key points to follow as the next step after the preparedness and response plan. The seven key points of the recovery road map are to (1) appoint lead planners, (2) engage stakeholders, (3) map gaps, (4) address gaps, and (5) engage donors, (6) track progress, and (7) review. The adaptation of these key points will be the recovery cornerstone.<sup>14</sup>

### Lesson Learned From China

China's health emergency response was based on four grades defined according to the incident gravity.<sup>17</sup> The evaluation of country preparedness and improvement was extremely important to ensure the readiness and outbreak response effectiveness.<sup>18</sup> The timing of the COVID-19 emergence was challenging, the cases had already steadily increased in China and the government was forced to make difficult decisions around the time of the annual Lunar New Year. During this time more than 1 million people travel to visit their families. The celebration leads to large gatherings, crowded buses, planes and significant movement across the country and globally.<sup>3</sup> The action taken in China built on lessons learned from the 2002-3 SARS outbreaks, where there was no emergency planning and no mechanism. However, after 2003, China established a plan that was later called: One plan, three strategies which consisted of four-level from top to community leadership.<sup>18</sup> China focused on traditional public health outbreak response tactics including: isolation; quarantine; social distancing; community containment; local government food provision for effective quarantine.<sup>3</sup>

### The following lessons can be learned from these early responses in China

The Chinese early responses to coronavirus were divided into three stages based on the disease outbreak, the required response, the situation of risk and ecological conditions. The situation of an outbreak emergency was also adapted to the level of emergency response mechanism in respect of assessed emergency grade.<sup>14</sup> Beijing showed that the emergency response must be based on four-party responsibilities (territorial, departmental, employer and individual responsibilities) which required us to consider the role of the employers and companies (Table 1).<sup>19</sup>

#### First stage: Before January 19, 2020: Initial partial control approach.

This phase was dedicated to the investigation, identification of a causative virus, notification, planning, initiation of public health pillars, and provision of initial technical protocol for diagnostic and control.<sup>20,21,22</sup>

- Outbreak announcement;
- Investigation and response by the National Health Commission (NHC) and China CDC;
- Huanan seafood and the wholesale market closed;
- Regular WHO and relevant countries information, the region and China's Hong Kong, Macao and Taiwan about the pneumonia outbreak;
- Implementation of some of 8 public health pillars and technical protocol issuance for Wuhan and WHO notification by the NHC. Emphasis on the point of entry to prevent the exportation and importation of cases for the Hubei surrounding provinces (Table 1);
- Wearing a mask to prevent the disease;
- Multisectoral mechanism initiated;
- Completion of gene sequencing by China CDC and isolation of Novel SARS CoV2;
- Adequate logistic preparation for medical equipment and contained people.

#### Second stage: Jan 20 to February 7, 2020: Intensive approach for outbreak intensity reduction.

Comprehensive adoption of various control measures in accordance with the law.<sup>21</sup>

- Establishment of the novel coronavirus infected pneumonia as a notifiable disease and its inclusion into infectious diseases and quarantine law;
- Ensure market supply and all medical requirements;
- Active treatment of cases, deaths reduction in Wuhan;
- Publication of the third version of Coronavirus diagnostic and treatment guideline western and traditional medicine;
- Designation of health facilities for the COVID-19 treatments;
- Contracting five companies for active cases and cluster finding and contact tracing;
- Daily communication on COVID-19 situation by NHC;
- Multisectoral mechanism enhanced by state counsel (social mobilisation, community communication and involvement, NGOs and international community support);

**TABLE 1: The 8 Public Health Prevention Pillars**

Pillars	Country Crisis Team	Companies Crisis Team
<b>Coordination, plan and monitoring</b>	<ul style="list-style-type: none"> <li>• Initiate multi-sectoral and multi-partner coordination mechanism;</li> <li>• Establish public health emergency organs for incident management;</li> <li>• Strategic preparedness and response plan along with Country operational preparedness and response plan, Monitoring and evaluation plan (M&amp;E), tracking effectiveness, review, and lessons learned.</li> </ul>	<ul style="list-style-type: none"> <li>• Appoint a company crisis team lead;</li> <li>• Identify and designate interdepartmental agents to participate in Crisis team;</li> <li>• Create Company COVID-19 preparedness and response plan, tracking effectiveness, regular situation report, and work patterns change policies within the company with alignment with the country situation.</li> </ul>
<b>Risk Communication and community engagement</b>	<ul style="list-style-type: none"> <li>• Initiate multi-sectoral and multi-partner coordination mechanism;</li> <li>• Establish public health emergency organs for incident management;</li> <li>• Strategic preparedness and response plan along with Country operational preparedness and response plan, Monitoring and evaluation plan (M&amp;E), tracking effectiveness, review, and lessons learned</li> </ul>	<ul style="list-style-type: none"> <li>• Company based communication plan, regular communication of policies, memos and all outbreak related information from the crisis team, Administrative work change policies;</li> <li>• Prepare and monitor internal information based on rumors or misinformation on the crisis and give real evidence based information to follow guidance and to ensure workplace community engagement;</li> <li>• Ensure changes are done and document lessons learned.</li> </ul>
<b>Surveillance, Rapid response and case investigation</b>	<ul style="list-style-type: none"> <li>• Case definition, Rapid and active case detection and Findings of the imported case and local transmission;</li> <li>• Case-based reporting within 24hours, transmission intensity, contacts traceability, disease trend, case fatality ratio;</li> <li>• Prepare trained response team for rapid case investigation and contact traceability, test existing system, and document lessons learned..</li> </ul>	<ul style="list-style-type: none"> <li>• Prepare manual and electronic reporting forms;</li> <li>• Inform the national surveillance system through existing reporting by the occupation clinics if you have the case;</li> <li>• Call the national rapid team investigation if there is a case to investigate.</li> </ul>
<b>Point of entry</b>	<ul style="list-style-type: none"> <li>• Initiate point of entry Public health emergency plan, temperature monitoring and traveling history and associated signs and symptoms, dissemination of current information, Risk assessment screening chart, Standard operating Procedures to manage diseased passengers;</li> <li>• Prepare equipped temporary isolation facilities and safe transport to a designated area for COVID-19;</li> <li>• Communicate information about travelers, monitor effectiveness, and adjust accordingly.</li> </ul>	<ul style="list-style-type: none"> <li>• The point of entry is one of the crucial areas to take care of in the organization; to understand the mechanism of disease entry and who has brought it, and help to know the traceability of his or her contacts (before entry screening chart);</li> <li>• Check and monitor temperature and flu-like symptoms would be with capital importance to orient the person to a designed occupational clinic for further investigation);</li> <li>• Prepare according to triage guidance with regular review and adjust accordingly.</li> </ul>

*Continued*

**TABLE 1: Continued**

Pillars	Country Crisis Team	Companies Crisis Team
<b>National Laboratories</b>	<ul style="list-style-type: none"> <li>• Guidance of specimen collection and test procedure, surge plan of materials in the needed test, liaise with the international laboratory, trained staff, safety, accessibility with free emergency numbers;</li> <li>• Link data with epidemiological analysis and reporting, develop quality assurance, and monitor effectiveness and document lessons learned.</li> </ul>	<ul style="list-style-type: none"> <li>• Training of laboratory staff for nasal and oral swab collection and liaise with the national laboratory for the test or if not done on-site liaise with crisis team and national laboratory;</li> <li>• Support the national laboratory to get the tests.</li> </ul>
<b>Infection prevention and Control</b>	<ul style="list-style-type: none"> <li>• Assess Infection prevention and control (IPC) capacity in the healthcare system and in the community: Health workers safety, correct PPE with respect of donning and doffing, Respect aseptic procedure of medical material, surface and objects disinfection, general hygiene monitoring and hand hygiene performance, Gloves usage respect rules of obligatory isolation and terminal hygiene and disinfection;</li> <li>• Trained teams to educate people through existing for behavior change such as avoid gathering, observe the social distance, staying home through community networks, local authorities, and monitor effectiveness.</li> </ul>	<ul style="list-style-type: none"> <li>• Occupational clinic staff and Medical infrastructure safety and environmental and industrial hygiene respect, surface disinfection, door handles, tables, phones; and other touchable electronic devices using 75% Alcohol based disinfectant or chlorine with concentration caution for avoiding industrial metals oxidation;</li> <li>• Educate people for Changing the behavior of handshaking, touching faces or colleagues, community gathering. Ensure the social and physical distancing at least one meter if approaching others;</li> <li>• Track the employee’s safety against the viral infection.</li> </ul>
<b>Case management</b>	<ul style="list-style-type: none"> <li>• Record and Follow WHO and CDC directive for Suspect cases, contacts, confirmed cases, health workers with signs and symptoms with a history of treating confirmed cases. Self-isolation to controlled isolation with the designated team;</li> <li>• Accurate and timely identification of clinical features in severe risks and appropriate early interventions;</li> <li>• Designated ambulance, comprehensive medical, nutritional, and psychological approaches.</li> </ul>	<ul style="list-style-type: none"> <li>• Build temporal isolation for the suspect while waiting for the application of governmental hospital directives;</li> <li>• Follow governmental emergency directives and call emergency numbers.</li> </ul>
<b>Operational and logistics</b>	<ul style="list-style-type: none"> <li>• Health professional workforce required existing and new infrastructures such as dedicated hospitals for COVID-19 Outbreak, ICU beds, and functional materials, Medical supplies, test requirement, patients and contacts tracking technologies, water, electricity, another source of energy and food supplies;</li> <li>• Surge material preparation</li> <li>• Engage with donors, local, and international NGOs.</li> </ul>	<ul style="list-style-type: none"> <li>• Ensure their employee’s safety, medical requirement and capacity to respect home confinement within the enforced period, help to get food supplies and another health requirement;</li> <li>• Surge materials for protection and for essential business continuity;</li> <li>• Liaise with local governmental authorities for support and finding out solutions for certain difficulties</li> </ul>

- Implementation of lockdown in Wuhan (traffic restriction and blockade of social-ecological structures such as markets, gatherings, trains, buses);
- Informing WHO and WHO declaration of SARS CoV2 as a public health emergency of international concern;
- Construction of two new Huoshenshan hospitals in Wuhan within one week;
- Development and opening of 16 Fangcang shelter hospitals for treating mild to moderated COVID-19 patients to minimize home transmission took place in home isolation. These hospitals had 3 characteristics (rapid construction, massive scale, and low cost) and were assigned 5 functions(isolation, triage, basic medical care, frequent monitoring, and rapid referral, essential living and social engagement);<sup>22</sup>
- Enhancement of admission and isolated cases treatment in Hubei.
- Environment disinfection;
- Extension of spring festival holiday for social distancing;
- Improvement of the treatment protocol and infection prevention and control(IPC);
- Maintaining the stable supply of commodities;
- Social distancing and hands washing with water and soap/ Use of hand sanitisers;
- Disinfection of surfaces and items such as keys and phones, computer, door handles.

### Third stage: After February 8, 2020: Rehabilitation

Orderly resumption of production in enterprises<sup>21</sup>

- Maintain a focus on cases treatment and prevent transmission;
- Risk assessment based focus for efforts intensification in regard to the risk of transmission;
- Establishment of the balance between infection prevention measures and socio-economic and sustainable development;
- Health insurance financial compensation;
- Technology-based contact tracing;
- Support of all provinces to Wuhan and other areas in Hubei province;
- Work resumed in phases and pre-school preparation;
- Re-opening of business with continuous social distancing, mask-wearing, hand washing and sanitising with hydro alcohol solution, sneezing and cough etiquette.

Although lockdown was understood to be difficult to be implemented in comparison to all of the other strategies, China managed to successfully apply it.<sup>23</sup> Lockdown was practically possible and yielded important results in Wuhan by blocking all the key nodes (cities, town, villages, airway lines, railways). Although Kaiser Permanente in Northern California proposed six measures to curb COVID-19, the USA didn't manage to overcome COVID-19.<sup>24</sup> China, USA, and other resource rich countries have a strong economy, classified to level 5 emergency readiness, high technology and infrastructure, strong health system, but only China experience to 2003 SARS CoV helped

the country to contain COVID-19.<sup>16</sup>

Due to the uncertainty of COVID-19 treatment and owing to its long incubation period and the fact that many cases can be asymptomatic; people have been requested to stay home for 14 days of quarantine. This approach has provided indirect protection for uninfected populations by breaking the chain of disease progression; which had a high basic reproduction number (R0) that estimated to be 1.95 by WHO and 2.5 in China. In addition, herd immunity was impossible to realise due to lack of vaccine, and the prohibition exposure to serious fatal disease.<sup>25</sup>

### The possibility of application of lessons learnt from China

Many of the prevention measures performed in China have been successfully applied globally and in Africa as well. The preventive measures such as social distancing, mask-wearing, hand washing and sanitising and handshaking avoidance. The active case, cluster finding and management, contact tracing, point of entry restriction and temperature checking was also applied.<sup>26</sup> According to CDC Africa, COVID-19 policy improvement and continuous communication by relevant authorities were also helpful to fight rumors. Due to the fact that many low and middle-income countries, especially in Africa have fragile economies, building new COVID-19 hospitals and improving emergency preparedness to level 5 appear difficult. However, the selection of existing structures that could be converted to temporary hospitals could be helpful. This can help to create monitored isolation, limiting community transmission, and elimination of hospital overcrowding.<sup>22</sup>

Drawing from these lessons, there have been great deliberations as to the possibility of population containment in Africa. In many parts of Africa, people live in rural areas where there is less congestion. However, many towns and cities are overcrowded, particularly in urban area.<sup>8</sup> Hence, in addition to the challenges of fragile economies, the low level of emergency readiness and ability to apply lock down scenarios could be inhibited by lack of infrastructure. According to the Economic Commission for Africa, 42 over 54 countries in Africa have applied full or partial lockdown. They estimated that Africa may lose 2.5% of annual GDP, equivalent to around \$65.9 billion for only a one-month full lockdown across the whole continent.<sup>27</sup> In addition, psychosocial issues, poverty, and hunger, missing routine vaccination may jeopardise the population health if an unplanned full and prolonged lockdown is implemented in African countries.<sup>28</sup> The resilience features that African countries have today are a young population, hypothesised unfavourable climate to the virus, viral diseases familiarities, and uncongested rural life.<sup>8</sup> However, international economic support is important to prevent further disasters that may arise as post-COVID-19 lockdown negative effect.<sup>29</sup>

### RECOMMENDATIONS

- Country plan and creation of different level joint teams: Involvement of Country Ministry of Health and World Health Organization; public health professionals, governmental and non-governmental organisations, Military, police, business companies, security organisations and economist,<sup>18,30</sup>
- Protection of frontline health professionals including Doctors, Clinical Officers, Nurses, Midwives and other allied health professionals to avoid panic and health system collapse;
- Isolation preparation for obligatory confirmed cases and non-confirmed cases in follow up;

- Prepare and counts all ICU beds available with functional materials to be early informed on the support capacity already available;
- Raise the red flag for international support;<sup>21,20</sup>
- Creation of government policies through the evolution of Covid-19 and decentralised safety enforcement;
- Strategic and operation Health promotion program and continuous research sharing;
- Establishment of solidarity fund for Social support to help high-risk zone (this was generated by NGOs and from unaffected provinces in China);<sup>21</sup>
- Ensure water availability, electricity and food distribution to people;
- Remote medical management for identification of cases with artificial intelligence by temperature measurement, radiologic examination interpretation.<sup>31</sup>
- Publication of COVID-19 crisis emergency number for anyone who has similar signs of the disease;
- Prepare areas and existing structures to be converted into cheap temporary hospitals like (stadium, gymnasium etc.) for healthy people. This can also eliminate hospital overcrowding as it did in fangcang;<sup>22</sup>
- Lockdown of all international and national points of entry. Except internal based borders pass for Social workers, Food delivery, Healthcare professionals, Emergency team, and patients;
- Confinement (staying at home) is the current strategy to halt the COVID-19. Hence plan it, apply it, follow it, and review it until recovery within the respect of human rights.

## CONCLUSION

Coronavirus disease-19 is currently exasperating the world by increasing cases and subsequent deaths. It has blocked the social-ecological networks (territories, towns, gathering places such market and churches, trains and planes travels) with a broad array of negative impacts (physical, psychological and economic impacts). Therefore, we encourage countries, companies and all organisation entities to apply these Chinese lessons learned for the benefit of the population at large.

We again suggest, for future preparedness, to spot and design places where to install temporary hospitals and isolation structures at the least cost. Establish a team to predict all possible outbreak in ten years and suggest early preparedness and response, and put in place measures of frontline early protection.

**Contributors:** Charles Nsanabera initiated this viewpoint and wrote the first draft. All authors contributed equally to the final manuscript.

**Declaration of interests:** We declare no competing interests

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# Efficacy and Safety of Fentanyl Compared With Morphine among Adult Patients with Cancer: A Meta-Analysis

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## ABSTRACT

**Background:** Cancer pain is experienced by numerous patients; thus, the main pain-relieving opioid analgesics, fentanyl and morphine, are of great importance. However, their analgesic efficacy and safety are different among individuals and are still controversial. The aim of this study was to compare the safety and efficacy of fentanyl and morphine among patients with cancer.

**Methods:** We performed a meta-analysis by searching PubMed and the Cochrane Library up to 01 April 2019. The search terms were fentanyl, morphine, opioids and cancer pain. All randomised controlled trials comparing fentanyl and morphine were included in the analysis.

**Results:** Overall, the initial search identified 2970 published studies; among them, 9 studies were included in the efficacy analysis and 8 studies were included in the safety analysis. The oral morphine versus oral transmucosal fentanyl subgroup analysis showed a mean difference(MD)=0.47[Confidence interval(CI):0.35-0.58] with an overall effect,  $Z=8.10$ ,  $P<.00001$ . The outcome of the oral morphine versus nasal/transdermal fentanyl subgroup indicated a MD=0.20[CI:0.3-0.37] with an overall effect,  $Z=2.24$  and  $P=.02$ .

For the oral morphine versus buccal/sublingual fentanyl subgroup, the analysis revealed a MD=1.80[CI:1.35-2.25] with an overall effect,  $Z=7.87$  and  $P<.00001$ .

The oral morphine versus other forms of fentanyl subgroup showed a MD=0.70[95%CI:0.34-1.06] with the test for the overall effect,  $Z=3.81$  and  $P=.0001$ .

Constipation, drowsiness, confusion and dry mouth were more common in the morphine group than in the fentanyl group, with a risk ratio=0.60[CI:0.37-0.97]; 0.93[CI:0.69-1.25]; 0.85[CI:0.23-3.13] and 0.54[CI:0.05-6.43], respectively.

**Conclusions:** Compared with oral morphine, fentanyl is safer and more effective. Moreover, fentanyl presents fewer side effects than morphine, especially constipation, drowsiness, confusion and dry mouth.

## BACKGROUND

Numerous patients experience Cancer pain, especially in the latest stages of the disease. Cancer pain is a critical problem and one of the most distressing symptoms in cancer patients.<sup>1-3</sup> For the past years, pain has been reported in 59%, 64% and 33% of patients who underwent cancer treatment, patients with advanced diseases and patients after curative treatment, respectively.<sup>4</sup>

The three most common pain rating scales for pain assessment are; the Numerical Rate Scale (NRS), Visual Analogue Scale (VAS), and Verbal Rating Scale (VRS).<sup>5</sup> These scales are used to estimate the Pain Intensity (PI) and to assess the efficacy of pain treatment.

Many opioids are used for relieving cancer pain.<sup>6</sup> Opioids are identified as; low pain, moderate to severe pain opioids. For greater efficacy, a combination of opioid therapies are used.<sup>7</sup> Several studies have been conducted to assess 1, 2 or more opioids compared to placebo or another opioid.<sup>8,9</sup> Thus, opioids are widely used in the treatment of many types of cancer pain.<sup>10</sup> However, patients often suffer from constipation, nausea, and vomiting after administration of opioids.<sup>11</sup> Thus, the safety and efficacy of cancer pain treatment require further exploration.

Several studies have reported that fentanyl is more efficient than morphine in relieving cancer pain. However, for others, it was suggested that fentanyl was equally effective as morphine and was considered to be the opioid of choice.<sup>9,12,13</sup> So, the safety and efficacy of cancer pain treatment needs further exploration. The objective of this meta-analysis was to compare the safety and efficacy of fentanyl and morphine among cancer patients.

## METHODS

### Inclusion/ Exclusion Criteria

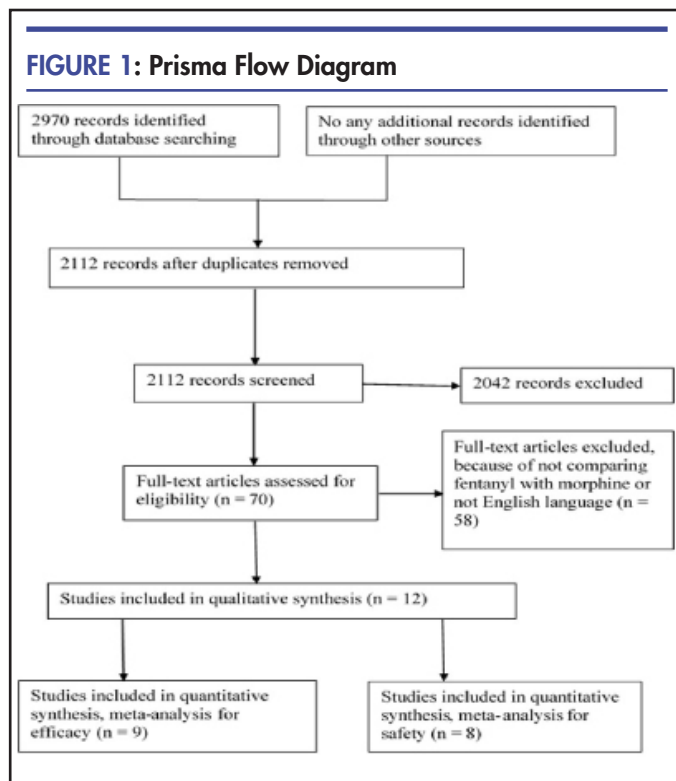
The eligibility criteria were assessed at 3 levels:

- 1) The common criteria for safety and efficacy were: a) Randomised Controlled Trials (RCT) or Prospective Studies, b) Comparison between at least fentanyl and morphine, and c) Studies published in English;
- 2) The specific criteria for efficacy were: a) Pain intensity assessed at least 3 times, including baseline; b) Pain rating scales expressed from 0 to 10 points; and c) Studies with outcomes expressed as the means or medians and SD (Standard Deviation) or with a similar inference;
- 3) The specific criteria for safety were: a) The side effects were

- a) Pain intensity assessed at least 3 times, including baseline;
- b) Pain rating scales expressed from 0 to 10 points; and c) Studies with outcomes expressed as the means or medians and SD (Standard Deviation) or with a similar inference;
- 3) The specific criteria for safety were: a) The side effects were assessed and b) Dichotomous data.

**Search Strategy and Data Extraction**

The PubMed and Cochrane Library databases were searched for relevant papers up to 01 April 2019. To identify all relevant studies, we used the search terms “fentanyl” AND “pain cancer” AND “morphine” OR “opioids”. A flowchart of the study selection is shown in **Figure 1**.



**Study Quality and Risk of Bias Assessment**

All of the authors worked independently to search for and assess studies for their methodological quality. The Cochrane Collaboration’s tool for assessing the risk of bias was used. This tool included 7 sources of bias: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias.<sup>14</sup> The risks of bias across studies are summarised in **Figure 2**.

**Statistical Analysis**

Mean Differences (MD) with 95% Confidence Intervals (CI) were calculated to assess the effect of continuous data, and the Risk Ratio (RR) was calculated for dichotomous data. The MD and RR were pooled using a random effects model to calculate a more conservative result.<sup>14</sup> Thus, MD>0 indicated a better outcome when using fentanyl, while MD<0 indicated a better outcome when using morphine; RR>1 indicated a high risk of side effects when using fentanyl, while RR<1 indicated a high risk of side effects when using morphine.

For heterogeneity, the estimate of the between-study variance was assessed by I<sup>2</sup>. Therefore, I<sup>2</sup>≤50% might not be significant and I<sup>2</sup>>50% might be significant.<sup>14</sup>

Subgroup analysis was performed according to the mode of drug administration or bioavailability for continuous data and using the type of side effects for dichotomous data. Review Manager (RevMan) [Computer program]. Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014 was employed for all statistical analyses. Some data across studies was not matched with the statistical study plan. The adjusted data is summarised in **Table 2**.

**RESULTS**

**Study Selection and Characteristics**

A total of 2,970 records were retrieved from the databases. Of these, 858 were excluded because of duplication. 2,112 studies were screened. Among these, 2,040 were excluded because of inappropriate titles. 70 articles were potentially eligible but 58 of them were removed because they did not compare morphine with fentanyl or were not expressed in English. 5 of the 12 remaining studies had appropriate safety and efficacy assessments. Finally, 9 studies were included in the meta-analysis for efficacy and 8 for the assessment of side effects. The total number of participants in different studies was 1,004 patients.<sup>15-26</sup> (Figure 1) 1 of the studies was conducted in the USA, 1 in the UK, 1 in Japan, 1 in the Netherlands, 1 in India, 1 in Europe and Indian, 1 in Spain and 5 were conducted in Italy. The study period varied between 1997 to 2017. Some of the study characteristics are shown in **Table 1**.

**Risk of Bias within Studies**

The risk of bias within the included studies (**Figure 2. B**) showed that most of the studies had a low risk of bias.

**Efficacy Assessment(Figure 3)**

When comparing oral morphine to oral transdermal fentanyl, fentanyl had a better outcome than morphine in relieving pain, with a mean Difference (MD)=0.47 [95% Confidence Interval (CI): 0.35-0.58]. The heterogeneity was not significant (I<sup>2</sup>=0% and P=.42). For the test of the overall effect, Z=8.10 and P<.00001.

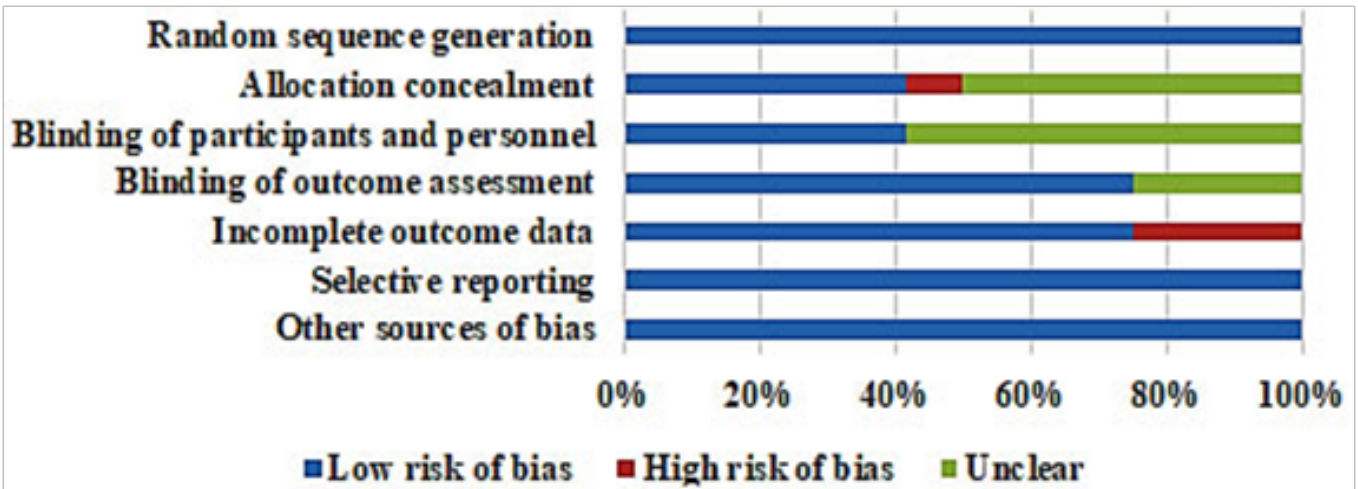
Considering oral morphine versus nasal and transdermal fentanyl, fentanyl was superior to morphine, MD=0.20 [95%CI:0.03-0.37]. The heterogeneity was not significant (I<sup>2</sup>=0% and P=.50), and for the overall effect, Z=2.24 and P=.02.

Fentanyl (buccal and sublingual) was superior to oral morphine in relieving pain, MD=1.80 [95%CI:1.35-2.25]. The test for the overall effect showed Z=7.87 and P<.00001. The heterogeneity was not significant (I<sup>2</sup>=0% and P=.45).

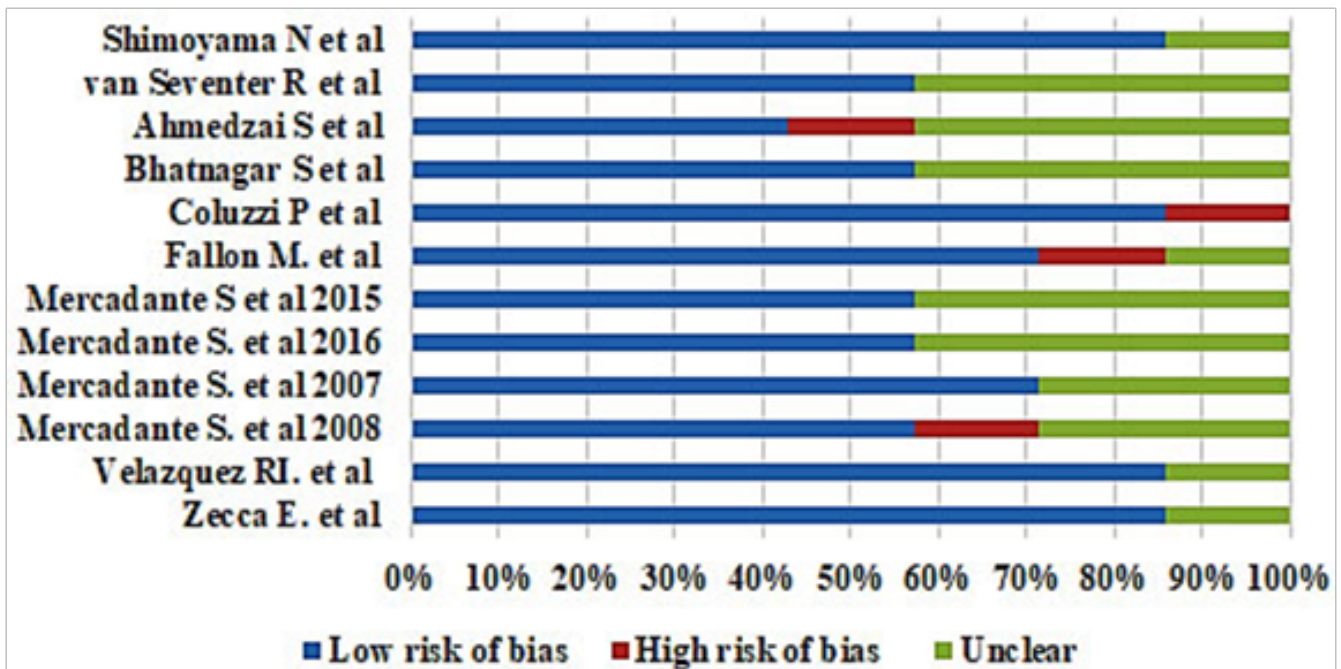
However, compared with parenteral morphine (intravenous and subcutaneous), fentanyl (transmucosal and sublingual) had lower effectiveness than morphine, MD=0.49, [95%CI:-1.17-0.20]. The heterogeneity was not significant (I<sup>2</sup>=0% and P=.57). For the overall effect, Z=1.40 and P=.16.

Fentanyl is still more efficient than morphine when oral morphine was compared with other forms of fentanyl, MD=0.70, [95%CI:0.34-1.06]. The test for the overall effect showed Z=3.81 and P=.0001. The heterogeneity was significant (I<sup>2</sup>=87% and P<.00001).

**FIGURE 2: Assessment of Risk of Bias**



**A. Risk of Bias across Studies: Summary**



**B. Risk of Bias of Individual Studies: Summary**

**TABLE 1: Characteristics of Included Studies in the Meta-Analysis**

Reference	Year and Country	Study Design	Participants	Time of Assessment	Route of drug administration
Bhatnagar S et al.(15)	2014, India	Prospective, Randomised, two arms, open label, active controlled, multi-centric clinical study	186	0,5,15,30,60 minutes	Oral Morphine Fentanyl
Coluzzi P et al.(16)	2001, USA	Double-blind, double-dummy, multiple cross-over	84	0,15,30,45,60 minutes	Oral
Fallon M. et al.(17)	2011, Europe-India	Multicenter, randomised, double blinded-double dummy, crossover	79	0,15,30,45,60 minutes	Oral
Mercadante S. et al.(18)	2015, Italy	Multicenter, randomised, crossover, controlled study	68	0,15,30 minutes	Oral
Mercadante S. et al.(19)	2016, Italy	Randomised, crossover, open-label study	45	0,15,30 minutes	Oral
Mercadante S. et al.(20)	Italy, 2007	Randomised, crossover, controlled study	25	0,15,30 minutes	Intravenous
Mercadante S. et al.(21)	Italy, 2008	Multicenter prospective randomised controlled study	72	0,1,2,3,4 weeks	Oral
Velazquez RI. et al(22)	2014, Spain	Prospective, double-blind, controlled-study	40	0,3,7,15,30 days	Oral
Zecca E. et al(23)	Italy, 2017	Double-blind, double-dummy, parallel-group, non-inferiority RCT	113	0,10,20,30,60 days	Subcutaneous
van Seventer R et al(26)	Netherlands, 2003	Prospective, randomised trial	131	28 days	Oral
NaohitoShimoyama et al(24)	Japan, 2015	Randomised, crossover, double-blinded placebo-controlled and non-blinded active drug controlled, comparative Phase III clinical trial	51	30 and 60 minutes	Oral
Ahmedzai S. et al(25)	UK, 1997	Randomised, open, two-period, crossover study	110	8, 16, 23, and 31 days	Oral

Notes: USA: United Nations of America; UK: United Kingdom, RCTs: Randomise Controlled Trials

**FIGURE 3: Forest Plots Comparing Efficacy Between Fentanyl and Morphine**

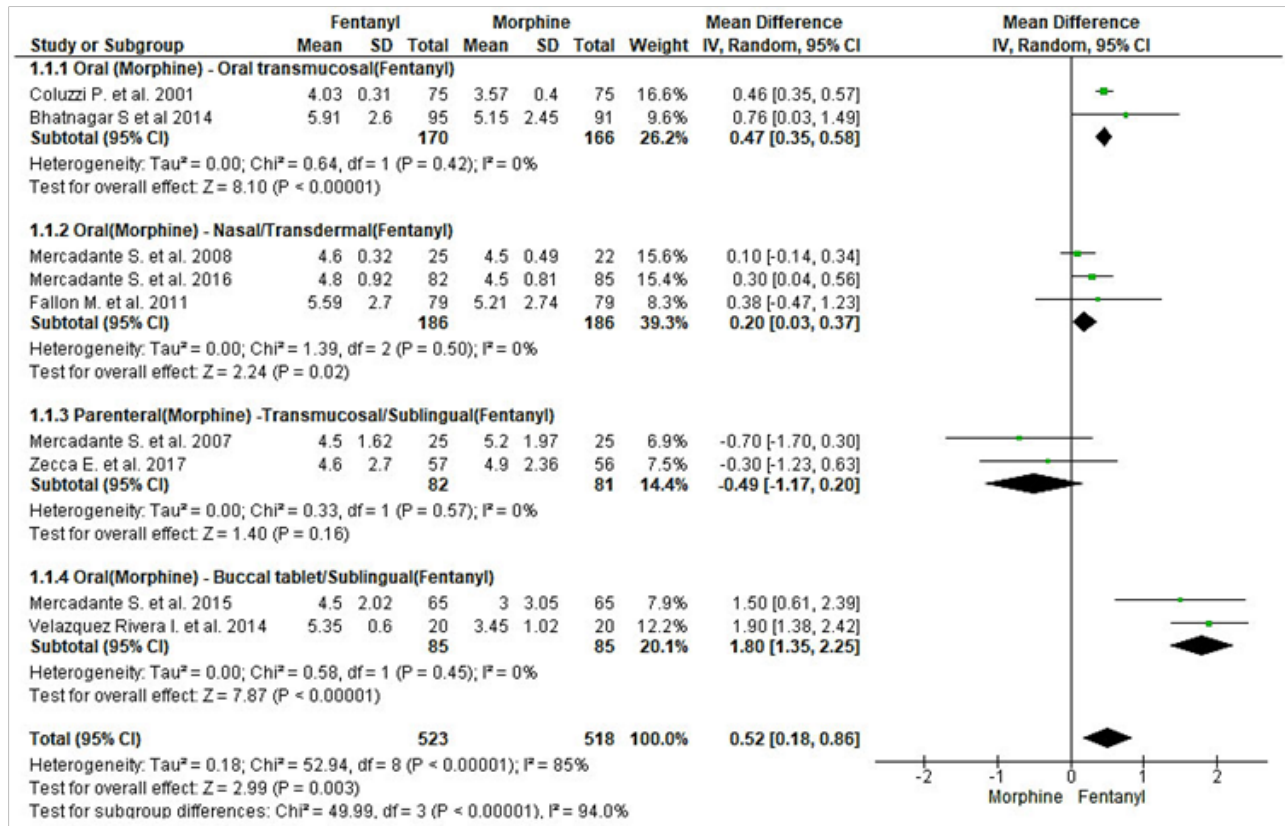


Figure 3.A Efficacy Based on Drug Bioavailability

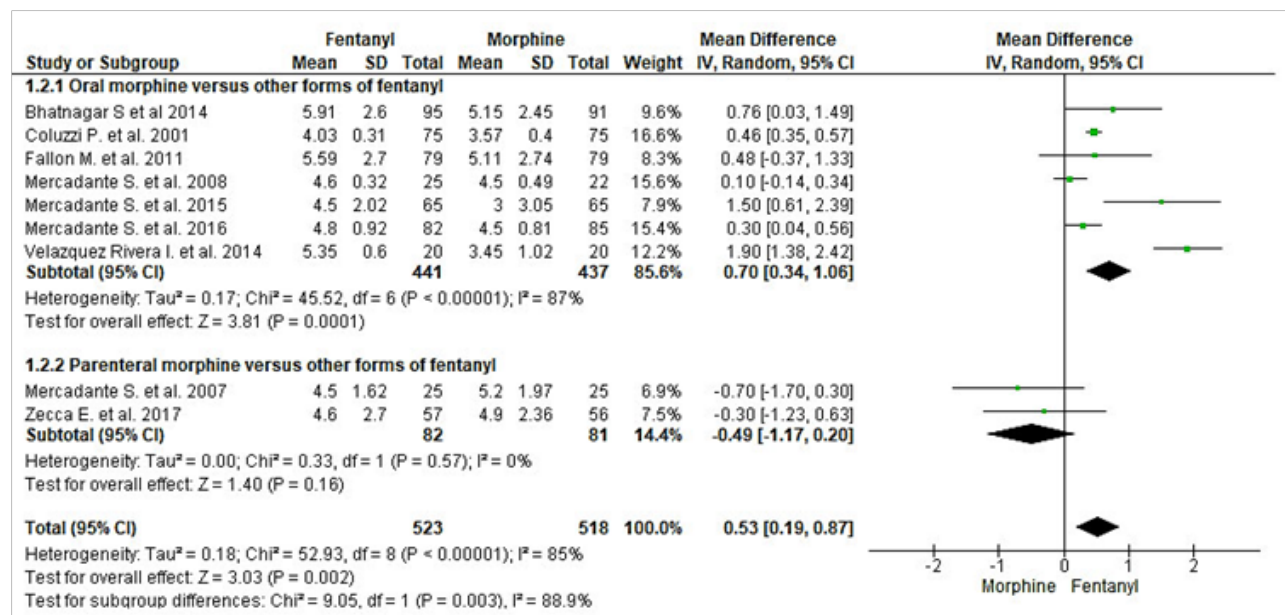
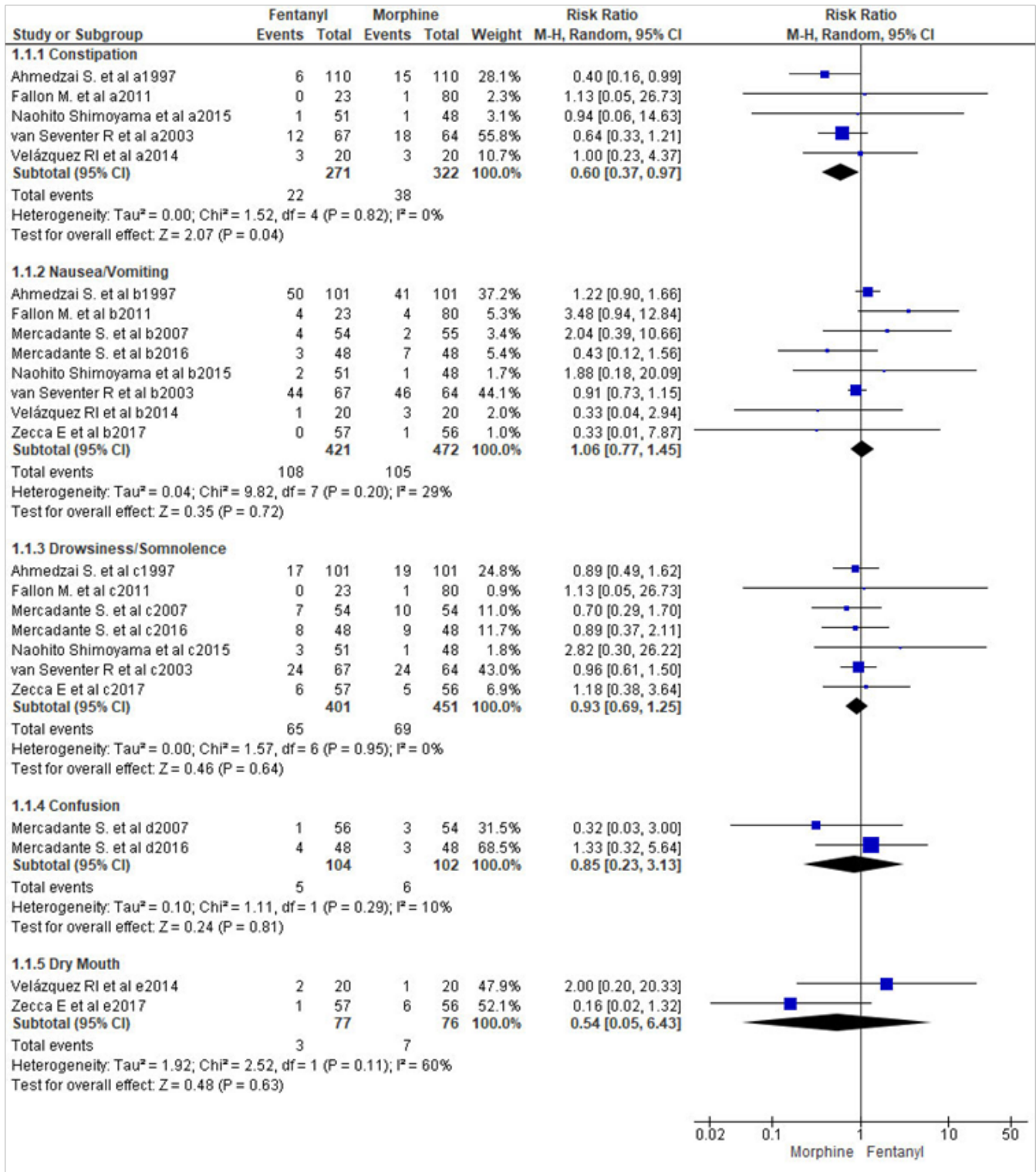


Figure 3.B Efficacy Comparison Between Fentanyl and Morphine Based on the Form of Morphine

**FIGURE 4: Forest Plot Comparing Fentanyl and Morphine's Side Effects**



**TABLE 2: Pain Rate Scale and Statistical Inference Adjustment**

Studies	Scale assessment	Statistical test	Adjustment
Bhatnagar S et al.(15)	NRS/PID	Mean SD	Subtraction
Coluzzi P et al.(16)	NRS/PID	Mean SD	SD from Jandhyala et al(9), Subtraction
Fallon M. et al.(17)	NRS/PID	Mean SEM	Mean and SEM estimated from figure by using Get Data Graph Digitizer software and then, Subtraction
Mercadante S. et al.(18)	NRS/PI	Mean SD	None
Mercadante S. et al.(19)	NRS/PI	Mean SD	None
Mercadante S. et al.(20)	NRS/PI	Mean CI	SD from CI
Mercadante S. et al. 2008 (21)	NRS/PI	Mean Range	SD from muni-software proposed by Wan X, Wang W, Liu J and Tong T.
Velazquez RI. et al(22)	VAS/PI	Mean SD	SD estimated from figure by using Get Data Graph Digitizer software
Zecca E. et al(23)	NRS/PI	Mean SD	None

NRS: Numerical Rate Scale; PID: Pain Intensity Difference; PI: Pain Intensity, SD: Standard Deviation; SEM: Standard Error of Mean, CI: Confident Interval, VAS: Visual Analogue Scale

**Assessment of Common Side Effects Assessment (Figure 4)**

For common side effects, the assessment showed that constipation appeared more commonly in the morphine group than in the fentanyl group with a Significant Difference, RR=0.60 [95%CI:0.37-0.97], and the heterogeneity was not significant (I<sup>2</sup>=0, P=.82). For the overall effect, Z=2.07 and P=.04.

Drowsiness, confusion and dry mouth seemed to be more common in the morphine group than in the fentanyl group. Their respective RRs was 0.93, [95%CI:0.69-1.25] 0.85, [95%CI:0.23-3.13] and 0.54 [95%CI:0.05-6.43]. However, the difference was not statically significant. There was no significant heterogeneity between studies assessing drowsiness (I<sup>2</sup>=0% and P=.95) and between those assessing confusion (I<sup>2</sup>=10% and P=.29). The tests for the overall effect showed the following effects: drowsiness, Z=0.46 and P=.64; confusion, Z=.24 and P=.81. The heterogeneity between studies assessing dry mouth was moderately significant (I<sup>2</sup>=60%, P=.11). For the overall effect, Z=0.48 and P=.63.

By contrast, nausea/vomiting seemed to be dominant in the fentanyl group, without statistical significance. Indeed, RR=1.06, [95%CI:0.77-1.45]. The heterogeneity was not significant (I<sup>2</sup>=29% and P=.20), and the test for the overall effect showed Z=0.35 and P=.72.

**DISCUSSION**

According to this meta-analysis, fentanyl relieved cancer pain better than morphine. The better effectiveness of fentanyl was evident when oral morphine was compared with other forms of fentanyl. When parenteral morphine was compared with other forms of fentanyl, morphine was more effective than fentanyl. However, this efficacy was not statistically significant.

It was also evident that patients taking morphine more frequently developed constipation than those who took fentanyl. Even drowsiness, confusion and dry mouth were more commonly developed in patients who took morphine, although the difference was not statistically significant.

This meta-analysis comparing fentanyl and morphine might provide some evidence and assistance for physicians and patients with the goal of relieving pain. The results of this study indicated that fentanyl administration should produce better results than oral morphine. This study supports the previous studies that suggested that fentanyl was more effective than morphine in relieving cancer pain. It also supports those that reported that fentanyl presented fewer side effects than morphine. However, this study clarifies some cases in which morphine should be more effective than fentanyl and when fentanyl seems to cause more side effects than morphine. This study should be used as a reference for future studies to clarify conditions under which fentanyl or morphine should be used.

The route of fentanyl administration remains an important point in relieving cancer pain. Indeed, before delivering the drug, physicians should determine the best route of fentanyl administration when they must choose between fentanyl and morphine. The nasal mode's advantage is that the venous outflow of the nasal mucosa bypasses the liver and enters systemic circulation, thereby avoiding the hepatic first-pass effect.<sup>13</sup> It has been reported that nasal fentanyl is similar to intravenous fentanyl in relation to pain control and the incidence of side effects.<sup>27</sup>

The oral transmucosal fentanyl citrate route provides rapid access into systemic circulation with greater bioavailability. The rapid onset of fentanyl is associated with its short duration of effect, making it an attractive option for the treatment of breakthrough cancer pain.<sup>28</sup> A recent network meta-analysis indicated that transmucosal fentanyl medications achieved a greater level of pain relief in a shorter time frame than oral morphine.<sup>29</sup> Sublingual fentanyl is provided as a small tablet that is composed of a combination of active drug particles and water-soluble carrier particles coated with a mucoadhesive agent.<sup>30</sup> Including the spray sublingual form, fentanyl is generally well tolerated and is recommended for use for the management of breakthrough pain in opioid-tolerant adult patients with cancer.<sup>28,31,32</sup>

A transdermal fentanyl formulation has been in clinical use since the 1990s.<sup>33</sup> It is used in palliative care and cancer pain.



A transdermal fentanyl formulation has been in clinical use since the 1990s.<sup>33</sup> It is used in palliative care and cancer pain. Lower rates of constipation have been demonstrated in terms of side effects, even in patients with terminal cancer.<sup>34</sup>

Subcutaneous delivery of fentanyl has been considered interchangeable with the intravenous route and presents a low incidence of adverse effects.<sup>35</sup> For patients undergoing caesarean section, a recent study found that subcutaneous fentanyl is an effective alternative to intravenous and intranasal routes of administration for pain management.<sup>27</sup>

Intravenous fentanyl has a duration of analgesia comprise between 30 and 60 minutes after an intravenous bolus.<sup>13</sup> Intravenous fentanyl can be delivered in a continuous infusion for the treatment of cancer pain in patients requiring high doses for patients who become refractory to other opioids or when other opioids cause intolerable side effects.<sup>36</sup>

Several studies concerning the use of buccal fentanyl in cancer have been conducted. These studies indicated that buccal fentanyl is well tolerated and may improve patient functioning, mood, and overall satisfaction in the management of breakthrough cancer pain.<sup>37-40</sup>

The addition of intrathecal fentanyl to spinal anaesthesia decreases opioid consumption during the period of highest analgesic demand after caesarean section.<sup>41</sup>

The transpulmonary fentanyl route remains an experimental phase for the management of acute or chronic pain. Its duration of action and half-life appear to be prolonged compared to intravenous fentanyl.<sup>28,42</sup>

In our meta-analysis, the included studies had some common points in the constitution of subgroups (**Figure 2**). Indeed, in the first subgroup (oral morphine versus transmucosal fentanyl), fentanyl had the same properties (transmucosal). In the second subgroup (oral morphine versus nasal and transdermal fentanyl), the nasal and transdermal routes for fentanyl were similar.<sup>13,43</sup> In the third subgroup (intravenous and subcutaneous morphine versus transmucosal and sublingual fentanyl), morphine was delivered in a route other than oral. For the fourth subgroup (oral morphine versus buccal tablet and sublingual fentanyl), the main common point was oral morphine.

The baseline of PI was not the same when comparing fentanyl with morphine and ranged from 8.40 to 4.8 for fentanyl and from 7.85 to 4.8 for morphine, which also explain the difference regarding pain relief.

There are two main findings of this meta-analysis. First, fentanyl is more effective in relieving pain among patients with cancer than oral morphine. Second, morphine causes more side effects, especially constipation, than fentanyl.

The results of this meta-analysis must be interpreted with caution. In fact, the mean of each study was a difference between two means (the baseline and final assessment means), indicating that the lower the mean difference, the lower the drug efficacy. This difference was the main challenge when interpreting continuous data in the meta-analysis, especially when continuous outcomes were measured in pre- and post-interventions.<sup>14,44</sup>

## CONCLUSION

This meta-analysis outlines the superior efficacy of fentanyl compared with morphine in relieving cancer pain. This meta-analysis clarifies that morphine causes more adverse events, especially constipation, than fentanyl. Fentanyl should be rec-

ommended for relieving cancer pain as a first-line drug and the route of drug administration must be considered. However, more studies are still needed for the generalisation of these findings. For example, comparisons between intravenous fentanyl versus intravenous morphine or other combinations should further clarify when to use these two analgesics.

## Limitations

There was only a small number of included studies, and in some studies, all of the necessary data were not provided, as shown in Table 2. The sample size of the 12 included studies was small, and 5 of the included studies were conducted in the same country.

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# Case Report of Ogilvie's Syndrome Following Emergency Haemostatic Subtotal Abdominal Hysterectomy at University Teaching Hospital of Butare, Rwanda

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## ABSTRACT

**Background:** Acute colonic pseudo-obstruction or Ogilvie's syndrome is a rare condition that usually develops due to a dysregulated autonomic nervous system following a medical or surgical condition. With delayed diagnosis, it may lead to bowel ischemia and perforation with poor prognosis.

**Case:** We report a case of a 33 years old female, Gravida 1, Para 1, who developed severe abdominal distension following abdominal haemostatic hysterectomy due to a severe postpartum haemorrhage and shock requiring epinephrine infusion after a spontaneous vaginal delivery. The postpartum haemorrhage was due to both atony and posterior cervical tear. Two initial administrations of neostigmine 2 mg mixed with atropine 0.5 mg were unsuccessful, but an insertion of a flexible recto-sigmoid cannula allowed a slight decompression. A subsequent third dose of neostigmine 2 mg mixed with atropine 0.5 mg was followed with a remarkable flatus evacuation and complete decompression.

**Conclusion:** Prompt diagnosis and management of Ogilvie's syndrome is crucial in order to avoid subsequent complications. In case of postoperative cecal and colonic distension without mechanical obstruction, Ogilvie's syndrome should be suspected as this will ensure timely and adequate management of patients at risk including obstetric patients.

## BACKGROUND

The first description of Ogilvie's syndrome was provided in 1948 by William Henry Ogilvie. The condition is characterized by signs and symptoms of a mechanical obstruction of the small or large bowel in the absence of a mechanical cause<sup>1</sup>. The true incidence is unknown, but it ranges between 9% and 19% among patients with risk factors such as severe infection, cardiac events, neurologic events, major surgery, and metabolic imbalance.<sup>2,3,12</sup>

The diagnosis of Ogilvie's syndrome is made based on signs of non-mechanical abdominal distension on a plain abdominal X-ray or CT scan<sup>7</sup>. The management depends on the severity of the syndrome and include supportive care, anticholinesterase medications, colonoscopy and surgery.<sup>8,9,10</sup>

In low resource settings without a readily available CT scan, it may be difficult to diagnose the syndrome. Suspicion of Ogilvie's syndrome based on the clinical presentation may avoid late diagnosis and subsequent complications. We report a case of Ogilvie's syndrome successfully managed in the Intensive Care Unit (ICU) at the University Teaching Hospital of Butare (UTHB), Rwanda.

## Case Presentation

A 33 years old female Gravida 1, Para 1, with a previous history

of pelvic inflammatory disease but no abdominopelvic surgery, was referred to the Obstetric unit of UTHB from a 153 km-distant district hospital for severe postpartum haemorrhage. The patient had experienced normal spontaneous vaginal delivery. The UTHB has 500 beds and 6 operating rooms. It conducts approximately 8,000 surgeries each year.

Upon arrival at the hospital, she had received 2 litres of Intravenous (IV) normal saline 0.9% and Lactate Ringer, epinephrine infusion and transfused with 2 units of packed red blood cells. Initially, a diagnosis of uterine atony was made and a haemostatic B-Lynch procedure performed without success.

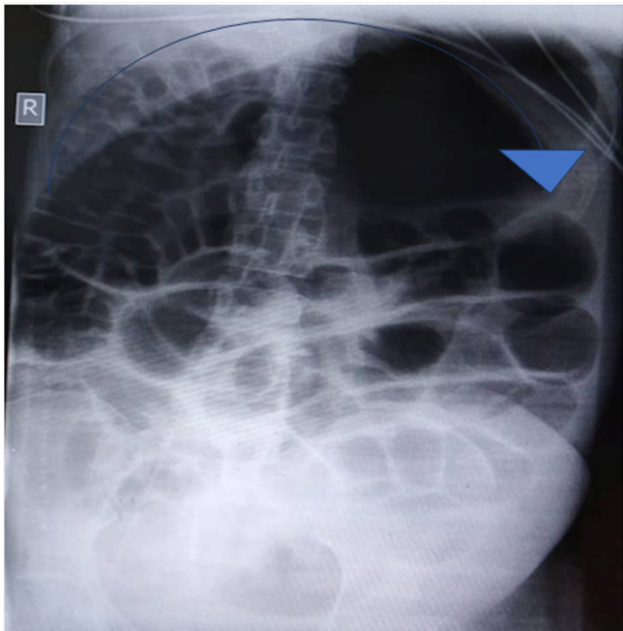
As she continued to bleed following subtotal haemostatic hysterectomy, a further clinical examination revealed a posterior cervico-uterine tear that was repaired successfully. She was transfused with additional 11 units of packed red blood cells, 7 fresh frozen plasma, 5 units of platelets and 3 units of cryoprecipitate.

Due to a persistent hemodynamic instability she was admitted to the ICU, and an infusion of epinephrine was maintained for 2 days. On the day 3 postICU admission, she developed a progressive abdominal distention while she was still under the instruction of not taking anything by mouth (*nihil per os*).

A physical examination revealed an abdominal distension and tenderness on palpation, tympanic on percussion with decreased

bowel sounds on auscultation. A plain abdominal X-ray showed dilated bowels (Figure 1).

**FIGURE 1: Plain abdomen radiography of the patient showing a dilatation of proximal part of the colon up to approximately the splenic flexure (Blue arrow).**



A digital rectal exam did not reveal any faecaloma and a paralytic ileus was suspected. Results of laboratory investigations indicated that levels of Full Blood Count (FBC), electrolytes, lactate, urea, and creatinine were in normal ranges. The patient was managed by decreasing the frequency and dose of opioids and the insertion of the nasal gastric tube (NGT) for aspiration without improvement.

On day 5, the ICU treating team evoked the diagnosis of uncomplicated Ogilvie syndrome. A slow IV injection of neostigmine 2 mg mixed with atropine 0.5 mg was administered without improvement. A second same dose was given on the following day but patients showed no improvement. Endoscope specialist was contacted for decompressive colonoscopy but was not readily available. A tentative insertion of a recto-sigmoidal cannula with a flexible tube allowed a first flatus evacuation. A third dose of neostigmine 2 mg mixed with atropine 0.5 mg was administered and was followed by a significant evacuation of flatus allowing a decompression of the abdomen and relieve of symptoms. On day 6 of her admission in ICU, the patient was successfully extubated and weaned from ventilator. She was discharged from ICU on day 7 to the Obstetric Unit, and discharged from the hospital on day 11 post ICU discharge without any complication or reoccurrence of any sign of abdominal distention.

## DISCUSSION

Ogilvie Syndrome also known as Acute Colonic Pseudo Obstruction (ACPO) was first described as an acute colonic obstruction in absence of mechanical obstruction in 2 patients di-

agnosed with retroperitoneal tumours infiltrating the splanchnic and destroying the coeliac plexus<sup>1</sup>. The syndrome usually occurs in hospitalized patients and commonly associated various conditions (Table 1) such as severe illness, surgery, or as a complication of a metabolic imbalance especially hypokalaemia.<sup>2,3</sup> The pathophysiology may involve an imbalance of the autonomic nervous system with an increased sympathetic tone over a decreased parasympathetic tone<sup>4</sup>. This results in a decreased motility of the proximal colon while distal colon whose parasympathetic innervation depends on the sacral spinal segments is conserved, thus obstructing this distal colon. Proximal colon and caecum are then massively dilated to the extent that this exposes to a high risk of colonic ischemia and perforation if an urgent decompression is not performed. When the syndrome is complicated by a perforation, the resulting peritonitis is associated with a high rate of mortality that can reach 40% in high income countries and probably be much higher in resource limited settings in low income countries<sup>5</sup>.

Complications are more likely to occur in case of delayed recognition generally after 6 days from initial symptoms and in case of high tension with a colonic dilatation exceeding 9-12 cm of the diameter of the lumen<sup>6</sup>.

**TABLE 1: Clinical conditions commonly associated with Ogilvie's syndrome<sup>2,3</sup>**

1. Trauma, especially fractures
2. Obstetrical surgery, especially involving spinal anesthesia
3. Pelvic, abdominal, or cardiothoracic surgery
4. Major orthopedic surgery
5. Severe medical illness, such as pneumonia, myocardial infarction, or heart failure
6. Neurologic conditions
7. Chemotherapy (eg, all-trans retinoic acid, methotrexate, vincristine)
8. Retroperitoneal pathology, such as malignancy or hemorrhage
9. One of the above plus metabolic imbalance or medication administration (eg, narcotics, phenothiazine, calcium channel blockers, alpha-2-adrenergic agonists, epidural analgesics)

Different predisposing factors are reported but obstetric, gynaecologic and pelvic surgeries are among the most important factors occurring in 20% of reported cases of Ogilvie syndrome<sup>6</sup>. Early diagnosis within 48 hours and a successful management achieved within a short time frame may play a significant role in avoiding any severe complication. The diagnosis is generally made upon signs and symptoms of abdominal distension with a plain abdominal X-ray displaying dilatation of the proximal colon without any distinguishable mechanical obstruction on CT-Scan when it is performed<sup>7</sup>. When there is a colonic perforation commonly complicating the syndrome, signs of peritonitis are remarked and a pneumoperitoneum is seen on both abdominal X-ray and CT-Scan.

Once recognized, the initial management of an uncomplicated Ogilvie's syndrome includes ruling out of predisposing factors like opioids, and a supportive management by giving IV fluids for resuscitation, correction of potential electrolytes imbalance and insertion of a nasogastric tube for gastric emptying. Anti-cholinesterase medications such as neostigmine and pyridostigmine, by the increase of the acetylcholine and its effects

on promoting colonic motor activity are also used in non-complicated cases. Neostigmine in particular, has successfully been used in more than 80% of cases<sup>8</sup>. The optimal dose is estimated to 2-2.5 mg administered as slow IV in a setting with close cardiac monitoring. Atropine should be available as bradycardia generally complicates this administration of neostigmine and may lead to an asystole among other complications<sup>8</sup>.

In some cases, neostigmine may cause colonic perforation due to resulting hyperperistalsis in the already largely dilated colon. However, perforation occurs when management of Ogilvie syndrome is delayed and particularly when administration of neostigmine is not attempted. Generally 2-3 doses are recommended<sup>8</sup>.

In case of neostigmine failure, alternative treatment is decompressive colonoscopy with or without insertion of decompressive colorectal tube. In up to 90% of cases, decompression occur as a result of colonoscopy<sup>9</sup>.

Surgical approach is only indicated in case of failure of those conservative approaches and in case of severe and ischemic colon and perforation.<sup>1,10</sup> Perendoscopic caecostomy has also been successfully used when conservative management failed but is indicated in the absence of ischemic colon and perforation. However, this technique may be associated with a high morbidity<sup>10</sup>. Finally, given the pathophysiology of this syndrome, a thoracic epidural analgesia owing to its inhibition of sympathetic effects, has also been successfully used in some cases of Ogilvie syndrome<sup>11</sup>.

## CONCLUSION

Prompt diagnosis and management of Ogilvie's syndrome is crucial in order to avoid subsequent complications. In case of postoperative cecal and colonic distension without mechanical obstruction, Ogilvie's syndrome should be suspected as this will ensure timely and adequate management of patients at risk including obstetric patients.

### List of Abbreviations

ICU: Intensive Care Unit  
UTHB: University Teaching Hospital of Butare  
IV: Intravenous  
FBC: Full Blood Count  
NGT: Nasal Gastric Tube  
ACPO: Acute Colonic Pseudo-Obstruction

### Declarations:

**Authors' contributions:** ET, MGM, EZ, and TT were associated with the case. ET and TT led the manuscript writing. All authors critically reviewed and approved the final manuscript.

**Ethics approval and consent for publication:** The patient provided an informed consent to report her information while keeping her privacy and confidentiality.

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## Two cases of Prune Belly Syndrome from Kagera Region Tanzania

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### ABSTRACT

Prune Belly Syndrome is a rare congenital disorder with unknown aetiology, consisting of a triad of abdominal muscle wall weakness, undescended testes, and urinary tract abnormalities. We are unaware of any preceding report of Prune Belly Syndrome in Tanzania, and here we describe two cases reported in Kagera region. The first case is a 2 month old boy with the triad of Prune Belly Syndrome along with pectus carinatum who died due to septicaemia. This case posed a diagnostic challenge at birth and during the natal period. Paucity of comprehensive knowledge of congenital malformations at the peripheral health facilities may have also contributed to the diagnostic challenge in the first place.

The second case is a neonate who was referred to regional referral hospital where he was diagnosed with Prune Belly Syndrome at the age of four weeks. Because of limited capacity to manage congenital malformations at the regional referral hospital, he was referred to an urologist at the zonal referral hospital. However, inadequacies in supporting systems to the parents compounded care of the neonate with Prune Belly Syndrome.

High index of Prune Belly Syndrome suspicion is needed in a resource limited setting in order to timely make diagnosis. There is also a need to strengthen institutional and individual's capacity for prenatal screening to detect congenital anomalies at an early stage of foetus development. Multidisciplinary management approach is necessary in order to improve the quality of life for patients with Prune Belly Syndrome. Psychosocial and medical support systems should be put in place in order to enhance preparedness for patient care in resource limited settings including equipping the referral hospital with different specialists and ensuring availability of basic investigations for patients.

### BACKGROUND

Prune Belly Syndrome (PBS) is a rare congenital disorder characterized by a triad of deficient abdominal wall muscles, cryptorchidism and urinary tract anomalies (including hydronephrosis). The syndrome affects 3.8 per 100,000 live male births<sup>1-4</sup>. Over 95% of patients are boys<sup>5</sup>. Some studies have suggested that the abdominal muscle deficiency is due to foetal abdominal distension of different causes including urethral obstruction with enlarged bladder and hydronephrosis. Also mesenchymal developmental defects have been suggested as the underlying defect<sup>1</sup>.

The cause of PBS is unknown<sup>6</sup>. Familial case reports and the higher incidence in males have suggested involvement of an X linked factor and recently mutations in the X linked gene *Filamin A* were reported<sup>7</sup>. However, in other cases an autosomal recessive mode of inheritance (OMIM #100100; *CHRM3* gene) has been suggested<sup>5</sup>.

Hydronephrosis and hydronephrotic kidneys have been found as features associated with PBS through abdominal ultrasound in 53.3% of cases<sup>5</sup>.

There are few reports from developing countries regarding the pattern of renal involvement and management outcome of patients with PBS. Lack of sufficient follow up to determine the course of the disorder may explain the existence of few PBS reports in developing countries<sup>8</sup>. Hydronephrosis and oligohydramnios found during antenatal care should raise suspicion of PBS and followed by systematic examination

and regular prenatal follow up<sup>1</sup>. We report two cases with clinical manifestations associated with PBS, including deficient abdominal wall muscles, hydronephrosis and cryptorchidism.

### Ethical Considerations

Permission to publish cases of two children with PBS was obtained from Regional Medical Officer. However, final decision was made by parents who consented for the publication of the case reports and any complementary image. Parents were informed that the identity of the child will be kept confidential

### Case Presentations

**Case 1:** A 2 month old boy from Kagera region, located in the Northwestern corner of Tanzania on the western shore of Lake Victoria, was admitted at Bukoba Regional Referral Hospital (BRRH) on 27<sup>th</sup> July 2018 as a referral case from Kabale dispensary in Bukoba district. Bukoba Regional Referral Hospital is owned by the Government with the capacity of 308 beds, of which 60 are for paediatric patients and 50 for surgical cases. At a time of admission, the mother reported that the child had fever, cough and difficulty in breathing for the past 3 days. He had no vomiting, no diarrhoea, and was passing urine normally. He had received 3 days of antibiotics prior to admission and was referred from Kabale dispensary to Bukoba Regional Referral Hospital following deterioration of his condition. Patient past medical history, family history and his mother's pregnancy history did not contribute to diagnosis

of PBS. He is the second born in a family with no history of PBS symptoms.

On physical examination his body temperature was 38.5 °C with an increased pulse rate and respiratory rate. His blood pressure was 105/65 mmHg. His weight for length was between median and -1SD. Abdominal examination revealed a floppy abdomen with poorly developed muscles, asymmetric with absent rectus abdominis muscles. There was no palpable mass, and his abdomen was soft. Both testes were undescended (Figure 1-4). Other systems were unremarkable.

FIGURE 1



FIGURE 3



FIGURE 4



FIGURE 2



Laboratory investigations (Table 1) showed leukocytosis, predominantly of lymphocytes, microcytic hypochromic anaemia and almost normal creatinine. Chest x-ray showed opacities in the right upper lobe, suggestive of right upper lobe pneumonia, and enlarged costal-chondral junctions suggestive of rickets (Figure 5). Abdominal ultrasound showed bilateral hydronephrosis (Figure 6). After investigations, the child was treated as a case of severe pneumonia, improved after seven days of antibiotics (ampicillin and gentamicin) and was discharged with iron supplements and cod liver oil. His parents were also counselled about PBS and the care they can give him at home. He was given an appointment to come back for follow up after one month and referred to Bugando zonal referral hospital in Mwanza for surgical consultation and urology review, but he never got there. However, the patient was not seen till three months later when he was brought with complaints of diarrhoea, vomiting and fever for two weeks for which he been receiving -

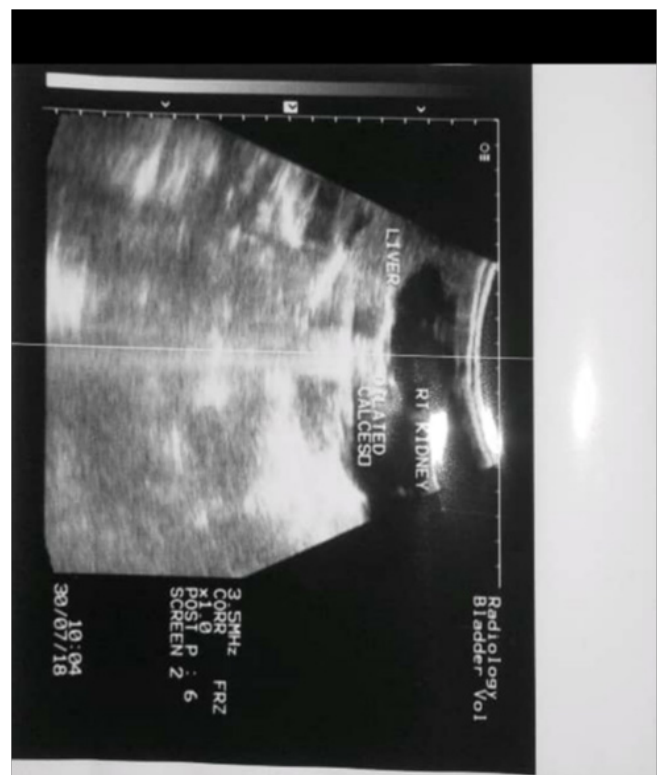
**TABLE 1: Laboratory Results**

Investigation	Case 1 On admission (27/07/2018)	On re-admission (26/11/2018)	Case 2 At OPD (27/09/2019)	Normal values
Creatinine	49.0 µmol/L		134.0 µmol/L.	53-110 µmol/L9.
WBC	16.2 x 103/mm <sup>3</sup>	39.2 x 103/mm <sup>3</sup>	8.1 x 103/mm <sup>3</sup>	2.0 – 12.3 x 103/mm <sup>3</sup>
Lymphocytes	66.8,%	9.4%	78.6%	20.0 – 40.0%
Granulocytes	24.9%	87.4%	7.1%	26.0 - 79.0%
Monocytes	8.3%	3.2%	14.3%	2.0 – 10.0%
Hb	9.9g/dl	7.3g/dl	13.8g/dl	11.0 – 16.5g/dl
MCV	75 µm <sup>3</sup>	69 µm <sup>3</sup>	87 µm <sup>3</sup>	80-100 µm <sup>3</sup>
MCH	20.0/pg	23.0 pg	29.4 pg	26.0 - 34.0pg
Platelets	228 x 103/mm <sup>3</sup>	438 x 103/mm <sup>3</sup>	315 x 103/mm <sup>3</sup>	145 - 450 x 103/mm <sup>3</sup>
RBC	4.98 x 106/mm <sup>3</sup>	3.15 x 106/mm <sup>3</sup>	4.7 x 106/mm <sup>3</sup>	4.70 – 5.63 x 106/mm <sup>3</sup>

**FIGURE 5**



**FIGURE 6**



had been receiving treatment at Kabale dispensary without improvement. On arrival, the child was severely ill, restless, had sunken eyes and skin pinch went back slowly. His temperature was 39.3°C, with increased pulse rate and respiratory rate and peripheral capillary oxygen saturation (SpO<sub>2</sub>) of 92% on air. Other systems were normal. Laboratory investigations (Table 1) showed severe leukocytosis and granulocytosis with microcytic



anaemia with low red blood cells (RBC). He was given intravenously administered antibiotics (Ceftriaxone) for treatment of suspected septicaemia, intravenous fluid to correct the hydration status, paediatric zinc, blood transfusion (140mls), and oxygen therapy. The child's condition continued to deteriorate and on the sixth day of admission he died.

**Case 2:** The second case is a neonate of 4 weeks, who came as a referral case from Rwamishenyi health centre in Bukoba Municipality on 27<sup>th</sup> September 2019 with suspicion of intestinal obstruction. On reviewing the patient at the paediatric clinic, his parent reported that they noted abdominal swelling on the left side since birth. He had no vomiting, no diarrhoea, no history of fever, no cough and was passing urine normally. He was breast feeding well and had received immunization, oral polio vaccine and Bacillus Calmette-Guerin (BCG) vaccine at birth. His prenatal, natal, postnatal and pregnancy history were not contributory. He was the first born in the family. There were no similar cases known in the family.

On physical examination a pulse rate (PR) of 148 beats/min, respiratory rate (RR) of 55 breaths/min and a body temperature (T) of 36.4 °C were noted. Abdominal examination revealed a flabby abdomen with poorly developed muscles, asymmetric, with absent rectus abdominis muscles with a soft mass on the left side of the abdomen. Both testes were undescended. On examination of the chest, pectus excavatum was noted (Figure 7 to 8) as well as normal vesicular breathing sounds. Other systems were unremarkable.

Laboratory investigations (Table 1) revealed increased creatinine level. Urinalysis showed pale yellowish urine, with pus cell 0-2/Hpf, RBCs >100Hpf. His complete blood count was normal. Abdominal ultrasound showed bilateral hydronephrosis (Figure 9).

After investigations, the child was treated with amoxicillin as a case of urinary tract infection, and was referred to urologist at Bugando zonal referral hospital in Mwanza for further management including management of impaired kidney function and possible orchidopexy.

## DISCUSSION

Prune Belly Syndrome (PBS) is a rare congenital disorder composed of anomalies of various organ systems. It is allied with tremendous morbidities as 50% have variable degrees of urinary pathology during their lifetime and 67% develop renal failure<sup>6</sup>. These two case reports describe PBS, one with pectus carinatum and the second case with pectus excavatum. The first case report describes a two months old boy with the triad of PBS as reported in previous publications.<sup>1,4,5</sup> In the majority of cases the diagnosis of PBS is made during infancy<sup>4</sup>, but with increased use of antenatal ultrasound more cases will be diagnosed and referred to a full facility centre before birth. In both cases no antenatal imaging was performed. Although the child in the first reported case was born at a health facility, his congenital malformation was not detected until 2 months when they were seen at a higher level of health facility (BRRH). This may indicate a low level of awareness among health professionals about PBS. However, there are very few published case reports of diagnosed PBS in East Africa<sup>10</sup> and we found none in Tanzania. Pectus carinatum is one of the musculoskeletal problems seen in our case (Figure 1) and was also reported in a previous publication<sup>11</sup>, however in the second case pectus excavatum was found (Figure 10). This was also described in previous publication<sup>2</sup>. The characteristics of congenital musculoskeletal problems correlate well with the

FIGURE 7



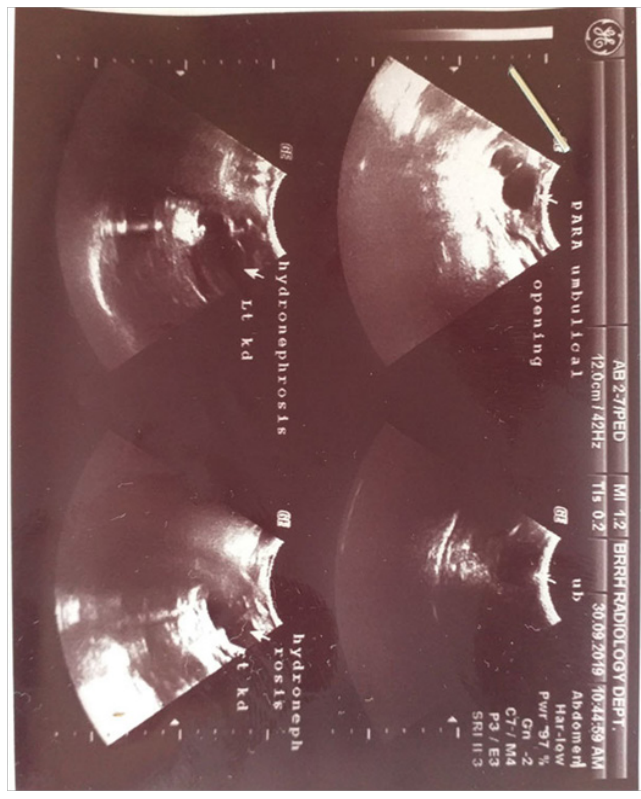
embryologic theory of PBS<sup>12</sup>. No other dysmorphisms were noted in both cases.

Other documented anomalies which coexist with PBS include cardiopulmonary, gastrointestinal and musculoskeletal anomalies<sup>11</sup>. Currently, there are chances for children with PBS to reach adulthood. However, morbidity related to the cardiopulmonary system including respiratory infection and sepsis can potentially affect their quality of life. The abdominal wall defect may not have life-threatening consequences but the inefficient contraction of the abdominal wall muscles is

**FIGURE 8**



**FIGURE 9**



believed to affect bladder, bowel, and pulmonary function, increasing the risk of recurrent urinary and respiratory tract infections<sup>4</sup>. As was seen in both cases, hydronephrosis was present, with the first case having normal creatinine level and the second case having elevated creatinine. Treatment for the first case was intended to save life by stabilizing the patient first. However, this was not successful despite the antibiotics and care given at our centre. After stabilization, a surgical team is of importance for further management. After communicating with an urologist, **case 1** was referred after correction of anaemia, however, he got septicaemia (clinical diagnosis) and died before being seen by an urologist. In the second case we

managed to make the diagnosis early and he was referred to the zonal referral hospital for further management including management for impaired kidney function and orchidopexy. There have been documented cases of testicular tumours developing in PBS patients, but overall, the risk does not appear to be greater than other patients with undescended testes<sup>4</sup>. Orchidopexy or removal of the testes are treatment modalities available to children with PBS. In our cases, this was one of the plans behind the referral to urologist. When timely orchidopexy has not been performed, removal of the testes is done to counteract the high risk of cancer associated with intraperitoneal testes. Our approach of these cases was to give the best treatment and care that was available in our setting. Nevertheless, unavailability of urologist, and of facilities for blood culture, C reactive protein and serum electrolytes in our hospital limited our approach to care for such patients.

**CONCLUSIONS**

In resource limited settings, diagnosis of PBS needs a high index of suspicion. In order to carry out the appropriate steps for management and follow up, timely diagnosis of PBS preferably during antenatal stage or shortly after birth is of great importance, especially at peripheral health facilities. Antenatal ultrasound facilities and sensitizing health personal at peripheral antenatal/obstetric health facilities are crucial for early diagnosis. Since the disease involves multiple organ systems, a multidisciplinary management approach, including psychosocial support, is necessary in order to advance the quality of life for patients with PBS which implies timely referral to a centre with adequate imaging, laboratory, paediatric and surgical/urological facilities. We recommend more training in the pre and postnatal recognition and management of syndromes including PBS for practitioners in lower level facilities. Referral facilities also need to be better staffed with various specialists and better equipped to care and treat PBS patients.

**Abbreviations**

- BP: Blood pressure
- BRRH: Bukoba Regional Referral Hospital
- CBC: Complete Blood Count
- OPD: outpatient department
- PBS: Prune belly syndrome
- PR: Pulse rate
- RBC: Red blood cell
- RR: Respiratory rate
- RUL: Right Upper Lobe
- SpO<sub>2</sub>: Stand for Peripheral capillary Oxygen Saturation
- T: Temperature
- WBC: White Blood Count

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**Author Contribution**

JPK; Concept development, first draft and progress review of manuscript  
 RNP; Progress review and manuscript writing  
 BH; Progress review and manuscript writing, final manuscript review and approval.  
 All authors read and approved the final manuscript.

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# Birth Preparedness and Complication Readiness among Women with Pregnancy and Childbirth related Complications at Kenyatta National Teaching and Referral Hospital, Kenya

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## ABSTRACT

**Background:** In developing countries, particularly those in Sub-Saharan Africa, women and newborns continue to face increased risks of mortality and morbidity during the time of pregnancy, birth and postpartum. Preparing for childbirth and being ready for complications is a key strategy in reducing maternal mortality and morbidity as this would reduce delay in obtaining skilled maternal care especially during childbirth. This survey was evaluating birth preparedness and complication readiness (BPCR) among women seeking services at Kenyatta National Teaching and Referral Hospital.

**Methods:** A cross-sectional hospital-based study was conducted among women admitted in the antenatal and postnatal ward. Data was collected using a standardised questionnaire. A respondent was considered to have satisfactory BPCR if she reported that she had identified the place of delivery, made prior financial arrangements and organised for means of transport to place of childbirth and/or for the time of obstetric emergencies ahead of childbirth.

**Results:** The survey recruited 353 women aged between 15 and 44 years. Majority were married (n=288, 81.6%) and unemployed (n=232, 65.7%). Additionally, most of the participants were multiparous (n=345, 97.7%) and had made at least 1 visit at the Antenatal Clinic during their current pregnancy (n=331, 93.8%). The proportion of women whose BPCR was rated as satisfactory was 56.7% (95% confidence interval, (CI) 49.7% - 63.6%). Factors associated with satisfactory BPCR included: being married (OR 10.66, 95% CI 5.21-21.83), having post-secondary education (OR 11.52, 95% CI 6.62-20.05), being in formal employment (OR 4.14, 95% CI 2.51-6.82), gestation >28 weeks (OR=1.83, 95% CI 1.08-3.09), multiparity (OR=1.87, 95% CI 1.21-2.88), visiting Antenatal Care Clinic (OR=9.31, 95% CI 2.70-32.09) and particularly visiting the clinic more than 2 times (OR=4.43, 95% CI 2.75-7.13).

**Conclusions:** The study documented sub-optimal BPCR. This highlights the need to review the current strategies and approaches being utilised to promote BPCR.

## BACKGROUND

Maternal mortality has continued to be a major public health problem globally. It is estimated that 830 women die daily from pregnancy and childbirth related causes. Globally, it is estimated that 303,000 maternal deaths occur annually. Sub-Saharan Africa (SSA) bears a disproportionately high burden accounting for 66% of the world's maternal deaths.<sup>1</sup>

Maternal deaths are thought to occur due to 3 main delays; delays in deciding to seek care, delays in reaching care, and delays in receiving care. These delays have many causes including; logistic and financial concerns, unsupportive policies and gaps in services, as well as inadequate community and family awareness and knowledge about maternal and newborn health issues.<sup>2</sup> Delays in deciding to seek care may be caused by failure to recognise signs of complications, failure to perceive the severity of illness, cost considerations, previous negative experiences with the health care system, and transportation difficulties. Delays in reaching care may be created by the distance from a woman's home to a facility or provider, the condition of roads, and a lack

of emergency transportation facilities. Delays in receiving care may result from unprofessional attitudes of providers, shortages of supplies and basic equipment, lack of health care personnel, and poor skills of health care providers.<sup>3</sup>

To address the 3 delays, implementation of Birth Preparedness and Complication Readiness (BPCR), a safe motherhood strategy has been recommended globally. It is estimated that exposure to BPCR interventions results in 18% reduction in neonatal mortality risk and a 28% reduction of in maternal mortality risk.<sup>4</sup> The BPCR strategy was incorporated in the World Health Organization (WHO) antenatal care package in 2005.<sup>5,6</sup> BPCR is a process of planning for birth and anticipating actions in case of obstetric emergencies in order to reduce delays in seeking skilled care.<sup>7</sup> The following elements are emphasised in BPCR: deciding on the desired place of birth, preferred birth attendant, location of the closest facility for birth and in case of complications- funds for expenses related to birth and/or complications; supplies necessary for giving birth, an identified labour and birth companion; an identified support person to look after

home and children while the woman is away, transport to a facility for birth or when complications arise; and identification of compatible blood donors when needed.<sup>5,7</sup>

Birth preparedness and complication readiness is implemented as part of focused antenatal care in Kenya. This takes the form of Emergency obstetric care (EmOC) and it includes a set of medical interventions or functions to manage life-threatening obstetric complications. At the basic level (meant to be provided in health centres), it includes intravenous (IV) administration of antibiotics, uterotonics, and anticonvulsants, manual removal of the placenta, removal of retained products of conception following miscarriage or abortion and assisted vaginal childbirth with forceps or vacuum extractor. Comprehensive emergency obstetric care, typically delivered in county hospitals includes; basic care, caesarean services, safe blood transfusion and skilled care during childbirth

Skilled care refers to the process by which a pregnant woman and her baby are provided with adequate care during pregnancy, labour, birth, and the postpartum (MacDonald and Starrs 2002). NFPA 2001b).

For this to be achieved, an enabling environment ought to be provided. Women with life threatening complications resulting from pregnancy or childbirth are prioritised and monitored closely but skilled care ought to be extended to all women during this period.

Despite such programmatic interventions, the maternal mortality in Kenya remains unacceptably high. In fact, Kenya is one of the 10 countries that accounts for nearly 60% of the global burden of maternal mortality. Currently, the Maternal Mortality Ratio (MMR) is 510 deaths per 100,000 live births. The decline in MMR over time has not been impressive considering that the MMR in 1990 was 687 deaths per 100,000 live births.<sup>8</sup> The figures are a far cry from the Sustainable Development Goals (SDGs) of reducing the MMR to less than 70 per 100,000 live births between 2016 and 2030.<sup>9</sup> With this background, there is urgent need to understand the BPCR practices in Kenya as well as the attendant facilitators and barriers to its implementation and uptake.

There is dearth of published literature on the status of BPCR in Kenya particularly among women attending referral hospitals. The present study aimed to fill this gap, at least in part, by documenting the current status of BPCR and factors associated with it among women seeking services at Kenyatta National Teaching and Referral Hospital (KNH).

## METHODS

### Study Design and Study Site

A hospital-based cross-sectional study was conducted between November 2014 and February 2015. The site of the study was KNH which is the largest referral hospital in East and Central Africa. The hospital has a capacity of 1,800 beds and annual inpatient coverage is estimated to be 89,000 patients. There are 6 wards that handle clients admitted for antenatal, delivery and postnatal care. The bed capacity of each of the wards is 32. Kenyatta National Hospital holds an antenatal care unit that reviews clients from Monday to Friday. Mothers undergo full antenatal profile that comprises routine investigations. Clients who are classified as high risk are monitored closely and those requiring close monitoring are admitted to an antenatal ward. Clients who come for antenatal care at the hospital have to un-

dergo complete antenatal profile.

### Study Population

The study population comprised of women admitted at KNH with pregnancy or childbirth related complications. Un-conscious/ semi-conscious clients and those who did not consent for this study were excluded.

### Sample Size

The hospital serves a population of over 10,000 (per year) women in their reproductive age (15-49) years (KNH, 2014).

The sample size was determined using Fisher's method as per (Mugenda and Mugenda, 2003).

$n = z^2pq/d^2$

n=desired sample size

z=standard normal deviate (1.96) that corresponds to 95% confidence level

p= the proportion in the target population with complications related to pregnancy and child birth unknown hence set at 50%.

q=1.0-p size

d=the degree of accuracy desired

$n = 1.96^2 \cdot 0.50 \cdot 0.50 / 0.05^2$

n=384

28 questionnaires were submitted having no data inscribed.

### Data Collection

An interviewer administered to participants semi-structured questionnaires which were used to collect data on socio-demographics, obstetric attributes and antenatal care clinic's attendance. A pre-test was conducted a month before the actual study and the questionnaire translated to Kiswahili for those participants who were not conversant with English. 5 research assistants were engaged for the duration of study and were pre-trained for the study. The time taken with a given participant was variable and ranged between 15 and 25 minutes.

### Statistical Analysis

Data was entered in Microsoft Excel and analysed using STATA 13, a general purpose statistical software package created in 1985 by Stata Corp. Categorical variables were summarised using frequencies and proportions. Chi-square ( $\chi^2$ ) test was used to assess the associations between the various independent variables and BPCR. The threshold for statistical significance during hypothesis testing was set at  $p < .05$ . The risk estimates are presented as Odds Ratios (OR) and the corresponding 95% Confidence Intervals (CI).

### Ethical Considerations

Ethical approval to conduct the study was obtained both from Kenyatta University Ethical Review Committee and Kenyatta National Hospital Ethical Review Board. Informed consent were sought from all the study participants after explaining to them the objectives of the study, procedures and also assuring them their right to refuse to participate in the study at any time. Participants were not required to provide their identification and filled questionnaires were stored in a lockable cabinet. Data was coded and entered safely in STATA

## RESULTS

### Socio Demographic Characteristics

A total of 353 women seeking emergency obstetric services at KNH were enrolled in the study. The age of the respondents

ranged from 15 to 44 years with 23(6.5%) and 35(9.6%) of the respondents being teenagers (≤19 years) and at least 35 years. Majority of the respondents were married 288 (81.6%), 232(65.7%) unemployed and 236(67.1%) had secondary school education or lower educational qualifications

**Obstetric Characteristics**

All participants in this survey were either pregnant 233(66.0%) or in the postpartum phase 120(34.0%). Of those who were pregnant, 132(56.7%) reported that their pregnancies’ gestation was more than 28 weeks. Asked if they had ever experienced any obstetric complications in the past, 160(45.3%) of the participants responded on the affirmative. Investigations into the parity of the respondents revealed that majority were multiparous 345(97.7%).

**Utilisation of Antenatal Care Services**

A vast majority of the women 331(93.8%) had made at least 1 visit at the antenatal clinic. The debut visits made were between 0 and 16 weeks and 17 to 28 weeks by 175(52.9%) and 117(35.3%) women respectively. 39 respondents had made their debut ANC visit in the period ranging from 29 to 40 weeks. On the number of antenatal visits made: 33(10.0%), 88(26.6%) and 73(22.1%) women had sought ANC services once, twice and thrice respectively. Moreover the proportion of women who had visited ANC 4 times were 19.6% (65) while 72 (21.8%) had made 5 visits or more. (Table 1)

**TABLE 1: Utilisation of Antenatal Care Services**

BPCR Attribute	Frequency (n=353)	%
<b>Made a plan of where to deliver (venue of delivery)</b>		
Yes	259	73.4
No	94	26.6
<b>Saved money towards delivery</b>		
Yes	293	83.0
No	60	17.0
<b>Made arrangement for transport</b>		
Yes	264	74.8
No/No response	89	25.2
<b>Birth preparedness and complication readiness</b>		
Satisfactory	200	56.7
Not satisfactory	153	43.3

**TABLE 1: Utilisation of Antenatal Care Services**

Characteristic	Frequency	%
<b>Did you attend antenatal care (n=353)</b>		
Yes	331	93.8
No	22	6.2
<b>Debut period in weeks (n=331)</b>		
0-16	175	52.9
17-28	117	35.3
29-40	39	11.8
<b>No. of antenatal visits (n=331)</b>		
1	33	10.0
2	88	26.6
3	73	22.1
4	65	19.6
≥5	72	21.8
<b>Received health education on danger signs (n=331)</b>		
Yes	263	79.5
No	68	20.5

**Birth Preparedness and Complication Readiness**

Itemised assessment of BPCR showed that 259(73.4%) and 293(83.0%) of the women had, respectively, identified the venue for delivery and saved money towards delivery, prior to childbirth. Additionally, 264(74.8%) of the interviewed women reported having made arrangements for transport to the place of childbirth or for the time of obstetric emergencies ahead of childbirth. Overall, 200(56.7%) of the respondents (95%CI:49.7%-63.6%) were found to have satisfactorily prepared for childbirth and were ready for the contingent complications. (Table 2)

**Factors Associated with Birth Preparedness and Complication Readiness**

**Socio-demographic variables and birth preparedness and complication readiness**

Table 3 presents the findings on the assessment of the association between BPCR and selected socio-demographic variables. A higher proportion of older women aged 30 years or more were found to be birth prepared and complications ready compared to their younger counterparts aged less than 30 years (63.5% versus 52.9% respectively). However, this association failed to attain statistical significance (Odds Ratio (OR) 1.55(95% CI 0.99-2.42), p=.054). The marital status of the respondent was statistically significantly associated with BPCR (p<.001). Married women were found to be approximately, 11 times more likely to be birth prepared and complications ready compared to the unmarried women (OR10.66,95% CI5.21-21.83). Having higher levels of education was statistically significantly associated with increased likelihood of BPCR (p<.001). A higher proportion of women who had secondary and post-secondary qualifications were prepared for birth and ready for complications when evaluated against those with lower educational qualifications (respectively, 75.1% and 20.8%, OR=11.52,95%-CI 6.62-20.05). Being in formal employment was associated with a fourfold increment in the probability of a woman being prepared for birth and ready for complications (OR=4.14,95%-CI2.51-6.82, p<.001).

**Obstetric characteristics, attendance of antenatal clinic and birth preparedness and complication readiness**

The study also sought to evaluate the BPCR and various obstetric attributes of the study participants. Although more women in the postpartum period were rated as birth prepared and complications ready compared to those who were pregnant at the time of the survey, this association was not statistically significant (60.0% against 54.9% respectively, OR 1.23 (95% CI 0.79-1.92), p=.336). Conversely, amongst those who were pregnant, significant variations in BPCR were observed depending on the gestation (p=.024). A woman whose gestation period was more than 28 weeks was 83% more likely to be BPCR compared to those whose gestation period was lower (OR1.83, 95%CI 1.08 -3.09). In terms of parity, having more than 1 child increased

the likelihood of being BPCR by 87% (OR 1.87, 95%CI 1.21-2.88,=0.004). A greater proportion of women who had experienced obstetrics complications in the past were found to prepared for birth and ready for complications compared to those who had never experienced obstetrics complications though this difference in the 2 groups was not statistically significant (60.6% versus 53.4% respectively, OR1.35(95%-

CI0.88-2.06),p=.171). Attendance of antenatal clinic (ANC) resulted in a nine-fold increment in the possibility of a woman being BPCR (OR9.31,95%CI2.70-32.09,p<.001). Moreover, an increase in the number of visits was shown to significantly increase the level of BPCR. Visiting ANC more than 2 times increased the probability of BPCR by about 4 times (OR4.43,95%CI2.75-7.13,p<.001) (Table 4).

**TABLE 3: Association Between Selected Socio-demographic Factors and BPCR**

Characteristic	Total	Satisfactory BPCR		OR*(95% CI†)	P-value
		Yes	No		
<b>Age (years)</b>					
≥30	126	80(63.5)	46(36.5)	1.55(0.99-2.42)	0.054
<30	227	120(52.9)	107(47.1)	Ref	
<b>Marital status</b>					
Married	288	190(66.0)	98(34.0)	10.66(5.21-21.83)	<0.001
Unmarried	65	10(15.4)	55(84.6)	Ref	
<b>Education</b>					
(Post-)Secondary	237	178(75.1)	59(24.9)	11.52(6.62-20.05)	<0.001
Primary	106	22(20.8)	84(79.2)	Ref	
<b>Employment</b>					
Formal	121	94(77.7)	27(22.3)	4.14(2.51-6.82)	<0.001
Informal	232	106(45.7)	126(54.3)	Ref	

**TABLE 4: Relationship Between Selected Obstetric Characteristics and BPCR**

Characteristic	Total	Satisfactory BPCR§		OR*(95% CI†)	P-value
		Yes	No		
<b>Pregnant or Postpartum</b>					
Postpartum	120	72(60.0)	48(40.0)	1.23(0.79-1.92)	.336
Pregnant	233	128(54.9)	105(45.1)	Ref	
<b>Gestation (weeks)</b>					
>28	132	81(61.4)	51(38.6)	1.83(1.08-3.09)	.024
≤ 28	101	47(46.5)	54(53.5)	Ref	
<b>Parity</b>					
>1	182	118(64.8)	64(35.2)	1.87(1.21-2.88)	.004
0 or 1	163	81(49.7)	82(50.3)	Ref	
<b>Previous obstetrics complications</b>					
Yes	160	97(60.6)	63(39.4)	1.35(0.88-2.06)	.171
No	193	103(53.4)	90(46.6)	Ref	
<b>Attended antenatal care clinic</b>					
Yes	331	197(59.5)	134(40.5)	9.31(2.70-32.09)	<.001
No	22	3(13.6)	19(86.4)	Ref	
<b>No. of ANC visits</b>					
>2	210	152(72.4)	58(27.6)	4.43(2.75-7.13)	<.001
1 or 2	121	45(37.2)	76(62.8)	Ref	

**DISCUSSION**

The current study demonstrated that over 50% of women interviewed reported to have been ready for birth and any complications that might arise during pregnancy or during labour. This proportion is slightly lower when compared to the findings of a study done in Sri Lanka where satisfactory BPCR was reported

in 83.5% of the study participants.<sup>10</sup> Further, a research done in East Pokot District, Midwest- Kenya documented much lower levels of BPCR: 28% of the women had satisfactory BPCR.<sup>11</sup>

In Bangladesh, less than a quarter (24.5%) of women were considered well prepared for birth.<sup>12</sup>

The disparities in the findings could be attributed to the differences in the study settings with our study being hospital based while the other studies were community-based. Moreover, the East Pokot and the Bangladesh study were conducted in hard-to-reach rural areas.<sup>11,12</sup> The inconsistencies in the findings could also be attributed to the variations in the study populations. For instance, this study focused on women who were pregnant as well as those who had delivered. The study conducted in East Pokot recruited pregnant women who were on the second and third trimesters<sup>11</sup> while the research conducted in Bangladesh recruited women who had delivered recently.<sup>12</sup>

About 3 in every 5 respondents in this study had made plans for a venue of delivery. In Adigrat, Ethiopia, 44.1% of the participants reported that they had identified a place of delivery.<sup>13</sup> The proportion is much lower than what was documented in the current survey which could be a reflection of the changes that have occurred over time with regard to promoting maternal and newborn health. On the other hand, research conducted in the slum of Kolkata, West Bengal, showed that 100% of the women had identified the place of delivery. The study was community based and enrolled recently delivered women.<sup>14</sup> This could probably explain the discordance in the findings.

Most of the respondents (74.8%) in this survey had made arrangements for transport to the venue of child delivery. This finding corroborates an Ethiopian study where 78.5% of the study participants had organised the mode of transportation to the venue of delivery.<sup>15</sup> Just like in this study, in Kericho County, Kenya, majority of the respondents had made arrangement for transport to the health facility at birth (81.9%).<sup>16</sup> On the contrary, a study done in KNH in 2008 observed that 55% of the interviewed had made prior arrangement for transport to the venue of delivery.<sup>17</sup> This could be due to the government's intensification of interventions aimed at promoting health in the recent past.

In this study, about 4 in every 5 women had had made the appropriate financial arrangements towards delivery and/or for obstetric emergency. Similarly, a study carried out in Ethiopia revealed that the overwhelming majority of the interviewed women (91.1%) had saved some money as part of BPCR.<sup>15</sup> Noteworthy is the fact that saving money was the most prevalent BPCR practice, a finding which is consistent with the findings of studies done in other areas including Bangladesh<sup>12</sup>, Ethiopia<sup>18</sup>, Ghana<sup>19</sup> and India.<sup>20</sup> This probably indicates that both women and their partners clearly understand that money is required to cater for delivery expenses and also to facilitate referral in case of complications.

Being married was positively associated with satisfactory BPCR. The finding possibly highlights the positive influence of psychosocial and, perhaps, financial contributions provided by the spouses with respect to BPCR. In line with this, studies have indicated that involvement of men increases uptake of BPCR practices.<sup>21,22</sup>

The survey found a significant association between education and BPCR with higher qualifications positively impacting on BPCR among the participants. These findings are in concordance with those of a study conducted in India<sup>23</sup> and South-eastern Nigeria.<sup>24</sup> Both studies showed that mother's education level had large positive effects on BPCR. Likewise, research conducted in Tanzania found that women with primary education and above were twice as likely to be prepared for birth and complications compared to those with no formal education.<sup>25</sup> Further, in Ethiopia, maternal education was found to be an independent predictor of BPCR practices with literate mothers being more

likely to be prepared for birth and its complications.<sup>26</sup>

Being in formal employment was associated with higher levels of BPCR among the respondents. This can be closely related to education since majority of the people who are in formal employment tend to be highly educated. This might also be related to the fact that educated and/or formally employed women are more likely to have better income and negotiating power in their societies thus making their own decision in matters affecting their health.

In concordance with the results from this survey, a study done in Central Ethiopia revealed that parity increased the likelihood of BPCR being satisfactory.<sup>27</sup> One of the probable explanations to this is that as parity increases, the exposure to information on BPCR increases due to increased number of ANC visits among other reasons.

Also, in this study, women who attended ANC were more likely to be birth prepared. Moreover, increased visits to the ANC was a significant predictor of favourable BPCR. In concordance with the findings of this study, research conducted in the Osun State of Nigeria showed that women who had more ANC visits were more likely to be prepared for birth.<sup>28</sup> Similar observations were documented in Bale Zone Ethiopia.<sup>18</sup>

A woman whose gestation was more than 28 weeks was more likely to have satisfactory BPCR. This, again, could be related to the increased ANC visits and subsequent exposure to information on BPCR. Other studies have also documented that ANC visits enhances BPCR.<sup>20,24,29</sup> On the other hand, some studies have refuted the role of ANC in promoting BPCR. For example, a study conducted in Abia State, Nigeria, reported that high ANC attendance did not yield corresponding high BPCR knowledge and actions.<sup>30</sup> This may be partly attributed to poor coverage of the content of the ANCs and possibly ineffective modes of communication between the service provider and the clients. For example, inability of the provider to convey his/her messages in the local language and the clients' not understanding well the language used by the provider. Additionally, the contents covered during ANC visits may not be comprehensive.

### Study Limitations

This survey being a hospital-based study, the findings cannot therefore be generalised to the entire community. The study site was a referral hospital and the presence of obstetric complication in the study participants may have had an influence on BPCR. As a result, the observations may not be generalisable to non-referral health facilities.

However, despite the highlighted limitations, the study provides key insights on the BPCR and associated factors among pregnant women in a referral hospital setting.

## CONCLUSIONS

The level of BPCR among women in the study population was sub-optimal. There is a need to review the current strategies and practices for promoting BPCR with a view to enhancing its uptake. The study also identified modifiable correlates of BPCR which should be put into consideration when rethinking of ways to enhance BPCR among pregnant women.

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# Knowledge on Prevention and Management of Preeclampsia and Eclampsia among Nurses in Primary Health Settings: Baseline Findings from an Interventional Study in Dodoma Region, Tanzania.

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## ABSTRACT

**Background:** Preeclampsia and eclampsia are conditions which increase maternal and foetal morbidity and mortality worldwide. These conditions are ranked as the second leading cause of maternal deaths. Nurses have a critical role in preventing and managing preeclampsia. However, their knowledge has not been evaluated particularly among those working in primary health facilities, where opportunities for continue education is limited.

**Objective:** To assess knowledge on prevention and management of preeclampsia and eclampsia among nurses working in the primary health care settings.

**Methods:** Analysis of baseline data from an intervention study which test the effectiveness of simulation-based training on obstetric and neonatal emergencies among nurses in managing maternal and newborn emergencies in primary health care settings. A total of 39 primary health centres within 7 districts in Dodoma Region were selected to take part in the interventional study. Individual participants were nurses working in maternity units were involved. 172 nurses were selected using a simple random method. Nurses' knowledge on prevention and management of PEE and its predictors were assessed using a self-administered questionnaire. Descriptive statistics analysis was done to determine the distribution of the background characteristics of nurses and logistic regression analysis was performed to explore predictors of nurses' knowledge

**Results:** Overall knowledge on preeclampsia and eclampsia was 88 (51.2%). Professional qualification was a predictor associated with a nurse's knowledge about preeclampsia and eclampsia. Registered nurses were more knowledgeable compared to enrolled nurses (AOR 3.311; CI, 1.62 to 6.768; *P* value = .001), years of working experience showed no association with knowledge on preeclampsia and eclampsia (AOR 0.98; CI: 0.39-2.47; *P* values = 0.970)

**Conclusion:** This study showed there is a critical knowledge deficiency in the prevention and management of preeclampsia and eclampsia among nurses working in maternal units of primary health care setting. Effective regular training on prevention and management of preeclampsia and eclampsia for frontline nurses is required in order to improve maternal and neonatal survival.

## INTRODUCTION

Worldwide, maternal and neonatal deaths are still a challenge and it is estimated to be 211 maternal mortality rates per 100,000 livebirths as of 2017. This represents a decrease of 38% from 2000<sup>1</sup>. However, neonatal mortality was estimated to be 18 per 1000 livebirth as of 2017. This represents a reduction of 30.6% from 2000.<sup>2</sup> In Sub-Saharan Africa, maternal mortality rate was estimated to be 525 per 100,000 livebirth as of 2017, a reduction of 38.7% from 2000<sup>1</sup>. Furthermore, the neonatal mortality is still high and estimated to be 27.2 per 1000 live birth as of 2017, this is a reduction of 40.7% from 2000.<sup>2</sup> In Tanzania, there is no significant change in maternal and neonatal deaths, it is estimated that maternal mortality rate (MMR), has reduced from 854 as of 2000 to 524 deaths per 100,000 livebirths in 2017<sup>1</sup>. While neonatal mortality rate (NMR) was 26 in 2010, it was 25 deaths per 1,000 livebirths as of 2015<sup>3</sup>. Hypertensive disorders in pregnancy are responsible for about 26% of maternal deaths worldwide, in Africa the disorders cause deaths for about 99%<sup>4</sup>. The vast majority

of maternal deaths occur in low income countries. The Tanzania Demographic and Health Survey (TDHS) 2015-16 reported that sixteen percent of maternal deaths were due to hypertensive disorders, including eclampsia<sup>5</sup>. Furthermore, PEE are the main cause of maternal, foetal and neonatal mortality especially in low resource countries<sup>5</sup>. Preeclampsia and eclampsia (PEE) are serious conditions which increase long term disability, maternal and foetal, morbidity and mortality worldwide.<sup>6,7</sup> Common hypertensive conditions during pregnancy include: new onset of high blood pressure during pregnancy (gestational hypertension), chronic hypertension, preeclampsia and eclampsia. Signs and symptoms of preeclampsia include: systolic blood pressure >140 mmHg, diastolic blood pressure above 90 mmHg, proteinuria (above 0.3g/24h), frontal headache, visual disturbance and epigastric pain and substantial maternal organ dysfunction<sup>8</sup>. Complications of eclampsia include cardiovascular disease, renal disease, cerebrovascular disease and shorten life expectancy<sup>9</sup>. Additionally, adverse foetal effects from PEE include intra-uterine growth restriction, small for gestational age, respiratory

distress syndrome, transient tachypnea of the newborn, anaemia, apnea, asphyxia, perior intraventricular haemorrhage, cardiomyopathy, cerebral palsy<sup>10,11</sup> and persistent pulmonary hypertension of the newborn<sup>12</sup>. Furthermore, preeclampsia and eclampsia are leading causes of perinatal mortality<sup>11</sup>.

There are complex factors that impact timely care of women with PEE. Lack of competent frontline (nurses) health care providers' diagnosis and management especially in the area of maternal and neonatal emergency care may account for these deaths<sup>13</sup>. This account for third delay model for appropriate and timely management. However, if the woman comes to the antenatal clinic (ANC) or labour ward early to receive appropriate care while the nurse receiving the woman does not know how to diagnose and manage the PEE, this would put the woman and her unborn baby at increased risk of severe morbidity and or deaths.

Early detection, rapid response, accurate management and timely delivery of women with preeclampsia with severe features and eclampsia reduces maternal and foetal complications and deaths. Nurses' knowledge and skills about diagnosis and management of these conditions is critical factor in maternal and neonatal morbidity and mortality.

In Tanzania, the primary health centres are the entry point for most patients including pregnant women who seek health care services whenever needed. The primary health care centres are run by the clinical officers and few by the medical officers. Furthermore, majority of nurses who are working in the health centres are those with certificate and few with diploma in nursing. Moreover, the nursing training for those with diploma covers maternal and neonatal emergencies including PEE while those with certificate are not trained in maternal and neonatal emergencies<sup>14</sup>. Nurses with certificate level of training are able to conduct normal delivery only, and equipped with skills to assist their senior nurses with diploma or health care providers (clinical and medical officers) in emergency or complicated labour. However, in real situation these nurses in some of health care centres are working independently without guidance from higher level nurses, clinical or medical officers.

In the rural areas most of the health centres are public ones, while in urban there are public and private health centres. In Dodoma, the health centres have the capacity of serving an average of 10,772 population, and the number of nurses per health centre ranges from 3 to 20.

The referral health system in Tanzania is of a pyramidal pattern operating upwards from the lowest level which is the community. Patients are referred from community to dispensary, then to health centres, to district, to regional referral hospital, to consultant hospitals and national and or specialized hospitals. The referral system of patients from one level to another follows the skills which are required to address the problems of the patients. Moreover, the government has established an open-door policy, and hence patients can be referred from lower level to higher if the other referral levels lack the required skills<sup>15</sup>.

Nurses are crucial frontline healthcare providers in Tanzania's healthcare facilities. Their knowledge and skills in managing obstetric emergencies are of paramount importance. They must be able to provide timely lifesaving emergency care and correctly identify women needing referral to a higher level of care<sup>16</sup>. Healthcare training programs for nurses on the prevention and management of eclampsia have been shown to reduce adverse

outcomes in critical patientcare settings<sup>17</sup>. Moreover, strengthening on the job training regarding emergency care helps to improve nurses' level of knowledge of PEE management<sup>18</sup>.

Essential knowledge for handling maternal emergencies, including eclampsia, is a prerequisite to appropriate treatment and referrals for mothers. Lack of core knowledge leads to poor decision making and management of emergency maternal health conditions. Furthermore, insufficient knowledge can be attributed to delays in treatment and referrals<sup>19,20</sup>. Adequate knowledge is required to correctly identify women with preeclampsia with and without severe features. This foundational knowledge helps ensure timely evidence based decision making and care based on international guidelines. In Central Tanzania, the knowledge of nurses about the management of PEE, is not well known. Therefore, the aim of this study was to assess nurses' knowledge on managing PEE and identify the predictors of nurses' knowledge in the primary health care setting in Dodoma Region.

## METHODS

### Study Design and Target Population

This paper present analysis of baseline data from an intervention study which aim at testing the effectiveness of simulation-based training on obstetric and neonatal emergencies among nurses in managing maternal and newborn emergencies in primary health care settings. The study was conducted between May and June 2017, exploring nurses' knowledge on PEE. Study participants were nurses working in antenatal ward, labour, postnatal and theatre units.

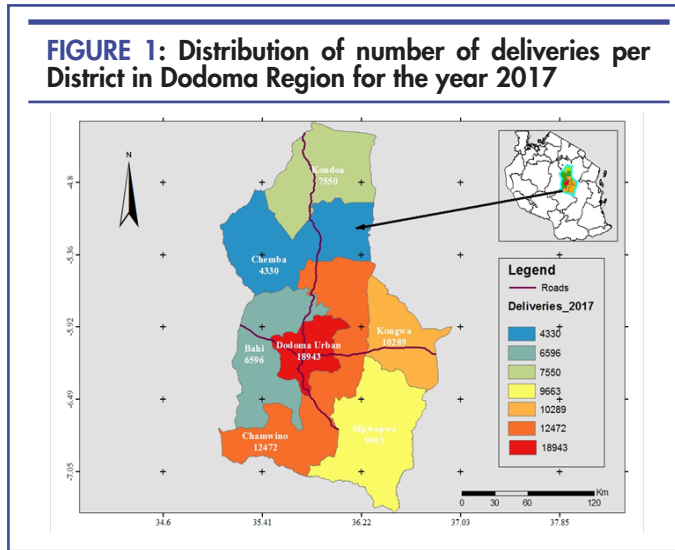
### Study Setting

This study was conducted in all seven districts in Dodoma Region namely Mpwapwa, Kogwa, Chamwino, Dodoma Municipal, Bahi, Chemba and Kondoa. A total of 39 health centres in the region (27 government, 4 faith based organization, 3 parastatal and 5 private). All health centres included in the study are providing ANC services free of charge. On average, a health centre serves 10,772 population, and staffed with 3 to 20 number of nurses. Dodoma Region was selected for this study because of high maternal deaths of 512 per 100,000 livebirths compared to the surrounding regions Singida (468), Manyara (376) and Iringa (292) per 100,000<sup>21</sup>.

### Sampling Technique and Sample Size

The districts were selected purposively due to high maternal deaths in Dodoma Region and all 39 health centers in Dodoma were included in the study. Simple random method was used to select participants from maternity units (antenatal, labour ward, and postnatal) and theatre unit. A 50% rule based on researcher's convenience was considered as a criterion for a decision for the number of nurses to recruit from health centres. Therefore, for each health centre half of its nurses were included in the study. This is due to shortage of nurses, in the health centres, nurses are working in multiple sections, and they don't have specific work. A self-administered questionnaire was used to assess nurses' knowledge on the prevention and management of PEE. A total of 176 study participants were recruited based on a sample size calculation using the Kish and Leslie formula<sup>22</sup> ( $n = \frac{Z^2 p(1-p)}{e^2}$ ) whereby n is a minimum sample size, z is a constant, standard normal variation (1.96 for 95% confidence level) p = 11.8% a prevalence reported by the study conducted in Moshi municipality in northern Tanzania on the evaluation of knowledge and management practices of hyper tension in preg-

nancy<sup>23</sup>. Considering a margin of error (e) of 5%. The minimum required sample size was 160 and we added 10% for non-response. The total sample size was 176 nurses and response rate was 97.7%.



**Data Collection Tool**

In this study, data was collected using a standardized questionnaire in Kiswahili, the national language of Tanzania. Knowledge about PEE was assessed using a standardised and validated questionnaire which contained 10 items with a total of 20 correct answers. The tool was adapted from Jhpiego education materials<sup>24,25</sup>. The questionnaire contained three sections. The first section reviewed the nurses' demographic characteristics, the second section explored their educational background and the third section assessed nurses' knowledge about the management of obstetric emergency including PEE. Each item with a correct response received one point and incorrect responses were scored as zero. Respondents who scored 15 marks and above (75% and beyond) were categorized into adequate knowledge group. Those who scored below 15 marks were categorized into inadequate knowledge group. Before the actual data collection process, a pilot study was conducted with 20 nurses working at district hospital to test the tool's ability to obtain needed information prior to data collection and to identify confusing or ambiguous questions. Ambiguous questions were reworked or removed. Nurses included in the pilot study were not included in the final study.

**Data Collection Procedure**

The study was conducted in the antenatal ward, labour ward, postnatal ward and theatre units where nurses provide care to mothers with PEE. Participation in the study was voluntary. Self-administered questionnaire was completed by each nurse in the presence of researcher and assistant. Clarification was provided in case participants were not clear or had questions about the tool.

**Dependent and Independent Variables**

The dependent variable was the knowledge of nurses on management of PEE. Independent variables included age, sex, experience working in the maternal unit, professional qualification, duration of professional training and timing of work shift.

**Data Analysis**

Data entry and statistical analysis were performed using IBM SPSS Statistics for Windows version 20.0 (IBM Corp, Armonk, NY, USA)<sup>26</sup>. Descriptive analysis was performed to explore distribution of demographic characteristics of respondents. Knowledge items were computed to obtain total knowledge score which was categorized into adequate knowledge and inadequate knowledge. Thereafter, a cross tabulation analysis was performed to assess relationship between categorical variables. Chi-square test was used to determine significant relationship between categorical variables. Significant relationships were further analyzed by performing simple logistic regression analysis. All variables with significant relationship with knowledge (P value < .05) were included in the multiple logistic regression.

**Ethical Considerations**

Ethical clearance was obtained from the Institutional Research Review Committee of the University of Dodoma in Dodoma Region, Tanzania. Permission to conduct the study was obtained from the Regional Medical Officer and the District Medical Officers from respective districts within Dodoma Region. The aim of the study was clearly explained to the participants before signed the consent form. The participants were informed that participation in the study was completely voluntary and they can withdraw at any stage without incurring any consequences. There was no reasonable risk of harm to the participants. The anonymity of the participants was ensured by not having any identification on the data collection tool so that information would not be traced back to individuals. Confidentiality was guaranteed by storing data in a safe and locked place, and only the researcher had access to the raw data.

**RESULTS**

A total of 172 nurses from 39 health centres in Dodoma Region participated in the study. This corresponds to a 97.7% response rate. Mean age the nurses who responded to the questionnaire was 37.3 years (SD±11.393) and majority were females 145 (84.3%) and most 109 (63.4%) being enrolled nurses (certificate level of training). Three quarter of them had completed educational training of less than three years with slightly above half of them working in maternity unit for less than 5 years and received training on management and prevention of PEE as part of their nursing education (See Table 1).

**Level of nurses' knowledge on management of pre-eclampsia and eclampsia**

Based on the operational definition used in this study, only 88 (51.2%) were found to have adequate knowledge on the management of pre-eclampsia and eclampsia. Those who scored 75 percent and above on the self-administered questionnaire were categorised as having adequate knowledge (See Figure 2).

**Nurses' responses to question related to knowledge on prevention and management of eclampsia**

Nurses were given 10 multiple answer questions, with total of 20 correct answers. Most nurses 160 (93%) were able to correctly identify the recommended drug to be used for prevention and management of severe preeclampsia and eclampsia and 148 (86%) nurses were able to recognize the drug of choice for the management of high blood pressure. However, few nurses, 67 (39%), were able to know the type of intravenous fluid to be given to mothers with eclampsia (See Table 2).

**TABLE 1: Nurses' Demographic Characteristics N=172**

Demographic characteristics		Frequency	Percentage (%)
Sex	Male	27	15.7
	Female	145	84.3
Age Group (Years)	20-29	63	36.6
	30-39	39	22.7
	40 and above	70	40.7
Level of professional	Enrolled nurses	109	63.4
	Registered nurses	63	36.6
Years of professional training	Less than or equal to 3	120	69.8
	Above 3	52	30.2
Experience in the health sector	Less than 5 years	70	40.7
	5 years and above	102	59.3
Experience in maternity (years)	Less than 5 years	95	55.2
	5 years and above	77	44.8
Pre-service training on eclampsia management	Yes	90	52.3
	No	82	47.7
Night shifts	No	56	32.6
	Yes	116	67.4
Number of shifts per day	Two	27	15.7
	Three	145	84.3

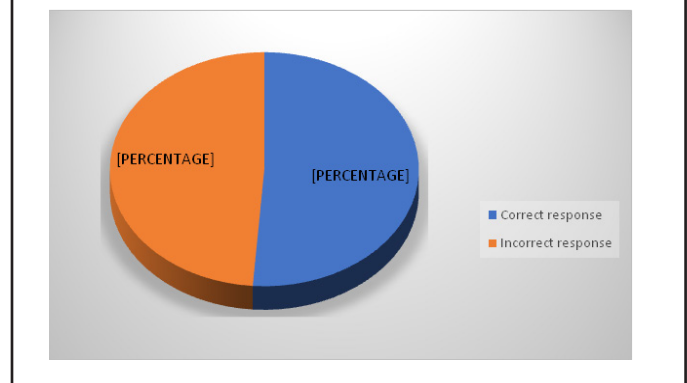
**Factors associated with nurses' level of knowledge on prevention and management of preeclampsia and eclampsia.**

In cross tabulation analysis, nurses' level of knowledge on prevention and management of PEE was significantly associated with age ( $P < .001$ ), professional qualification ( $P$  value = .002), duration of professional training ( $P$  value = .034), working experience in the health sector ( $P < .001$ ) and experience in maternity unit ( $P < .001$ ). High proportion of older (70%), more qualified nurses (66%) and those with longer years of professional training (64%) and experience (63%) had adequate knowledge on management of PEE (See Table 3).

In binary logistic regression, age, professional qualification, years of training and work experience maintained their significant association with nurses' level of knowledge on management of PEE. Registered nurses, those aged 40 years and above, and those with longer duration of professional training and working experience were more likely to have adequate knowledge on management of PEE (Table 4). However, in multiple logistic regression, only professional qualification maintained its significant association with knowledge on management of PEE. Registered nurses were three times more likely (AOR

3.3; 95% CI, 1.6 to 6.8) to have adequate knowledge on management of PEE than enrolled nurses (See Table 4).

**FIGURE 2: Knowledge Level Regarding Pre-eclampsia and Eclampsia Management**



**DISCUSSION**

This study aimed to assess nurse's knowledge of PEE, their prevention and management and associated factors among nurses working in the primary health care setting in Dodoma Region, Tanzania. Out of 172 study participants, 88 (51.2%) had adequate PEE management knowledge. Nurses' knowledge level on management of PEE in the current study was somehow comparable to a previous study conducted in public health facilities in Dar es Salaam, Tanzania which reported 76 (55%) of nurses as knowledgeable<sup>27</sup>. Nurses in the current study were less knowledgeable compared with results of the study conducted in Egypt which reported that 30% of nurses had poor knowledge regarding eclamptic care<sup>28</sup>. However, another study conducted in Egypt reported that 17% of nurses had optimal knowledge on management of preeclampsia<sup>8</sup>. Differences between these studies may be explained by approaches to pre-service and in-service training, lack of empowerment and also, lack of supportive supervision. Regardless, findings from all of these studies demonstrate that knowledge on PEE management is low among frontline nurses in these low resource settings.

Although majority of nurses (93.6%) knew that magnesium sulphate (MgSO<sub>4</sub>) is the drug of choice for the management of woman with eclampsia or preeclampsia with severe, few nurses (38.4%) knew its maintenance dose and how to correctly assess for toxicity after administration of MgSO<sub>4</sub>. Our study results are similar to other studies whereby nurses were also able to correctly identify MgSO<sub>4</sub> as the medication of choice. However, the specifics of MgSO<sub>4</sub> dosing, administration and monitoring is of grave concern<sup>29</sup>. The low knowledge observed in the current study for the management of PEE, may reflect low knowledge in other areas of maternal health care, including antenatal, intrapartum and postpartum care, which ultimately affects maternal and neonatal outcomes. Appropriate and timely care at the health facility is crucial to improve outcomes and avoid delays in care. Better understanding the factors that contribute to such delays will help the health system improve care quality and outcomes<sup>20</sup>. The current study revealed majority had been working as nurses in maternity for less than five years. This means nurses with good working experience in maternal a-

**TABLE 2: Number and Percentage of Nurses with Correct Responses to Prevention and Management of Preeclampsia and Eclampsia**

Questions	Frequency (%)
<b>What are the immediate managements during fit?</b>	
Shout for help	112(65.1)
Ensure the woman airway is open	143(83.1)
<b>What care should be provided for a women after convulsion?</b>	
If available give oxygen 4-6 liters per minutes by mask or canula.	124(72.1)
Observe color for cyanosis and need for oxygen.	82(47.7)
Aspirate the mouth and throat as necessary	155(90.0)
<b>What kind of assessment/physical examination needed after convulsions/fits</b>	
Observe color for cyanosis and need for oxygen, Check for aspiration: lungs should always auscultated after the convulsion has ended, Check vital signs and fetal heart rate.	87(50.6)
<b>The recommended intravenous line for managing eclampsia is</b>	
Normal saline (NS) or Ringer's lactate	67(39.0)
<b>The recommended drug used to control convulsion in management of eclampsia is Magnesium sulfate</b>	160(93.0)
The recommended dose of that drug (selected in question 5) during control of convulsion is	
Gives Magnesium sulfate 20% solution, 4g IV slowly over 5-10 minutes OR 10 g of Magnesium sulphate, each buttock 5g with 50% solution deep IM injection with 1 ml of 2% lignocaine in the same syringe.	66(38.4)
<b>What is the prevention of toxicity of drug selected in question 5?</b>	
Assess respiratory rate. Is respiratory rate at least 16 per minute?	131(76.2)
Assess patellar reflexes. Is Patellar reflexes present?	113(65.7)
Assess urinary output. Is Urinary output at least 30 mL per hour over preceding four hours?	133(77.3)
<b>What are the immediate measures in case the toxicity of the drug selected in question 5 happens?</b>	
Withhold or delay the drug if respiratory rate falls below 16 per minute	86(50.0)
Withhold or delay the drug if Patellar reflexes are absent and Urinary output falls below 30 ml per hour over the preceding 4 hours.	94(54.7)
Assess ventilation and give Calcium Gluconate 1gm (10 ml in 10% solution).	127(73.8)
If diastolic blood pressure remains above 110mmhg, the recommended group of drugs used is	
Antihypertensive drugs (nifedipine or hydralazine)	148(86.0)
<b>Others management of eclampsia includes</b>	
Insert an indwelling urinary catheter to monitor urinary output and proteinuria, do a bed side clotting test, never leave the woman alone (convulsion followed by aspiration of vomit may cause death to a woman and fetus)	93(54.1)
Record drug administration and findings on the woman 's record, Share your findings to a woman and as appropriate to her partner or family member	91(52.9)
Explain management, based on diagnosis, and the importance for pregnancy, labor and delivery.	60(34.9)

This Table describe the steps of management of pre-eclampsia and eclampsia; showing nurses response to the given questions

nd neonatal emergencies management are not retained in the labour ward. Our results differed with study conducted in Northern Nigeria whereby most of health providers had mean number of 9.6 year experience in managing PEE, and most of them knew MgSO<sub>4</sub> is the drug of choice in preventing and treating PEE.<sup>30</sup> The experienced nurses in labour ward should be considered as a good resource for teaching newly employed nurses on management of eclampsia and other maternal and neonatal emergencies.

The current study revealed educational preparation as a key predictor of an individual nurse's knowledge of management of preeclampsia and eclampsia. After controlling for possible confounders, registered nurses were three more likely to be knowledgeable about PEE management compared to enrolled nurses. In Tanzania, registered nurses complete educational training

programs for 3 years (2008-present) or 4 years (prior to 2008) compared to enrolled nurses who receive 3 years (prior 2008) or 2 years (2008-present) of educational preparation. A difference in knowledge and also skills among differently trained nurses has been demonstrated in other settings in Sub-Saharan Africa<sup>31</sup>. Policymakers and educators need to consider the effectiveness of 2 year certificate nurse training programs compared with registered nursing training programs. It appears that there are major knowledge gaps despite comprehensive curricula. Innovative approaches are needed in all types of nurse training programs in Tanzania to ensure foundational knowledge and skills in obstetric and neonatal emergencies, including severe preeclampsia and eclampsia. To ensure that every birth attendant is truly skilled<sup>32</sup>, frontline nurses require core knowledge and fluency in lifesaving skills for mothers and neonates. To th-

**TABLE 3: Factors Associated With Nurses' Level of Knowledge on Prevention and Management of Preeclampsia and Eclampsia (N=172)**

Demographic characteristics		Knowledge on PEE management		$\chi^2$	P-value
		Inadequate(%)	Adequate (%)		
<b>Sex</b>	Male	17(63.0)	10(37.0)	2.558a	0.110
	Female	67(46.2)	78(53.8)		
<b>Age (years)</b>	20-29	42(66.7)	21(33.3)	18.348a	0.001
	30-39	21(53.8)	18(46.2)		
	40 and above	21(30.0)	49(70.0)		
<b>Level of professional</b>	Enrolled nurses	63(57.8)	46(42.2)	9.564a	0.002
	Registered nurses	21(33.3)	42(66.7)		
<b>Duration of professional training</b>	Less than or equal to 3	65(54.2)	55(45.8)	4.512a	0.034
	Above 3	19(36.5)	33(63.5)		
<b>Experience in the health sector</b>	Less than 5 years	46(65.7)	24(34.3)	13.456a	0.001
	5 years and above	38(37.3)	64(62.7)		
<b>Experience in maternity unit</b>	Less than 5 years	57(60.0)	38(40.0)	10.583a	0.001
	5 years and above	27(35.1)	50(64.9)		
<b>Number of shifts per day</b>	Two shifts	10(37.0)	17(63.0)	1.785a	0.182
	Three shifts	74(51.0)	71(49.0)		
<b>Working night shift</b>	No	28(50.0)	28(50.0)	.045a	0.832
	Yes	56(48.3)	60(51.7)		
<b>Pre-service training on eclampsia</b>	Yes	49(54.4)	41(45.6)	2.375a	0.123
	No	35(42.7)	47(57.3)		

at end, there is a need to examine the duration of study for licensure and effectiveness of pre-service training for nurses in Tanzania.

## CONCLUSION

This study demonstrated a critical gap in knowledge among frontline nurses providing maternal health care in Dodoma, Tanzania. One wonders about other key knowledge gaps among maternal health nurses in this setting. At a minimum, nurses are in dire need of regular refresher trainings that focus on lifesaving knowledge and skills for obstetrics, including the management of pre-eclampsia and eclampsia. Strengthening on job training will help nurses' readiness for obstetric emergencies, including early detection, proper management and timely referral. By improving the knowledge and skills of frontline nurses, we can improve maternal and neonatal outcomes. We also, recommend continuing medical educations (CMEs) within the department and supportive supervision to empower nurse's knowledge on obstetric emergencies.

**Limitation of the study:** The study was conducted in all districts of Dodoma region only, therefore these results cannot be generalized to all nurses in Tanzania. The data collection was done for the period of one month (May to June 2017), to obtain for representative data we would have longer time.

## Abbreviations

TDHS: Tanzanian Demographic and Health Survey

PEE: Pre-eclampsia and eclampsia

MgSO<sub>4</sub>: Magnesium Sulphate

WHO: World Health Organization.

Jhpiego: Johns Hopkins Program for International Education in Gynaecology and Obstetrics.

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**TABLE 4: Predictors of Nurses' Knowledge on Prevention and Management of Preeclampsia and Eclampsia (N = 172)**

Demographic characteristics	OR	95% C.I.		p value	AOR	95% C.I.		p value
		Lower	Upper			Lower	Upper	
<b>Sex</b>								
Male	1							
Female	1.98	0.85	4.62	0.114				
<b>Age (years)</b>								
20-29	1							
30-39	1.71	0.76	3.89	0.197	1.20	0.34	4.28	0.776
40 and above	4.67	2.25	9.70	0.000	4.19	0.97	18.22	0.056
<b>Professional qualification</b>								
Enrolled	1							
Registered	2.74	1.43	5.23	0.002	3.31	1.62	6.77	0.001
<b>Duration of professional training</b>								
< 3 years	1							
≥ 3 years	2.05	1.05	4.01	0.035	0.98	0.39	2.47	0.970
<b>Experience in H/S</b>								
<5 years	1							
≥ 5 years	3.23	1.71	6.10	0.000	1.35	0.35	5.25	0.661
<b>Experience in the maternity unit</b>								
< 5 years	1							
≥ 5 years	2.78	1.49	5.18	0.001	0.96	0.31	2.96	0.937

**Authors' contributions:** Angelina Joho led the conceptual, design, acquisition of data, analysis, interpretation of data, and drafting of the manuscript. Stephen Kibusi, Alex Ernes and Ipyana Mwampagatwa guided the conception, design and acquisition of the data, analysis and interpretation, and critically revised the manuscript for intellectual content. All authors read and approved the final manuscript.

**Data Availability:** Data set is available upon request to the corresponding author.

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# Assessment of Maternal Health Services Quality at Juba Teaching Hospital, South Sudan

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## ABSTRACT

**Background:** Client satisfaction is an important outcome of healthcare services and is regarded as an indicator for quality of care. Not much research has been conducted to investigate satisfaction with maternal health care in Sub-Saharan Africa and especially no or little in South Sudan. This study was carried out to assess quality of maternal health services (MHS) at Juba Teaching Hospital, South Sudan.

**Methods:** This cross-sectional research study was done among women of reproductive age at a time of taking their infants for routine immunization services in June to July 2015. A structured questionnaire was used to gather information by interviewers. The data were analysed using SPSS Statistics v20. The frequency tables were for describing data and chi-square test and logistic regression were used to determine whether there was statistical association of sociodemographic factors with satisfaction with MHS.

**Results:** Of 207 women, 193 (93.0%) were satisfied with the services. There was statistically significant association of family monthly income with antenatal care and delivery care satisfaction [OR at 95%CI = 8.30 (2.04 – 33.79), p-value=0.003 and OR at 95%CI = 0.12 (0.03 – 0.56), p-value = 0.007 respectively]. Furthermore, there was a significant association of education attainment with place of delivery [OR at 95%CI = 3.06 (1.40 – 6.71), p-value = 0.005]

**Conclusion:** Women were satisfied with maternal healthcare services. Level of education and monthly family earnings were associated with maternity care. Hence, there should be emphasis on the education of women and their earnings.

## BACKGROUND

Maternal health service (MHS) is a set of services related to maternity health care. These health services cause a serious concern worldwide. Among others, MHS incorporates antenatal care, delivery care and postnatal health service.

Global Statistics stood at 289,000 maternal deaths in 2013.<sup>1</sup> The developing nations accounted for 289,000 (99.0%) with region of sub-Saharan Africa (SSA) alone accounting for 62.0% (179,000) of global deaths followed by Southern Asia at 69,000 (24.0%).<sup>1</sup> For South Sudan, there was a substantial estimation of about 3,000 maternal deaths as of the year 2013.<sup>1</sup>

While the proportion of pregnant women in developing countries with attendance of four antenatal clinic (ANC) visits is estimated at about 52.0%, the low-income countries also stood at around 38.0% of pregnant women who attended four times or more ANC visits.<sup>2</sup> For South Sudan around 46.7% of pregnant women attended one ANC visit.<sup>3</sup>

It has been globally reported that 66.0% of mothers attended delivery care at health facilities.<sup>4</sup> In developing countries, there were 53.0% of pregnant mothers who gave birth at health facilities.<sup>5</sup> This proportion for the SSA<sup>6</sup> and South Sudan estimated at 40.0% and 14.0% respectively.<sup>6</sup>

Importantly, It has been shown that there has been no or little literature on the proportion of postnatal care at global, regional and national levels. Nevertheless, this was estimated at about

30.3% for developing countries.<sup>5</sup>

South Sudan has one of the highest maternal mortality rates in the world and this necessitated the greater attention to maternal and child health services in the country. This attention is apparently indicated in its strategic development plan: “To increase the utilization and quality of health services with emphasis on maternal ... health.”<sup>3</sup> South Sudan maternal deaths are estimated at 2054 per 100,000 live births<sup>7</sup>. South Sudan maternal deaths estimated at 3000. The maternal deaths have substantially increased by 46.1% between 2013 and 2014.

Ministry of Health Republic of South Sudan envisions “a healthy and productive population, fully exercising its human potentials”, with the mission of providing quality healthcare to all the people of the nation, especially most vulnerable women and children.<sup>3</sup>

Juba Teaching Hospital (JTH) is one of the government institutes implementing quality healthcare in South Sudan.<sup>3</sup> The hospital serves Central Equatoria State and acts as highest referral hospital for entire South Sudan, which has about 8.26 million people.<sup>3</sup> The services include, but not limited to ANC, delivery and postnatal care (PNC).<sup>3</sup> Despite Ministry of Health Republic of South Sudan and its health partner’s interventions on quality of mother and child health (MCH) services around 46.7% of pregnant women attended ANC visit.

Despite Ministry of Health Republic of South Sudan and its health partner’s interventions on quality of mother and child health (MCH) services around 46.7% of pregnant women attended ANC visit. Skilled health professionals attend only 14.7% of deliveries and institutional deliveries account for about 12.3% of births.<sup>3</sup> This could be due to quality issues of MHS and in particular the ANC, delivery and PNC services. Unfortunately, the level of quality of MHS and postnatal care in South Sudan are unknown. Consequently, there is paucity of information regarding the proportion of MHS utilization among mothers accessing Juba Teaching Hospital (ANC, delivery and PNC), the level of mothers’ satisfaction towards the quality of MHS among mothers attending at Juba Teaching Hospital and mothers’ demographic factors influencing their satisfaction with quality of MHS. These limitations of quality in maternal health care could explain the observed increase in mortality in South Sudan.

This study assessed the quality of MHS quality among women accessing the Juba Teaching Hospital from June to July 2015. Findings obtained would fill this knowledge gap and would be useful for objective and evidence-based decision making by the Ministry of Health, Republic of South Sudan and its health development partners. Moreover, good practices and lesson learned would be nationally established and used to improve health delivery services at large as well as to enhance the health of mothers in particular.

**Objectives**

The main objective was to assess the quality of MHS at Juba Teaching Hospital in South Sudan. The specific objectives were to establish the level of mothers’ satisfaction towards the quality of MHS and to determine mothers’ socio-demographic factors influencing their satisfaction with quality of MHS.

**METHODS**

**Research Design and Rationale**

The study design was cross-sectional health facility based to assess the quality of MHS in 2015. The cross-sectional study design produces valid research outcomes particularly when the research has been about quality of care.<sup>5, 8, 9</sup>

**Study Site**

This study was carried out in JTH in 2015. The hospital is a government health facility which is situated in Juba city of Central Equatoria State. Juba city also is served as national capital city of South Sudan. The study was conducted in Juba with anticipation that the findings obtained would be incorporated into health policy and translated into useful and implementable health strategies for improvement of MHS. In addition, the choice of JTH was also due to its accessibility. Sudan Government established this teaching hospital in order to serve medical students of the health college of the University of Juba.<sup>26</sup>

South Sudan has since adopted this health facility as its main national referral hospital after its secession from Sudan in a referendum that resulted in its declaration of independence as of July 2011. JTH now serves not only as medical school teaching hospital, but also as a highest referral hospital for the entire country of South Sudan.<sup>26</sup> The hospital offers health service that range from primary to tertiary health care. These services include, but not limited to antenatal care, delivery care, and post-natal services. Furthermore, it provides expanded program

for immunisation, pharmaceutical services, health promotion as well as intensive care, accident and emergency services, voluntary counselling and testing of HIV/AIDs, caesarian section services among others<sup>27, 28</sup>

**Study Population**

The study population were women aged between 15 and 49 years of age who were accessing MCH services at JTH during in 2015.

**Eligibility Criteria**

**Inclusion Criteria:** Consenting women who were between 18 and 49 years of age with infants; were accessing child health-care, the routine immunisation services at JTH; and were with parity of two or more were eligible for this study.

**Exclusion Criteria:** Women who declined to consent were excluded from participation in this study.

**Sample Size**

While the outcome of this research appeared to be categorical data, the following formulae were appropriate to be applied:

$$n_0 = [Z^2 p (1 - p) ] / d^2 \dots\dots\dots(1)$$

where

- $n_0 \equiv$  initial estimated sample size
- $Z \equiv$  level of statistical confidence interval at 95% that has standard value of 1.96
- $P \equiv$  proportion of satisfaction with MHS was set to be 50% or 0.5. This was because, it was unknown.
- $d \equiv$  degree of accuracy that was required, that is, margin of error =5% or 0.05

$$\text{Thus, } n_0 = [(1.96)^2 * 0.5 (1 - 0.5) ] / (0.05)^2 = 384$$

Initially, the study participants were 384 according to the estimation of the above formula for infinite population.

However, the population of mothers who were accessing the routine immunisation services at Juba Teaching Hospital were known or their sample frame 403 women .Hence, the following finite population correction factor for proportion was applied:

$$n = n_0 / [ 1 + ( n_0 / N ) ] \dots\dots\dots(2)$$

where

- $n \equiv$  estimated sample size
- $n_0 \equiv$  initial estimated sample size, that was 384 women
- $N \equiv$  Sample frame, that was 403 women. These were estimated number of women who registered their children for routine immunization at Juba Teaching Hospital. As a result of the preceding formulae, the representative sample size was 196.68 women. This figure was round into 197 women. This was because the women are discrete data, not continuous data.

With the margin of error was 5%, the sample size was brought about to 207.

**Sampling Technique**

A simple random sampling procedure was used in selecting the study participants attending routine immunisation service at JTH in South Sudan. This procedure was applied because the participants of this research study were homogeneous. In the procedure, the women were listed by numbering them. Simple

random tables were used so as to eliminate the bias in recruiting the study participants. The research assistants interviewed the selected study participants using structured questionnaire. As soon as the interview was finished with one woman, the next was interviewed. The language used in the interviews was Arabic.

### Study Unit

The Study unit was an individual woman who has accessed the routine immunisation at JTH in South Sudan.

### Study Variables

The independent variables were age, religion, education level, occupation, employment status, family income per month in South Sudanese Pound (SSP), marital status, type of marriage and parity. The dependent variable was level of mothers' satisfaction with MHS (ANC, delivery care and PNC).

### Data Source

The source of data was primary data interviewing the women at the routine immunisation at JTH.

### Data Collection Techniques and Instrument

The face-to-face interview was conducted in collecting data by research assistants that were recruited based on their competencies in administering questionnaire, conducting interview as well as previous experience in this context. At routine immunization service delivery at JTH, eligible women were interviewed. The purpose, objectives and method of the study were explained to each woman. They were assured that the research did not carry any physical harm. Furthermore, the high degree of confidentiality and privacy were also guaranteed and particularly anonymity of their responses in the entire research process. Afterwards, informed consent was received by signing on the consent form. This interview procedure was conducted repeatedly until the process of data collection was completed.

The tool that was used in collecting data was structured questionnaire which was drawn from three previously used questionnaires. These were adapted to this research study. Some questions were derived from previous relevant studies.<sup>10</sup> Other questions were drawn from research study about client satisfaction with healthcare.<sup>11, 12</sup>

The data collection tool was organized into two sections: Section I: Demographic factors; Section II: MHS utilization and satisfaction (antenatal care, delivery care and postnatal service). The women of reproductive age were requested to rate the level of their satisfaction with the services using five (5) scale ranging from very poor to excellent.

### Data Management and Analysis Techniques

Using EpiData version 3.1, the software questionnaire was designed, prepared and checked (legal range, jump, must enter value label). This designing process was carried out after the data had been cleaned up for omission and errors during the data collection process. After wards, the data were entered into the EpiData (CDC, USA) so as to form database (rec) that was exported into statistical package for social science (SPSS statistics, IBM, USA) data base (spv) for analysis phase.

Since the outcome of this study was categorical variables, cross tabulation and logistic regression were conducted using SPSS statistic version 20. The process was carried out in order to check up for chi-square test, Fisher exact values, Spearman correlation, odd ratios, confidence interval at 95% level, P-val

ues; and to determine whether there was an association between sociodemographic factors with maternal healthcare satisfaction. This stage was also conducted after some incompatible data were transformed into dichotomous variables. The data were validated and reduced for logistic regression analyses. Furthermore, frequencies and percentages were carried out. For the numeric variables, mean and range were summarised.

### Quality Control Techniques

The quality control procedures consisted of a preliminary visit, training of research assistants and data management.

Both preliminary visit to the hospital and the Ministry of Health were conducted so as to get acquainted with ethical procedures of conducting the research study.

Training of research assistant on the study protocol was carried out for five days, with emphasis on the use of random tables and conducting interview.

Pre-test of the questionnaire were carried out for 5% of the sample size at the hospital. It was found that the questionnaire was well understood therefore remained unchanged. The pre-test findings were included in the analysis.

Quality of data was ensured by checking for quantitative data completeness, clearing, entering into Epidata; data validating, coding, and transforming until they were presentable for the analysis.

### Ethical Consideration

The ethical consideration is significant particularly the research study involving human participants. This consideration was constituted of several stages.

To start with, the official letter was obtained from the university – International Health Science for conducting this research after the research proposal was reached.

Afterwards, the letter and seven (7) hard copies of the research proposal were submitted to the Ethical Committee at the Ministry of Health Republic of South Sudan for close review.

Subsequently; while the Ministry of Health acknowledged the importance of the study proposal to fill the gaps in knowledge to improve the health care provision for mothers of reproductive age, the proposal was authorized to be conducted (Ethical letter reference number MOH-RSS/15/07/014).

At Juba Teaching Hospital; the purpose, objectives and significance of the study were clarified to each study participant. Furthermore; the risk, privacy and confidentiality of conducting the research were surely explained to each woman of childbearing age. Then, the opportunity was given for the questions. Accordingly, the feedback was provided.

Finally, the face-to-face interview was administered in a conducive environment after the informed consent was obtained by signature or thumb print.

## RESULTS

### Sociodemographic Factors of the Mothers

The Table 4.1 shows descriptive analysis of the mothers' demographic characteristics. A total of 207 women were interviewed with the response rate of 100%. The mean age of the respondents was 27±4.9, the youngest was 19 years old and the oldest was 42 years old. The proportion of the participants within the

range of 18 to 35 years of age was the highest (94.2%). With regard to level of education, 158 of the mothers (76.3%) had gone through primary education with only 8.2 % having attained higher education. Unemployment accounted for more than half (53.1%) of the women while low proportion of them (12.5%) reported to have had a self-employment. The mean monthly income of the family was US\$407.81; the lowest family income per month was US\$15.6 and the highest was US\$2821.32 with very wide standard deviation (US\$328.26). There were 202 (97.4%) married women and approximately two-third (64.7%) of them indicated to have had a monogamous union. Most of them (85.5%) were multipara or parity of 2 to 4 births. The mean parity of the mothers as 3.15±1.52. The lowest figure was 2 and the highest was 9 births.

**TABLE 4.1: Sociodemographic Factors of the Mothers**

Sociodemographic factors	n=207	Percent
<b>Age*</b>		
18-35years	195	94.2
35-49years	12	5.8
<b>Religion</b>		
Christian	187	90.3
Islam	18	8.7
Others	2	1.0
<b>Level of education</b>		
No formal education	49	23.7
Primary education	78	37.7
Secondary education	63	30.4
Tertiary education	17	8.2
<b>Occupation</b>		
Housewife	184	88.9
Others	23	11.1
<b>Employment status</b>		
Employed	71	34.3
Unemployed	110	53.1
Self-employed	26	12.6
<b>Monthly income*</b>		
<US\$300	94	45.4
US\$300-600	76	36.7
US\$600-900	16	7.7
US\$900-1200	16	7.7
>US\$1200	5	2.4
<b>Marital status</b>		
Married	202	97.6
Separated/widow	3	1.4
Others	2	1.0
<b>Type of marriage</b>		
Monogamy	134	64.7
Polygamy	73	35.3
<b>Parity</b>		
Multipara	177	85.5
Grand multipara	30	14.5

\*upper included in next category

### Level of Mothers' Satisfaction with MHS

The results displayed in Table 4.2 show counts and proportions of overall satisfaction, dissatisfied/satisfied with antenatal, delivery and postnatal care. Of the 142 mothers, 132 (92.9%) were satisfied with ANC while 10 (7.0%) were dissatisfied. Regarding the satisfactory level with ANC, good was the highest score, 81 (57.0%).

Out of the 146 women, only 10 (6.8%) were dissatisfied with the delivery care whereas 136 (93.1%) were satisfied. Of those women, good also emerged to be the highest degree of satisfaction, 84 (57.5%) in terms of delivery care.

Of the 200 mothers who received postnatal care services, 184 (92.0%) were satisfied while 16 (8.0%) were dissatisfied.

**TABLE 4.2: Level of Mothers' Satisfaction With Maternal Health Services**

Variables	n=207	Percent
<b>ANC overall satisfaction*</b>		
Dissatisfied	10	7
Satisfied	132	93
<b>Delivery overall satisfaction**</b>		
Dissatisfied	10	6.8
Satisfied	136	93.2
<b>PNC overall satisfaction***</b>		
Dissatisfied	16	8
Satisfied	184	92
<b>Level of ANC satisfactory*</b>		
Very poor	6	4.2
Poor	4	2.8
Good	81	57
Very good	33	23.2
Excellent	18	12.7
<b>Level of delivery satisfactory**</b>		
Very poor	4	2.7
Poor	6	4.1
Good	84	57.5
Very good	37	25.3
Excellent	15	10.3
<b>Level of PNC satisfactory***</b>		
Very poor	6	3
Poor	10	5
Good	119	59.5
Very good	40	20
Excellent	25	12.5
<b>Maternal care satisfaction</b>		
Satisfied	193	93
Dissatisfied	14	7

Variation within n (\*n = 142, \*\*n = 146, \*\*\*n = 200) was due to systemic exclusion using questionnaire. Satisfied = Excellent, very good and good. Dissatisfied = poor and very poor

**TABLE 4.3: Results of Relation Between the Demographic Factors and Satisfaction With MSH**

Variables	Delivery dissatisfied: n (%)	Overall Satisfaction satisfied: n (%)	Total: n (%)	P Value
<b>Age group</b>				.430
18-35years	10 (100)	128 (94.1)	138 (94.5)	
35-49years	0 (0.0)	8 (5.9)	8 (5.5)	
<b>Religion</b>				.430
Christian	8 (80.0)	124 (91.2)	132 (90.4)	
Islam	2 (20.0)	11 (8.1)	13 (8.9)	
Others	0 (0.0)	1 (0.7)	1 (0.7)	
<b>Level of education</b>				.317
No formal education	0 (0.0)	26 (19.1)	26 (17.8)	
Primary education	4 (40.0)	54 (39.7)	58 (39.7)	
Secondary education	4 (40.0)	45 (33.1)	49 (33.6)	
Tertiary education	2 (20.0)	11 (8.1)	13 (8.9)	
<b>Occupation</b>				.832
Housewife	9 (90.0)	125 (91.9)	134 (91.8)	
Others	1 (10.0)	11 (8.1)	12 (8.2)	
<b>Employment status</b>				.444
Employed	2 (20.0)	50 (36.8)	52 (35.6)	
Unemployed	6 (60.0)	72 (52.9)	78 (53.4)	
Self-employed	2 (20.0)	14 (10.3)	16 (10.9)	
<b>Monthly family income</b>				.004*
<US\$300	2 (20.0)	67 (49.3)	69 (47.3)	
US\$300-600	3 (30.0)	52 (38.3)	55 (37.7)	
US\$600-900	4 (40.0)	8 (5.9)	12 (8.2)	
US\$900-1200	1 (10.0)	8 (5.9)	9 (6.2)	
>US\$1200	0 (0.0)	1 (0.7)	1 (0.7)	
<b>Marital status</b>				.860
married	10 (100)	132 (97.1)	142 (97.3)	
Separated/widow	0 (0.0)	3 (2.2)	3 (2.1)	
others	0 (0.0)	1 (0.7)	1 (0.7)	
<b>Type of marriage</b>				.111
Monogamy	9 (99.0)	89 (65.4)	98 (67.1)	
Polygamy	1 (10.0)	47 (34.6)	48 (32.9)	
<b>Parity</b>				.343
multipara	8 (80.0)	122 (89.7)	130 (89.1)	
grand multipara	2 (20.0)	14 (10.3)	16 (10.9)	

\*P value &lt; 0.05

### The Influence of Demographic Factors on Satisfaction With MHS

The Tables 4.3 and 4.4 illustrate bivariate analysis of mothers' demographic factors that determine the satisfaction with antenatal care, delivery care and postnatal service, respectively. Cross tabulations were used whereby Pearson Chi-Square, Fisher's Exact Test and Spearman correlation were conducted.

Almost half [66 (46.5%)] of the women who attended ANC had a monthly family income of less than US\$300. Of those mothers, 63 (47.7%) were satisfied with ANC while 3 (30.0%) were dissatisfied. The significance of the monthly family in-

come with ANC satisfaction was 0.001 (chi-square test [df=4, n=207]= 18, P=.001). Since the significance value was less than .05, there had been a statistically significant relation between the monthly family earning and satisfaction with the ANC. This association appeared to be statistically inverse (Spearman correlation = -0.19, P=.024), that is, the lower the family income, the higher the satisfaction with the ANC service.

Similarly, family monthly income had significant association with delivery care service satisfaction (Pearson chi-square [df=4, n= 207] = , P<.05).Of the respondents who gave birth at the Juba Teaching Hospital 146 (70.5%) with the income less than US\$300, 49.3% were satisfied; among those with earning

**TABLE 4.4: Results of Relation Between the Demographic Factors and Satisfaction With PNC**

Variables	PNC Overall Satisfaction		Total: n (%)	P Value
	dissatisfied: n (%)	satisfied: n (%)		
<b>Age group</b>				.292
18-35years	16 (100)	172 (93.5)	188 (94.0)	
35-49years	0 (0.0)	12 (6.5)	12 (6.0)	
<b>Religion</b>				.862
Christian	15 (93.8)	166 (90.2)	181 (90.5)	
Islam	1 (6.8)	16 (8.7)	17 (8.5)	
Others	0 (0.0)	2 (1.1)	2 (1.0)	
<b>Level of education</b>				.495
No formal education	2 (12.5)	44 (23.9)	46 (23.0)	
Primary education	5 (31.3)	71 (38.6)	76 (38.0)	
Secondary education	7 (43.8)	55 (29.9)	62 (31.0)	
Tertiary education	2 (12.5)	14 (7.6)	16 (8.0)	
<b>Occupation</b>				.078
Housewife	12 (75.0)	165 (89.7)	177 (88.5)	
Others	4 (25.0)	19 (10.3)	23 (11.5)	
<b>Employment status</b>				.354
Employed	8 (50.0)	61 (33.2)	69 (34.5)	
Unemployed	7 (43.8)	98 (53.3)	105 (52.5)	
Self-employed	1 (6.3)	25 (13.6)	26 (13.0)	
<b>Monthly family income</b>				.959
<US\$300	8 (50.0)	82 (44.6)	90 (45.0)	
US\$300-600	6 (37.5)	68 (37.0)	74 (37.0)	
US\$600-900	1 (6.3)	15 (8.2)	16 (8.0)	
US\$900-1200	1 (6.3)	14(7.6)	15 (7.5)	
>US\$1200	0 (0.0)	5 (2.7)	5 (2.5)	
<b>Marital status</b>				.245
married	15 (93.8)	180 (97.8)	195 (97.5)	
Separated/widow	1 (6.3)	2 (1.1)	3 (1.5)	
others	0 (0.0)	2 (1.1)	2 (1.0)	
<b>Type of marriage</b>				.155
Monogamy	13 (81.3)	117 (63.6)	130 (65.0)	
Polygamy	3 (18.8)	67 (36.4)	70 (35.0)	
<b>Parity</b>				.086
multipara	16 (100)	155 (84.2)	171 (85.5)	
grand multipara	0 (0.0)	29 (15.8)	29 (14.5)	

between US\$300 and US\$600, 38.3% were satisfied; and of those with more than US\$1200 income, only 0.7% were dissatisfied with the delivery care.

Overall, there was no statistically significant association between the level of satisfaction with MHS and age group, religion, level of education and occupation. There was also no significant association between degree of satisfaction with employment status, marital status, type of marriage and number of children ever born alive to the women.

### Logistic Regression Analysis

There are enormous demographic and health system factors that influence satisfaction of women of reproductive age with maternal healthcare services. In bivariate analysis (shown in the tables 4.5 and 4.6), it was observed that only monthly family

income and level of education were the factors with statistically significant association. Multivariate analysis revealed that 80.3% (114) of the women who had earned less than US\$600 on monthly basis were satisfied with the ANC service and were the majority. The significance level and odd ratio with 95% confidence interval were  $P=0.003$  and 8.30 (2.04 – 33.79), respectively. There was therefore a statistically significant association between the monthly family income with ANC service. This analysis was consistent with the findings in bivariate analysis.

The multivariate analysis results indicated that 81.5% (n=119) of the mothers with the same monthly income were satisfied with the delivery care service,  $P=0.007$  and odd ratio with confidence interval=0.12 (0.03 – 0.56). Hence, there was statistically significant association that conformed with the bivariate results.



**TABLE 4.5: Results of Logistic Regression for Sociodemographic Factors and ANC Satisfaction**

Variables	n	(%)	OR	(95% CI)	P Value
<b>Age</b>					
<30*	112	(78.8)	1.00		
>30	30	(21.1)	2.33	(0.40 - 13.42)	.343
<b>Religion</b>					
Christian*	129	(90.8%)	1.00		
Non-Christian	13	(9.2)	1.03	(0.11 - 10.01)	.983
<b>Education</b>					
None*	36	(25.4)	1.00		
Literate	106	(74.6)	0.71	(0.15 - 3.32)	.666
<b>Employment</b>					
Yes*	66	(46.5)	1.00		
No	76	(53.5)	1.24	(0.29 - 5.29)	.775
<b>Monthly family income</b>					
<US\$500*	114	(80.3)	1.00		
>US\$500	28	(19.7)	8.30	(2.04 - 33.79)	.003**
<b>Type of marriage</b>					
Monogamy*	93	(65.5)	1.00		
Polygamy	49	(34.5)	1.27	(0.30 - 5.31)	.745
<b>Parity</b>					
<4*	125	(88.0)	1.00		
>4	17	(12.0)	0.28	(0.02 - 3.95)	.345

\*reference category, \*\*P value < 0.05

## DISCUSSION

### Level of Satisfaction with MHS

Results of this study indicated that the satisfaction of the women of reproductive age with the quality of MHS was at 93.0%. The satisfaction with quality of ANC, and delivery care were at 93.0% while for PNC services it was at 92.0%. It had been noticed that the rates of satisfaction with ANC and delivery care were similar and slightly higher than that of PNC.

The rate of MHS satisfaction of 93.0% found in this study was higher than that of 76.8% reported in an Egyptian study.<sup>13</sup> Studies conducted in Bangladesh<sup>14</sup>, Pakistan<sup>15</sup>, India<sup>16</sup> and Nepal<sup>17</sup> reported satisfaction rates of 62.4%, 61.0%, 51.5%, and 47.8% respectively.

Additionally, in this study satisfaction with the respondents with ANC services was 93.0%. This had a difference of 11.9 % higher than the 81.1% reported in a previous study at a University College Hospital in Nigeria<sup>18</sup>. Furthermore, the satisfaction rate with the ANC services was much higher than those from a research studies undertaken in Western Ethiopian (60.4%)<sup>8</sup> and Egypt (59.8%).<sup>13</sup>

Furthermore, the results of this research study revealed that satisfaction with DC services stood at 93% which is higher to rates reported in previous studies in Ethiopia (80.7%)<sup>19</sup>, in Egypt (68.7%)<sup>13</sup> and South Africa (51.9%).<sup>20</sup>

Moreover, satisfaction with PNC was at 92.0% in this study which is also much higher than satisfaction rates found in studies undertaken in South Africa (51.9%)<sup>20</sup> and in India (22.6%).<sup>16</sup>

Satisfaction level with MHS which combine ANC, DC and PNC services was the highest when compared to findings from previous studies conducted in different developing countries. This observation might explain the high proportions of the utilisation of care recorded, thus affirming the notion that the higher the satisfaction with the quality of maternal healthcare services, the higher the utilisation of the care. This conforms to the hypothesised conceptual framework of this study.

### Determinants of Satisfaction with MHS

There are many sociodemographic and health system factors that influence clients' satisfaction with MHS. This research study revealed only one factor that was monthly family income which had a statistically significant association with MHS. The women with the lower monthly income level were more likely to be satisfied with the quality of MHS than those women with high income. This was consistent with the findings of previous study conducted<sup>21</sup> on quality of MHS in five states of Nigeria. The authors identified that there was statistically significant association of MHS satisfaction with the income.

Furthermore, it was consistent with empirical evidence of recent research study conducted<sup>8</sup> on satisfaction with focused ANC service and associated factors among pregnant women attending focused ANC at health centres in Jimma town, Jimma zone, South West Ethiopia. The authors had demonstrated that there was a statistically significant association of income with the satisfaction with the care. Similarly, a study on MHS in Uganda reported that the income was significantly associated with ANC services of antenatal.<sup>22</sup> However, the results of this study were

**TABLE 4.6: Results of Logistic Regression for Demographic Factors and Delivery Satisfaction**

Variables	n	(%)	OR	(95% CI)	P Value
<b>Age</b>					
<30	118	(80.8)	1.00		
>30	28	(19.2)	1.26	(0.126 - 12.55)	.844
<b>Religion</b>					
Christian	132	(90.4)	1.00		
Non-Christian	14	(9.6)	0.40	(0.06 - 2.45)	.325
<b>Occupation</b>					
Housewife	134	(91.8)	1.00		
Others	12	(8.2)	0.83	(0.06 - 11.01)	.887
<b>Employment</b>					
Yes	68	(46.6)	1.00		
No	78	(53.4)	0.38	(0.07 - 2.09)	.268
<b>Monthly family income</b>					
<US\$500	119	(81.5)	1.00		
>US\$500	27	(18.5)	0.12	(0.03 - 0.56)	.007**
<b>Type of marriage</b>					
Monogamy	98	(67.1)	1.00		
Polygamy	48	(32.9)	6.02	(0.67 - 53.65)	.108
<b>Parity</b>					
<4	130	(89.0)	1.00		
>4	16	(11.0)	0.33	(0.03 - 3.18)	.338

\*reference category, \*\*P value < 0.05

inconsistent with findings from a previous study on perception and satisfaction with quality of ANC services among pregnant women at the University College Hospital, Ibadan, Nigeria. Those authors had reported that there was no significant association of satisfaction with income.<sup>18</sup> Additionally, assessment of factors influencing patients' satisfaction with peripartum care at Germiston Hospital Maternity Unit in South Africa revealed that there was no statistically significant association with family monthly income.<sup>23</sup>

Although some findings of this research have shown insignificant statistical association of age, religion devotion, occupation, marital status and parity with satisfaction of the mothers towards quality of MHS, there was a statistical association of education attainment and monthly family earnings with MHS satisfaction. This implies that education attainment and level of income influence satisfaction, which in turn enhances the utilization of MHS. Furthermore, this means that these findings also confirm the hypothesized conceptual framework of this study.

### Study Limitations

This study was health facility based study and therefore limited to only those women who were attended at the health facility. A community based study would have been better so as to incorporate those women who did not go to the health facility. This was response study and has only provided a "snapshot in time" of quality of MHS at JTH. Recall bias was another limitation inherent in this type of study but it was partly mitigated by good probing techniques of research assistants during the data

collection process.

## CONCLUSION AND RECOMMENDATIONS

### Conclusion

The satisfaction with quality of maternity care was high. The satisfaction with ANC, DC and PNC services were also high. It was established that only a monthly family income had a significant association with ANC and DC services.

### Recommendations

The satisfaction with quality of care is dynamic with time, there is therefore a need to continue improving quality of healthcare that meets the expectations of the women of reproductive age. Since this research did not include data from the community and private health facilities, it is recommended to conduct further research to determine the quality of MHS among women at community level and among mothers in public and private health facilities.

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# Pregnant Women Level of Satisfaction on Quality of Care in Reproductive and Child Health clinic at Huruma Designated District Hospital in Rombo District, Kilimanjaro Region, Tanzania.

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## ABSTRACT

**Background:** The clients' level of satisfaction is an important measure in assessing the quality of health care services provided in health facilities, and is important in enhancing the utilisation of health care services.

**Objectives:** This study aimed to determine pregnant women's level of satisfaction on the quality of care in the Reproductive and Child Health (RCH) clinic at Huruma Designated District Hospital, Rombo Kilimanjaro.

**Methodology:** A cross-sectional study was conducted from May to June 2018 using the Donabedian model. Using systematic sampling, 270 pregnant women were selected to participate in the study. Data was collected using a pre-tested Service Quality (SERVQUAL) questionnaire. Descriptive statistics were performed using univariate and bivariate analysis, and one sample t-test to compare mean gap scores. The principal component analysis was employed to identify key items that measure the quality of care. A p-value of <.05 was considered statistically significant.

**Results:** Overall, pregnant women's level of satisfaction on the quality of care in the Reproductive and Child Health clinic at Huruma DDH was 48.5%. The overall mean gap score ( $\pm$ SD) for the level of satisfaction was -0.53 ( $\pm$ 1.69) signifying dissatisfaction with the quality of care. The overall level of satisfaction was associated with level of education ( $p < .001$ ), occupation ( $p = .003$ ), residence ( $p = .035$ ). The levels of dissatisfaction in the 5 service dimensions were: empathy (-0.05), responsiveness (-0.09), assurance (-0.10), tangible (-0.13), and reliability (-0.17).

**Conclusion:** Overall, pregnant women were dissatisfied with the quality of care provided. Pregnant women who are educated, being employed, and residing in Rombo were more likely to report dissatisfied with the quality of care. To improve the quality of care, lack of adequate staff and inadequate knowledge of the staff at RCH, and improvement in staff-clients interactions, and keeping scheduled appointments need to be improved.

## BACKGROUND

Globally, pregnancy and childbirth claim the lives of an estimated 303,000 women annually; with 50% of these deaths occurring in Africa.<sup>1</sup> According to the 2015-2016 Tanzania Demographic and Health Survey and Malaria Indicator Survey, the maternal mortality rate in Tanzania was estimated at 386/100,000 live births, compared to 12/100,000 live births in developed countries.<sup>1,2</sup> Besides, data shows that 98% of pregnant women attended Reproductive and Child Health (RCH) care at least once during their pregnancy, whereby 51% attained the recommended 4 visits. Furthermore, data shows that 64% received assisted-delivery at a health facility.<sup>2</sup> Poor quality of RCH care is a key attribute of suboptimal institutional delivery in Tanzania and high maternal mortality rates.<sup>2</sup>

Clients' satisfaction is a measure of the quality of care of health system performance,<sup>3</sup> and manifests itself as distribution, access, and utilisation of health services.<sup>4</sup> Evidence from studies conducted in developed countries has shown that the overall level of satisfaction on the quality of RCH care among pregnant women differs from country to country, ranging from 81.5% in Belgium<sup>5</sup> to 90% in Kazakhstan.<sup>6</sup> In sub-Saharan Africa, similar differentials on the overall level of satisfaction on the quality of

care were noted. The level of satisfaction ranged from 61.9% in Ethiopia,<sup>7,8</sup> to 81.1% in Nigeria.<sup>9</sup> To improve the quality of health care services, the Tanzanian government has made efforts through the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDEC), using different approaches to improve quality of care.<sup>4</sup> These approaches include: supplying essential drugs for free and at low cost, provision of maternal and child health services for free in public health facilities, community education on maternal and childbirth, and increasing the number of health facilities.<sup>10</sup> This study used the Donabedian model<sup>11</sup> to determine pregnant women's level of satisfaction with the quality of care in the RCH clinic in the study area.

Briefly, the Donabedian model includes 3 key domains: structure, process, and outcome, which are interrelated in the assessment of the quality of care. The Donabedian model underscores the likelihood of a good structure to increase good process, which increases a good outcome (i.e, patients' satisfaction). The justification of selecting the Donabedian model in this study is based on substantial empirical evidence for its ability to generate information on the quality of care.<sup>11</sup> Irrespective of the many studies conducted in Tanzania on patients' level of satisfaction

with the quality of care, there is a paucity of data regarding pregnant women's level of satisfaction with RCH services in a Designated District Hospital<sup>12</sup> in rural Tanzania. Therefore, this study aimed to determine pregnant women's level of satisfaction on the quality of care in an RCH clinic in rural Tanzania. Findings from this study will add knowledge to the literature by assessing how the Donabedian model might explain pregnant women's level of satisfaction on the quality of care, and provide recommendations for improvement of RCH services offered at the hospital.

## METHODS

### Study Design and Area

A cross-sectional study was conducted at Huruma DDH in the Rombo district from May to June 2018. Rombo is 1 out of 6 districts of the Kilimanjaro region. Huruma DDH is in the Rombo district council located in the north eastern part of the Kilimanjaro Region, Tanzania.

Huruma DDH serves Rombo District, which has an estimated population of 260,963 (Male=124,520(47.7%); Female=136,435(52.3%).<sup>13</sup> Women of childbearing age(15 to 49 years) were 6,640. Rombo district has a total of 45 health facilities (37 dispensaries, 6 health centres, and 2 hospitals). Huruma DDH has a catchment area of 50,000 to 60,000, with 280 official bed capacity. As a DDH, it receives referred patients from other facilities within the catchment area and neighbouring Kenya. During the time of the study, approximately, 40 to 50 pregnant women per day attend the RCH clinic, which runs 5 days a week.

### Study Population

The study population comprised all pregnant women who attended the RCH clinic at Huruma DDH during the study period and consented to participate in the study. Participants who were mentally handicapped, re-attendances, and those with serious ill conditions were excluded.

### Sample Size and Sampling

A single population proportion sample size determination formula was used to calculate the sample size. Based on a study conducted by Olomi et al. (2017), the patients' level of satisfaction in the Kilimanjaro region was 20%<sup>14</sup> and this was taken to calculate the sample size. A margin error of 5%, non-response rate of 10% and the desired level of Confidence Interval at 95% were included in the formula as follows:  $N = Z^2 \times P \times (100 - P) / E^2$  where by N= Estimated Sample Size, Z=Standard Normal Deviation of 1.96<sup>2</sup> corresponding to 95% Confidence Interval (CI), P = Proportion of outcome under study and E= Marginal Error at 5%.<sup>15</sup>

A minimum sample size of 245 was calculated, and adding 25 respondents (ie, 10% non-response rate), the actual estimated sample was 270. A systematic sampling based on the projected daily attendance at the RCH clinic and a list of attending clients obtained from the clinic register book was used to select participants in the survey. To determine the first interviewee, a simple random technique was employed by drawing a piece of paper written YES among 4 pieces of paper in a box placed at the registry section. A systematic sampling technique was employed to obtain the rest of the interviewees who met the inclusion criteria.

A formula  $N/n$  was used to obtain the sampling interval where

by, N= the total number of clients attending at the RCH clinic per day and n= the estimated sample size.<sup>15</sup> The RCH clinic at Huruma DDH runs daily, which gave a total of 28 days for data collection in 4 weeks but only weekdays were considered which gave a total of 20 days. Number of clients who had to be interviewed per day = Total number of clients for the study/Number of days. The number of clients who had to be interviewed per day =  $270/20 = 13.5, \sim 14$ . Therefore, the number of respondents who had to be interviewed per session for the first 19 days comprised of 14 respondents but 4 respondents on the last day of the interview to accomplish a total of 270 study participants.

Anonymously, structured SERVQUAL questionnaire was adapted and then adopted to address the study objectives.<sup>16</sup> The SERVQUAL questionnaire comprises 5 service dimensions (tangibles, reliability, responsiveness, assurance, and empathy) to determine clients' level of satisfaction on the quality of care. There are 2 categories of questions in assessing clients' level of satisfaction with regard to SERVQUAL questionnaire: 1) Expectation questions and 2) Perception questions.

The questionnaire was developed in English with back-and-forth translation to Kiswahili, the local language in Tanzania. The SERVQUAL questionnaire in Kiswahili was then piloted with a convenient sample of n=30(pregnant women) for validity and reliability. Based on the pilot testing, minor adjustments were done. Trained research assistants with previous experience in quality of care research conducted the data collection process.

### Study Variables

The independent variables in this study included: socio-demographic characteristics (age, religion, marital status, level of education, occupation, and residence). Pregnant women's level of satisfaction was the dependent variable in this study and was assessed by asking the level to which they were satisfied with the quality of care by looking at the gap between their expectations and perceptions using 4 point-Likert scale questions (rating points on the scale). (Table 1)

### Data Management and Analysis

Data was edited, cleaned, coded, entered, and analysed using Statistical Package for Social Sciences (SPSS) version 20.1 (SPSS for Windows; SPSS, Chicago, IL, USA). Descriptive statistics such as frequency, percentages, the measure of central tendency (dispersion) for continuous variables were computed. The chi-square and p-value were used to assess the level of significance and strength of association in categorical variables. To calculate the mean gap score of the client's level of satisfaction, the following procedures were used: A total score (in %) was calculated for each domain (e.g. responsiveness) for both expectation and perception questions. Subtracting perception score from expectation score derived the total gap score. A one-sample t-test was used to compare means of continuous variables (client's expectations versus perceptions). The gap implies the level of clients' satisfaction with the quality of care. Quality of care is deemed indifferent or sufficient when the client's level of satisfaction is equal or greater than the expected level of service or vice versa.<sup>16</sup>

Also, Principal Component Analysis (PCA) was employed to identify the subgroups of the SERVQUAL items forming subscales. Before performing PCA, the suitability of data was assessed. A Correlation Coefficient was set at a cut off point of .3 or above. The Kaiser-Meyer-Okin value-which was used to assess sampling adequacy was set at a cut-off point of .6.

Bartlett’s test of sphericity was used to support the factorability of the correlation matrix. Besides, a Catell’s scree test, and an eigenvalue of over 1.0 which represents the amount of the total variance explained by a factor, were used to inspect the plotting of each eigen value of the factors to find a point at which the shape of the curve changes direction and becomes horizontal.

All factors above the break in the plot and with eigenvalues of over 1.0 were retained for further analysis. Finally, further analysis was done using the Varimax method, to try to minimize the number of variables with high loadings on each factor.

This research adhered to the STROBE guidelines for cross-sectional studies.<sup>17</sup>

**Ethical Consideration**

Ethics approval was obtained from Kilimanjaro Christian Medical University College Research Ethics and Review Committee (CRERC) with ethical clearance number 569. Permission to conduct the study was sought from the Huruma DDH administration. Both written and verbal consent was obtained from eligible respondents at RCH clinic after they have been explained about the study objectives. Respondents were informed that their participation was voluntary, and they can withdraw at any stage of the study. Respondents were assured that their withdrawal from the study will not affect their RCH care. To ensure confidentiality and privacy, respondent identification numbers instead of their names were used. Also, all interviews were conducted in a private place.

**TABLE 1: Donabedian domains and expected response options measured in the survey**

Domains	No. of items	Sample questions (response options)	Alpha
<b>Tangibles</b>	5	“I expect doctor of this RCH clinic to prescribe good drugs” (1= Strongly disagree to 4= Strongly agree)	.85
	5	“I am satisfied doctor of this RCH clinic has prescribed good drugs” (1= Strongly disagree to 4= Strongly agree).	
<b>Reliability</b>	4	“I expect staff of an excellent RCH clinic to have good communication and information skills” (1= Strongly disagree to 4= Strongly agree).	.78
	4	“I am satisfied staff of this RCH clinic have good communication and information skills” (1= Strongly disagree to 4= Strongly agree).	
<b>Responsiveness</b>	7	“I expect staff of an excellent RCH clinic to provide prompt service to clients” (1= Strongly disagree to 4= Strongly agree)	.81
	7	“I am satisfied staff of this RCH clinic offer prompt services” (1= Strongly disagree to 4= Strongly agree).	
<b>Assurance</b>	5	“I expect laboratory results of the excellent RCH clinic will be timely availed”. (1= Strongly disagree to 4= Strongly agree)	.76
	5	“I am satisfied laboratory results of this RCH Clinic are timely availed” (1= Strongly disagree to 4= Strongly agree).	
<b>Empathy</b>	5	“I expect staff of an excellent RCH clinic to listen to clients adequately”. (1= Strongly disagree to 4= Strongly agree).	.84
	5	“I am satisfied staff of this RCH Clinic listen to me adequately” (1= Strongly disagree to 4= Strongly agree).	
a Example of expectation questions			
b Example of perception questions			

## RESULTS

A total of 270 female participants were included with a response rate of 100%. The mean ( $\pm$ SD) age of the participants was 26( $\pm$ 5.12) years. More than two-thirds of 173(64.0%) were aged between 21 and 29 years. The majority, 238(88.1%) were Christians, 207(76.7%) were married, 133(49.3%) had secondary school education and 240(88.9%) reside in Rombo. (Table 2)

**TABLE 2: Socio-Demographic Characteristics of Study Participants (N=270)**

Characteristic	Frequency	Percentage
<b>Mean age (<math>\pm</math>SD) Years</b>		
26.0( $\pm$ 5.12)	270	100
<b>Age groups</b>		
$\leq$ 20	35	13.0
21-29	173	64.0
$\geq$ 30	62	23.0
<b>Religion</b>		
Christian	238	88.1
Muslim	32	11.9
<b>Marital Status</b>		
Married	207	76.7
Single	63	23.3
<b>Level of Education</b>		
Primary education	79	29.2
Secondary education	133	49.3
College/University	58	21.5
<b>Occupation</b>		
Employed	83	30.7
Self employed	95	35.2
Unemployed	92	34.1
<b>Residence</b>		
Rombo	240	88.9
Other places	30	11.1

### Overall Pregnant Women Level of Satisfaction with the Quality of Care

The overall pregnant women’s level of satisfaction with the quality of care in the RCH clinic at Huruma DDH was 48.5% (n=131/270). The overall mean gap score ( $\pm$ SD) for pregnant women’s level of satisfaction was relatively small -0.53( $\pm$ 1.69) signifying dissatisfaction among pregnant women in RCH service provision. The mean expectation score was 17.56 while the mean perception score was 17.03. Therefore, the mean gap score (mean perception score-mean expectation score) was -0.53 for all the service dimensions assessed.

### Socio-Demographic Characteristics and Overall Level of Satisfaction with the Quality of Care

In this study, 3 socio-demographic characteristics, namely; the level of education, occupation, and residence were associated with the overall level of satisfaction of the quality of care. Preg-

nant women with secondary education had higher proportions of being dissatisfied with the quality of care compared with pregnant women with primary education (69.2% Vs 27.8%;  $p<.001$ ). Pregnant women who were employed were dissatisfied with the quality of care compared with unemployed pregnant women (66.3% Vs 41.3%;  $p=.003$ ). Dissatisfaction with the quality of care was highest among pregnant women residing in Rombo compared to those residing outside the district (53.8% Vs 33.3%;  $p=.035$ ). Table 3

The 54 items of the SERVIQUAL scale were subjected to Principal Component Analysis (PCA). Before conducting PCA, the suitability of the data for factor analysis was assessed. Inspection of the correlation matrix revealed the presence of many coefficients of .3 and above. The Kaiser-Meyer-Olkin value was .93, exceeding the cut-off point of .6, and Bartlett’s test of Sphericity was statistically significant ( $p=.000$ ). Principal Component Analysis revealed the presence of 10 components with eigenvalues exceeding 1, explaining 42.4%, 6.9%, 4.9%, 4.1%, 3.7%, 3.3%, 2.6%, 2.3%, 2.0%, and 1.9%. These 10 components explained a total of 74% of the variance.

Using Catell’s scree test, 2 components above the breakpoint on the scree plots of factors for both expectation and perception scale were retained for further analysis. Further analysis using the Varimax method revealed strong loading eight (8) factors with both components. The 8-factor solution explained a total of 49.4% of the variance, with component 1 contributing 26.7%, and component 2 contributing 22.7%. The 8 items included: empathy (4 items), assurance (2 items), responsiveness (1 item), and reliability (1 item). Internal reliability of the items as indicated by Cronbach’s coefficients of .95 for expectation subscale and .96 for perception subscale. (Table 4)

## DISCUSSION

This study was conducted to determine pregnant women’s level of satisfaction with the quality of care provided at the RCH clinic in Huruma DDH, in the Rombo district. In general, the overall pregnant women’s level of satisfaction was 48.5% with a relatively small overall mean gap score signifying overall dissatisfaction with the quality of care. This finding is contrary to studies done in Oman (59%),<sup>18</sup> Ethiopia (60.4%),<sup>8</sup> Belgium (81.5 %),<sup>5</sup> and Nigeria (81.1% to 90%).<sup>9,19</sup> The probable explanation on the observed differentials could be because of variations in the study areas, the study populations, different level of expectations among patients, or actual lower levels of perceived quality of services provided.<sup>14</sup>

In this study, we found that some pregnant women’s socio-demographic characteristics were important in determining their level of satisfaction. 3 socio-demographic characteristics namely; the level of education, occupation, and residence were important determinants for pregnant women’s level of satisfaction with the quality of care. These findings are in line with studies conducted in Malaysia,<sup>20</sup> and Ibadan, Nigeria.<sup>9</sup> However, this finding is contrary to a study conducted in Ghana.<sup>21</sup>

For instance, dissatisfaction with the quality of care among employed pregnant women, in our study could be explained by the fact that women who are employed have higher expectations about the care they will receive. An alternative explanation could be their financial capability to pay for care in different health facilities irrespective of the charges or costs of treatment.<sup>5</sup>



**TABLE 3: Socio-Demographic Characteristics of Study Participants and Patients' Level of Satisfaction (N=270)**

Characteristic	Frequency(%)	Satisfied (%)	Dissatisfied (%)	Chi-square (p-value)
<b>Age Groups</b>				6.532(.083)
≤20	35 (13.0)	23 (65.7)	12 (34.3)	
21-29	173 (64.0)	84 (48.6)	89 (51.4)	
≥30	62 (23.0)	24 (38.7)	38 (61.3)	
<b>Religion</b>				1.765 (.184)
Christian	238 (88.1)	119 (50.0)	119 (50.0)	
Islam	32 (11.9)	12 (37.5)	20 (62.5)	
<b>Marital Status</b>				977(.323)
Married	207 (76.7)	97 (46.9)	110 (53.1)	
Single	63 (23.3)	34 (54.0)	29 (46.0)	
<b>Level of Education</b>				35.961 (.000)*
Primary education	79 (29.2)	57 (72.2)	22 (27.8)	
Secondary education	133 (49.3)	41 (30.8)	92 (69.2)	
College/University	58 (21.5)	33 (56.9)	25 (43.1)	
<b>Occupation</b>				11.433 (.003)*
Employed	83 (30.7)	28 (33.7)	55 (66.3)	
Self employed	95 (35.2)	49 (51.6)	46 (48.4)	
Unemployed	92 (34.1)	54 (58.7)	38 (41.3)	
<b>Residence</b>				4.450 (.035)*
Rombo	240 (88.9)	111 (46.2)	129 (53.8)	
Other places	30 (11.1)	20 (66.7)	10 (33.3)	

\* p-value less than .05

**TABLE 4: Varimax Rotation of Two Factor Solution for SERVQUAL Items**

Items	Component 1 Expectation score	Component 2 Perception score
1. RCH staff paid attention to my individual medical concerns.	.64	.81
2. RCH staff are polite, comforting and encouraging to me when faces with medical problems.	.57	.80
3. RCH staffs have built good rapport and ready to offer medical assistance.	.65	.79
4. RCH has adequate staff to attend pregnant women.	.42	.76
5. RCH staffs showed compassionate to me	.48	.74
6. RCH staffs have adequate knowledge to answer my questions.	.61	.74
7. RCH staffs showed willingness to help pregnant women.	.69	.70
8. RCH staff kept my scheduled appointments.	.57	.69
% of variance explained	26.7%	27.7%
Cronbach's alpha coefficients	.95	.96

Our study also found that pregnant women's level of satisfaction significantly differs by place of residence. Most pregnant women from Rombo were dissatisfied with the quality of care than those coming from outside the district. The most plausible explanation for the current observation could be the familiarity with health care providers at the RCH clinic. An alternative explanation could be the fact that Huruma DDH is the only dis-

trict hospital, hence pregnant women lack alternative hospitals to compare the quality of care. Of all the 5 dimensions used to assess pregnant women's level of satisfaction in this study, participants were least satisfied with the empathy dimension, followed by assurance, reliability, tangible, and responsiveness. The gap scores, which represent the discrepancy between pregnant women's expectation and perception for all 5 dimensions

on quality of care, were negative.

According to the Donabedian model, empathy is used to assess the process domain.<sup>11</sup> Empathy items which explained most of the dissatisfaction on quality of care were failure to pay attention to individuals' medical concerns, failure to show compassion, lack of politeness, comforting, and encouragement to pregnant women when facing medical problems, and inability to build a good rapport and lack of readiness to offer medical assistance.

The observed level of dissatisfaction of pregnant women on RCH staff's inability to build a good rapport and readiness to offer medical assistance, for example, underscores the importance of establishing staff-client relationships, to enhance the quality of care at RCH clinic. Existing evidence shows that there is a strong link between the client's satisfaction and retention in the health care delivery system.<sup>22</sup>

The assurance dimension in the Donabedian model is used to assess the structure domain.<sup>11</sup> In this study, assurance items, which explained most of the dissatisfaction on quality of care, were lack of adequate staff to attend pregnant women, and inadequate knowledge of staff to respond to pregnant women's questions. For instance, the observed level of dissatisfaction of respondents on inadequate staff at the RCH clinic substantiates the major challenge of limited human resources for health sector in the Tanzanian health care delivery system.<sup>23,24</sup> This observation calls for increased efforts by the government of Tanzania, through the MoHCDGEC to address the issue of the lack of health care personnel at all levels of the health care delivery system, including the RCH clinic, at Huruma DDH.<sup>24</sup>

However, this finding should be interpreted with caution, because the study did not assess the actual number of health care personnel attending pregnant women at the RCH clinic. Our finding is contrary to a study done in Egypt using the SERVQUAL tool, whereby pregnant women were more satisfied with adequate staff in the RCH clinic.<sup>25</sup>

The responsiveness dimension is used to assess the process domain in the Donabedian model.<sup>11</sup> Of all the 7 items used to assess responsiveness, pregnant women were dissatisfied with the lack of RCH staff willingness to help pregnant women, when medical help is needed. Considering that dissatisfaction can be a major de-motivating factor in the use of RCH care, enhancing health providers' willingness to help pregnant women could result in a better relationship with the clients, ultimately improving the quality of care. Finally, the reliability dimension is used to assess the process domain as per the Donabedian model.<sup>11</sup> Of all the 4 items used to assess reliability, respondents were least satisfied with the inability of RCH staff to keep their scheduled appointments. Existing evidence suggests that continuity in seeing the same health care provider during scheduled appointments could result in more regular consultations.<sup>5,22</sup> It is imperative for the hospital management at Huruma DDH to make sure that scheduled appointments are adhered to by RCH staff for the betterment of the quality of care at the RCH clinic.

### Limitations and Strengths of the Study

This study has some limitations. The study design used cross-sectional which measures only the outcome of interest but is unable to identify the causality of the outcome of interest. Furthermore, the study focused on interviewing only pregnant women but excluded the health care providers, which might affect the study findings in terms of assessing the client-provider interactions. Further research is needed among pregnant

women and health care providers in similar settings which will assess the effect of client-provider interactions. Selection bias could not be avoided completely in this study, because we only recruited pregnant women who attended the RCH clinic, and were unable to reach pregnant women without any access to RCH care. Also, selection bias is a possibility since the study excluded pregnant women younger than 18 years old due to ethical reasons. Although this study did not gather information on the number of pregnancies, another limitation that should be put into consideration is that women with few numbers of pregnancies may have limited experiences with RCH care compared to women with many numbers of pregnancies.

The SERVQUAL questionnaire added strength to this study because it is a standardised universal tool used to measure the quality of care, which has been used in different settings. Although several studies supported the validity and reliability of the SERVQUAL questionnaire, it should be tested with more demographical and culturally diverse samples.

## CONCLUSION AND RECOMMENDATIONS

This study provides useful insights for enhancing the quality of care for pregnant women attending RCH clinics. The results showed that generally pregnant women were dissatisfied with the quality of care, evidenced by negative gaps between perceptions and expectations scores, which imply that pregnant women's expectations were not met. Pregnant women with secondary education, being employed and residing in Rombo were more likely to report dissatisfaction with the quality of care. To improve the quality of care, lack of adequate staff and inadequate knowledge of the staff at RCH, and improvement in staff-clients interactions, and keeping scheduled appointments need to be improved.

**Competing interests:** The author(s) declare that they have no competing interests.

### Authors' contributions

SK, MK, RS conceived the study, acquired the data, did the analysis, and drafted the manuscript. FM and BN participated in the design of the study, data analysis, interpretation of results, writing of the manuscript from draft to submission. All authors read and approved the final manuscript.

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# Health Related Quality of Life Post Labour Induction with Misoprostol Versus Dinoprostone At Muhimbili National Hospital in Dar Es Salaam, Tanzania: A cross Sectional Study

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## ABSTRACT

**Background:** Labour induction using Misoprostol or Dinoprostone results to similar maternal and foetal clinical outcomes. However, the clinical outcome measures have rarely been combined with effects of interventions on patients' health related quality of life. This study aimed to assess postpartum health related quality of life of parturient after labour induction with vaginal administration of misoprostol versus dinoprostone.

**Methods:** This was a comparative cross sectional study in which pregnant women who underwent labour induction with misoprostol and dinoprostone during the study period were included. Data were collected within 24 hours post-delivery using the 36 item short form health survey questionnaire which consists of 24 attributes distributed in five domains including bodily pains and physical performance three attributes each, mental health seven attributes, general health two attributes, social functioning six attributes and three attributes for labour induction satisfaction. We first estimated scores of all attributes in each domain using Likert scales and then the domain scores were converted into a 0 to 100 scales to express in percentage of total scores. Quality of life was compared in the two study groups using the independent samples T Test. Multivariate regression analysis was performed to control for marital status, gravidity, parity, baseline cervical status, time interval from induction to delivery and mode of delivery.

**Results:** Women who received misoprostol reported better health related quality of life compared to those who received dinoprostone (mean score 92.89 vs. 87.25;  $P < .00$ ). Misoprostol group had significantly higher scores in all domains of health related quality of life; reduced bodily pain (93.76 vs. 84.19;  $P < .00$ ), physical performance (83.64 vs. 73.58;  $P < .00$ ), mental health (96.40 vs. 93.55;  $P < .00$ ), general health (93.78 vs. 90.23;  $P = .01$ ), social functioning (94.81 vs. 91.25;  $P < .00$ ) and satisfaction perceptions (94.96 vs. 90.71;  $P < .00$ ).

**Conclusion:** Health related quality of life information is of particular value in routine care of natal and postnatal mothers. Current and updated guidelines should address the impacts of labour induction interventions on maternal health related quality of life, and encourage the use of quality of life information in provision of holistic natal and postnatal care services. Clinical trials are recommended to determine the effectiveness of labour induction with either of the two methods and address the historical adverse outcomes associated to the use of misoprostol.

## BACKGROUND

Induction of labour is a commonly performed intervention in pregnancy worldwide<sup>1-6</sup>. It is offered when the benefits of ending the pregnancy outweigh the benefits of continuing with it<sup>7,8</sup>. Misoprostol and dinoprostone are the widely used labour induction methods in most countries.<sup>9-12</sup> Misoprostol is a synthetic analogy of prostaglandin E1 whereas dinoprostone is a formulation of prostaglandin E2. In pregnancy, these prostaglandins acts on the cervix and uterus bringing about softening of the cervix<sup>13</sup> and contraction of the uterine muscles<sup>14</sup>. Together, these effects cause effacement, and dilation of the cervix. Both misoprostol and dinoprostone are reported to be commonly used for cervical ripening and induction of labour in some of maternity units in Tanzania. At Muhimbili National Hospital (MNH), 52.5% of patients undergoing labour induction receive

dinoprostone and 32.5% receive misoprostol<sup>6</sup>. While in Kili-manjaro Christian Medical Centre in northern Tanzania 18% of patients who undergo labour induction receive prostaglandins<sup>18</sup>. There is a wide range of literature on clinical outcomes of labour induction with misoprostol versus dinoprostone<sup>16,17,19,20</sup>. Labour induction using misoprostol results to more vaginal birth in some studies<sup>16,17</sup> and less vaginal birth in other studies<sup>20</sup>. The incidences of abnormal uterine activity are similar in women receiving misoprostol and dinoprostone<sup>17,20</sup> and more common among women receiving misoprostol in some studies<sup>21,22</sup>. Meconium staining of the liquor is reported commonly among women receiving misoprostol<sup>17,19,20</sup> as well as in women receiving dinoprostone<sup>16,22</sup>. Incidences of low scores (Apgar score of <7 at five minutes) are similarly reported among women receiving misoprostol and dinoprostone<sup>16</sup> and commonly reported among women receiving dinoprostone in other studies<sup>17,20</sup>.

Complication free vaginal delivery is the primary goal of labour induction<sup>7,8</sup>. A method that is associated with increased vaginal birth would enhance women's Health Related Quality of Life (HRQoL) post-delivery<sup>23</sup>. Postpartum women following vaginal birth are less likely to have problems with mobility, self-care, routine activities, pain or discomfort<sup>23</sup>. However, some studies reports no differences in postpartum HRQoL by mode of delivery<sup>24</sup>. Although misoprostol and dinoprostone appear to be equally effective, clinical outcome measures have rarely been combined with effects of interventions on patients' HRQoL.

Health related quality of life in the context of this study refers to a multi-dimensional concept of personal reported health status that comprises of domains related to physical, mental (eg, energy level, mood) and their correlates including health risks and conditions, functional status and social sustenance after receiving the treatment<sup>25</sup>. We conducted a quality of life study in order to identify HRQoL post-delivery with the aim of planning for appropriate nursing interventions to respond to health care needs of the involved patients and guide the choice of a better labour induction method. Therefore, the aim of the study was to assess and compare the postpartum HRQoL of women after induction of labour with vaginal administration of misoprostol versus dinoprostone in the form of tablets.

## METHODS

### Study Design and Settings

A comparative cross-sectional study was conducted at Muhimbili National Hospital, the tertiary referral and teaching hospital with capacity of 1650 beds located in Dar es Salaam, Tanzania. The hospital receives referral patients from Dar es Salaam regional hospitals and other hospitals from within the city and other regions in Tanzania. Pregnant women attend antenatal care run in clinics that are conducted from Monday to Friday by a team of Gynaecologists and Obstetricians, medical doctors, resident doctors and nurse midwife. On averages one hundred and fifty pregnant women attend per day.

Pregnant women at a gestation age of 28 weeks and above are admitted to the general obstetric unit. The unit has 8 wards located within two maternity blocks, with the capacity of 350 beds. The labour ward located within the main block has twenty delivery beds and a total of twenty five nurse midwives. The nurse midwives works in shifts of eight hours with each shift consisting of five nurses. About 60 deliveries are conducted at the labour ward every day of which nearly 5% are preceded by labour induction<sup>6</sup>.

Labour induction decision is made by the general obstetric unit team under the gynaecologist and obstetrician consultant during antenatal care clinic and ward rounds. The women scheduled for elective induction are admitted one day prior to the procedure for pre induction evaluation. Induction is initiated with either misoprostol or dinoprostone vaginal tablet. After the initiation of labour induction, women are observed in the wards until active phase of labour is established. Thereafter they are transferred to the labour ward for monitoring of labour progress, and possibly augmentation with intravenous oxytocin. Consequently, intermittent foetal heart rate monitoring is initiated in the labour ward using Doppler foetal monitor.

### Study Population

The study population consisted of two groups; a group of parturient undergoing induction of labour with misoprostol and those

receiving dinoprostone.

### Sample Size

Sample Power analysis was used to estimate sample size of 200 study participants. The sample size was calculated using two proportions of vaginal deliveries following labour induction with misoprostol and dinoprostone<sup>20</sup> by using the formula

$$n \text{ (each group)} = \frac{(p_0q_0 + p_1q_1)(z_{1-\alpha/2} + z_{1-\beta})^2}{(p_1 - p_0)^2}$$

Where n = the minimum required sample size,  $z_{(1-\alpha/2)}$  = single sided confidence level which is 95% and  $Z_{\beta}$  = power which was set at 80%,  $P_0$  = proportion of vaginal deliveries in the misoprostol group (78%) and  $P_1$  = proportion of vaginal deliveries in the dinoprostone group (59%). A sample of 90 participants for each group was initially estimated. Applying the adjusted sample size formula for anticipated 10% attrition rate,  $q = n/1-f$  (where q is adjusted sample size; n is original sample size; and, f is estimated non-response rate), the initial minimum sample size estimate was adjusted from 90 to 100 participants. Therefore, a minimum of 200 participants were required in this study.

### Sampling Procedure

We invited all pregnant women who were planned for labour induction during the antenatal care clinics and ward rounds, to participate in this study. Subsequent on obtaining written informed consent, all eligible expectant mothers were randomly selected until the target sample size was attained. The inclusion criteria were labour induction with either misoprostol or dinoprostone, gestation age of 28 weeks and above, a viable singleton pregnancy in cephalic presentation and intact membranes. We excluded women who had a known lethal foetal congenital anomaly, eclampsia and/or hypersensitivity to either of the products used for labour induction.

The protocol for pharmacological labour induction at MNH involves regular vaginal administration of a 25 microgram misoprostol tablet or a 3 milligram dinoprostone tablet. The gynaecologist and obstetrician consultant or resident medical doctor insert the tablet deep into the posterior fornix of the vagina at an interval of six hours. The number of doses depends on cervical status. The maximum was four for Misoprostol and two for dinoprostone. All study women were taken care of by the attending physician, and were managed according to the institution's protocol.

### Outcome Measures

Primary outcome measures were the quality of life domains assessed within 24 hours post-delivery. The measured quality of life domains were bodily pain, physical performance, mental health, general health, social functioning and labour induction satisfaction. Secondary outcome measures included the mode of delivery, and foetal-maternal complications which included foetal heart rate abnormalities, Apgar score of less than 7 at 5 minutes, meconium staining of the liquor, perineal trauma, postpartum haemorrhage, diarrhoea, vomiting and the need for blood transfusion.

### Data Collection

Data were collected from September 2017 to March 2018. A case record form was used to collect clinical data from patient

file and delivery register. Information on maternal HRQoL was obtained by using a Swahili version of the 36 item Short Form (SF-36) Health Survey generic questionnaire. The questionnaire consist of 24 attributes distributed in five domains including bodily pains and physical performance three attributes each, mental health seven attributes, general health two attributes, social functioning six attributes and three attributes for labour induction satisfaction. A team of investigators who are conversant in maternal health and fluent in both English and Swahili reviewed the translation individually and then in a group. Consensus was reached in all the items. Pretesting of the questionnaire was done among parturient undergoing induction of labour at a regional referral hospital in Dar es Salaam. The researchers participated to see whether the questions are clear and represent what is needed. The questionnaire was administered to study participants by the principle investigator during the first 24 hours following childbirth. The Likert scales (with five options) were used to form attributes in each domain. The item scores in each domain were scaled in a positive direction with the highest scores indicating better quality of life. Reliability testing of the generic version estimated using internal consistency method resulted in Cronbach's alpha scores of 0.94 for a sample of 3,445 patients<sup>26</sup>.

### Data Analysis

The collected information was entered into IBM SPSS Statistics for Windows version 23.0 (IBM Corp, Armonk, NY, USA). Data were analysed to compare the rates of different maternal and neonatal outcomes as well as quality of life in the two study groups using independent samples T test. The Multivariate regression analysis was performed to control for potential confounders including the marital status; gravidity, parity, baseline cervical status, time interval from induction to delivery and mode of delivery.

### Ethical Clearance

The study was ethically approved by the Muhimbili University of Health and Allied Sciences, Senate Research and Publication Committee with certificate reference number MU/PGS/SAEC/Vol.IX/. The permission to conduct this study was obtained from the MNH administration. Written consent was obtained from all women prior to the initiation of labour induction after explaining the aim and procedures of the study. Women were informed that they can withdrawal from study at any time and will continue receiving quality management of their labour according to the hospital protocols.

## RESULTS

A total of 228 women participated in the study, whereby 106 women were those induced with misoprostol and 122 with dinoprostone. (See Table 1)

With exception of model of delivery and parity, other baseline obstetric and socio-demographic characteristics were similar in the two study groups. Significantly high proportion of women in misoprostol group 88 (83.0%) achieved vaginal delivery-compared to 85 (69.7%) in the dinoprostone group (Table 1).

### Maternal and Foetal Adverse Outcomes Post Treatment

No differences in maternal and foetal adverse outcomes were observed following labour induction with misoprostol and dinoprostone (See Table 2) Women in both groups experienced good HRQoL outcomes but those in misoprostol group had significantly better HRQoL outcomes than women in dinoprostone

group (See Table 3). Women who received misoprostol were more likely to have better HRQoL outcomes than those who received dinoprostone for labour induction. Though some of the outcomes of HRQoL domains did not vary with the type of drug used to induce labour, women in misoprostol group were more likely to experience reduced bodily pain AOR 1.37; 95% CI, 1.07 to 1.71 and physical functioning AOR 4.84; 95% CI, 1.23 to 19.04 (See Table 4).

## DISCUSSION

This study offers important insights into how labour induction with vaginal administration of misoprostol and dinoprostone tablets impact on maternal postpartum HRQoL. It generates hypotheses for the differences in quality of life in the two study groups. Our findings show that women who received misoprostol significantly scored higher in all six domains of HRQoL compared to those who received dinoprostone. These findings indicate that, misoprostol could improve health outcomes of women in the early postpartum period compared to dinoprostone.

Women who received misoprostol scored higher on physical functioning and bodily pain domains compared to those who received dinoprostone. These findings were possibly due to low rate of caesarean deliveries in the misoprostol group. High rates of caesarean deliveries in the dinoprostone group possibly contributed to bodily pain, impaired physical performance and emotional events. Similar findings were observed in previous studies<sup>27,29</sup>, in which women who delivered by emergency caesarean section had worse physical HRQoL scores.

Our study findings also show that women who received misoprostol had higher scores on mental health domain compared to those who received dinoprostone. These findings could be explained by the low incidence of foetal adverse outcomes in the misoprostol group. The proportions of foetal heart rate abnormalities and Apgar score of less than 7 at five minutes were common in the dinoprostone group. Cases of meconium stained liquor occurred only in the dinoprostone group. Worries concerning the wellbeing of the new born perhaps contributed to poor mental HRQoL scores among women in the dinoprostone group.

General health perceptions were measured in terms of feelings of satisfaction or dissatisfaction with one's health status. Misoprostol group had higher general health domain scores compared to dinoprostone group. These findings could be supported by the high scores on reduced bodily pain, physical functioning and mental health domains among women in the misoprostol group. Having enhanced general health, women who received misoprostol were delighted to socially interact and achieve social relations. Comparison with other studies is limited as most studies compare maternal HRQoL between women undergoing induction of labour versus expectant management.

Regarding the mode of delivery, our results show lower incidences of caesarean section deliveries among women in the misoprostol group compared to the dinoprostone group. These findings may be associated to the better HRQoL among women in the misoprostol group reported after adjustment for mode of delivery in the multivariate regression analyses. This is consistent with the natural course of recovery after childbirth. However; these results are inconsistent with a number of previous studies<sup>30,31</sup>. The quality of life domain scores were similar in the vaginal and caesarean section groups at two weeks and six weeks postpartum among primiparas women<sup>30,31</sup>.

**TABLE 1: Women's Baseline Characteristics by Labour Induction Drug**

Characteristics	Misoprostol (n = 106)	Dinoprostone (n = 122)	P value
<b>Age, years</b>			
Mean (SD)	28.60 (5.26)	30.10 (6.21)	0.06
<b>Gestation, weeks</b>			
Mean (SD)	38.16 (3.18)	38.37 (2.60)	0.59
<b>Parity, n (%)</b>			
0	32 (30.2)	51 (45.1)	0.13
1	31 (29.2)	35 (28.7)	0.13
2+	43 (40.6)	36 (29.5)	0.06
<b>Number of living children</b>			
Mean (SD)	1.32 (1.25)	1.06 (1.29)	0.12
<b>Marital status, n (%)</b>			
Married	84 (79.2)	103 (84.4)	0.46
Unmarried	18 (17.0)	17 (13.9)	0.47
Cohabiting	4 (3.8)	2 (1.6)	0.86
<b>Initial Bishop score</b>			
Mean (SD)	2.30 (1.73)	3.34 (2.40)	0.00
<b>Induction reason, n (%)</b>			
Postdate	42 (39.6)	43 (35.2)	0.34
Pre eclampsia	37 (34.9)	35 (28.7)	0.34
Gestational hypertension	9 (8.5)	16 (13.1)	0.32
Other maternal medical conditions	17 (16.0)	23 (18.9)	0.21
Previous unfavourable pregnancy outcome	1 (0.9)	5 (4.1)	-
<b>Birth weight, kilograms</b>			
Mean (SD)	2.87 (0.74)	2.88 (0.72)	0.94
<b>Mode of delivery, n (%)</b>			
Vaginal deliveries	88 (83.0)	85 (69.7)	0.00
Caesarean section deliveries	18 (17.0)	37 (30.3)	-

**TABLE 2: Maternal and Foetal Adverse Outcomes Post Treatment**

Adverse outcomes	Misoprostol (n = 106) n (%)	Dinoprostone (n = 122) n (%)	COR (95% CI)	AOR (95% CI)	P value
Perineal trauma (lacerations, tear)	34 (32.1)	38 (31.1)	0.99 (0.55 – 1.67)	1.54 (0.56 – 4.18)	0.39
Nausea and Vomiting	16 (15.1)	17 (13.9)	0.91 (0.44 – 1.91)		0.80
Diarrhoea	13 (12.3)	23 (18.9)	1.66 (0.79 – 3.47)		0.17
Postpartum haemorrhage	3 (2.8)	1 (0.8)	0.28 (0.29 – 2.77)		0.27
Blood transfusion	5 (4.7)	2 (1.6)	0.34	(0.64 – 1.77)	0.19
Apgar Score <7 at 5 minutes	2 (1.9)	6 (4.9)	2.69 (0.53 – 13.62)	2.29 (0.39 – 13.29)	0.36
Meconium stained liquor	0 (0.0)	3 (2.5)	-	-	-
FHR abnormalities	1 (0.9)	6 (4.9)	1.69 (0.04 – 18.75)	1.70 (0.09 – 18.79)	0.06

COR: Crude Odds Ratio                      AOR: Adjusted Odds Ratio                      FHR: Foetal Heart Rate

**TABLE 3: Mean Scores of Health Related Quality of Life for Each Domain in the Misoprostol And Dinoprostone Study Groups**

Domain	Misoprostol (n= 106) Mean (SD)	Dinoprostone (n=122) Mean (SD)	Mean difference	95% CI	P value
Reduced bodily pain	93.76 (9.03)	84.19 (18.33)	9.56	5.70 - 13.42	0.00
Physical functioning	83.64 (15.85)	73.58 (19.38)	10.05	5.39 – 14.72	0.00
Mental health	96.40 (5.00)	93.55 (6.31)	2.84	1.34 – 4.35	0.00
General health	93.78 (9.34)	90.23 (10.69)	3.55	0.92 – 6.19	0.01
Social functioning	94.81 (7.53)	91.25 (8.00)	3.55	1.51 – 5.59	0.00
Satisfaction perceptions	94.96 (10.63)	90.71 (11.43)	4.25	1.36 – 7.15	0.00
Overall HRQoL mean scores	92.89 (6.54)	87.25 (8.83)	5.64	3.58 – 7.69	0.00

**TABLE 4: Effects of Drug Induced Labour on Health Related Quality of Life Outcomes (Misoprostol compared to Dinoprostone)**

Domain	Misoprostol (n = 106) n (%)	Dinoprostone (n =122) n (%)	COR (95% CI)	AOR (95% CI)	P value
Reduced bodily pain	97 (91.5)	85 (69.7)	4.69 (2.14 – 10.28)	1.37 (1.07 – 1.71)	0.00
Physical functioning	71 (67.0)	58 (47.5)	2.24 (1.30 – 3.83)	4.84 (1.23 – 19.04)	0.02
Mental health	104 (98.1)	117 (96.7)	1.77 (0.31 – 9.90)	0.78 (0.73 – 8.30)	0.83
General health	99 (93.4)	108 (88.5)	1.83 (0.71 – 4.72)	1.77 (0.57 – 5.47)	0.31
Social functioning	100 (98.0)	103 (92.0)	3.04 (1.40 – 6.61)	2.92 (0.42 – 20.27)	0.27
Satisfaction perceptions	98 (92.5)	106 (86.9)	1.84 (0.75 – 4.51)	1.44 (0.45 – 4.60)	0.53
Overall HRQoL score	100 (98.0)	97 (80.8)	11.85 (2.72 – 51.64)	10.070 (2.02 – 56.99)	0.01

COR: Crude Odds Ratio

AOR: Adjusted Odds Ratio

Similar findings were reported among multiparas women at eight weeks postpartum<sup>31</sup>. The reason why our results are not consistent with the cited studies may be related to early timing of data collection within twenty four hours following childbirth that we employed in this study.

In this study, women who received misoprostol were highly satisfied with labour induction procedure compared to those who received dinoprostone. These findings were possibly contributed by high rates of vaginal birth and low incidences of maternal-foetal adverse outcomes among the women who received misoprostol. However, satisfaction rates in both study groups were higher compared to the rates reported in previous studies<sup>32,33</sup>. This variation perhaps was due to methodological differences. The cited studies employed a retrospective design

while in our study we applied prospective methods. Retrospective design is prone to recall bias. This is more likely to have contributed to the noticeable differences.

There was statistically significant difference in the baseline Bishop Score between the two study groups, with the average score of <3 and >3 in the misoprostol and dinoprostone group respectively. The Bishop Scores of >3 has been associated with increased proportion of vaginal birth in some studies<sup>34,35</sup>. Other studies have reported no difference in the proportion of vaginal birth among patients with Bishop Scores of <3 and >3<sup>36,37</sup>. In this study, low proportion of vaginal birth was observed in a group of patients with Bishop Score of >3. Perhaps the difference in baseline Bishop Scores did not influence the mode of delivery in this study. The major strength of this study is its de-



sign. Cross-sectional study with data collection within 24 hours of delivery lowered the recall bias, and likely contributed to collection of more accurate information. Power analysis was used to estimate the sample size which may permit generalizability of the results. Our study has a number of limitations. First, due to time limit we assessed HRQoL outcomes within 24 hours post-delivery, although follow up through the puerperium would have generated more findings. Second, we had no women's HRQoL data prior to undergoing labour induction; therefore we have no knowledge of whether women with poor HRQoL after labour induction already presented these levels before or during pregnancy. Therefore longitudinal studies including HRQoL assessment during pregnancy needs to be conducted.

Given the absence of contraindications, the study findings show misoprostol to be the best choice (other factors remaining constant) for induction of labour with enhancement of women's postpartum HRQoL. However, the choice for an optimal labour induction method may also need to be guided by economic evaluation comparison of the interventions. Whether labour induction with misoprostol versus dinoprostone has different cost implications should be part of future research.

## CONCLUSION

In women with clinical indications, labour induction with misoprostol results to better HRQoL post-delivery compared to dinoprostone. Health related quality of life information is of particular value in routine care of natal and postnatal mothers. Current and updated guidelines should address the impacts of labour induction interventions on maternal HRQoL, and encourage the use of quality of life information in provision of holistic natal and postnatal care services. Clinical trials are recommended to determine the effectiveness of labour induction with either of the two methods and address the historical adverse outcomes associated to the use of misoprostol.

## List of Abbreviations

FHR – Foetal Heart Rate  
 HRQoL – Health Related Quality of Life,  
 MNH–Muhimbili National Hospital  
 RCOG – Royal College of Obstetricians and Gynaecologists  
 SF-36 – 36-Item Short Form

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# Evaluation of Implementation Level of Community Health Strategy and Its Influence on Uptake of Skilled Delivery in Lurambi Sub County- Kenya

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## ABSTRACT

**Background:** Despite the widespread application of the community health strategy (CHS) in Kenya and evidence of its effectiveness in reducing health outcomes at the household level, data from Kakamega County, of which Lurambi sub-county is part of, still showed that skilled birth delivery was at 47% against the national estimate of 62% and a target of 90%. However, there was limited evidence on the level of CHS implementation and its association with the uptake of skilled delivery.

**Methods:** The study employed a cross-sectional analytic design. A structured validated community unit (CU) scorecard and a household questionnaire were used to collect quantitative data from the CUs through Community Health Extension Workers (CHEWs) and at the household level through mothers with children below 1 year. A random sample of 436 mothers from all the 38 Community Units (CUs) was included. CU functionality was assessed using 17 binary indicators (scored as 1 for a positive response, 0 otherwise) and total scores were expressed as percentages. Fully functional CUs scored  $\geq 80\%$  and semi-functional CU scored  $>50$  to  $<80\%$ . No CU was non-functional (scored  $\leq 50\%$ ). Data from the CUs were merged with data at the household level. Association between CU functionality and skilled delivery was assessed using multivariable binary logistic regression controlling for socio-demographic variables. Adjusted Odds Ratios (OR) and 95% Confidence Intervals (95%CI) are reported.

**Results:** A total of 38 CUs were assessed and of these, 26(68.6%) were fully functional and 12(31.4%) were semi-functional, 18(47.4%) had both household registers (MOH 513) and service delivery logbooks (MOH 514). Overall, 387(80.0%) of mothers had skilled birth deliveries, 263(68%) were from functional CUs and 124(32%) were from semi-functional CUs. Pregnant women were more likely to have skilled deliveries in fully functional CUs than semi-functional CUs (OR=1.3; 95% CI=1.1-2.4; p-value $<.001$ ). Other factors significantly associated with uptake of skilled delivery included receiving health education (OR=2.9; 95%CI =1.4-6.1, p=.005), being visited at least twice by Community Health Volunteers, CHVs (OR=1.9; 95%CI=1.1-3.5, p=.045), attending antenatal care clinics, ANC (OR=3.4; 95%CI=1.3-3.5, p=.012), receiving advice where to deliver (OR=4.1; 95%CI=1.8-9.4, p=.001).

**Conclusion:** 2 out of 3 community units were fully functional, and functionality was associated with increased uptake of skilled delivery. In a fully functional CUs, Community Health Volunteers provided health education through regular visits and they were able to provide a referral to health facilities for the pregnant women. To achieve national targets for skilled deliveries and universal health coverage, there is a need to ensure CUs are fully functional

## BACKGROUND

Globally, one-third (34%) of births take place at home without the help of a professional skilled birth attendant<sup>1</sup> which means that 45 million births are occurring at home without skilled health personnel each year.<sup>2</sup> A range of healthcare services throughout pregnancy, childbirth and the postnatal period is key to improving maternal and newborn health to reduce maternal and child morbidity and mortality.<sup>3</sup> Skilled attendants assist in more than 99% of births in developed countries compared with 62% in developing countries.<sup>1</sup> Presence of skilled medical personnel at child delivery is one of the key indicators towards the Millennium Development Goals (MDGs)<sup>5</sup> of improving maternal health and sustainable development globally to reduce maternal mortality ratio to less than 70 per 100,000 live births.<sup>4,6</sup> Globally, the goal is to have 80% of all births assisted by skilled medical attendants by 2005, 85% by 2010 and 90% by 2015.<sup>5</sup> A study from South India had shown that skilled assistance during delivery can reduce the risk of obstructed labour

and it is highly associated with the place of delivery.<sup>7</sup> In Africa, reports show that less than 50% of births are attended by a skilled health worker.<sup>6,8</sup> In Kenya, coverage of skilled deliveries was 62% while 61% of births were delivered at a health facility by 2014 while the maternal mortality ratio was 362 per 100,000 live births.<sup>6</sup> Neonatal deaths contributed to 60% of Kenya's infant mortality rate (52/1000 live births).<sup>9-14</sup> Prevention of maternal deaths and neonatal deaths can be achieved by ensuring that mothers deliver in the presence of skilled medical personnel. In Kenya's National Health Sector Strategic Plan (NHSSP II-2005-2010), a new approach to the delivery of health care services, known as the Kenya Essential Package for Health (KEPH) was outlined. The KEPH has six life-cycle cohorts and six service delivery levels.<sup>14</sup> One of the key innovations of KEPH was the introduction of level 1 service, which was aimed at empowering Kenyan households and communities to take charge of improving their own health.<sup>14</sup> In line with the vision 2030, the government intended to scale

up community units in the country, and also work towards improving the health service delivery at level one, (household level).<sup>14</sup> In 2007, the Kenya Ministry of Public Health and Sanitation adopted a community health strategy aimed at reversing the poor health outcomes to meet the Millennium Development Goals 4 and 5<sup>15</sup>.

The strategy also aimed at strengthening community participation and encouraging communities to take action towards their health through functional community units and linked health facilities. Community Health Strategy (CHS) is an approach to health care service delivery in Kenya by the Health Sector as an effort to revitalise Comprehensive Primary Health Care and also aimed to improve access to health care and health service indicators such as skilled delivery.<sup>14</sup>

The process of establishment of a community unit has been described adequately elsewhere.<sup>10,16-18</sup> In brief, it involves; The formation of committees at the community and health facility levels as governance/linkage structures; The identification and training of community health workers to support households in health improvement initiatives, as well as to maintain a village register, and facilitate dialogue at the household level; identification, training and deployment of community health extension workers (CHEWs) for each community unit as the facilitator of dialogue at the community level and supporter of CHVs. The information collected in the household registers is to be updated every six months by the community health volunteers. CHVs and CHEWs also dialogue sessions with community members and at households. The dialogue sessions are facilitated by CHVs during home visits and by CHEWs at general community meetings, while the health facility staff are expected to facilitate dialogue at the management committee meetings and the Sub-county Health Management Teams (SCHMTs) facilitated at sub-county health stakeholder forums.<sup>10,16-18</sup>

Ager et al developed a Community Health Unit (CHU) functionality scorecard and categorised CHUs as functional, Semi-functional, or Non-Functional.<sup>16</sup> A set of 17 indicators are used in the scoring and percentage score are generated. A positive score is assigned 1 and a negative score is assigned 0. The scores are then summed up and expressed as a percentage out of 17 indicators per CHU. Functional CHUs are those that score at least 80%, semi-functional CHUs scores  $\geq 50\%$  and  $< 80\%$  and non-functional CHU scores  $\leq 50\%$ .

However, despite the widespread application of the community health strategy in Kenya since its inception in 2006 and evidence that Community Health Strategy is effective in reducing health outcomes at household level especially where it is fully functional, skilled delivery in Kakamega County is still low at 47% compared to a national estimate of 62 %<sup>4</sup> which was still below the target of 90% of deliveries by 2015 and also still below the targets of Sustainable Development Goals of 90% skilled deliveries by 2030.<sup>4</sup> A study on the effectiveness of the community health strategy on health outcomes in Butere district established that when components of the strategy were fully implemented and sustained in different socio-demographic contexts, then a participatory community planning based on household information drives improvement of health indicators.<sup>18</sup> There is limited data on levels of functionality of community units and its influence on the uptake of skilled birth deliveries in Lurambi Sub-County. In this study, we hypothesized that mothers were more likely to have skilled deliveries if they were residing in a fully functional community unit than if they were residents of

non-functional or semi-functional community units.

## METHODS

### Study Site

The study was undertaken in Lurambi Sub County in Kakamega County of Western Kenya. Lurambi sub-county has an estimated population of approximately 160,229 living in the area of about 161.8 square Kilometres. The sub-county just like the rest of the county depends primarily on agriculture and most farmers grow sugarcane as the main cash crop. Most of the food crops are grown on a small scale annually. The main crops are sugarcane, maize, bean, cassava, finger millet, and sorghum. Maize forms the staple food for the sub-county. It has 53 health facilities out of which 20 are public, 29 are private and 4 are faith-based or owned by non-governmental organisations

### Study Design

This was an analytic cross-sectional study using quantitative methods of data collection and had two components. The first component assessed the functionality of Community Health Units and the second component assessed the association of CHU functionality and skilled delivery. The study was conducted both at the community unit and at household levels.

### Study Population

The study focused on all 38 Community Health Units within the Lurambi sub-county. The Community Health Extension Workers (CHEWs) were the respondents for the CHU assessment. A total of 38 CHEWs were interviewed, one in each CHU. The Community Health Units were assessed based on their functionality concerning 5 parameters: Training, Community Health committees, Community Based Health Information System (CBHIS), Community Dialogue and Community Action Days. The household survey focused on the women with children below 1 year (n=6871)

### Sample Size and Sampling Technique

Lurambi sub-county had 38 Community Health Units and all were included in the assessment hence total coverage. The sample size for the mothers was calculated using an estimated skilled delivery prevalence of 47% for Kakamega County for Z-score of 1.96 at a 95% Confidence Interval and a 5% Level of Precision. The minimum sample size was 382 and a maximum target of 458 having added a non-response rate of 20%. A Stratified sampling technique was used to sample women from functional and semi-functional Community Health Units. The total number of Functional Community Units was first determined, and villages were selected from each of the community units using a simple random sampling method. A list of women with children below 1 year was obtained from the household register from each village within the community units. The list was organised per village and community unit. Women who delivered less than 1 year, or who are not usual residents of the study area or those who delivered outside the study area were excluded.

All the 38 Community Health Units in the Lurambi sub-county were included. A simple random sampling technique was used to select eligible respondents from the list of women with children below 1 year in the sampled villages. At least 30% of the villages were sampled.

### Data Collection

The study used structured questionnaires for household inter

views and a checklist for functionality assessment as the main data collection instruments. The research assistants were recruited, selected and trained on study procedures which included questionnaire content and on ethical considerations. The training took two days. The household interviews were conducted at the household levels amongst the eligible mothers. Interviews were conducted in Kiswahili for all respondents. The assessment assessing the functionality of Community Units was done using the CHUs functionality scorecard. This tool was administered at the linked health facilities where key informal interviews were conducted with health facility personnel in charge. A tool for assessing the functionality of community health units was adopted from the African Medical and Research Foundation.<sup>16</sup> The tool has 5 parameters which include Training of Community health volunteers for 10 days, Community Health Committee for 5days training, CHC meetings, holding community dialogue monthly and action days and lastly ensuring that the Community-Based Health Information System is always updated. These 5 parameters are further broken down into 17 elements (Table 4) which are scored 1 for a positive response and 0 for a negative response. The scores are summed up and percentages calculated based on the number of positive responses out of 17 elements. A functionality categorisation is then used to classify whether the CUs are functional, semi-function or non-functional. If the overall percentage score is  $\geq 80\%$  then CU is Fully function, between  $>50\%$  to  $<80\%$  is semi-function and  $\leq 50\%$  is non-functional.<sup>16</sup>

The data collection period of reference was October 2015 to September 2016. Focal persons were interviewed on the checklist for functionality. These are contact persons of the CHUs. For the household interviews, a list of eligible mothers was obtained from CHVs based on the household registers from different villages and those who consented were interviewed

### Data Analysis

The functionality of the CUs was done using a score sheet from a checklist where the scores were classified as fully functional, semi-functional or not functional. All mothers were linked to the specific CUs through the village of residence. Descriptive statistics were used to assess functionality. Functionality (full versus semi) of the CU was the main independent variable while skilled delivery was the main outcome. There was no non-functional CUs as per the classification. Chi-square test and logistic regression were used to assess the association between functionality and skilled birth deliveries. Odds ratio at 95 % Confidence Intervals (OR, 95%CI) was reported while  $p$ -value  $< .05$  denoted significant results. Data entry and analysis were done using statistical package for social sciences version 20 (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp).

### Ethical Considerations

Approval to carry out the study was obtained from Great Lakes University of Kisumu Ethical Committee (Ref: No. GREC/018/256/2016), Permission to carry out the study was also approved by the National Commission for Science, Technology, and Innovation (ref: NACOSTI/p/17/74545/17004), Kakamega County Health Management Team and National Commission for Science and Technology. Permission to conduct this study was also received from the Lurambi Sub County Health Management Team and the local administration to conduct interviews. Written informed consent was obtained from respondents and each one of them was informed of their rights and obligations. They were informed that there was no risk; le

gal, social or psychological of participating in the study and participation was purely voluntary. The data collected from study participants were kept strictly confidential in password-protected computers only accessible to the investigators. Participants were only identified by a code. No names of participants were collected in this study.

## RESULTS

### Socio-demographic characteristic of participants and Community Units

A total of 436 women were interviewed. Of this 156(35.8%) were aged between 16 and 24, 217(49.8%) were aged between 25 and 35 years while the minority 3(0.7%) were aged between 45 and 55 years. On the level of education, 181(41.5%) had only primary education, 181(39.2%) had secondary education, 74(17.0%) had tertiary education and 10(2.3%) had no education. Over three-quarters of the respondents, 336(77.1%) took less than an hour to get to a nearby health facility, 95(21.8%) took between 1 and 5 hours and 15(1%) took over 5 hours. One third, 129(32.2%) of the respondents were housewives, 88(21.9%) were farmers, 49(12.2%) were daily labourers, 102(25.4%) were self-employed and 33(8.2%) were civil servants. On respondent's husband's level of education, 155(35.6%) had only primary education, 41.0% had secondary education, 99(22.7%) and minority 3(0.7%) had tertiary education and no education respectively (Table 1).

### Classification of Community Health Strategy Elements by Level of Community Unit Functionality

Of the 38 CUs assessed, 26(68.4%) were fully functional while 12(31.6%) was semi-functional. No community unit was not functional. Out of the key elements of Community health strategy, the Community Health Volunteers held all regular monthly meetings 38(100%) as required. Dialogue and action days were also held in both functional and semi-functional units. However, training of CHEWs, the existence of trained Community Health Committees, and trained Community Health Volunteers all stood at 34(89.5%). There was a shortage of reporting tools (MOH 513 and MOH 514) in both functional and semi-functional units at 15(55.6%) and 3(27.3%) respectively. On referral booklets (MOH100), 13(34.2%) of all CHVs did not have booklets (Table 2)

### The Influence of Community Health Strategy Elements on Uptake of Skilled Delivery

Pregnant women from functional community health units 296(68%) were more likely than those who were from semi-functional 146(32%) to have skilled delivery (OR=3.0; 95% CI, 1.8-4.9,  $p < .001$ ). About 366(94.6%) of those who had received health education were more likely to uptake skilled delivery as compared to those who did not receive health education (OR=2.9; 95% CI, 1.4-6.1,  $p = .005$ ). Pregnant women who were visited by CHV's more than twice (50.6 %) were more likely to have skilled delivery than those who were not visited 196(50.6%)(OR=1.9; 95%CI, 1.0-3.5,  $p = .045$ ). Pregnant women who attended ANC, 76(97.2%) (OR=3.4; 95% CI, 1.3-9.0,  $p = .012$ ) and those who received advice on where to deliver (376 (97.2%)(OR=4.1; 95% CI, 1.8-9.4;  $p = .001$ ) were more likely to have skilled delivery as compared to those who did not attend ANC or those who did not receive advice on where to deliver respectively (Table 3)

**TABLE 1: Distribution of the Study Population by Socio-Demographic Factors and Functionality of Community Units**

Demographic information	Overall (N=436) n (%)	Functional (n=299) n (%)	Semi-functional (n=137) n (%)	Fisher Exact test P-Value
<b>Age in years</b>				<b>0.304</b>
16 – 24	156(35.8)	104(34.8)	52(38.0)	
25 – 35	217(49.8)	150 (50.2)	67(48.9)	
36 – 44	60 (13.8)	43(14.3)	17(12.4)	
45 – 55	3(0.7)	2(0.7)	1(0.7)	
<b>Level of Education</b>				<b>0.481</b>
Primary	181(41.5)	118(39.5)	63(46.0)	
Secondary	171(39.2)	114(38.1)	57(41.6)	
Tertiary	74(17.0)	59(19.7)	15(10.9)	
None	10(2.3)	8(2.7)	2(1.5)	
<b>Time to health Centre</b>				<b>0.107</b>
Less than 1 hour	336(77.1)	228(76.3)	108(78.8)	
1-5 hours	95(21.8)	67(22.4)	28(20.4)	
Over 5 hours	5(1.1)	4(1.3)	1(0.7)	
<b>Occupation</b>				<b>0.374</b>
Farmer	88(21.9)	57(20.4)	31(25.4)	
Daily labourer	49(12.2)	35(12.5)	14(11.5)	
Self-employed	102(25.4)	76(27.3)	26(21.3)	
Housewife	129(32.2)	84(30.1)	45(36.9)	
Civil servant	33(8.2)	27(9.7)	6(4.9)	
<b>Occupation of husband</b>				<b>0.167</b>
Farmer	102(23.4)	63(21.0)	39(28.4)	
Daily labourer	144(33.0)	98(32.8)	46(33.6)	
Business	132(30.3)	90(30.1)	42(30.7)	
Civil servant	58(13.3)	48(16.1)	10(7.3)	
<b>Husband's education level</b>				<b>0.207</b>
Primary	155(35.6)	101(33.8)	54(39.4)	
Secondary	179(41.0)	116(38.8)	63(46.0)	
Tertiary	99(22.7)	79(26.4)	20(14.6)	
None	3(0.7)	3(1.0)	0(00.0)	

Descriptive statistics on the association of community health strategy and functionality

## DISCUSSION

### Implementation Levels of Community Health Strategy

The study established that most of the community health units (68.6%) in Lurambi Sub County meet at least 80% functionality assessment scores of the strategy and are fully functional while the rest of the CUs are semi-functional. This shows higher levels of implementation compared to report on community health services in Kenya conducted in Turkana, Kibera, and Machakos which established that only 28% were fully functional and the majority were semi-functional.<sup>15</sup> The study has also established that mothers living within fully functional CUs were more likely to have skilled delivery than those from semi-functional CUs. This finding is supported by findings of AMREF Health Africa in one of its programs in Makueni County which was using the

CHUs and they reported that skilled birth delivery improved from 37.5% to 44.2% in 12 months.<sup>16</sup> The Community Strategy had set an ambitious target of reaching 16 million Kenyans (3.2 million households) being enrolled by 2009 which was yet to be achieved by 2017. The strategy also aimed at strengthening community participation and encouraging communities to take action towards their health through functional community units and linked health facilities. Community Health Strategy (CHS) is an approach to health care service delivery in Kenya by the Health Sector as an effort to revitalize Comprehensive Primary Health Care. Community Health Strategy performs a key role in the renewal of comprehensive Primary Health Care in Kenya. It improves access to health care thus improves health service indicators such as skilled delivery.<sup>14</sup> The community health strategy introduced the community-based approach as the mechani-

**TABLE 2. Classification of community health strategy elements by level of community unit functionality**

Community Health Strategy elements	Overall (N=38) n (%)	Functional n (%)	Semi-functional n (%)	Fisher's Exact Test P-Value
<b>Two Trained CHEWs</b>				<b>0.065</b>
Yes	34(89.5)	26(96.3)	8(72.7)	
No	4(10.5)	1(3.7)	3(27.3)	
<b>Existence of trained CHC (1-13)</b>				<b>0.065</b>
Yes	34(89.5)	26(96.3)	8(72.7)	
No	4(10.5)	1(3.7)	3(27.3)	
<b>Trained CHVs as per the Population</b>				<b>0.074</b>
Yes	34(89.5)	24(88.9)	10(90.9)	
No	4(10.5)	3(11.1)	1(9.1)	
<b>CHVs have MOH 513aand 514b</b>				<b>0.110</b>
Yes	18(47.4)	15(55.6)	3(27.3)	
No	20(52.6)	12(44.4)	8(72.7)	
<b>Availability of MOH 516c</b>				<b>0.326</b>
Yes	34(89.5)	25(92.6)	9(81.8)	
No	4(10.5)	2(7.4)	2(18.2)	
<b>All CHVs have referral booklets MOH 100d</b>				<b>0.024</b>
Yes	25(65.8)	21(77.8)	4(36.4)	
No	13(34.2)	6(22.2)	7(63.6)	
<b>Quarterly CHC meetings are held</b>				<b>0.0653</b>
Yes	35(92.1)	25(92.6)	10(90.9)	
No	3(7.9)	2(7.4)	1(9.1)	
<b>CHVs hold monthly meetings</b>				<b>NA</b>
Yes	38(100.0)	27(100.0)	11(100.0)	
No	0(00.0)	0(00.0)	0(00.0)	
<b>Monthly dialogue days are held</b>				<b>0.289</b>
Yes	37(97.4)	27(100.0)	10(90.9)	
No	1(2.6)	0(0.0)	1(9.1)	
<b>Quarterly action days are held</b>				<b>0.078</b>
Yes	37(97.4)	27(100.0)	10(90.9)	
No	1(2.6)	0(0.0)	1(9.1)	

aMOH 513: Household Register  
 bMOH 514: Service delivery logbook.  
 cMOH 516: Community Chalk Board  
 dMOH 100: Referral booklet

sm through which households and communities take an active role in health and health-related development issues. The primary approach was to establish Community Health Units (CUs) to serve a local population of 5,000 people, enlisting Community Health Volunteers (CHVs) who each are directly responsible for the delivery of services to the communities.<sup>19</sup>

According to the Kenya vision 2030 and the second National Health sector strategic plan, the community health strategy ap-

proach ensures that Kenyan communities have the capacity and motivation to take up the essential role in health care delivery.<sup>16</sup> This study established that the program has made progress in implementation level by addressing issues pertinent to the community health strategy such as; Having 2 trained CHEWs, the existence of trained CHC, trained CHVs, availability of MOH 516, MOH 513, MOH 514 and MOH 100, SCHMT supervision, Community Health Volunteers monthly meetings, Community Health Volunteer reporting rate of above 80%, quarterly CHC meetings, quarterly dialogue days and quarterly action days.

**TABLE 3: The Influence of Community Health Strategy Elements on Uptake of Skilled Delivery**

Community Health Strategy	Overall (N=436) n (%)	Skilled Delivery n (%)	Unskilled Delivery n(%)	Adjusted Odds Ratio (95% CI)	P values
<b>Functionality</b>					
Functional	299(68.6)	263(68.0)	36(32)	3.0(1.8-4.9)	<.001*
Semi-functional	137(31.4)	124(32.0)	13(68)	Ref	
<b>Received Health Education</b>					
Yes	403(92.4)	366(94.6)	37(5.4)	2.9(1.4-6.1)	.005*
No	33(7.6)	21(5.4)	12(94.6)	Ref	
<b>Times Visited by CHVs</b>					
None	74(17.0)	62(16.1)	12(83.9)	Ref	
Twice	142(32.6)	129(33.3)	13(66.7)	1.3(0.7-2.5)	.394
More than twice	220(50.4)	196(50.6)	24(49.4)	1.9(1.1-3.5)	.045*
<b>Attended ANC</b>					
Yes	418(95.9)	376(97.2)	42(2.8)	3.4(1.3-9.0)	.012*
No	18(4.1)	11(2.8)	7(97.2)	Ref	
<b>Received Advice Where To Deliver</b>					
Yes	411(94.3)	376(97.2)	35(2.8)	4.1(1.8-9.4)	.001*
No	25(5.7)	11(2.8)	14(97.2)	Ref	
<b>Having Health Insurance Cover</b>					
Yes	101(23.2)	99(25.6)	2(74.4)	2.4(1.2-4.7)	.011*
No	335(76.8)	288(74.4)	47(25.6)	Ref	
<b>CHV Referred You To Hospital for Delivery</b>					
Yes	253(58.0)	236(61.0)	17(39)	1.8(1.1-3.0)	.012*
No	183(42.0)	151(39.0)	32(61)	Ref	
<b>Who Decided Where You Were To Give Birth</b>					
Myself	186(42.7)	160(41.4)	26(58.6)	Ref	
My husband	45(10.3)	34(8.8)	11(91.2)	0.4(0.1-1.0)	.059
Self and husband	162(37.2)	153(39.5)	9(60.5)	0.3(0.1-0.9)	.026*
CHV	43(9.9)	40(10.3)	3(89.7)	0.5(0.2-1.5)	.208
<b>Difference Between Giving Birth at Health Facility</b>					
Yes	407(93.3)	370(95.6)	37(4.4)	6.1(2.2-16.9)	.001*
No	13(3.0)	9(2.3)	4(97.7)	1.1(0.3-4.8)	.897
Don't know	16(3.7)	8(2.1)	8(97.9)	Ref	

The multivariable logistics regression was used to generate adjusted odds ratios. The variables adjusted for are in Table 1 considered confounder for the uptake of skilled deliveries

### Level of Uptake of Skilled Delivery

This study has established that 80% of the skilled deliveries were in the health facilities and 68.6% of women who had skilled delivery were more likely to be from fully functional units than those from semi-functional. The results also revealed that 92.4% of the women received health education, which might have helped in knowing the risks and benefits of skilled delivery. This finding is supported by a study in Ghana which established that there is a statistically significant association between women's health education and skilled delivery.<sup>20</sup>

The high prevalence of skilled deliveries could be attributed to

the messages and influence of community health volunteers.

The study further established that 94.6% of the women who received health education on skilled delivery were more likely to have skilled delivery compared to those who did not receive health education. This is because those who are educated are aware of the risks of giving birth in an unskilled manner. A study also found that mothers who are educated can make wise decisions about their health than their counterparts; this is consistent with the findings of this study.<sup>21</sup> The results showed that women were 4.2 times more likely to deliver in hospitals from Community Units with 2 CHVs trained than those who are not.



**TABLE 4: The 17 Functionality Elements Of A Community Health Unit Organised Sequentially To Represent The Journey That It Follows From Inception To Maturity**

no	Components	Yes(1), No(0)
1	CHEWs trained	
2	CHC trained	
3	CHVs trained	
4	CHVs supplied with CHV kits	
5	All trained CHVs have MoH 514	
6	CHV reporting rate above 80%	
7	CHU has a chalkboard	
8	All trained CHVs have referral booklets	
9	CHU action plan developed	
10	Quarterly CHC Meeting held	
11	CHVs monthly Meetings	
12	All reporting CHVs (MoH 514) receiving stipend	
13	Monthly dialogue days held	
14	Quarterly Health Action Days held	
15	DHMT supervisory visit conducted	
16	CHU has bicycles for use by CHVs	
17	CHU having a sustainable initiative(IGAs)	
Total Score out of 17		xx
Percentage (%) Score		xx
Key	Functionality	Categorisation
Yes-Fulfilled/positive (Score one=1)	≥80%	Functional
No-Not fulfilled/negative (Score zero=0)	>50 to <80%	Semi-Functional
	≤50%	Non-Functional
Note: The three (3) cardinal elements (15, 16, 17) MUST all be fulfilled for a CU with ≥80% score to be functional		

A report on Community Health in Kibera Kenya also emphasised that women who were frequently visited by CHVs are more likely to have skilled delivery since CHVs encourage women to go to health facilities during delivery.<sup>22</sup> This finding is also consistent with the findings where CHWs had a great impact on increasing the uptake of health services.<sup>22</sup> In a multivariate logistic analysis of the variables, it was established that a fully functional community unit, trained Community Health Volunteers, trained Community Health Committees, and community dialogue was significantly associated with skilled delivery. These findings were in agreement with a report on strengthening the Community Health Information Systems which established that dialogue days led to increased skilled deliveries.<sup>23</sup> Moreover, a study investigated the contribution of CHCs on maternal health and the results showed that CHC strengthens and enhances maternal health care and promotes skilled delivery.<sup>24</sup>

**Strength and Weaknesses of the Study**

The first strength of this study is that it is the first study to the

best of our knowledge, to assess the association between the functionality of a community unit with skilled birth deliveries and in this study region. The study has linked CU functionality with deliveries to establish that a fully functional community unit provides an opportunity to improve skilled birth deliveries in this region. This calls for a more investment and budgetary allocation to ensure all community units are fully functional. The study further adopted an analytic design and multivariable models to assess the ecological relationship between CHS and Skilled birth deliveries, thereby demonstrating that in resource-poor settings such data can be obtained and analysed to inform policy decisions.

The study has several limitations. Firstly, the influence of CHS functionality on skilled birth delivery is an ecological relationship and is only assessed at 2 levels; the community unit level and at the individual mother’s level and the analysis may be affected by ecological fallacy; what happens at the population level is not necessarily what happens to everyone in the population. Secondly, other confounding factors such as education level of mothers, distance to the health facility, cultural and socioeconomic factors which were not included in the analysis because they were not collected. Lastly, the study was purposively done in one-sub-county limiting the level of generalisability.

**CONCLUSION**

Community health strategy is an appropriate platform to deliver community-based interventions. Women residing in fully functional health facilities were more likely to deliver in health facilities hence fully functional community units are key to ensure skilled deliveries. Women were more likely to have skilled deliveries if the community units have at least 2 trained CHVs. This is a key emphasis on capacity building for the CHV who influence the health actions of the expectant women. In conclusion, the implementation of a community health strategy is not universal amongst the community health units. Skilled deliveries are still low in the semi-functional community health units. Some of the recommendations of the study would be that there is a need for universal training of the Community Health Committee, Community Health Extension Workers and Community Health Volunteers. There is a need to ensure access to tools by the CHVs particularly the Household register (MOH 513), the service delivery logbook (MOH 514) and referral booklet (MOH 100) for effective service delivery. The government should ensure the improvement of the level of uptake of skilled delivery through cost-effective and sustainable measures to meet the Millennium Development Goal. A future research area could be the cost-effectiveness of the community health strategy on improving skilled birth delivery and the costs of implementation of community health strategies in similar settings.

**DECLARATIONS**

**Ethics Approval and Consent to Participate**

The proposal was approved by GLUK Research Ethics Committee (GREC) Ref: No. GREC/018/256/2016 on Friday, September 16, 2016. It was also approved by the National Commission for science, technology, and Innovation on 14<sup>th</sup> June 2017 Ref NACOSTI/p/17/74545/17004. The respondents were interviewed at the household level. Written informed consent was obtained from respondents and each one of them was informed of their rights and obligations. They were informed that there was no risk to risk either legal, social or psychological by participating in the study and an aspect of voluntarism ensured

among the participants. The study did not have a medical treatment component. The data collected from study participants were kept strictly confidential and participants were only identified by a code

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# The Pattern and Level of Knowledge on Obstetric and Newborn Danger Signs and Birth Preparedness among Pregnant Women in Dodoma Municipal: a Cross Sectional Study

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## ABSTRACT

**Background:** Unacceptable high maternal mortality rates remain a major challenge in many low-income countries. Early detection and management of antenatal risk factors and good preparation for birth and emergencies are critical for improved maternal and infant outcomes. The aim of this study was to understand the pattern and level of knowledge on obstetric and newborn danger signs, Individual Birth Preparedness and Complication Readiness (IBPACR) among pregnant women in Dodoma Municipal.

**Methods:** A quantitative cross sectional study was carried out between February and June 2018. A random selection of participants was employed to achieve a sample size of 450 pregnant women. A standard semi-structure questionnaire was used to collect data and descriptive analysis was carried out by using SPSS software to see the pattern and level of knowledge on obstetric danger signs and individual birth preparedness.

**Results:** The mean age of participants was 25.6 years ranging from 16 to 48 years and majority 326 (72.4%) had 2 to 4 pregnancies. Only 203(45.1%) of the pregnant women were able to tell 8 and above danger signs with at least 1 from each of the 4 phases, with the most known obstetric danger signs being vagina bleeding during pregnancy 287(63.8), labour and delivery 234(52.0%), after delivery 278 (61.8) . 164 (36.4%) of the participants reported fever and difficult in feeding 182 (40.4%) as danger signs in newborn. Furthermore, only 75(16.7%) of the participants reported to be prepared for birth and complications. The most known component of birth preparedness was preparing important supply which are needed during birth 283 (62.9%).

**Conclusion:** Results of this study showed a low level of knowledge on obstetric and newborn danger signs as well as poor individual birth preparedness and complication readiness. Important predictors of knowledge level and birth preparedness were found to be age, education level, gestation age at first visit and husband involvement in Antenatal visit and care.

## BACKGROUND

Identification and management of antenatal risk factors at early stage and good preparation are important for positive maternal and newborn.<sup>1</sup>

Despite of a number of Global and National efforts to improve women's health, the death of women during pregnancy, childbirth and after childbirth remains an unresolved challenge in many developing countries, including Tanzania.<sup>2</sup> Almost 2 decades since the initiation of the Safe Motherhood Initiative, maternal mortality is still soaring high in many developing countries, about 830 women die from pregnancy or childbirth related complications around the world everyday.<sup>3</sup>

The maternal mortality ratio in developing countries in 2015 was 239 per 100 000 live births versus 12 per 100000 live births in developed countries. There are large disparities between countries, but also within countries and between women with high and low income and women living in rural areas versus women living in urban areas.<sup>3</sup> The estimated Maternal

Mortality Rate in the 2015-2016 Tanzania Demographic and Health Survey (TDHS- MIS) report was 556/100000 live births which is higher compared to the 2010 TDHS report which was 454/100000 live births.

Dodoma is among the regions with the highest maternal mortality rates in Tanzania. According to the 2012 census , Dodoma ranked the 9<sup>th</sup> high burdened region with a maternal mortality rate of 512/100,000 live births.<sup>4</sup>

Maternal Mortality trends in Dodoma Region for the past 5 years were as follows: – 2012:60 deaths, – 2013:71 deaths, – 2014:69 deaths, – 2015:64 deaths and 2016:49. Trends of Perinatal death were: - 2012:599 deaths, – 2013: 630 deaths, – 2014:715 deaths, – 2015:484 deaths, – 2016:517 deaths. The district with the highest number of maternal and perinatal deaths was Dodoma Municipal (Personal communication with the Dodoma Region Reproductive and Child Health Coordinator June, 2017)

In most developing countries, the underlying cause of maternal

deaths during pregnancy and postpartum are attributed to 3 crucial delays; These include; ( 1) Identifying life threatening event danger signs and making the decision to go to the health facility (2) Delay in reaching the health facility and (3) Delay in receiving appropriate and adequate care at the health facility.<sup>5</sup>

Low knowledge about danger signs delays obstetric care seeking behaviours which thus contributes to high maternal mortality and morbidity worldwide.<sup>6</sup> A study assessing determinants and awareness of danger signs and symptoms during pregnancy and complications among women in Jordan showed that 84.8% of the women interviewed were not aware of danger signs and symptoms of pregnancy complications.<sup>7</sup>

Another study was conducted in Chamwino District in Dodoma, Tanzania, the results showed that only 25.2% out of 428 respondents were knowledgeable about obstetric danger signs during pregnancy, childbirth and after childbirth.<sup>8</sup> Studies in Tanzania have found that most women are not aware of danger signs of obstetric complications.<sup>2</sup>

Birth preparedness is a strategy to promote timely use of skilled maternal care especially during childbirth, based on the theory that preparing for childbirth reduces delays in obtaining this care. The proportion of preparing for birth and its complications has been found to be low in low-resource settings.<sup>9</sup>

A study on birth preparedness and complication readiness among recently delivered women in Chamwino showed that only 58.2 % of the respondents were considered as prepared for birth and its complications. The proportion of women prepared for birth and its complications was found to be low.<sup>10</sup>

Pregnant women and their families often ignore early warning signs due to lack of adequate knowledge and information about danger signs during pregnancy and labour and therefore delay in seeking health care services.<sup>11</sup> Some of the factors that influence knowledge level and birth preparedness include; education level, parity, gravidity and age of a woman.

This study aimed at understanding the influencing factors on the level of knowledge on obstetric and newborn danger signs, individual birth preparedness and complication readiness among pregnant women in Dodoma Municipal.

## METHODS

### Study Design

Descriptive cross-sectional study was conducted in Dodoma Municipal from February to June 2018, among pregnant women. Dodoma Region is 1 of Tanzania's 30 administrative regions and the location of the capital city of the country. It lies centrally in the eastern-central part of the country; it is about 300 miles (480 km) off the coast. Dodoma Urban District is 1 of the 7 districts of Dodoma region. It is bordered to the west by the Bahi district, and to the east by Chamwino District. According to the 2012 Tanzania National Census, the population of Dodoma Urban District was 410,956 covering an area of 2,576 square kilometres.<sup>12</sup> Dodoma was one of the regions with the highest maternal mortality rates in Tanzania in 2012, Dodoma ranked the 9<sup>th</sup> high burdened region with a maternal mortality rate of 512/100,000 live births.<sup>4</sup> Within the municipal, there are 2 major Public Health facilities;

the Makole Health Center which serves as the main antenatal care facility with an inpatient bed capacity of 55 beds and the Dodoma Regional Referral Hospital which is the highest level referral hospital in the region with an inpatient bed capacity of 420. In this study, pregnant women attending antenatal care and delivery services at Makole Health Centre, Chamwino Dispensary with the capacity of serving 100 pregnant women per day and 200 under 5 children per day and the Regional referral hospital were included in the study

**FIGURE 1. Dodoma Region Map**



Source: Google Map

### Study Population

The study consisted of pregnant women attending Antenatal Care (ANC) visits in the health facilities of Dodoma Municipal

### Sampling Technique

A purposive sampling method was used to get Dodoma Region, Dodoma Municipal and the Health care facilities offering ANC and delivery care services in Dodoma Municipal. Participants were selected randomly. Participants who met the inclusion criteria and agreed to participate in the study on that particular day were listed together, where by every 3rd pregnant woman on that list was selected.

### Sample Size Calculation

The sample size was 450 pregnant mothers, which was obtained by using the following formula, and by using the Maternal Mortality ratio of Tanzania Demographic and Health Survey of 2015/2016, which was 556/100,000. Then;

$$n = z^2 p (1-p) / e^2$$

Where n= sample size

z= standard normal deviation of 1.96 corresponding to 95% confidence interval

p=proportion of the target population estimated using the 2015/2016 maternal mortality ratio for Tanzania; 556/100,000 live births.

e=0.05.

$$n = (1.96)^2 * 0.006 (1 - 0.006) / (0.05)^2$$

n=439.94 minimum sample size, plus 5% Attrition

An estimated sample of 450 pregnant women were included in the study.

### Definitions of variables

**i) Dependent variables:** Knowledge of obstetric and newborn danger signs, individual birth preparedness and complication readiness.

**ii) Independent variables:** parity, education level, age, gravidity and marital status.

### Measurements of variables

**i) Knowledge of the key obstetric danger signs (during pregnancy, childbirth, postpartum and in newborn) was scored as follows;**

Those who did not mention any of the danger signs in all the 4 phases were considered to have no knowledge. Participants who mentioned up to 3 danger signs with at least 1 from each phase were considered to have low knowledge. Women who mentioned 4 to 7 danger signs with at least 1 from all the 4 phases were considered to have moderate knowledge of obstetric danger signs and the respondent was considered to be knowledgeable if she mentioned at least 8 danger signs. This method of scoring was adopted and modified from the study done in Southern Tanzania.<sup>13</sup> This scoring method was again grouped into 2 groups of adequate knowledge and inadequate knowledge in the final analysis.

The key danger signs in the 4 phases included:

**Phase 1:** Danger signs during pregnancy (vaginal bleeding, swollen hands/face, severe headache, blurred vision, lower abdominal pain).

**Phase 2:** Danger signs during labour/childbirth (severe vaginal bleeding, prolonged labour (>12 hours), convulsions, difficulty in breathing and retained placenta).

**Phase 3:** Danger signs during postpartum (severe vaginal bleeding, foul-smelling vaginal discharge, and fever).

**Phase 4:** Danger signs in the new-born; pitched cry, difficult feeding (unable to suckle), fits (convulsions), loss of consciousness, hot to touch (hyperthermia), difficult breathing, jaundice, failure to pass urine /stool in the first 24 hours.<sup>8</sup>

**ii) Individual birth preparedness and complications readiness was scored as follows:**

Participants were asked to name items needed to prepare for birth and for emergencies. This was aimed at verify whether a participant was aware of the basic steps of Individual Birth Preparedness and Complication Readiness (IBPACR) i), Knowing Expected Date of Delivery (EDD) which was confirmed in her Reproductive and Child health 4 (RCH4) card, ii). Participants were also asked whether they had already identified a skilled birth attendant, iii) Identified the mode of transport for delivery and/or for obstetric emergency, iv) Saved money, v) Identified at least two blood donors, vi) Prepared supplies for birth and emergencies, vii) identified someone to escort them to labour, viii) Identified someone to take care of the family in her absence etc. Participants who scored 4 and above out of 9 basic steps were classified as having IBPACR while those who scored less than 4 were classified as “not having IBPACR. This scoring method has been previously used in studies which assessed women’s level of birth preparedness and complications readiness at Chamwino District, Dodoma.<sup>10</sup>

### Data Collection

Semi-structured questionnaire with both closed and open-ended questions was developed to be interviewer-administered. This ensured that those unable to read and write could fully participate and also to ensure optimal capturing of all the needed information. The questionnaire included questions on socio-demographic characteristics, knowledge of key danger signs during pregnancy, childbirth, postpartum and danger signs in newborn, individual birth preparedness and complication readiness.

The questionnaires was first developed in English and then translated to Kiswahili which is the National language of Tanzania and the language used by the study population. The questionnaire was adopted from Jhpiego and modified to fit the Tanzanian context<sup>14</sup> also from Tanzania Demographic and Health Survey 2015/2016 and from Nepal Demographic and Health Survey.<sup>15</sup>

### Data Analysis

In this study, data was analysed using the Statistical Product for Service Solutions (SPSS) software program version 21. Before conducting the analysis, error checking (data cleaning) was performed by using frequency distribution tables to see if all the data were entered correctly. Each variable was manually cross-checked to ensure validity and reliability of the findings. Scores that were out of range were corrected to avoid distortion of the statistical analysis. Descriptive analysis was used to analyse participant’s characteristics to determine the frequencies and percentage of their distributions and also the pattern of level of knowledge and individual birth preparedness.

### Ethical Considerations

Permission to conduct this study was obtained from the University of Dodoma Research Committee. Ethical research clearance and research approval letters were obtained from the Graduate Office, University of Dodoma. Authorization to conduct the study in Dodoma Municipal and in the selected health facilities was obtained from Dodoma Urban District director and medical officer in charge of Human rights. Privacy, and Confidentiality were considered in this study. Research objectives, risk, and benefits of the study were well explained to the participants. Verbal and written consent were obtained from the participants and the questionnaires were answered voluntarily.

## RESULTS

### Social demographic and obstetric characteristics of the participants

A total of 450 pregnant women were included in the analysis, with a response rate of 100%. The mean age was 25.6 years (SD=6.1) with a minimum age of 16 years and maximum age of 48 years. As shown in Table 1 below, the most prominent age group n= 334(74.2%) ranged between 20 and 34 years.

On top of that, more than half of the participant, n= 264(58.6%) had primary school level of education and few with college/university education n=39(8.7%). Out of 450 respondents n=353(78.4%) were currently in marital union (married/cohabiting). This study also explored the Obstetric characteristics among the study participants. As indicated below, out of 450 participants n=326(72.4%) had 2 to 4 pregnancies .

**TABLE 1: Social Demographic and Obstetric Characteristics of the Participants N=450**

Variable		n(%)
Age (years)	< 20	71(15.8)
	20-34	334(74.2)
	≥ 35	45(10%)
Education status	Primary school	264(58.7)
	Secondary school	147(32.7)
	College/University	39(8.6)
Occupational status	Non-employed	144(32.0)
	Self-employed	298(66.2)
	Employed	8(1.8)
Marital status	Not married	97(21.6)
	Married	353(78.4)
Gravidity	1	97(21.6)
	2-4	326 (72.4)
	≥5	27(6.0)
Parity	1	121(26.9)
	2-4	309(68.7)
	≥5	20(4.4)
Gestation age at first visit in weeks	1-12 weeks	2(42.7)
	13-20 weeks	258(57.3)
Age at first pregnancy in years	<20yrs	214(47.4)
	20-34yrs	234(52.0)
	≥35 yrs	2(0.6)

The minimum age of the respondent being pregnant at first was 14 years and maximum was 38 years with their mean age and standard deviation being 20 years(3.4).Other results are as shown in Table 1.

**Level of Knowledge on Obstetric and Newborn Danger Signs**

Study participants were asked to mention obstetric and newborn danger signs which they know. It was found that overall score of the participants with adequate knowledge on obstetric and newborn danger signs was n=203 (45.1%) whereas 247 (54.9%) had inadequate knowledge. On knowledge level, individual scoring 8t and above with at least 1 from each of the 4 phases was regarded as having adequate knowledge and scored less termed as having inadequate knowledge.

**Level of Knowledge on Specific Key Obstetric and Newborn Danger Signs**

The most known obstetric danger signs was vagina bleeding during pregnancy 287(63.8), labour and delivery 234(52.0%), after delivery 278 (61.8) and 164 (36.4%) of the study participants reported fever and difficult in feeding 182 (40.4%) as danger signs in newborn; other results are as shown in Table 2

**Pattern and Level of Knowledge on Obstetric and Newborn Danger Signs within Different Categories**

Pattern and level of knowledge differed within individual categories. Participants in the age group of 20 to 34 years were more knowledgeable on obstetric and newborn danger signs compared to other age groups. Also participants with college and university level of education scored higher than the lower levels of education. Other results are as shown in Table 3.

**Practices on Individual Birth Preparedness and Complication Readiness**

Study participants were asked to tell how they have prepared themselves for birth and complications. It was found that only n=75 (16.7%) of the participants were able to tell at least 4 or more of the basic components of individual birth preparedness and complication readiness where as n=375 (83.3%) could not tell. On IBPACR score, participants who scored a total of 4 or more out of the 8 basic steps of IBPACR were classified as being prepared for birth.

**Knowledge of the Basic Components of IBPACR among the Study Participants**

Participants were asked to tell the components of IBPACR ; the most known components by the study participants were saving money n= 277 (61.6%), Also most of the participants n=283 (62.9) said preparing important supply such as clothes as shown in Table 4.

**Pattern and Practice of IBPACR within Different Categories**

As shown in Table 5; Results showed that Pattern and practice of individual birth preparedness was more observed among pregnant women who started their first ANC visit within the first 3 months of pregnancy, n=44 (19.5%) as compared to those who started late. On top of that, pregnant women who were accompanied by their husband to ANC clinics were more prepared compared to those who were not accompanied.

**DISCUSSION**

Evaluating level of birth preparedness and complication readiness among pregnant women can also be measured by assessing knowledge of obstetrics danger signs.<sup>14</sup> Having knowledge on obstetrics danger signs is an essential step in recognition of complications and enables one take appropriate action to access emergency care.<sup>8</sup> Knowledge about danger signs among pregnant women is the key factors which influence timely access to care. The findings from this study showed a low level of obstetric and newborn danger signs but was higher compared to the study which was done in Ethiopia.<sup>16</sup> The low knowledge on obstetric and newborn danger signs might be due to high proportion of pregnant women who had only primary level of education in this study. The most mentioned danger signs were vaginal bleeding during pregnancy, labour and delivery, severe vaginal bleeding after delivery and foul-smelling vaginal discharge, fever and convulsions as danger signs in newborn.

Education level and the number of pregnancies (gravidity) were good predictors of knowledge on danger signs. Participants with college/University level of education were more knowledgeable on key danger signs compared to those with lower education levels, these findings mirrors the findings of the study in Uganda on Obstetric danger signs and birth preparedness practices who also find education level to be an important factor.<sup>17</sup> On top of that, participants with 2 to 4 number of pregnancies were also

**TABLE 2: Scores of Knowledge on Specific Key Obstetric and Newborn Danger Signs**

Key danger signs during pregnancy	n (%)	
	Yes	No
Vaginal bleeding	287 (63.8)	163 (36.2)
Swollen hands/face, ankle	131 (29.1)	319 (70.9)
Severe headache and blurred vision	56 (12.4)	394 (87.6)
Severe lower abdominal	152 (33.8)	298 (66.2)
Decreased or absent fetal Movements	52 (11.6)	398 (88.4)
Contractions/Labor pain before completed 37 weeks	31 (6.9)	419 (93.1)
<b>Key danger signs during labor/delivery</b>		
Severe vaginal bleeding	234 (52.0)	216 (48.0)
Prolonged labor (>12 hours)	56 (12.4)	394 (87.6)
Fits/Convulsions	38 (8.4)	412 (91.6)
Difficult breathing	39 (8.7)	411 (91.3)
Early rupture of membrane	35 (7.8)	415 (92.2)
<b>Key danger signs after childbirth</b>		
Severe vaginal bleeding	278 (61.8)	172 (38.2)
Foul-smelling vaginal discharge	148 (32.9)	302 (67.1)
Fever and convulsion	55 (12.2)	395 (87.8)
Placenta not delivered within one hour after delivery	38 (8.4)	412 (91.6)
Breast or nipple pain and fail to breastfeed	26 (5.8)	423 (94.0)
Severe headache and blurred vision	42 (9.3)	408 (90.7)
<b>Key danger signs in the newborn</b>		
High Pitched cry	179 (39.8)	271 (60.2)
Difficult feeding (unable to suckle)	182 (40.4)	268 (59.6)
Fits (convulsions) or loss of consciousness	73 (16.2)	377 (83.8)
Fever	164 (36.4)	286 (63.6)
Difficult breathing	39 (8.7)	411 (91.3)
Unable to pass urine and stool or both within 24 hours after delivery	19 (4.2)	431 (95.8)
Bleeding from the umbilical cord	54 (12.0)	395 (87.8)
Failure to cry immediately after birth	60 (13.3)	390 (86.7)
Jaundice/yellowish coloration	53 (11.8)	397 (88.2)

more knowledgeable compared to other categories.

Birth preparedness and complication readiness knowledge is derived from a combination of knowledge about obstetric and newborn danger signs. In this study, the prevalence of birth preparedness and complication readiness was estimated to be only 16.7%. This prevalence was found to be very low, similar to that of a study which was done in Mpwapwa district in Tanzania.<sup>18</sup> Factors, such as education level and gestation age at first visit also played a greater role on birth preparation and complication readiness. Participants with college or university education level and those who start their initial ANC visit within the first 12 weeks of pregnancy were more prepared compared to other categories. These findings are similar with the study in Ethiopia on birth preparedness<sup>19</sup>

All these factors could also be explaining the reasons for the high maternal mortality prevailing in Tanzania, because most of the women seem not to be prepared for birth and for emergencies and they are not much aware of the key obstetric and newborn danger signs that make them delay in making the decisions once problem arises.

## CONCLUSION

The study findings showed a low level of obstetric and newborn danger signs as well as individual birth preparedness among pregnant women in Dodoma Municipal. Level of knowledge differed among different age group, parity and gravidity. These findings reveal a need for innovative community-based educational strategies to increase the levels of knowledge about birth preparedness and complication readiness among pregnant women, which may help in minimizing and stop preventable maternal and newborn deaths. Also early booking for Antenatal care should be promoted at the community level, which may help in early identification and diagnosis of diseases and their related complication during pregnancy, labour and after delivery.

## Strength of the Study

The finding of this study showed a low level of knowledge on key danger signs and birth preparedness which provides an alert to the Government and other stakeholder on health related issue on where we are and where should we improve, as we still have high number of maternal death in Tanzania and specifically in Dodoma

**TABLE 3: Pattern and Level of Obstetric and Newborn Danger Signs within Different Categories N=450**

Variable		Key danger signs	
		Inadequate knowledge n(%)	Adequate knowledge n(%)
Age (years)	< 20	45(63.4%)	26 (36.6)
	20-34	180(53.4%)	154(46.1%)
	≥ 35	22(48.9%)	23(51.1%)
Education status	Primary school	154 (58.3%)	110 (41.7%)
	Secondary school	73 (51.3%)	74 (48.7%)
	College/University	20 (49.7%)	19 (50.3)
Accompanied by husband	Yes	88(53.3%)	77(46.7%)
	No	159(55.8%)	126(44.2%)
Gravidity	1	101 (58.4%)	72 (41.6%)
	2-4	126(51.0%)	121 (49.0%)
	≥5	20 (66.7%)	10 (33.3%)
Parity	1	110(57.6%)	81 (42.4%)
	2-4	126 (52.5%)	114 (47.5%)
	≥5	11(57.9%)	8 (42.1%)
Gestation age at first visit in weeks	1-12 weeks	123 (54.4%)	103(45.6%)
	13-20 weeks	124 (55.4%)	100(44.6%)
Age at first pregnancy in years	<20yrs	109 (58.3%)	78 (41.7%)
	20-34yrs	138(52.9%)	123(47.1%)
	≥35 yrs	0 (0.0%)	2 (100.0%)

**TABLE 4: Knowledge on individual component of IBPACR**

Basic IBPACR components	n (%)	
	Yes	No
know the expected date of delivery	169(37.6)	281(62.4)
Identify a skilled birth attendant	21(4.7)	281(62.4)
Identify the health facility which can be used in case of emergency or for childbirth	33(7.3)	417(92.7)
Identify 2 potential blood donors who would donate blood in case of Emergency	32(7.1)	418(92.9)
Preparing important supplies such as clothes needed for child birth	283(62.9)	167(37.1)
Identify a person who will escort to the health facility during an emergency	49 (10.9)	401(89.1)
Identify and arrange for transportation	143 (31.8)	307(68.2)
Saving money for delivery or for emergency	277 (61.6)	173(38.4)



**TABLE 5: Pattern and practice of IBPACR within different categories N=450**

Variable		IBPACR categories IBPACR not prepared n(%)	IBPACR prepared n(%)
Age (years)	<20	54(86.7%)	17(13.3%)
	20-34	282(84.4%)	52(15.6%)
	≥ 35	39(76.1%)	6(23.9%)
Education status	Primary school	227(86.0%)	37(14.0%)
	Secondary school	121(82.3%)	26(17.7%)
	College/University	27(69.2%)	12(30.8%)
Accompanied by husband	Yes	134(81.2%)	31(18.8%)
	No	241(84.65%)	44(15.4%)
Gravidity	1	138(90.0%)	35(10.0%)
	2-4	210(85.0%)	37(15.0%)
	≥5	27(79.8%)	3(20.2%)
Gestation age at first visit in week	1-12 weeks	182 (80.5%)	44(19.5%)
	13-20 weeks	193 (86.2%)	31 (13.8%)

**Study Limitations**

The findings of the study could have been affected by the study setting, Dodoma Urban where the infrastructure are more improved compared to infrastructure in rural areas. Also, women in urban areas are more educated compared to those in rural areas, so these findings should not be generalised but instead more studies need to be done in these areas to come up with precise conclusions

**Abbreviations**

- ANC - Antenatal care
- MMR - Maternal Mortality Ratio
- MoHCDGEC - Ministry of Health Community Development Gender, Elderly and Children
- TDHS-MIS - Tanzania Demographic and Health Survey- Malaria Indicator Survey
- WHO - World Health Organization
- EDD - Expected Date of Delivery
- RCH4 - Reproductive and Child Health four
- UDOM - University of Dodoma
- IBPACR - Individual Birth Preparedness and Complication Readiness
- NBS -Nation Bureau of Statistics

**Authors' Contributions**

TJM led the conception, design, data collection and drafting of the manuscript, SK advises on the context and methodological part. AE and AL revised the manuscript critically and give their expert idea. All authors read, contributed to and approved the final manuscript.

**Availability of Data and Materials**

Data set is available upon request to the corresponding author.

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# Knowledge and Utilisation of Intermittent Preventive Treatment of Malaria among Pregnant Women in Muramvya Health District, Burundi, 2018

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## ABSTRACT

**Background:** Intermittent Preventive Treatment in pregnancy (IPTp) of malaria is a key component of malaria control strategy in Burundi. *Sulfadoxine-pyrimethamine* (SP) is the drug of choice. Despite the evidence of the effectiveness of IPTp strategy using SP in reducing the adverse effects of malaria during pregnancy, the uptake and coverage in Burundi is low. This study was carried out to assess the knowledge and utilisation of IPTp among pregnant women of Muramvya Health District and determine factors that influence the uptake.

**Methods:** This was a community based cross sectional study conducted from 16<sup>th</sup> to 28<sup>th</sup> September 2018. A total of 370 pregnant women were recruited from selected settlements of MURAMVYA Health District. A structured questionnaire was administered to elicit information on socio-demographic characteristics, knowledge, and utilisation of IPTp. Epi-Info 7.2.2.6 and Microsoft Excel 2016 software was used to perform univariate, bivariate and multivariate analyses.

**Results:** Among the 370 pregnant women, 310 (83.8%) had taken IPTp-SP at least once in the index pregnancy. However, only 76 (24.5%) had completed the minimum required three doses. Having formal education (aOR=2.5, 95% CI [1.2–5.2], P= .016), parity (aOR=2.1, 95% CI [1.1–4.2], P= .033), and living at less than 5 km from the health facility (aOR=4.1, 95% CI [1.7–9.6], P=0.001) were found to be independent determinants of utilisation (at least one) of IPTp-SP. Also, having formal education (aOR=5.0, 95% CI [2.1–24.3], P<.001), and gestational age at first ANC visit (aOR=3.3, 95% CI [1.4–7.7], P=.005) were found to be independent determinants of taking optimal dose (three+) of IPTp-SP in Muramvya Health District.

**Conclusion:** The findings of this study show the low rate of pregnant women receiving the optimal dose of IPTp-SP. The study established that the major factors for IPTp-SP utilisation are; educational level, distance from home to the health facility, parity and the gestational age at the first ANC visit. It is therefore recommended that healthcare providers in Muramvya district should intensify sensitization and awareness campaign on the importance of girl child education and early ANC attendance in order to increase uptake and utilization of IPTp-SP for improved health outcomes.

## BACKGROUND

Malaria is an infectious disease caused by *protozoan* parasites from the members of *Plasmodium* genus that can be transmitted by the bite of infected female Anopheles mosquito or by a contaminated needle or transfusion.<sup>1</sup> 4 major parasite species are known to cause disease in humans, namely *Plasmodium falciparum*, *Plasmodium vivax*, *Plasmodium ovale* and *Plasmodium malariae*. *Plasmodium knowlesi*, originally known to cause simian malaria, is now recognized as the 5<sup>th</sup> human malaria parasite.<sup>2</sup> Malaria due to *Plasmodium falciparum* is the deadliest of all types.<sup>3</sup> Globally, an estimated 3.4 billion people in 92 countries are at risk of being infected with malaria and 1.1 billion are at high risk (>1 in 1000 chance of getting malaria in a year). According to the World Malaria Report 2018, there were 219 million cases of malaria globally in 2017 (uncertainty range between 203 to 262 million) and 435,000 malaria deaths, representing a decrease in malaria cases and deaths rates of 18% and 28% since 2010, respectively. The burden was heaviest in the WHO African Region, where an estimated 93% of all malaria deaths occurred, and in children aged under 5 years, who accounted for 61% of all deaths.<sup>4</sup> In Burundi, according

to data from the National Health Information System (NHIS), malaria is the main cause of morbidity and mortality recorded in health facilities in the general population. It is responsible for 67.1% of the reasons for consultations in the country, and 60% of deaths in hospitals are due to malaria. The incidence rate went from 32.7% in 2010 to 81.5% in 2017. The prevalence rate is estimated at 50.5% in children under 5 years.<sup>5</sup> Pregnant women compared to non-pregnant women are at increased risk of malaria infection and the severity of clinical manifestation experienced by these women and their foetus depend on the level of pre-pregnancy immunity. *Plasmodium falciparum* malaria during pregnancy is a well-known cause of maternal and foetal morbidity and mortality and it is clearly an important contributor to both maternal anaemia and low birth weights.<sup>7</sup>

Subsequently, pregnant women suspected of having malaria should be assessed and treated in accordance with national protocols. The consequences of malaria during pregnancy vary with transmission intensity. When the transmission is high, maternal anaemia is common, and on the infant, low birth weight due to foetal growth restriction and/or premature delivery is frequent. In low transmission areas, when non-immune pregnant

women become infected, malaria infection may become severe and life-threatening, requiring emergency treatment. Maternal complications include acute lung injury, severe Hypoglycaemia and coma while pregnancy loss due to miscarriage or stillbirth is also frequent. Most studies conducted in sub-Saharan Africa showed that approximately 25 million pregnant women are at risk of *P. falciparum* infection every year. One in four women has evidence of placental infection at the time of delivery.<sup>9</sup> *Plasmodium falciparum* infections during pregnancy in Africa rarely result in fever and therefore remain undetected and untreated.<sup>10</sup>

Malaria infection during pregnancy causes an estimated 900,000 low birth weight deliveries worldwide and may contribute to 100,000 infant deaths annually.<sup>11</sup> In low-risk zones, episodes of severe malaria are significantly associated with stillbirths, spontaneous abortion, premature delivery, and maternal death. Although pregnant women in malaria-endemic areas have a higher rate of parasitemia compared to non-pregnant women, in some cases, infection is largely asymptomatic because some degree of pre-existing immunity is retained during pregnancy.<sup>12</sup> However, malaria immune women are still susceptible to placental malaria because malaria parasites may become sequestered in the placenta and peripheral blood smears may fail to show evidence of infection.<sup>13</sup> Both situations are conducive for low birth weight and subsequently, infant mortality.<sup>14</sup> Successful prevention of these infections reduces the risk of severe maternal anaemia by 38%, low birth weight by 43%, and perinatal mortality by 27% among *pauci-gravidae*.<sup>15</sup>

The World Health Organization (WHO) recommends a package of control and prevention measures to prevent malaria among the most vulnerable group such as pregnant women and children under 5 years of age. Thus, in malaria transmission areas, all pregnant women should sleep under Insecticide-Treated Net (ITN). In addition, in areas of stable transmission of *P. falciparum*, all pregnant women should be given the Intermittent Preventive Treatment (IPT) with *Sulfadoxine-pyrimethamine* (SP) which is one of the key interventions recommended by WHO to bolster the prevention of asymptomatic infections among pregnant women living in moderate to high-risk regions. and has risen since 2010.<sup>16</sup> Each year, among the approximately 840 million persons at risk of malaria in endemic countries in sub-Saharan Africa, an estimated 35 million pregnant women could benefit from IPTp.<sup>17</sup>

World Health Organization has identified potential core elements of monitoring studies of IPTp – SP to include review of ANC (number and timing of IPTp – SP doses) and birth weight data through routine health system records and cross-sectional studies.<sup>14</sup> Researchers have identified that adherence to these preventive measures in pregnancy helps in reducing the adverse consequences of malaria in pregnancy such as reducing the risk of maternal anaemia, placental parasitaemia and low birth weight.<sup>18</sup>

In 2012, WHO updated its policy to promote initiation of IPT of malaria in pregnancy in all areas with moderate-to-high malaria transmission in Africa, as early as possible in the second trimester.<sup>19</sup> WHO has observed a slowing of efforts to scale-up intermittent preventive treatment of pregnant women (IPTp) Despite the advances in the adoption of the policy by several African countries, the utilisation rate remains low.<sup>17</sup> World Health Organisation has observed a declining effort to scale up IPTp in a number of African countries. In high – burden countries, IPTp noticeably lags behind other malaria control measures.<sup>20</sup> As of 2016, thirty six (36) African countries have adopted a policy of providing three or more doses of IPTp with SP to pregnant

women.<sup>21</sup> The Roll Back Malaria partnership initiative set the IPTp2 uptake target at 100% by 2015.<sup>22</sup> However, among the 23 countries that reported in 2016, an estimated 19% of eligible pregnant women received three or more doses of IPTp, compared with 18% in 2015 and 13% in 2014.<sup>17</sup> This does not appear to be due to low levels of ANC attendance. Uncertainty among health workers about IPTp – SP administration for IPTp may have also played a role. Simplified IPTp messages and health worker training have been shown to improve IPTp coverage.<sup>17</sup>

In March of 2015, following several years of extensive support from USAID and UNICEF, Burundi launched IPTp as a National Policy, adding it to the package of services available through the Antenatal Clinic (ANC). In this regard, all pregnant women should receive the first dose of three tablets (IPTp1), which providers administer under their direct observation at the ANC facilities from the 15<sup>th</sup> week of gestation. Recipients of IPTp1 should access subsequent doses during each of the scheduled monthly visits to ANC facilities.<sup>14</sup> Hence all pregnant women should access the second and third doses of IPTp – SP within the 20<sup>th</sup> and 24<sup>th</sup> week of pregnancy respectively.<sup>23</sup>

Several researchers have been interested in factors that affect the utilisation of IPTp. Lack of knowledge among women and the community about the importance of early ANC booking and IPTp – SP use is one of the challenges that contribute to the low uptake of IPTp in many countries. Other factors include the negative attitude of women toward IPTp – SP, cultural beliefs that inhibit revealing pregnancy early and the distance to the health centre.<sup>4</sup> Late registration (i.e. within or after pregnancy week 20) and irregular attendance behaviour of pregnant women for ANC services were viewed as a challenge in the efforts to increase IPTp coverage.<sup>25</sup>

In September 2016, 18 months after IPTp implementation, Burundi accounted for 21.0% of pregnant women who completed at least two doses of SP/Fansidar. In 2017, the annual count-down to 2030 report showed that only 13.0% of eligible women in Burundi have received three doses of IPTp – SP during their pregnancy.<sup>26</sup> In Muramvya province, only 8.1% of eligible pregnant women have completed three doses in 2016, which is below the national level target.<sup>27</sup>

Despite the low rate of IPTp – SP utilisation, ANC attendance is estimated at over 90% nationally in Burundi.<sup>28</sup> In Muramvya province, 99.3% receive antenatal care from a trained provider while 51.4% perform at least four antenatal visits.<sup>27</sup> Given these figures, there are indeed challenges in the utilisation and operationalisation of IPTp – SP. In Burundi generally and Muramvya Health District in particular, no study had ever been carried out to assess the level of knowledge of mothers toward IPTp–SP and identify determinants of the utilisation of IPTp among pregnant women. Therefore, this study aimed to establish the level of knowledge of pregnant women of Muramvya Health District on IPTp – SP, the utilisation level, and factors affecting its use. This will add to the growing body of knowledge needed for malaria programming for Muramvya Health District and the Ministry of Health by providing strategic information to complement facility-based malaria data sources. The survey will provide community data on key malaria prevention indicators especially the uptake of IPTp–SP. The study will help identify individual or client factors that contribute to IPTp uptake. This will provide situational specific evidence that could guide in developing long – lasting interventions. In particular, findings of this study will enable Muramvya Health District to design more effective behaviour change communication campaigns,

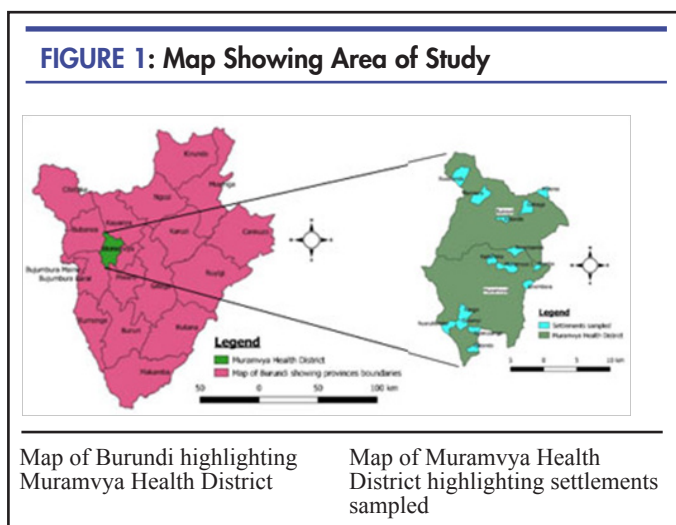
by designing messages that are tailored to the needs of the people in Muramvya health district.

## METHODS

### Study Area

The study was conducted in Muramvya Health District, 1 of the 2 districts in Muramvya Province, northwest Burundi. Its climate is tropical with 4 seasons, a small rainy season (October to December), a short dry season (January to February), a long rainy season (March to May) and a long dry season (June to September). It covers 42 wards across 2 communes, Bukeye (18) and Muramvya (24). It has 1 general public hospital, 12 Public Primary Health centres and 4 private primary health facilities. The projected population of Muramvya district according to the 2008 census is 186,785 out of which 2.5% represents pregnant women at third term (4,670).<sup>29</sup>

In 2017, consultation due to malaria was 28.8%, acute respiratory infection 23.6%, pneumonia 4.8% and *helminthiasis* 3.7% and approximately 22.3% of pregnant women of Muramvya Health District had at least 1 episode of malaria during their pregnancy in 2017.<sup>30</sup>



### Study Population

The study population included pregnant women who were in their third trimester, living/residing in selected settlements of Muramvya Health District. Pregnant women in their third trimester who were severely ill and or HIV positive on *cotrimoxazole prophylaxis*, and those who refused to grant informed consent were excluded from the study.

### Study Design and Sample Size

Community based cross-sectional survey was conducted in September 2018. The minimum required sample size of this study was determined using single population proportion formula ( $n = Z^2pq/d^2$ )<sup>31</sup>. Using the utilisation rate of IPTp1 (p) of 38.0%<sup>27</sup>, the confidence interval of 95% ( $Z=1.96$ ), and the precision (d) of 5%<sup>32</sup>

$$n = \frac{1.96^2 * 0.38(1 - 0.38)}{(0.05)^2} = 362$$

As the target population is less than 10,000, the minimum sample was adjusted by a finite population correction

factor:  $f = N / (n + N - 1) = 4670 / (362 + 4670 - 1) = .93$ , then  $n' = n * f = 362 * 0.93 = 336$ . Considering an anticipated no response rate (r) of 10%,  $n = 336 + 336 * 10\% = 370$ .

### Sampling Procedure

A multi-stage sampling technique was adopted to select 370 pregnant women in their third trimester of pregnancy residing in Muramvya health district.

#### First Stage: Selection of District

Muramvya Health province accounts for 2 health districts; Muramvya Health District and Kiganda Health District. The selection of Muramvya Health District was done by simple random sampling using balloting method.

#### Second Stage: Selection of Catchment Area

The selected district is divided into 12 catchment areas distributed around 12 public primary health centres and stratified into rural (8) and urban (4). The second stage involved a random selection of 1 urban and 3 rural catchment areas from the 12 catchment areas in Muramvya Health District using simple random sampling technique by balloting. The allocation of the catchment areas was done proportionate to the size of the urban and rural catchment areas.

The names of urban catchment areas were written on pieces of paper, placed in a container and shuffled. 1 catchment area (Muramvya) was randomly selected.

The names of rural catchment areas were also written on pieces of paper, placed in a container and shuffled. Thereafter, 3 catchment areas were randomly selected; hence Ryarusera, Rusarendu and Giko were selected.

#### Third Stage: Selection Of Settlements

The list of all the settlements in each of the selected catchment areas was obtained and 25% of settlements in each selected catchment area were selected using simple random sampling technique by balloting. Therefore, a total of 5 settlements were selected from the urban catchment area while a total of 9 settlements were selected from the rural catchment areas.

**Muramvya Catchment Area:** This catchment area has 19 settlements around Muramvya Health centre. 5 settlements were randomly selected. The names of all 19 settlements were written on pieces of paper, placed in a container and shuffled. After, five settlements were randomly selected; Kadahoka, Rwantamba, Busanga, Muramvya I, Bumba, and Kirembera.

**Ryarusera catchment area:** This catchment area has 18 settlements around Ryarusera Health centre. 5 settlements were selected. The names of all 18 settlements were written on pieces of paper, placed in a container and shuffled. After, five settlements were randomly selected; Nyarusange, Nyaruhombo, Gasenyi, Rango and Gatando

**Giko catchment area:** This catchment area has 9 settlements around Giko Health centre. 3 settlements were selected. The names of all 9 settlements were written on pieces of paper, placed in a container and shuffled. After, 3 settlements were randomly selected; Mirama, Gahaga, and Kibande.

**Rusarendu catchment area:** This catchment area has 8 settlements around Rusarendu Health centre. 2 settlements were selected. The names of all 8 settlements were written on pieces

of paper, placed in a container and shuffled. After, 2 settlements were randomly selected; Rusarendu and Muremera. In total 14 settlements were selected and visited to recruit a total of 370 pregnant women in their third trimester of pregnancy.

#### Fourth Stage: Selection of Respondents

The selection of pregnant women in their third trimester of pregnancy to participate in the study in each sampled settlement was done using a systematic sampling technique. Assuming that each pregnant woman in her third trimester of pregnancy represents an eligible household, a list of eligible households was developed in each selected settlement, sampling interval was determined for each settlement and applied accordingly; balloting was employed to determine the first enrollee and the sampling interval was then added to select the subsequent enrollees. When the selected household did not fulfil the inclusion criteria, the immediate neighbourhood was automatically selected. The sample size was distributed among the settlements proportionate to size allocation using the estimate number of pregnant women in their third trimester of pregnancy based on 2008 census

#### Data Collection

Information was obtained from respondents using a pre-tested structured questionnaire which was administered to selected consenting pregnant women from each selected settlement who are in their third trimester of pregnancy. The questionnaire was written in English language and translated to Kirundi Language and was administered by 12 trained local interviewers in Kirundi. The questionnaire comprised of questions on socio-demographic characteristics, obstetric history, knowledge of pregnant women to IPTp and its use.

#### Data Management

After collection, data was checked for its quality in terms of completeness and errors. Open Data Kit (ODK) Version 1.16.0 (ODK-collect, University of Washington, USA) was used for data entry and coding. Data was exported to Microsoft Excel version 2016 (Microsoft Corporation, USA) and cleaned. Univariate analysis was conducted to compute frequencies and proportions. Bivariate analysis at 95% confidence interval was used to compare association between the independent variables and the outcome variables. A *p*-value equals or less than .05 was considered significant. Multivariate logistic regression analysis was also conducted to determine independent association between some factors that were significantly associated with IPTp utilisation at level of bivariate analysis. Respondents' knowledge on IPTp was also assessed as good, fair, or poor Knowledge. This was determined by asking respondents a set of seven (7) about IPTp-SP; – to who it is given, – the purpose of taking it, – when it is recommended, – number of doses pregnant women should take during ANC and interval between doses of IPTp-SP. Correct answer was scored 1 while incorrect answer was scored 0 and the maximum obtainable score was 7. The correct responses for each respondent were summed up and the percentage score calculated. Respondents were grouped into 3 groups based on their final score. Those with score equal or above 70% were considered as having good knowledge, those with score between 50% to 69% were considered as having fair knowledge, while those with score less than 50% were considered as having poor knowledge of IPTp-SP<sup>14</sup>. Epi-Info version 7.2.2.6 (Epi-Info™, Centers for Disease Control and Prevention

(CDC) in Atlanta, Georgia (USA)) was used for data analysis. Tables as well as charts were used to summarise data obtained from the study.

#### Ethical Considerations

The ethical approval was obtained from the Burundi National Ethical committee and permission was sought and obtained from Burundi Ministry of Health and Fight against AIDS. The 4 basic ethical principles of justice, beneficence, non-maleficance, and respect for individual's autonomy were observed. All participants were fully informed about the purpose of the study, potential benefits and the fact that their participation is voluntary. Informed consent was inquired and obtained from all participants before beginning of interview. Furthermore, information sourced was kept confidential. Participants were assured that the information would be used for research purpose only, with access limited to the involved investigators only and stored in a coded password protected computer. Participants were informed that the result of the research will be shared with the District Health Officers, the Ministry of Public Health and Fight against AIDS, the Ahmadu Bello University (ABU) and other stakeholders to support decisions aimed at making the IPTp intervention more responsive.

#### RESULTS

A total of 370 pregnant women were interviewed. Their mean age of 28.3±5.6 years and 211 (57.0%) of them were in the age group of 20 to 29 years. Many of the respondents 353 (95.4%) were married. Sixty-nine (18.6%) were nullipara, 252 (68.1%) were multiparous and 49 (13.2%) were grand multiparous. [Table 1].

#### Accessibility to PHC Centres and Time of Registration at Antenatal Clinic

347 respondents (93.8%) attended the clinic and only 67 (18.1%) reside at least 5 km to the clinic. Out of 370 pregnant women interviewed, 343 (92.7%) had visited ANC, at least once during the index pregnancy. More than half of the pregnant women 192 (56.0%) booked during the first trimester. The mean number of ANC visit among the studied subject was 2.2 (±1.0), and only 34 (9.9%) had four (4) visits or more.

#### Knowledge of IPTp

Among the 370 respondents, 309 (83.5%) were aware of IPTp-SP. Among those who were aware of IPTp-SP, 289 (93.5%) of them knew that IPTp-SP is given to pregnant women at ANC. Majority, 277 (89.6%) of the respondents knew that IPTp-SP is given to prevent both mother and baby from contracting malaria. About 179 (57.9%) of the respondents knew that the first dose of IPTp-SP should be taken during the second trimester of the pregnancy, and 166 (53.7%) knew the required number of doses of IPTp-SP that should be taken during ANC while only 44 (14.2%) knew the monthly interval between doses. Out of 309 who were aware of IPTp-SP, majority 252 (81.6%) declared to get information about IPTp-SP through ANC staff during ANC visits and 18 (5.8%) through the radio/TV. Only 2 (0.6%) reported that they heard about IPTp-SP from Community Healthcare workers. In general, after scoring respondents' knowledge, 98 (31.7%) had good knowledge on IPTp-SP. [Table 2]

#### Utilisation of IPT in the Index Pregnancy

Among 370 pregnant women, 310 (83.8%) had taken IPTp-SP at least once in the index pregnancy and 301 (97.1%) were

**TABLE 1: Socio – Demographic Characteristics of Respondents**

Socio – demographic variables	Frequency (N=370)	Percent
<b>Age group</b>		
<20	13	3.5
20–29	211	57.0
30–39	137	37.0
>40	9	2.4
<b>Marital status</b>		
Married	353	95.4
Single	14	3.8
Widow/Divorced	3	0.8
<b>Parity</b>		
0	69	18.7
1–4	252	68.1
≥5	49	13.2
<b>Education</b>		
No formal education	95	25.7
Primary	236	63.8
Secondary/Tertiary	39	10.5
<b>Occupation</b>		
Farmer	331	89.5
Civil servant	14	3.8
Others	25	6.7
<b>Location</b>		
Rural	295	79.7
Urban	75	20.3
<b>Religion</b>		
Christianity	363	98.1
Islam	5	1.4
None	2	0.5

among those who have heard of IPTp. Among those who were taking IPTp, only 76 (24.5%) had completed the minimum required 3 doses; thus, the overall utilisation of IPTp–SP among the respondents was good in only 24.5%. According to the description of use by respondents, 310 respondents mentioned that 3 tablets were dispensed to them, and all used the 3 tablets, giving compliance rate of (100.0%). There was difference in IPTp–SP utilisation across the studied catchment areas. The Giko catchment area had the highest proportion (45.7%) of pregnant women who had taken at least 3 doses of IPT while Muramvya has the lowest proportion (8.8%) [Figure 2].

**Factors Affecting the IPTp–SP Uptake**

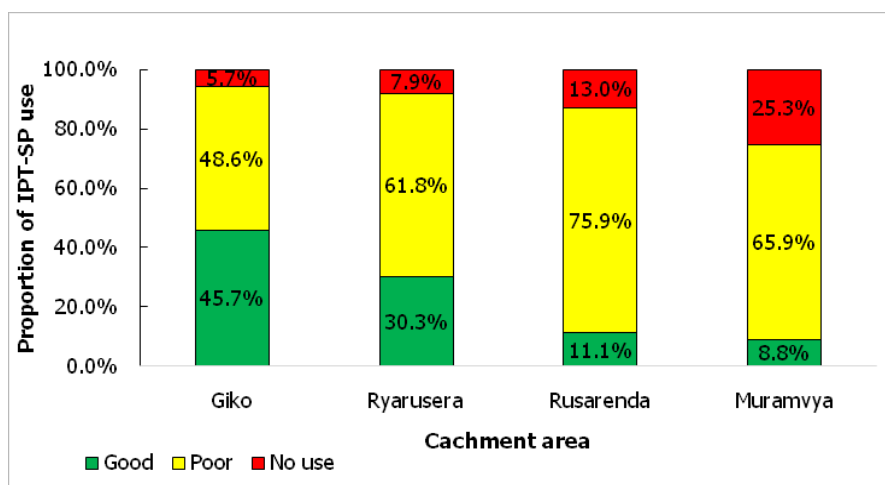
Having any formal education was found to be positively associated with the uptake of IPTp–SP by the pregnant women. Living at less than 5km from the health facility (OR=2.1, 95% CI [1.1–2.2], P=.039), was positively associated with the uptake of IPTp–SP by the pregnant women, and having good knowledge on IPTp–SP (OR=57.0, 95% CI [16.1–353.1], P<.001), were found to be positively associated with the uptake of IPTp–SP by the pregnant women.

To assess independent determinants influencing the uptake of IPTp–SP, determinants with a P≤ .2 in bivariate analysis were put into unconditional logistic regression. Education, parity, having good knowledge on IPTp–SP, and residing less than 5km from the Health Facility were found to be independent determinants of IPTp–SP uptake. [Table 3 and 4]

**Factors Affecting the Good Utilisation of IPTp – SP**

Gestational age at first ANC (OR=2.8, 95% CI [1.3–6.7], p-value=.011), living in rural area (OR=2.2, 95% CI [1.1–4.7], P=.048), and having formal education were found to be determinants of good IPTp–SP utilisation. Again, having good knowledge on IPTp (OR=3.4, 95% CI = [1.8–7.0], P<.001), was found to be a determinant of good utilisation of IPTp–SP. After controlling for possible confounders, Education (aOR=5.0, 95% CI [2.1–24.3], P<.001), gestational age at first ANC visit (aOR=3.3, 95% CI [1.4–7.7], P=.005), and knowledge on IPTp (aOR=2.5, 95% CI [1.4–4.5], P=.010) were found to be independent determinants of good utilisation of IPTp–SP. [Table 5]

**FIGURE 2: Overall IPTp – SP utilisation by catchment area**



**TABLE 2: Knowledge of Pregnant Women of Muramvya Health District on IPTp-SP**

Knowledge Variable	Frequency (N=309)	Percent
<b>IPTp-SP IPTp-SP is normally given to:</b>		
Pregnant women	289	93.5
HIV positive person	11	3.6
Don't know	9	2.9
<b>Purpose of giving IPTp-SP</b>		
To prevent mother and baby from malaria	277	89.6
To treat mother and baby from malaria	25	8.1
Don't know	7	2.3
<b>Time of starting IPTp-SP during pregnancy</b>		
1st trimester	52	16.8
2nd trimester	179	57.9
3rd trimester	21	6.8
Don't know	57	18.4
<b>Required number of IPTp-SP doses in pregnancy</b>		
One	17	5.5
Two	16	5.2
Three or more	166	53.7
Don't know	110	35.6
<b>Interval between doses</b>		
Monthly	45	14.6
Fortnightly	172	55.7
Don't know	92	29.8
<b>Overall</b>		
Good	98	31.7
Fair	110	35.6
Poor	101	32.7

## DISCUSSION

Our findings show that most of the pregnant women interviewed were aware of IPTp-SP and knew that IPTp-SP is given to pregnant women at ANC to prevent mother and baby from malaria. However, the overall knowledge of IPT was good only in 31.7% of pregnant women who were aware of it. Studies from Nigeria, Ghana<sup>14,34-36</sup> have also shown the low level of knowledge of IPT-SP among pregnant women. However, about 70% of respondents had good knowledge on IPTp in Ghana in 2016. This difference in findings may be explained by the time when the study was conducted. Our study was conducted in 2018, only three years of implementation of IPTp as part of ANC package while the study of Hajira *et al* was conducted in 2015, after eight years of IPTp implementation in Ghana.<sup>37</sup> Most of the respondents did not know the number of required doses and the regular interval at which IPTp-SP should be taken during ANC which is the same with the result of the study conducted in Hohoe Municipality of Ghana where they found that majority of the pregnant women did not know the correct interval.<sup>36</sup> Some of these disparities noted from this study could be explained by variations in literacy levels, place of residence, methodology, or timing of the studies.

This knowledge gap may also be due to lack of personal and institutional updates on new interventions in preventing malaria during pregnancy in the district or even from the gap in number of staffs who might not have enough time to explain to all the pregnant women during ANC visit. Thus, the key informants interviewed complained that the staff is not enough, this may have influenced the time allocated to health talks. It may also be as a result of lack of budgetary support in train-

ing of Community Healthcare Workers (CHCWs) who could sensitise communities on IPTp-SP, and others malaria control strategies. It was also found that the source of information was mostly from healthcare workers during ANC. This may explain the low implication of CHCWs in sensitisation of community on malaria and its preventive measures especially the IPTp-SP. The evidence from this study indicate that 83.8% of women have taken at least 1 dose of IPTp-SP during the index pregnancy. Our results differ from 2016 to 2017 Burundi Demographic and Health Survey (BDHS) which reported that proportion of women receiving at least 1 dose SP during their third trimester of their pregnancy was 18.4% in Muramvya province lodging Muramvya Health District.<sup>27</sup> This may be explained by the time difference that there could have been improvement in accessing and utilising health care service through time. 2016 to 2017 BDHS was conducted after 18 months of IPTp-SP implementation while our study was conducted 40 months after. The IPTp-SP uptake rate in our study is also higher than the findings of the study conducted in rural areas of the western part of Kenya in 2005, where only 41% had taken at least 1 dose of SP in their third trimester of pregnancy<sup>14</sup>, and the study conducted in 2014 to 2015, where 68.0% of pregnant women were taking IPT-SP during their pregnancy in Tanzania.<sup>38</sup> The study conducted in Cote d'Ivoire showed that 83.7% women received  $\geq 1$  dose of IPT-SP as prophylaxis against malaria during their pregnancy.<sup>39</sup> However, the SP uptake in this study is lower than that of Ghana, which revealed that 98.5% of the pregnant women of Sunyani Municipality of Ghana received at least one (1) dose of SP during the current pregnancy.<sup>37</sup> These differences may have been mainly due to the time between the implementation of IPTp-SP programme and the conduction of this study



**TABLE 3: Factors Affecting the IPTp – SP Uptake in Muramvya Health District**

Variable	IPTp uptake		OR [95%CI]	P– value
	Yes Freq (%)	No Freq (%)		
<b>Age (years)</b>				
<35	243 (84.4)	45 (15.6)	1.2 [0.6 – 2.3]	.683
≥35	67 (81.7)	15 (18.3)		
<b>Marital status</b>				
Married	297 (84.1)	56 (15.9)	1.6 [0.4 – 5.0]	.617
Not married	13 (76.5)	4 (23.5)		
<b>Parity</b>				
0–4	231 (86.2)	37 (13.8)	1.8 [1.0 – 3.2]	.059
≥5	79 (77.5)	23 (22.5)		
<b>Location</b>				
Urban	68 (90.7)	7 (9.3)	2.1 [1.0 – 5.2]	.102
Rural	242 (82.0)	53 (18.0)		
<b>Education</b>				
Formal	238 (86.5)	37 (13.5)	2.1 [1.1 – 3.7]	.022
Non – formal	72 (75.8)	23 (24.2)		
<b>Occupation</b>				
Farmer	271 (81.9)	60 (18.1)	0.0 [0.0 – 0.4]	.007
Others	39 (100.0)	0 (0.0)		
<b>Distance from home to ANC</b>				
<5km	260 (85.8)	43 (14.2)	2.1 [1.1 – 2.2]	.039
≤5km	50 (74.6)	17 (25.4)		
<b>Mode of transportation</b>				
Foot	287 (82.7)	60 (17.3)	0.0 [0.0 – 0.6]	.060
Vehicle/bike	23 (100.0)	0 (0.0)		
<b>Knowledge on IPTp–SP</b>				
Good	97 (99.0)	1 (1.0)	57.0 [16.1 – 353.1]	<.001
Poor	104 (64.2)	58 (35.8)		

**TABLE 4: Unconditional Logistic Regression for Independent Determinants of the Uptake of IPTp–SP**

Variables	aOR	95%CI	P–value
Education (Formal/No–formal)	2.5	1.2–5.2	.016
Parity (0–4/≥5)	2.1	1.1–4.2	.033
Knowledge on IPTp – SP (Good/Poor)	68.3	15.5–300.2	<.001
Location (Urban/Rural)	1.1	0.4–2.9	.834
Distance from home to ANC (≤5km/>5km)	4.1	1.7–9.6	.001
Occupation (Farmer/Other)	2.0	0.7–6.0	.208

World Health Organization has also revealed the increase in the IPTp–SP uptake through years; the proportion pregnant women who took at least 1 dose of SP has raised from 45% in 2010 to 56% in 2016<sup>40</sup> and dropped down to 54% in 2017.<sup>4</sup> The gestational age at the first ANC visit is believed to be very important to the coverage of IPTp–SP. Early registration increases one’s opportunity of receiving the recommended doses of SP, given ANC is attended regularly and SP is available. Late first ANC attendance has been found to be a factor of incomplete doses of IPTp–SP.<sup>14</sup> In this study, the median gestational age of first ANC visit was found to be 11 weeks (range 3 to 31), majority of the respondents booked during the first and second trimesters

(50.6% and 40.8% respectively). Our findings are similar to a study conducted in Arusha Region of Tanzania where 39.4% of the pregnant women registered their first ANC attendance in the first trimester while 60.6% registered in or after their second trimester.<sup>41</sup> However, the findings of this study differ from those of Mutengene Health Area, Mt Cameroon where 2.2%, 59.7%, and 38.1% enrolled in the first, second and third trimester respectively.<sup>25</sup> Our results also are different from the findings from Kano, North west Nigeria where the majority of women booked in the second trimester (13 to 24 weeks).<sup>35</sup> This means that pregnant women in Muramvya Health District start attending the ANC early enough which could allow them to receive

**TABLE 5: Association Between Respondents’ Socio–Demographic Characteristics, Other Factors and Good Utilisation of IPTp–SP**

Variable	IPTp utilisation		OR [95%CI]	P-value	aOR [95%CI]	P-value
	Good Freq (%)	Poor Freq (%)				
<b>Age (years)</b>						
<35	62 (25.5)	181 (74.5)	1.3 [0.7 – 2.5]	.437	-	
≥35	14 (20.9)	53 (79.1)				
<b>Gestational age at 1stANC visit</b>						
Early	68 (28.0)	175 (72.0)	2.8 [1.3 – 6.7]	.011	3.3 [1.4 -7.7]	.005
Late	8 (11.9)	59 (88.1)				
<b>Marital status</b>						
Married	74 (24.9)	223 (75.1)	1.8 [0.4 – 8.4]	.651	-	
Not married	2 (15.4)	11 (84.6)				
<b>Parity</b>						
0–4	55 (23.8)	176 (76.2)	0.9 [0.5 – 1.6]	.731	-	
≥5	21 (26.6)	58 (73.4)				
<b>Location</b>						
Rural	66 (27.3)	176 (72.7)	2.2 [1.1 – 4.7]	.048	1.7 [0.8–3.9]	.184
Urban	10 (14.7)	58 (85.3)				
<b>Education</b>						
Formal	69 (29.0)	169 (71.0)	3.7 [1.7 – 9.3]	.001	5.0 [2.1–12.3]	<.001
Non–formal	7 (9.7)	65 (90.3)				
<b>Distance from home to ANC</b>						
≤ 5 km	64 (24.6)	196 (75.4)	1.03 [0.5 – 2.2]	.999	-	
>5 km	12 (24.0)	38 (76.0)				
<b>Knowledge on IPT</b>						
Good	64 (31.1)	142 (68.9)	3.4 [1.8 – 7.0]	<.001	2.5 [1.4 – 4.5]	.002
Poor	12 (11.5)	92 (88.5)				

the recommended 3 doses of SP according to National Strategy. This early ANC booking may be explained by the Burundi government strategy of free healthcare services to pregnant women. In addition, the district provides a kind of motivation for pregnant women who book early for their first ANC visits as declared by our key informants. However, despite the early first ANC visit, the mean number of ANC visits among pregnant women interviewed was 2.1±1.1 (range 1 to 6). Most of the women 41.1% had two (2) visits, those who had 3 visits were 27.7% and only 9.9% had four (4) visits or more. On this, the findings are similar with those from Jigawa where the mean number of ANC visits was found to be 2.7 (range 1 to 6). Most of the women 51.2% having two (2) visits and only 9.3% had four (4) visits.<sup>14</sup> In a study on Implementation of intermittent preventive treatment with *sulphadoxine-pyrimethamine* for control of malaria in pregnancy conducted in Kisumu, western Kenya, where about 50% of the women attended their first ANC in the third trimester, about 25% received 2 doses of SP.<sup>42</sup> The results of this study showed that, among those women who have taken at least 1 dose SP, only 24.5% have completed the 3 recommended doses which is considered as good utilisation of IPTp–SP. This rate is higher than the report of 2016 to 2017 BDHS where only 8.1% of pregnant women of Muramvya province reported having completed the 3 doses of IPT<sup>27</sup>, and Countdown to 2030 report where about 13.0% of pregnant women received 3 doses or more in 2016 in Burundi.<sup>26</sup> This may have been due to the improvement overtime from the beginning of the programme. Our findings are close to the WHO

report on malaria where 22% of eligible pregnant women received at least 3 doses of IPTp–SP in 2017.<sup>4</sup> The results of this study showed differences between others studies conducted in others countries. In 2016, the study conducted in Jigawa state of Nigeria found that only 1.4% pregnant women have received at least 2 doses of SP.<sup>14</sup> This finding is in contrast from a study in Ghana which showed that not less than 70% received at least 3 doses of SP<sup>37</sup>, and the one conducted in Arusha Region, Tanzania where 48.4% had received >3 doses of SP-IPT<sup>41</sup>. These differences may be due to time differences. The poor utilisation of IPTp–SP among pregnant women in this study suggests that many pregnant women are not benefiting from the laudable initiative aimed at reducing the level of maternal and neonatal mortality associated with malaria in pregnancy, despite the fact that majority of these women register early for antenatal care. Bearing in mind that Burundi rank high among countries with high maternal and neonatal mortality rate.<sup>43</sup> Different determinants have been identified to be independently associated with utilisation/non utilisation and the good/poor utilisation of IPTp–SP. These are; - education level, - parity, - distance from home to the health centre, - gestational age at the first ANC visit, and the level of knowledge on IPTp–SP. Education improves health, while health improves learning potential. Education and health complement, enhance and support each other; together, they serve as the foundation for a better world.<sup>44</sup> Increasing women’s education increases antenatal healthcare use, potentially owing to changes in women’s cognitive skills, economic resources, and autonomy.<sup>45</sup>

use, potentially owing to changes in women's cognitive skills, economic resources, and autonomy.<sup>45</sup> In Rubavu district of Rwanda, education was associated with the utilisation of health service, in 2012.<sup>46</sup> This study revealed that having any formal education was positively associated with the utilisation and the completion of at least 3 doses of SP. This finding agrees with the study conducted in Tanzania in 2012<sup>47</sup> and 2017<sup>41</sup>, where education associated with uptake of >3 doses of. From 1990 to 2013, education was one of key determinants of IPTp coverage.<sup>48</sup> However, the study conducted in Sagamu, rural town in Western Nigeria, found education level to be not associated with the utilisation of IPTp-SP. This difference may have been to the study population, in that study, about 92.2% have formal education<sup>49</sup> contrarily to our study. Even though it was not statistically significant, the study conducted in Pobè-Adja-Ouèrè-Kétou health zone in Benin show the poor utilisation of IPTp-SP among pregnant women with no any formal education.<sup>50</sup>

In this study, it was found that parity was associated with IPTp utilisation. Therefore, pregnant women who have taken at least 1 dose of SP were more likely to have low parity than those who did not. However, among those who were using IPTp-SP, the parity was not associated with the completion of the minimum of 3 doses of SP. The study conducted by in Jigawa State, Nigeria and in Pobè-Adja-Ouèrè-Kétou health zone in Benin found that parity were not associated with the coverage of IPTp-SP.<sup>14</sup><sup>50</sup> However, in South-West Nigeria, the study conducted in 2012 reported the increasing uptake of IPTp with increasing parity.<sup>49</sup>

The distance from home to the health centre may play a role in IPTp-SP coverage.<sup>51</sup> This was confirmed in our study where pregnant women who have taken at least 1 dose of IPTp-SP were more likely to be living less than 5km from the health centre. However, it was not affecting the completion of minimum 3 doses among those who were utilising the IPTp-SP. The study in Jigawa state of Nigeria found no relationship between distance and uptake of IPTp-SP.<sup>14</sup> This difference may have been to the study population because, they used the ANC based while our methodology was community based. In the study conducted in Mali in 2016, health workers considered non-attendance or late attendance at ANC among the top barriers to IPTp-SP uptake while women and family members saw ANC as valuable, they noted cost and distance as significant barriers to healthcare seeking.<sup>52</sup> The study conducted in Benin in 2012 did not found any association between the distance and the IPTp-SP coverage.<sup>50</sup>

Despite the median gestational age at first ANC of 11 weeks (range 3 to 31) and the high proportion of women who took the first dose, which is an opportunity for the pregnant women to receive the recommended 3 or more doses of IPTp-SP, the utilisation of SP still low. However, early first ANC attendance was found to positively affect the completion of the minimum 3 doses of IPTp-SP. Thus, all key informants stated that the many challenges that affect the rate of utilisation of IPTp-SP were the late first ANC booking and the irregularity in subsequent ANC visits. This finding highlights the need for appropriate dissemination of the current intermittent preventive treatment for malaria guidelines and further scrutiny of the quality of the antenatal care services provided at the primary health care centres by healthcare workers and particularly in the communities by CHCWs. The analysis from 5 Africa countries have shown that the facilities having IPTp guidelines and having implemented IPTp as part of their routine ANC services was major determinant of IPTp delivery.<sup>53</sup> This is to ensure that opportunities for malaria prevention are not missed because of the weaknesses of

the health care system. This position is particularly important because ANC attendance rates even in rural communities in Burundi are usually high.<sup>27,28</sup> Early ANC booking was also found to be positively associated with the utilisation of IPTp-SP in Bukoba, Tanzania<sup>24</sup> and in Ekiti State of Nigeria.<sup>34</sup> The study conducted in 2016 also confirmed that pregnant women of the Pobè-Adja-Ouèrè-Kétou health zone in Benin who attended the ANC at 3 months or less were more likely to have been given at least 1 dose IPTp-SP.<sup>50</sup> In Ghana, in 2015, the study established the relationship between gestational age at first ANC attendance and the number of doses given.<sup>55</sup> In other hand, the study conducted in Tanzania in 2015 didn't find the significant relationship between ANC start date and doses of SP received.<sup>56</sup>

The level of knowledge on IPTp-SP was found to be an independent determinant of the completion of required doses. This is similar to the findings of the study conducted in a rural town in Western Nigeria, and in Bugiri District in south-eastern Uganda.<sup>49, 57,58</sup> Others studies conducted in Tanzania in 2015,<sup>56</sup> have not established the link between the knowledge on IPTp-SP and its utilisation. Other individuals' factors like age, marital status, to be resident in urban or rural area were not found to affect the utilisation or the completion of minimum 3 doses of SP. The free maternal health care policy being implemented in the district could have helped to overcome these factors as barriers to accessing healthcare through the ANCs. This was in agreement with previous study in Tanzania<sup>54</sup> and Jigawa state of Nigeria<sup>14</sup> where individual or client factors were not found to be associated with second dose SP administration. A study done in Malawi also showed that age was not associated the utilisation of IPTp-SP.<sup>59</sup> In Kano and Ekiti States, Nigeria, studies conducted didn't find association between IPTp-SP uptake and respondent age which is similar to the finding from this study.<sup>34,35</sup>

## CONCLUSION

This study revealed a high level of awareness, however, the level of knowledge about IPTp-SP was low. The findings of this study show the high rate of women receiving the first dose of SP; however, the rate of women receiving the minimum 3 doses was very low. The prevalent factors that could affect the utilisation of IPTp-SP in Muramvya Health District were educational level, parity, distance from home to the health centre, gestational age at the first ANC visit, and the level of knowledge on IPTp-SP. The high antenatal attendance of pregnant women and the availability of the drug are important opportunities available for improvement of IPTp-SP program in order to achieve good utilisation of IPTp-SP that can help in reducing malaria in pregnancy generally in Burundi and Muramvya Health District in particular.

## Limitations

The respondents may not have recalled all that happened during their ANC visits leading to recall bias. However, this was minimized by showing samples of SP to them in order for them to relate their responses to the drug in question.

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# Prevalence and Factors Associated with Home Childbirth with Unskilled Birth Assistance in Dodoma-Tanzania: A Cross Sectional Study

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## ABSTRACT

**Background:** Improving maternal health is one of the goals to be achieved under the Sustainable Development Goal (SDG) number 3. Worldwide, half a million of women die each year from pregnancy and childbirth related complications which can be prevented by skilled birth assistance. One of the determinants of maternal health is place of childbirth. Giving birth at home leads to a high risk of maternal and child mortality. The aim of the study was to determine the prevalence and factors associated with choice of home childbirth in Dodoma Municipality.

**Methods:** A community based cross section study using multistage sampling was used to obtain the sample in which 2,523 women who gave birth within 3 years prior to the date of the study from different wards of Dodoma municipal were interviewed. The data obtained were entered and analysed using SPSS version 20. Binary logistic regression analysis was used to establish predictors of home childbirth with unskilled birth assistance.

**Results:** A total of 1,174 (46.5%) women had home childbirth with unskilled birth assistance. After adjusted for the confounders, predictors of home childbirth with unskilled birth assistance among study respondents were level of education [primary education, AOR=0.69 at 95% CI=0.557-0.854, p<.001; secondary education, AOR=0.492 at 95% CI=0.358-0.676, p<.001 and above secondary education, AOR=0.35 at 95% CI=0.16-0.765; p<.01]; marital status [married women, AOR=0.686 at 95% CI=0.547-0.86, p<.001]; occupation of a mother [peasant, AOR=1.508 at 95% CI=1.214-1.874, p<.05]; parity [2 to 4 children, AOR=1.316 at 95% CI=1.028-1.684, p<.05; More than 4 children, AOR=2.006 at 95% CI=1.427-2.82, p<.001]; number of antenatal visits [4 or more antenatal visits, AOR=0.451 at 95% CI=0.204-0.997, p<.05] and walking distance [less than 5kilometres, AOR= 0.797 at 95% CI=0.674-0.943, p<.001]

**Conclusion:** The findings of this study suggest a need for health education in the community on the importance of skilled birth delivery. There is also a need for the government to roll out the implementation of Primary Health Services Development Program (PHSDP-MMAM) which addresses the delivery of health services within 5 kilometres to ensure fair, equitable and quality health services to the community.

## BACKGROUND

Maternal mortality rate is still a challenge to public health system worldwide. Globally, in 2015 about 303,000 women died due to pregnancy and childbirth with 99% of this death occurring in developing countries.<sup>1</sup> Almost all of these deaths occurred among rural poor communities with unskilled birth assistants.<sup>1</sup> Between 1990 and 2015, maternal mortality declined worldwide from 385 to 216 deaths per 100,000 live births.<sup>2</sup> However maternal mortality rate remain unacceptably higher in sub Saharan countries with the lifetime risk of dying during pregnancy being 1 in every 41 women.<sup>1</sup> Tanzania is among the developing countries with highest maternal mortality ratio, estimated at 556 deaths per 100,000 live birth.<sup>3</sup>

Most women in developing countries die due to complications that arise during pregnancy and while giving birth. Maternal deaths are caused by both direct and indirect cause. About 75% of these deaths are caused by direct causes such as severe bleeding, infections, high blood pressure and unsafe abortion while the other 25% being contributed by diseases like malaria and Acquired Immune Deficiency Syndrome (AIDS).<sup>4</sup>

More than 2.5 million neonates died within their first 28 days of life in 2016, contributing up to 45% of global under 5 deaths worldwide.<sup>6</sup> Globally, the trend of neonatal mortality reportedly decreased from 37 deaths per 1,000 live births in 1990 to 19 deaths per 1,000 live births in 2016.<sup>7</sup>

The burden of neonatal mortalities in sub-Saharan Countries is high, however, the trend of neonatal mortality showed a decrease from 46 neonatal deaths per 1000 live births in 1990 to 26 neonatal deaths per 1000 live births in 2016.<sup>7</sup> 77% of these deaths occurred in 2 regions, the Southern Asia (39%) and sub-Saharan Africa 38%.<sup>7</sup>

Tanzania is among the countries in Sub-Saharan region with the highest neonatal mortality rate of 25 deaths per 1,000 live births.<sup>4</sup>

There exist variations in neonatal mortalities in Tanzania. Dodoma region located in central Tanzania is among the regions with high neonatal mortality (29 deaths per 1,000 live births) above the national average.<sup>4</sup>

Globally, in the year 2015, infectious diseases, prematurity and

complications during labour and delivery were the main causes of deaths among neonates.<sup>4</sup> Other causes of death were preterm birth complications, sepsis and *meningitis*.<sup>8</sup> There is direct relationship between low use of skilled health personnel for delivery and maternal and neonatal mortalities. As clearly defined by WHO “skilled health personnel” are competent maternal and newborn health professionals educated, trained and regulated to national and international standards.<sup>1</sup> Birth attended by skilled health personnel have proven to reduce maternal and neonatal mortalities.<sup>9</sup> Worldwide up to 80% of birth were attended by a skilled personnel in the latest 2012 to 2017.<sup>1</sup> Sub Saharan Africa has also shown some advancement over the same period with about 50% of deliveries attended by a skilled personnel.<sup>1</sup> In the year 2017 the number of birth attended by skilled health personnel worldwide was 78% while in developing countries only 56% of births were attended by skilled health personnel.<sup>15</sup> In Tanzania, births under skilled attendants seems to have taken a step ahead from about 52% of all births being conducted in a health facility and 48% at home in 2010<sup>10</sup> to 64% of births being conducted in a health facility with a skilled health personnel and 36% of the remaining cases takes place at home.<sup>3</sup>

High incidences of neonatal and maternal morbidity and mortality rates have been displayed amongst unplanned home birth which is not conducted by skilled health personnel.<sup>11</sup> Postpartum hemorrhage and retained placenta are some of the main adverse outcome of home delivery.<sup>11</sup> Hypothermia and infections are more associated with neonates who are born at home without the help of skilled health personnel.<sup>12</sup> Double neonatal mortality rate occur among home births.<sup>13</sup> Babies born in unplanned home birth without the help of a skilled health attendant are at a higher risk of developing some complications due to hypoxia, infections, respiratory distress, hypothermia acidosis and prematurity.<sup>13</sup>

It is important that mothers deliver their babies in a suitable setting, where there is skilled health personnel, required lifesaving equipment and sterile conditions which can lessen the risk of complications.<sup>14</sup> Tanzanian government through its National Road Map Strategic Plan to improve Reproductive, Maternal, Newborn, Child & Adolescent Health (2016 to 2020) has set aside resources to increase births assisted by skilled birth attendants.<sup>15</sup> The aim of the government through its Ministry of Health is for all women to access skilled birth assistance during childbirth. Child survival and good maternal outcome are a result of health facility delivery where an appropriate care from a well-trained team of health personnel is ensured.<sup>13</sup>

A number of studies have worked out factors which influence home childbirth with unskilled assistance to be; low risk perception<sup>16</sup>, low male involvement<sup>17</sup>, poverty<sup>18</sup>, high parity<sup>18</sup>, low knowledge about birth preparedness and complication readiness.<sup>19</sup>

Limited data is available on the factors influencing home childbirth with unskilled birth assistance among women in Dodoma Region. The objective of this study was to determine the factors associated with home childbirth with unskilled birth assistance in Dodoma Region

## METHODS

### Study Design and Setting

A descriptive cross sectional study was conducted between March and April 2016 in Dodoma Municipality, Tanzania.

Dodoma municipality is subdivided into 4 divisions (Urban, Hombolo, Kikombo and Zuzu Division) comprising of a total of 30 wards and 42 villages/streets. Dodoma Region lies in the eastern-central part of Tanzania and it is the capital city of the country. According to the 2012 national Census, the region had a population of 2,083,588 and population density of 50 people per square kilometres. It covers an area of 41,310 square kilometres (NBS, 2012). Female population accounts for 51.3% of the total population. The annual population growth rate is 2.1% with a sex ratio of 95 males to 100 females [NBS, 2012]. The region’s health care service structure comprise of 7 hospitals, 32 health centres, and 269 dispensaries, most of which provide reproductive and child health services.<sup>19</sup> The most dominant ethnic group is Gogo but other ethnics exist too such as Sandawe, Rangi Sukuma, Chagga. People of this area are involved in economic activities like business, livestock keeping, office work and farming.<sup>21</sup> figure 1 below.

**FIGURE 1: Map of Dodoma Region Showing the Study Area**



### Study Population

The study population was all women of childbearing age who gave birth at the time of data collection and within 3 years prior to data collection.

### Inclusion Criteria

All women of child bearing age who were physically and mentally well, had given birth within 3 years prior to the study, and accepted to sign the consent form for the agreement to participate in a study.

### Exclusion Criteria

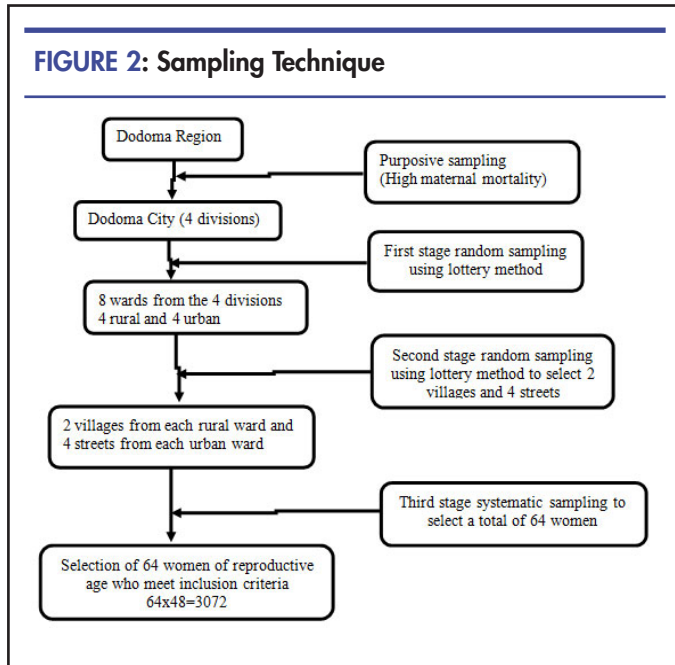
Mentally ill mothers plus those that declined to sign the consent form were not included.

### Sample Size

The sample size was calculated using Kish Leslie’s formula,  $n = z^2 p(1-p)/e^2$  where, n is sample size, z=standard normal deviation set at 1.96 at 95%CI, p=prevalence of home delivery in Dodoma region which is 51%<sup>3</sup> and e= maximum error, assumed to be 5%

$$n = \frac{(1.96)^2 \times 0.51(1-0.51)}{0.05^2} \text{ from each selected wards} = 384; 8 \text{ wards} \times 384 = 3,072$$

$(0.05)^2$   
Therefore, the total sample size was 3,072



**Sampling Technique**

The three-stage sampling technique was used to obtain the required sample size.

In figure 2, multistage sampling techniques was used to obtain study participants. Dodoma city was selected purposively and all 4 divisions of Dodoma City were included in the study. First stage sampling techniques using simple random sampling (lottery) was used to obtain 8 wards from each division. Second stage sampling using simple random sampling (lottery) was used to obtain 2 villages from each rural ward and 4 streets from each urban ward. The third stage used systematic sampling to select 64 women of reproductive age who met inclusion criteria. In this stage, all hamlets in rural villages were listed and each contributed equal number of women to be included in the study. The first household were selected randomly and were assessed for inclusion criteria. Upon meeting the inclusion criteria and consented to participate, they were included in the study. The next household in a predetermined direction was visited and assessed for inclusion criteria. If the visited household did not meet the inclusion criteria, it was skipped and the followed household was visited until the required number of participants were reached. In the street, similar procedure was used to enrol participants in the study.

**Data Collection**

Household survey using structured open and closed ended questionnaire was used. The English version interview questions were translated into Swahili to obtain data from the study participants and to ensure they understand the contents properly. Prior to data collection, the questionnaire was pretested in Madukani Ward, which has almost similar characteristics as the wards selected for study. The questionnaire was modified accordingly before being used in the study. It was administered by 4 research assistants who had recently graduated from medical school and were trained by principal investigator for 3

days before the start of data collection. Questionnaire was given to each eligible woman to fill in. For participants who didn't know how to read and write, face to face interview was conducted by research assistants and the information obtained was filled in by the research assistant

**Data Analysis**

The data collected through questionnaires was first coded, and entered into SPSS version 20, owned by IBM corporation company in Chicago city found in The united states of America. Data cleaning was performed before analysing the data so as to identify the incorrect data, missing data during entering and duplicate data. Then data were subjected to simple descriptive statistical analysis. Binary logistic regression model was used to determine association between dependent and independent variable. The variables were entered into bivariate and multivariate logistic regression analysis in order to determine their independent effects in home delivery. The Adjusted ORs and their corresponding 95% Confidence Interval (CI) were obtained. The level of significance was set at P <.05.

**Ethical Consideration**

Permission letter to conduct this study was obtained from Research and Ethical Committee of the University of Dodoma. Permission from the local authorities to collect data to the wards and streets was also obtained. The rights of the participant were well protected by obtaining informed consent in oral and written form. Each participant was informed of her right to refuse to participate or not. Confidentiality was assured among the respondent who agreed to participate in the study. The study had ethical clearance number UDOM/DRP/IRRC/14/VOL V/31

**RESULTS**

**Socio-demographic Characteristics**

A total of 2,523 women were interviewed in this study which make a respond rate of 82%. Majority of interviewed women were aged between 21 and 34 years. 1,588 (62.9%) 1576(62.5%) had primary level education, 1,812 (71.8%) were married, and 1497 (59.3%) had 2 to 4 children Table 1.

**Prevalence of Home Childbirth among Study Respondents**

Majority of study participants 1,349 (53.5%) used health facilities for childbirth, 746(29.6%) of deliveries occurred at home assisted by a traditional birth attendant or a relative, 303(12%) of deliveries occurred in traditional birth attendant's home and 125(5%) occurred on the way to a health facility Therefore, the deliveries which occurred in health facilities were 1,349 (53.5%) and those which occurred outside health facilities were 1,174 (46.5%). In this study, deliveries that occurred outside health facility are termed as home childbirth assisted by unskilled birth attendants (see fig. 3 below). In table 2 below, all women background characteristics showed a significant relationship with place of childbirth.

**Predictors of Use outside Health Facility/Home Childbirth among Study Respondents**

After adjusted for the confounders, predictors of home childbirth among study respondents were; level of education [primary education, AOR=0.69 at 95% CI=0.557-0.854, p<.001; secondary education, AOR=0.492 at 95% CI=0.358-0.676, p<.001 and above secondary education, AOR=0.35 at 95% CI=0.16-0.765; p<.01]; marital status [married women,



**TABLE 1: The Socio-demographic Characteristics of Interviewed Women (N=2,523)**

Variables	Frequency(n)	Percent (%)
<b>Age group of a participant</b>		
15-20	328	13
21-34	1,588	62.9
35-49	607	24.1
<b>Level of Education of a Participant</b>		
No formal education	514	20.4
Adult education	58	2.3
Primary education	1,576	62.5
Secondary education	330	13.1
Above secondary education	45	1.8
<b>Tribe of a Participant</b>		
Gogo	1,628	64.5
Rangi	394	15.6
Others	501	19.9
<b>Marital Status of a Participant</b>		
Not married	470	18.6
Married	1,812	71.8
Separated	241	9.6
<b>Occupation of the Mother</b>		
House wife	518	20.5
Peasant	1,289	51.1
Pastoralist	134	5.3
Self employed	524	20.8
Employed by the government	48	1.9
Others	10	0.4
<b>Parity of a Participant</b>		
1	545	21.6
2- 4	1,497	59.3
> 4	481	19.1
<b>Antenatal Visit</b>		
Yes	2,370	93.9
No	153	6.1
<b>Number of Antenatal Visits</b>		
No antenatal visit	153	6.1
<4 visits	1,445	57.3
>4 visits	925	36.7
<b>Was the Place of Childbirth Intended?</b>		
Yes	1,828	72.5
No	695	27.5
<b>Distance to Nearby Health Facility</b>		
< 5km	1,373	54.4
> 5km	1,150	45.6

AOR=0.686 at 95% CI=0.547 -0.86, p<.001]; occupation of a mother [peasant, AOR=1.508 at 95% CI=1.214-1.874, p<.05]; After adjusted for the confounders, predictors of home childbirth among study respondents were; level of education [primary education, AOR=0.69 at 95% CI=0.557-0.854,

p<.001; secondary education, AOR=0.492 at 95% CI=0.358-0.676, p<.001 and above secondary education, AOR=0.35 at 95% CI=0.16-0.765; p<.01]; marital status [married women, AOR=0.686 at 95% CI=0.547 -0.86, p<.001]; occupation of a mother [peasant, AOR=1.508 at 95% CI=1.214-1.874, p<.05];

**TABLE 2: The Relationship between Women Background Characteristic and Place of Childbirth (N=2523)**

Variables	Health Facility		Home childbirth		X2	p-value
	Frequency (n)	Percent(%)	Frequency (n)	Percent (%)		
<b>Age Group of a Participant</b>						
15-20	182	7.2	146	5.8	11.65	**
21-34	879	34.8	709	28.1		
35-49	288	11.4	319	12.6		
<b>Level of Education of a Participant</b>						
No formal education	209	8.3	305	12.1	65.36	***
Adult education	30	1.2	28	1.1		
Primary education	857	34	719	28.5		
Secondary education	219	8.7	111	4.4		
Above secondary education	34	1.3	11	0.4		
<b>Marital Status of a Participant</b>						
Not married	221	8.8	249	9.9	26	***
Married	1,025	40.6	787	31.2		
Separated	103	4.1	138	5.5		
<b>Occupation of the Mother</b>						
House wife	306	12.1	212	8.4	36.9	***
Peasant	624	24.7	665	26.4		
Pastoralist	89	3.5	45	1.8		
Self employed	289	11.5	235	9.3		
Employed by the government	35	1.4	13	0.5		
Others	6	0.2	4	0.2		
<b>Parity of a Participant</b>						
1	333	13.2	214	8.5	43.42	***
2-4	820	32.5	677	26.8		
≥4	196	7.8	283	11.2		
<b>Antenatal visit</b>						
Yes	1,303	51.7	1067	42.3	35.86	***
No	46	1.8	107	4.2		
<b>Number of antenatal visits</b>						
No antenatal visit	46	1.8	107	4.2	69.24	***
<4	577	22.9	348	13.8		
≥4	726	28.8	719	28.5		
<b>Distance to nearby health facility</b>						
< 5km	766	30.4	608	24.1	6.005	*
> 5km	583	23.1	566	22.4		

Indicate significant at \*p<.05, \*\*p<.01 and \*\*\*p<.001.

parity [2 to 4 children, AOR=1.316 at 95% CI=1.028-1.684, p<.05; More than 4 children, AOR=2.006 at 95% CI=1.427-2.82, p<.001]; number of antenatal visits [4 or more antenatal visits, AOR=0.451 at 95% CI=0.204-0.997, p<.05] and walking distance [less than kilometres, AOR= 0.797 at 95% CI=0.674-0.943, p<.001] (see Table 3)

## DISCUSSION

The current study investigated the prevalence and factors associated with home childbirth. The prevalence of home child

birth. The prevalence of home childbirth was found to be 46.5%. This result was higher than the country national coverage of 36%<sup>3</sup> and higher than what have been observed in the study conducted in Ethiopia in which 6.8% of women gave birth at home.<sup>22</sup> The possible explanation for the variation in the study findings between these studies could be due to the differences in educational level and variation in socio-economic status of respondents which may have influences in selection of place to give birth. Therefore, awareness about the importance of health facility delivery and the risk of home delivery is needed

**TABLE 3: Bivariate and Multivariate Logistic Regression Analysis to determine the predictors of home childbirth (N=2523)**

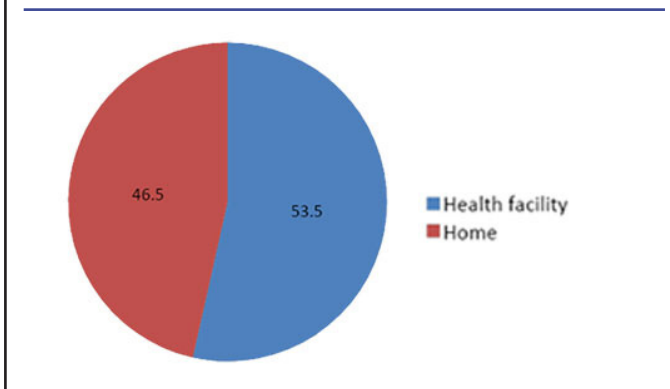
Variables	OR	95% CI		p-value	AOR	95% CI		P-value
		Lower	Upper			Lower	Upper	
<b>Age Group of a Participant</b>								
15-20	1				1			
21-34	1.005	0.792	1.277		0.977	0.728	1.31	
35-49	1.381	1.054	1.808	*	0.877	0.611	1.258	
<b>Level of Education of a Participant</b>								
No formal education	1				1			
Adult education	0.64	0.371	1.102		0.776	0.439	1.37	
Primary education	0.575	0.47	0.704	***	0.69	0.557	0.854	***
Secondary education	0.347	0.26	0.463	***	0.492	0.358	0.676	***
Above secondary education	0.222	0.11	0.447	***	0.35	0.16	0.765	**
<b>Marital Status of a Participant</b>								
Not married	1				1			
Married	0.681	0.556	0.835	***	0.686	0.547	0.86	***
Separated	1.189	0.87	1.626		0.963	0.684	1.356	
<b>Occupation of the Mother</b>								
House wife	1				1			
Peasant	1.538	1.251	1.891	***	1.508	1.214	1.874	***
Pastoralist	0.73	0.49	1.088		0.718	0.474	1.088	
Self employed	1.174	0.918	1.5		1.383	1.066	1.793	*
Employed by the government	0.536	0.277	1.038		1.027	0.491	2.147	
Others	0.962	0.268	3.451		0.793	0.21	2.995	
<b>Parity of a Participant</b>								
1	1				1			
2-4	1.285	1.052	1.569	*	1.316	1.028	1.684	*
>4	2.247	1.749	2.886	***	2.006	1.427	2.82	***
<b>Antenatal Visit</b>								
No	1				1			
Yes	0.352	0.247	0.502	***	0.608	0.276	1.335	
<b>Number of Antenatal Visits</b>								
No antenatal visit	1				1			
<4 visits	0.609	0.515	0.721	***	0.671	0.303	1.483	
≥4 visits	2.349	1.638	3.369	***	0.451	0.204	0.997	*
<b>Distance to Nearby Health Facility</b>								
>5km	1				1			
< 5km	0.818	0.699	0.957	*	0.797	0.674	0.943	**

Indicate significant at \*p<.05, \*\*p<.01 and \*\*\*p<.001.

The study found that maternal education level has a high influence on choice of place of childbirth. Women with no formal education were more likely to deliver at home compared to women with higher education. Those with primary education were 36% less likely to deliver at home while women with secondary education were 51% less likely to give birth at home. This shows that the more educated the woman is the more likely she would ensure a hospital delivery. This may be because educated mothers have confidence in making their own choices

and stick to them and ask for the quality care they desire. Other previous studies conducted in Ethiopia, Kenya and Nepal indicated that the mother's education being lower than primary level is associated with a high prevalence of home delivery.<sup>23-25</sup> Also most of materials in the antenatal clinics are being provided in writing such as posters. This might be difficult for mothers with no formal education to grasp the material and feel like they are left out, so instead they decide to just be at a where they will be comfortable and not feel like they are left out.<sup>26</sup>

**FIGURE 3: The Prevalence of Home Childbirth in Dodoma**



In most of our societies, marital status tends to have an influence on health seeking behaviour. In our study, single mothers were more likely to give birth at home and married women were 32% less likely to give birth at home. A birth process is an amazing experience for almost every woman. It is a moment that no woman can forget and that is why most women will prefer to have the best experience worth remembering. They would want people around to support them through the pregnancy and childbirth. For single mothers this kind of support may not be enough. For married women getting the support from her husband, mother in law and her family may be of help to influence the mother to give birth at the health facility most especially when the husband is the one that makes decision in the family. This is in agreement with the studies that were conducted in Nigeria and Kenya.<sup>23,27</sup> However, this is in disagreement with the study done in Gambia in which marital status had no influence on a place of delivery for women.<sup>28</sup>

What the mother does for a living can influence her decisions when it comes to pick a place of delivery. This study revealed that peasant women were 1.5% more likely to deliver at home as compared to housewives. Being a peasant can be too demanding for an African mother. Sometimes this can even limit the time that a woman is supposed to focus on her health and her pregnancy. The work may tend to take a greater part of her life and with this the woman may not have a chance to access the information on the importance of giving birth at the health facility and hence she may not see the importance of it at all. This is in line with previous studies that showed occupation of the mother can influence home delivery.<sup>29</sup>

Giving birth to most of the mothers is all about experience. The attitude of a prime gravida may not be the same as that of the multipara. This study can vividly prove that women with parity of 2 to 4 were 1.3% more likely to deliver at home while those of more than 4 children were 2 times more likely to give birth at home. If a woman gave birth more than 4 times without any complications, she may see it as just a normal process hoping that everything will just go smoothly as other pregnancies and there is nothing to worry about. This is even more likely to happen to those women who had their last birth at home. The woman feels like she has enough experience to handle all that without the help of medical personnel. The other reason can be that the responsibility of taking care of the children is put on the hands of the mother, with this in mind the mother of higher parity will be concerned with who will take care of the family once she is gone and this can affect her decision. This is in

agreement with other studies which were conducted in Ethiopia and Tanzania.<sup>30,31</sup>

Antenatal visit plays a vital role when it comes for a woman to pick a place of delivery. There is a lot of helpful health information that women get from these ANC visits. This study shows that women with less than 4 antenatal visits were 40% less likely to deliver at home compared to women who have never attended any antenatal care. Also, women with more than 4 antenatal visits were 2 times more likely to give birth at a health facility compared to women who never attend antenatal clinic. Women with more antenatal visits are less likely to give birth at home possibly because of the content of health education and understanding the risk factors that may accompany home delivery. This is in line with studies conducted in other countries indicating that more antenatal care visits decrease the likelihood of giving birth at home.<sup>32</sup> The findings from this study is in contrary with the findings reported in Ethiopia.<sup>22</sup>

In most of developing countries, there is no enough health facilities. Even the few that are there may be too far for some women to access them. This has been a major setback in increasing facilities delivery. In this study women who lived less than 5km from the health facility were 21% less likely to give birth at home compared to women who lived more than 5km from the health facility. This can be due to variety of reasons including the fact that some women cannot afford the transport fare to reach the health centre. Also, due to lack of birth preparedness knowledge, most women do not have a transport plan in hand in case of sudden labour. Another reason is, the physical characteristic of a particular place which makes it hard to make it to the nearby health facility on time even when the transport is accessible. Some women also feel burdened to leave their family behind and go far to seek health care. Women may also feel like they are disturbing their relatives who will have to travel long distances to check them up in the health care facility. This is in line with other previous studies which indicated that distance to the health facility has an association with home delivery.<sup>28,29</sup>

The strength of this study is the use of large sample size which allow researchers to better determine the average values of prevalence of home childbirth in Dodoma Region. Also, the study used quantitative study approach which allow the generalisation of the findings. Nevertheless, this study is not without limitations. It was a cross-sectional study which relied on participants recalling the past event which could introduced recall bias. The limitation was minimised by including women who gave birth during the time of data collection and who had given birth in the period of 3years prior the time of data collection.

## CONCLUSION

The number of women who are not using health facilities for childbirth is still high thus requiring prompt intervention. The predictors of using health facilities for childbirth were; the level of education of pregnant women, marital status, parity where the more the number of children a woman has the less likely she will use the health facility for childbirth, number of antenatal visits where those with few visits are less likely to use health facility for childbirth and distance of Health Facility where women living far from health facilities are less likely to use health facilities for childbirth. More innovative interventions are needed to increase the use of health facilities for childbirth in this central part of Tanzania.

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**Availability of Data and Materials:** The datasets used during the current study are available from the corresponding author on reasonable request.

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## Trends in Hospitalisation for Human Immunodeficiency Virus in a Tertiary Hospital in Dar es Salaam, Tanzania: A Case study

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### ABSTRACT

**Background:** Reports on systematic evaluation of the impact of antiretroviral therapy (ART) on patients' hospitalisation in Sub-Saharan Africa (SSA) and Tanzania in particular are scarce. We aimed at documenting the trends of hospital admissions at Muhimbili National Hospital (MNH) following scale up of free access to ART in Tanzania.

**Methods:** Records for all admissions at MNH from June 2005 to June 2015 were reviewed. We extracted data from Hospital Information Management System as well as from patients' charts. Data extracted included diagnosis at discharge, reason for admission and thereafter assessed admission trends over the decade. We summarised the data as frequency and percentages. We compared proportions using Chi squared test,  $P < 0.05$  was deemed significant.

**Results:** Overall there were 209,101 admissions during the study period (June 2005 to June 2015) and 7864/209,101 (3.8%) were due to HIV infection. Whereas 598/4,519 (13.2%) of all admissions in 2005 were due to HIV, only 345/13,119 (2.6%) of admissions in 2015 were HIV-related; showing a significant drop over time ( $P$  value for trend  $< .001$ ). Generally, females 3887/6679 (58.2%) were more likely to be admitted than males (41.8%). Median CD4 count for admitted HIV patients was 143 cells/ $\mu$ l. Majority of admissions occurred in the medical wards 3643/5310 (68.6%). Discharge diagnoses were Tuberculosis 1396/6482 (21.5%), anaemias 1016/6482 (15.6%), malignancies 789/6482 (12.2%), CNS infections 541/6482 (8.3%) and chronic kidney disease 308/6482 (4.8%). Three leading AIDS defining malignancies among hospitalised patients included Kaposi's sarcoma 380/789 (48.2%), carcinoma of the cervix 77/789 (9.8%), and Non-Hodgkin's lymphoma 44/789 (5.6%).

**Conclusion:** Despite drastic drop of HIV related admissions at Muhimbili National Hospital over the years, the infection remains a problem of the adults, largely females suffering from medical conditions and presenting with severe immunosuppression. Tuberculosis remained the most common opportunistic infection among hospitalized HIV infected patients. Anaemia and cancers became more important causes of admission than was diarrhoea which had been the most common among HIV infected patients in pre-ART era.

### BACKGROUND

At the end of 2018, an estimated total of 75 million people had been infected with Human Immunodeficiency Virus (HIV) and about 32 million people had died of HIV globally since the beginning of the epidemic in 1980. Globally, 37.9 million [32.7 to 44.0 million] people were living with HIV at the end of 2018. The WHO African region remains most severely affected accounting for two-thirds of the people living with HIV worldwide. In Africa, it is estimated that 1 in every 25 adults (3.9%) is living with HIV<sup>1</sup>. Adolescent girls and young women aged 15-24 years have up to eight fold higher rates of HIV infection compared to their male peers and do acquire HIV infection 5-7 years before men<sup>2</sup>.

Diseases related to HIV infections were first reported in Tanzania from Kagera region in 1983<sup>3</sup>. By the end of 1986 cases of acquired immunodeficiency syndrome (AIDS) had been reported from all regions of Tanzania mainland. Parallel to an explosion of hospital admission of patients with full blown AIDS, patients with tuberculosis increased more than three folds. Unprecedented number of patients with other HIV related clinical conditions including Kaposi's sarcoma were also hospitalized in increasing numbers beginning the early 1980's<sup>3</sup>.

Cases of AIDS were first reported at the then Muhimbili Medical Centre (now Muhimbili National Hospital), Dar es Salaam in 1984. Prevalence studies done beginning 1986 among medical admissions, pregnant women, and blood donors in Dar es Salaam showed that HIV infection was wide spread in the general population<sup>4</sup>. In early 1990's the prevalence of HIV among malnourished children was 25% compared to 1.5% in non-malnourished children<sup>5</sup>. HIV prevalence among pregnant women in 1984 was 3.2%, reached a peak of 16% in 1989<sup>4</sup> and then steadily declined thereafter, reported to be 3.3% by 2008<sup>6</sup>.

A high HIV seroprevalence and increased HIV-associated mortality were reported among patients with deep bacterial infections in the medical wards of Muhimbili<sup>7</sup>. A study involving 517 patients hospitalized in the medical wards with fever during February to April 1995 found that 55% of patients tested positive for HIV-1<sup>8</sup> while 10.5% of surgical admissions in the same hospital from 2001 to 2002 were HIV infected<sup>9</sup>. A total of 118/145 (81%) of surgical patients who confirmed to have blood stream infection were HIV infected<sup>7</sup>. The prevalence of HIV infection among patients hospitalised in the same hospital with pulmonary tuberculosis and/or extra-pulmonary tuberculosis during the 1990s ranged from 33% to 50%<sup>10-12</sup>.

In late 1990s patients who presented with pyomyositis significantly presented with higher rate of HIV seropositivity (62%) than were non-patient controls (12%).<sup>7</sup>

In the 1990s free ART were not provided to a large part of Sub Saharan Africa (SSA) including Tanzania due to high cost of the antiretroviral drugs and lack of adequate laboratory capacities. Beginning 1996 combination therapies with three antiretroviral drugs were found to be more effective in lowering HIV viral load thus became standard of care for patients with HIV disease including AIDS in the industrialised countries.<sup>13,14</sup> In early 2000s physicians in Tanzania prescribed first line ART drugs in different combinations including dual therapy with zidovudine and lamivudine or triple therapy with Zidovudine, Nevirapine and Didanosine or Zidovudine, Nevirapine and Stavudine. It was not until 2005 that HIV treatment in Tanzania was standardized to 3 drug combinations after the release of the first HIV guideline. The use of 3 drug combinations resulted into decreased hospitalisation and mortality rates with resultant increased life expectancy in different countries.<sup>15-17</sup> Moreover, during the ART era, there has been a shift of causes of deaths from AIDS defining to non AIDS defining illnesses.<sup>18,19</sup>

In 2004 Tanzanian government launched a countrywide provision of ART to AIDS patients, commencing with a pilot clinic at Muhimbili National Hospital (MNH). National data for HIV prevalence among adults aged between 15 years and 49 years gradually fell from 7% to 5.1% in 2003/4 and 2011/12 respectively.<sup>20,21</sup> The 2016 National HIV survey found a National prevalence of HIV at 5.0%, a similar figure as that of 2011/12.<sup>22</sup> With increased access to ART the average number of personal admissions due to HIV in various parts of the world fell by 39% early in 2000 and the overall number of hospital admissions due to HIV fell by about 10% to 65%. This study therefore intended to document the trends of hospital admissions at MNH following free access and wide scale up of ART services in Tanzania.

## METHODS

### Study Design, Site and Data Sources

This hospital based cross sectional descriptive study aimed at describing trends in admission rates and reasons for admission over time following free ART access in November 2004. Hospital based data was collected at Muhimbili National Hospital (MNH), the largest tertiary hospital in the country and a university teaching hospital situated in the city of Dar es Salaam. MNH is a 1,500 bed facility, attending 1,000 to 1,200 outpatients weekly, and admitting 1,000 to 1,200 inpatients per week. It receives referral cases predominantly from within the city of Dar es Salaam and from all over the country. Figure 1 shows the location of Dar es Salaam city and its districts within Tanzania. We used electronic hospital information system and patients' paper files as source of the collected information on hospital admissions and the reasons for admission respectively.

### Data Collection Procedures

Since electronic data was available from June 2005, we collected data on hospital admissions from June 2005 to June 2015. Information on date and number of admissions was extracted from the electronic records. We reviewed patients' paper files to collect information on causes of admissions and discharge diagnoses. Each admission was treated as a separate entity and analysed as such.

For this study, we included everyone who was admitted in the hospital in the specified time frame and we had no exclusion

criteria. We obtained file registration numbers of all admitted HIV infected patients and thereafter retrieved the respective files from the records department. The investigators reviewed each of the patients' files. Clinical record forms were used to record the extracted data from hospital records. The information collected included socio-demographic data, HIV status, WHO HIV staging, CD4 cell counts, and status of antiretroviral therapy use, discharge diagnosis, duration of hospital stay and admission outcome (discharge or death). HIV status was ascertained by looking at the case notes. Some patients were already known to be HIV infected at the time of admission while some were tested and diagnosed with HIV infection during an index admission.

### Statistical Analysis

Absolute numbers of admissions due to HIV over the study period are presented graphically to show the general admission trends over time. Proportions of HIV admissions overtime were calculated by dividing the total number of admissions due to HIV per year by the total number of hospital admissions in that particular year. We used STATA 12.0 statistical package (StataCorp, Texas U.S.A) to analyse the data, and Chi Square statistics test ( $\chi^2$ ) was performed to compare proportion of admissions due to HIV over time.  $P < .05$  was considered significant. Causes of admissions are presented as absolute numbers as well as proportions

### Ethical Approval and Consent to Participate

The study obtained ethical clearance from the Muhimbili University of Health and Allied Sciences (MUHAS) Institutional Review Board, reference number MU/DRP/AEC/Vol.XVIII/139. The MNH management authorized unrestricted access to hospital records to extract required information for this study. The clinical request form (CRF) only included hospital registration numbers and patient's initials and not names. CRFs were kept locked in filing cabinets and made accessible to authorized personnel only.

## RESULTS

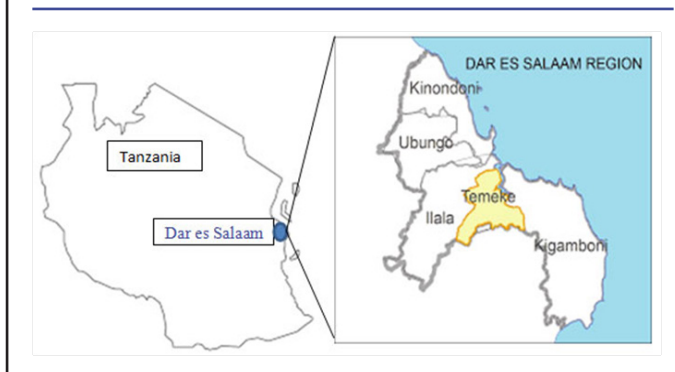
In the span of 10 years, there were a total of 7,864 (3.8%) admissions due to HIV out of 209,101 total hospital admissions. Absolute numbers of admissions in the hospital over the years were as shown in Figure 2. Admissions due to HIV dropped drastically from 13.2% (598/4519) in 2005 to 2.6% (345/13,119) in 2015 (See Table 1) [Chi square=1748.473;  $P < .001$ ] Comparison of hospital base (MNH) and general HIV prevalence in the city of Dar es Salaam is depicted in Figure 3. Decline of HIV prevalence was observed in both hospital and city surveys.

Out of 7864 HIV-related admissions, we managed to find 6874 (87.4%) patients' files, from which data was extracted. Females constituted 3887/6874 (58.2%) of the total HIV related admissions. Of the 6874 admissions only 5310 had recorded ward of admission. Majority of HIV related admissions were commonly found in medical wards 3643/5310 (68.6%). Other wards where HIV patients were admitted included surgical 795/5310 (15.0%), paediatric 531/5310 (10.0%), gynaecology 290/5310 (5.5%), 19/5310 (0.4%) emergency medicine/ICU, 21/5310 (0.4%) obstetrics and 11/5310 (0.2%) psychiatry. Of the HIV related admissions, majority were on ART (61.6%) and adults (87.6%) aged  $\geq 18$  years (See Table 2). Median CD4 cell counts (IQR) was 143 cells/ $\mu$ l (ranging from 48 cells/ $\mu$ l to 320 cells/ $\mu$ l) whilst median (IQR) hospital stay was 7 days (ranging from 3 to 14 days) (Not shown in the Table).



**TABLE 1: Proportion of HIV-related admissions from June 2005 to June 2015**

Year	Total Hospital admissions	HIV-infected Number	HIV-infected Percentage
2005	4,519	598	13.2
2006	9,463	775	8.2
2007	6,238	723	11.6
2008	25,201	1611	6.4
2009	28,734	736	2.6
2010	26,988	587	2.2
2011	26,774	561	2.1
2012	21,578	703	3.3
2013	18,742	369	2.0
2014	27,745	856	3.1
2015	13,119	345	2.6
TOTAL	09,101	7,864	3.8

**FIGURE 1: Location of Dar es Salaam City and Its Districts within Tanzania**

Out of 6874 reviewed patient's files, only 6482 (94.3%) had documented discharge diagnoses. The leading diagnoses were tuberculosis 1396/6482 (21.5%), followed by anaemia 1016/6482 (15.6%), malignancies 789/6482 (12.2%), central nervous system (CNS) infections 541/6482 (8.3%), chronic kidney disease 308/6482 (4.8%), while cardiovascular diseases and diarrhoea each accounted 3.6% (235/6482 and 231/6482 respectively). Chest infections other than tuberculosis were seen in 218/6482 (3.4%) while other forms of infections were seen in 206/6482 (3.2%) of the total admissions. (See Table 3)

## DISCUSSION

The trend of HIV admissions at Muhimbili National Hospital showed a drastic drop from year 2005 to 2009 then plateaued to year 2015. The drop in number of patient admissions can be largely attributable to ART use and a decrease in HIV prevalence in the general population. However, the drop might as well be due to the fact that other public and private facilities are now more willing to hospitalize people with HIV disease. The present analysis has shown that there had been a surge of admissions among HIV negative individuals between years 2007 and 2014 probably due to more admissions of patients with non-communicable diseases owing to full operationalised

cardiac building and renal services in the hospital which were not there before. Furthermore, the hospital bed capacity has expanded owing to existence of the new Paediatric block and the release of 2 wards from Muhimbili Orthopaedic Institute to Muhimbili National hospital. This surge can also partly be explained by the growth of the city's population which has almost doubled from the 2,487,288 people in 2002 to 4,364,541 population in 2012. It is estimated that there were 5,166,570 million people in Dar es Salaam in 2015.<sup>25,26</sup>

We have had an increase in Non-Communicable Diseases (NCDs) like diabetes mellitus, hypertension and chronic kidney disease due to an increase in aging population. Generally, national HIV surveys had shown a decrease in HIV prevalence in Tanzania from 7.2% in 2004<sup>20</sup> to 5.1% in 2012.<sup>21</sup> This drop of prevalence has been reported in neighbouring countries as well as in most of Sub-Saharan countries.<sup>2,27,28</sup> In Kenya HIV prevalence dropped from 7.2% in 2007 to 5.6% in 2012<sup>28</sup> whilst in Uganda HIV prevalence dropped from 7.8% at the first survey round 1989/1990<sup>29</sup> to 6.2% in 2017.<sup>27</sup> All these findings are consistent with the findings of the present study.

Admissions from female patients were predominant, so were medical admissions and adult admissions. Predominance of female and adult admissions is attributable to higher rates of HIV infection among females than males and among adults than children in Tanzania.<sup>21</sup> The median CD4 count was low indicating that HIV hospital admissions were predominantly among those with severe immunosuppression. The causes of admissions among HIV infected patients were largely tuberculosis, anaemia and cancers in that order, collectively constituting 49.3% of all admissions. Since the advent of HIV infection tuberculosis has remained the number one cause of morbidity and mortality among HIV infected patients.<sup>30,31</sup> Tuberculosis has also remained the major cause of admission in Kenya.

In the present study, diarrhoea ranked the 7<sup>th</sup> as the cause of admissions. This is a change of pattern from the situation in the pre-ART era when chronic diarrhoea used to be one of the most common complaints among HIV infected patients. Opportunistic infections' (OIs) pattern in the pre-ART era in Uganda showed that diarrhoea <1 month (30.6%) was the second common OI after oral candidiasis (34.6%) followed by geohelminths (26.5%), *M.tuberculosis* (17.7%), malaria (15.1%) and bacterial pneumonia (11.2%). In the Ugandan case, ART was able to change the pattern to geohelminths (32.4%), diarrhoea <1 month (25.6%), *M.tuberculosis* (18.2%) and oral candida (18.1%).<sup>33</sup>

Among cancer admissions, Kaposi's sarcoma (KS) was the most common cause of admissions. Kaposi's sarcoma has been reported to have declined in other parts of the world. In Europe and U.S.A the rates of KS have declined by 30% to 50% since the introduction of ART.<sup>34</sup> Despite Tanzania's achievement of the 2015 millennium goal number 6c of reducing 50% of TB prevalence and deaths from the 1990 values in the year 2013,<sup>35</sup> tuberculosis remained the leading cause of admissions among HIV infected patients. In the present study TB was the number one cause of admission. It has been found that the rate of HIV-TB co-infection depends on the rate of HIV infection in the community.<sup>36</sup> This fact explains why TB is still rampant, even after a drop of HIV prevalence in Tanzania. TB was the most common opportunistic infection in a study in India<sup>37</sup> and the third common opportunistic infection in Ethiopia.<sup>38</sup>

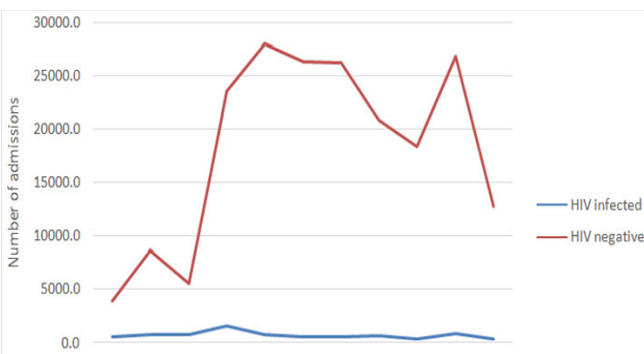
Anaemia was the second most common cause of admission,

**TABLE 2: Characteristics of HIV Infected Patients Hospitalised in Muhimbili National Hospital From June 2005 To June 2015, N=6874**

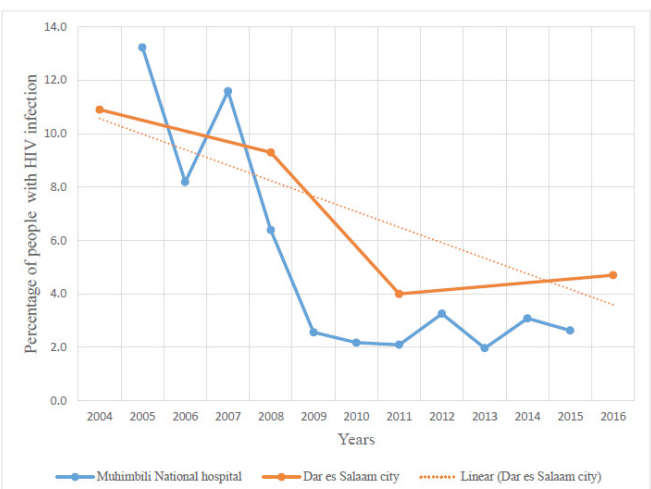
Characteristic	Missing numbers (%)	Frequency	Percentage
<b>Sex</b> N=6679	195 (2.8)		
Male		2792	41.8
Female		3887	58.2
<b>Admitting ward</b> N=5310	1564 (22.8)		
Medical		3643	68.6
Emergency medicine department/ICU		19	0.4
Gynecological wards		290	5.5
Pediatric wards		531	10.0
Psychiatry wards		11	0.2
Surgical wards		795	15.0
Obstetric wards		21	0.4
<b>Age groups</b> N=6732	142(2.1)		
0-4		496	7.4
5-17		340	5.0
18-25		515	7.7
26-35		1968	29.2
36-45		1926	28.6
46-55		937	13.9
56+		550	8.2
<b>ART use</b> N=6704	170 (2.5)*		
Yes		4132	61.6
No		2572	38.4

ICU=Intensive Care Unit  
 \*ART status unknown

**FIGURE 2: Absolute Number of Admissions from June 2005 to June 2015 Years**



**FIGURE 3: Comparison of Hospital Base (MNH) and General HIV Prevalence in the City of Dar es Salaam**



**TABLE 2: Causes of Admissions of HIV Infected Patients in Muhimbili National Hospital From June 2005 to June 2015, N= 6482\***

SN.	Diagnosis	Frequency	Percentage
1.	Tuberculosis of any form	1396	21.5
2.	Anemias	1016	15.6
3.	Cancer	789	12.2
4.	CNS infections	541	8.3
5.	Chronic kidney disease (CKD)	308	4.8
6.	Cardiovascular diseases	235	3.6
7.	Chronic Diarrhea	231	3.6
8.	Chest infections other than Tuberculosis	218	3.4
9.	Other Infections	206	3.2
10.	Malnutrition	198	3.0
11.	Surgical conditions other than cancer	161	2.5
12.	Noninfectious Central nervous system diseases	159	2.5
13.	Encephalopathy from any cause	155	2.4
14.	Oral/Esophageal candidiasis	118	1.8
15.	Psychiatric disorders	82	1.3
16.	Peptic Ulcer Disease	73	1.1
17.	Unspecified diagnosis in HIV	64	1.0
18.	Skin diseases (noninfectious)	64	1.0
19.	Liver diseases (noninfectious)	49	0.8
20.	Septicemia	47	0.7
21.	Others	372	5.7

CKD included diagnoses such as CKD, Nephrotic syndrome and HIV associated nephropathy (HIVAN)

Liver diseases included all liver diseases other than viral hepatitis and malignancies

Genital viral infections included genital herpes and genital warts

ENT= Ear, Nose and throat

\*Only 6482 patients had documented discharge diagnoses

having been mainly secondary to HIV infection itself, HIV drug-induced or treatment failure. A study in Ethiopia found that Zidovudine-based ART and duration on ART predicted anaemia among ART experienced patients while presence of opportunistic infections (tuberculosis being among them) and rural residence predicted presence of anaemia among ART naïve patients.<sup>39</sup> Anaemia has been found to be an independent risk factor for death among HIV-infected patients<sup>40</sup> and among HIV/TB co-infected patients.<sup>41</sup>

### Limitations

Due to inadequate documentation, some information from the hard copy files were missing. Files of some patients were nowhere to be seen due to inadequate filing system and record keeping of the paper based files. Since HIV testing was not done to all admitted patients, it is possible that some patients might have been hospitalized with HIV related diseases but were categorised as HIV uninfected, and thus leading to under estimation of proportion of HIV related admissions.

### CONCLUSION

There has been a drastic drop of HIV related admissions at Muhimbili National Hospital from the year 2005 despite the fact that total hospital admissions have been on increase. HIV remains a problem of the adults, largely females. HIV infected patients were more likely to be admitted with medical conditions

than others. Severe immunosuppression was prominent among the admissions. Despite the availability of ART and effective anti-tubercular drugs, tuberculosis remained the most common opportunistic infection and a cause of admission. Anaemia and cancers have become more important causes of admission than were diarrhoea and other infections, which had been the most common conditions in the preART era.

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# Assessing the Feasibility of Adapting a School-Based HIV Prevention Intervention to Include Voluntary Male Medical Circumcision and Vaccination for Human Papilloma Virus Prevention

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## ABSTRACT

In 2012, there were 2,454 cases and 1,676 deaths from cervical cancer in Kenya. Human Papilloma Virus (HPV) is responsible for 99% of all cervical cancers. National cervical cancer prevention guidelines recommend HPV vaccination among HPV-naïve pre-adolescent girls' prior to onset of sexual activity preferably through school-based interventions. Similarly, Voluntary Male Medical Circumcision (VMMC) programs also reduce sexually transmitted infections like HIV, and ideally should also be conducted prior to the onset of sexual activity. The Families Matter! Program (FMP) is a school-based evidence-based HIV prevention intervention for parents and guardians of pre-adolescents aimed to enhance protective parenting practices in order to reduced sexual risk-taking among adolescents. In this paper we describe how we will recruit a cohort of 55 parent-child dyads in a primary school in Kisumu County then implement and evaluate an adapted FMP program that incorporates VMMC promotion and HPV vaccination in conjunction. It is anticipated that the intervention will enhance parental-child communication about sexual matters, promote safe sexual practices and uptake of biomedical prevention interventions and overall reproductive health among the pre-adolescents

## BACKGROUND

Cervical cancer is the second most common cancer in women living in resource limited settings. There were approximately 445 000 new cases in 2012 in resource limited settings contributing to 84% of the new cases worldwide. In 2012, approximately 270 000 women died from cervical cancer; more than 85% of these deaths occurring in low- and middle-income countries.<sup>1</sup> Among patients with cancer, the survival rates of those in sub Saharan Africa is 21% compared to 70% in the US.<sup>2</sup> The Nairobi Cancer registry documented that between 2004 and 2008, there were 8,982 cases of cancer in Nairobi with 5,093 among women. Cervical cancer contributed to 21% of the cancer cases among women.<sup>3</sup> In Kenya in 2012, there were 2,454 cases of cervical cancer cases, 1,676 cancer deaths and a cervical cancer screening coverage rate of 3.2% among women aged 18-69 years.<sup>4,5</sup> Human Papilloma Virus (HPV) is responsible for 99% of all cervical cancers. HPV subtypes 16 and 18 cause up to 70% of all cancers.<sup>1</sup> Human Immunodeficiency Virus (HIV) is postulated to facilitate the progression of HPV infection to cervical cancer.<sup>6</sup> The prevalence of cervical cancer is therefore unsurprisingly highest in developing countries which also bear the burden of HIV.<sup>1,7</sup>

Cervical cancer can be prevented through HPV vaccination among pre-pubescent girls. The Kenya cervical cancer prevention guidelines recommend the administration of HPV vaccine to pre/early adolescent prior to onset of sexual activity. This should preferably be done through a school-based program targeting girls in primary school from classes 4-8, corresponding to an age range of 9 to 13 years. The rationale for this age group is that they are HPV-naïve and will have the highest antibody

response to the vaccine.<sup>8</sup> Whilst awareness of cervical cancer has been shown to promote uptake of HPV vaccine,<sup>9</sup> barriers exist, and studies suggest that some Kenyan parents of adolescent children fear that that administration of an HPV vaccine could encourage their daughters to have sex. Published literature documents HPV vaccine uptake of 31% and completion of 70%.<sup>9</sup> Furthermore, the HPV vaccine is not yet available in routine clinical care in Kenya.

Male Circumcision (MC) has also been shown to have a protective effect against Sexually Transmitted Infections (STIs) like HPV and HIV. Male circumcision (MC) reduces the risk of STI and HIV acquisition in men by 35% and 60% respectively.<sup>10, 11</sup> The Kenya Voluntary Male Medical Circumcision (VMMC) strategy (2014/5-2018), aims to reduce new HIV infections by increasing the proportion of men aged 15-49 that are circumcised to 80%. For the greatest effect in preventing HIV acquisition, MC should be performed prior to the onset of sexual activity.<sup>12</sup> Published literature documents a VMMC uptake of 71% through school-based programs.<sup>13</sup> In Kenya sexual activity has been documented to begin early, prior to 15 years of age.<sup>14</sup> As such, school based interventions have been widely implemented to reach large numbers of adolescents with HIV and SRH messages.<sup>15</sup>

Families Matter! Program (hereafter referred to as FMP) is an evidence-based HIV prevention intervention for parents and guardians of adolescents aged 9-12 years. The exclamation is placed to emphasise the importance of the families in helping adolescents avoid risky behaviour such as early sexual activity and drug abuse. FMP aims to enhance protective parenting practices that are associated with reduced sexual risk-taking among adolescents and promote parent-child communication

about sexuality and risk reduction. FMP provides education on HIV prevention, STI risk reduction and contraception. Families Matter! Program was modified to the Kenyan context from the US-based Parents Matter! Program in 2003-2004. Following its implementation, the programme was evaluated and shown to be acceptable and also retained its effectiveness in promoting parental skills, parent-child communication and adolescent sexual risk reduction.<sup>18</sup> FMP retention rates of 90% have been documented.<sup>17</sup> During implementation, Kenyan parents reported having felt ill-equipped to discuss sexual matters with their children.<sup>16</sup>

FMP’s theoretical framework is guided by four theories. Firstly *the social learning theory*, to encourage parents to provide supportive environments, reinforce competencies, supervise their children and reduce contact with poor role models. Secondly *the problem behaviour theory* to bolster children’s competencies, promote positive behaviour and reduce opportunities to engage in risk behaviour. Thirdly the *theory of reasoned action* equips parents with skills to communicate their own attitudes and norms to their adolescents to modify the adolescent’s behaviour. Finally, *the social cognitive theory* enhances parents’ efficacy in their ability to communicate with their children about sexual topics.<sup>19</sup>

Nationally interventions to provide HPV vaccination, VMMC and family education are currently provided in isolation.<sup>8, 15, 17</sup> We propose to provide an adapted FMP program that incorporates VMMC promotion as a component of HIV prevention and HPV vaccination as a component of STI risk reduction among parents/guardians at one public primary school within Kisumu County to enhance HPV prevention. In this paper we describe our methods that we propose to undertake and specific aims we intend to achieve in order to assess the feasibility of implementing an adapted FMP in the Kenyan setting.

## METHODS

### Study Design and Setting

We will conduct a cohort study among parent-child dyads within one public primary day school in Kisumu County.<sup>20</sup> Kisumu County was chosen based on its high HIV prevalence (16% vs. 5% country wide),<sup>21</sup> the highest proportion of young persons whose age of sexual debut was before 15 years (21% vs. 12%) and the highest prevalence of STIs (3% vs. 2%) among sexually active persons in the reproductive age group.<sup>21</sup> Day primary schools provide a suitable target population of children in classes 4-8 from which to draw children who are in daily contact with their parents to enhance parent-child communication.<sup>18</sup>

### Study Population

The study population will be comprised of parents of at least one pre/early-adolescent male or female child (aged 9-12 years) in day schools. The age range chosen is ideal for each of the three programs i.e. FMP 9-12 years,<sup>18</sup> HPV vaccination 9-13 years,<sup>8</sup> VMMC 10-14 years,<sup>15</sup> all of which are best delivered before the onset of sexual activities.<sup>14</sup> The parents must give informed consent, commit to attending all six FMP sessions, bring their child to the 5<sup>th</sup> session and participate in ‘home assignments’.<sup>18</sup> Only one eligible child per household will be included in the study. Pre/early adolescent boys that have already undergone VMMC (and subsequently their parents) will be ineligible for inclusion. Similarly, pre/early-adolescent girls that have already received HPV vaccination will also be excluded (along with their parents). Where either parental consent or assent from the

pre/early-adolescent cannot be obtained, the parent-child dyad will be ineligible for inclusion.

### Sample Size

To design the evaluation study, we developed a series of specific aims and corresponding hypotheses:

To determine the uptake and completion rate of HPV vaccine and associated parent and child characteristics among pre/early-adolescent girls who participated in an adapted school-based FMP

*We hypothesize that promotion of HPV vaccine uptake through FMP will double vaccine uptake from 31% to 62% while maintaining the same completion rates of 71%*

To determine the uptake of VMMC and associated parent and child characteristics among pre-adolescent boys who participated in a school-based FMP

*We hypothesize that FMP will attain a VMMC uptake of 80% from the inception of the program to the 6 months booster session*

To document lessons learnt during the promotion of HPV vaccination for pre/early-adolescent girls and VMMC for pre/early-adolescent boys through a school-based FMP.

*We hypothesize that the program will provide valuable lessons as to the feasibility and outcome of promotion of HPV vaccine uptake and VMMC through a school-based FMP program*

We based our subsequent sample size computation on HPV vaccine uptake of 31% and completion of 70%<sup>9</sup> and VMMC uptake of 71% through school based programs<sup>13</sup> as well as and FMP retention rates of 90%<sup>17</sup> documented in the literature. Using HPV vaccine uptake (in order to obtain the largest sample size<sup>22</sup>), and sample size formula for calculation of difference in proportions, to double HPV vaccine uptake (from 31% to 62%) with a significance level of 5% and power of 90% would require a sample size of 50.<sup>23</sup>

$$n = \frac{[p_1(1 - p_1) + p_2(1 - p_2)] X C_{p,power}}{(p_1 - p_2)^2}$$

$$\begin{aligned} n &= \frac{[0.62(1-0.62) + 0.31(1-0.31)] X 10.6}{(0.62-0.31)^2} \\ &= 49.1 \\ &= 50 \end{aligned}$$

To adjust for an attrition rate of 10%, a total of 55 dyads will be recruited to participate.<sup>20</sup> Given the FMP recommends groups of 12-18 participants, we will recruit four groups of approximately 15 parent-child dyads. To improve retention rates, we will provide transport reimbursement and refreshments during sessions. Although absenteeism will be discouraged, make-up sessions will be given for parents who miss a session and are willing to continue with other sessions. We will attempt to make-up for missed sessions by having parents attend make-up sessions in alternate groups as this can affect group dynamics.<sup>18</sup>

### Procedures

**Adaptation of the FMP program:** The current FMP curriculum<sup>18</sup> will be adapted to include information on VMMC<sup>15</sup> and

HPV vaccination<sup>8</sup> that is currently found in different HIV program guidelines by a team of health program managers and certified FMP providers.

**Notification of County Health Management Teams, School Heads and participating health facilities:** The County Health Management Team (CHMT) will be contacted to obtain approval to conduct the study. We will adapt the methods used by a school-based VMMC program in the former Nyanza province when conducting school-based VMMC projects.<sup>15</sup> The County Health Promotion Officers (under the guidance of the County Director for Health) who will be involved in the study will notify the County Education Officers who will in turn get in touch with the School heads of the potentially participating schools. Once a school is finally chosen, the study team will make an inception visit to plan study implementation with the school head. We will also involve the head of the participating health facility to ensure that the facility is equipped to implement study procedures

**Recruitment of potential participants:** During a Parents-Teachers meeting, a study team member will make a short presentation about the study. Interested parents/guardians will be asked to provide their names and contact details. Interested parents will be contacted at a later date and informed of the study procedures. Those that are willing to participate will be invited to the study's first formal meeting at the school grounds (or at an alternate suitable venue) where study procedures will be presented in detail and written consent obtained from those willing to consent to participate in study procedures.

**Implementation of the adapted FMP program:** This will be delivered by a certified FMP trainer through six 2-hours' sessions; five sessions will be administered over a 5-week period and the 6th will be conducted six months after the 5th session. The first 5 sessions will involve (i) getting to know you and understand your child, (ii) effective parenting, (iii) parents' role in sexuality education; the information in this session will also include HPV vaccination and MC for HPV prevention, (iv) how to increase your comfort and skills in discussing sexuality issues and (v) discussing sexuality and handling peer pressure. In the 6th session, (vi) a booster session will be done to review the FMP. This will be done with parents who participated in the school health program whether or not they accepted to vaccinate their daughters or allow their sons to undergo VMMC. Minutes of each of the meetings will be documented for analysis.<sup>18</sup>

**Intervention Provision:** Vaccine administration and VMMC services will be availed for free at a selected public health facility for a 7 months' period from the beginning of FMP implementation. The pre/early -adolescents that undergo any procedures at the selected facility will be linked to the study by the use of study-specific referral forms and unique study-specific identifiers.

### Data Collection

Parental-child dyads will be assigned dyad-specific interlinked participant identifiers. E.g. if a parent is FMP-1-0; his or her child will be identified as FMP-1-1. Our study will therefore be able to link parent and child information to uptake. The same identifiers will be noted on the vouchers which participants will be requested to present to a selected health facility should they take up the VMMC/HPV vaccination interventions. Data will be collected from parents and their pre/early adolescent children separately using, paper or electronic data collection tools.

Data from parents/guardians will include demographic information i.e. age, sex, relationship to the child, education level, marital status, occupation, number and ages of other children, communication with their children about sexual matters, knowledge about HIV and cervical cancer, participation in cervical cancer screening programs for females and VMMC programs from males, whether they are from a traditionally-circumcising or non-circumcising community, etc. Data from the adolescents will include demographic information, e.g. age, sex, education level, knowledge on HIV prevention and source of that knowledge, communication with their parent about sexual matters, etc. Data will be collected at baseline (prior to the 1st session) and after completion of the 5th session. During each session, anonymised deliberations will be documented and analysed to document experiences of the participants. Data will be entered into an MS Access Database and uploaded into SAS 9.2 for analysis.<sup>24</sup>

### Data Analysis

Measures of central tendency and proportions will be used to summarise characteristics of parent child-dyads. One parent-child dyad will be considered as one unit. HPV vaccine uptake will be described as the proportion of eligible adolescent girls who received the HPV vaccination during the study period. Among those who received the initial dose of HPV vaccine, HPV completion will be described as having received all the 3 doses of HPV. Logistic regression will be used to describe parental and child characteristics associated with HPV vaccine uptake and completion. VMMC uptake will be described as the proportion of eligible pre/early-adolescent boys who underwent VMMC during the study period. Logistic regression will be used to describe parental and child characteristics associated with VMMC uptake.<sup>20</sup> All assumptions regarding type, independence, normality and variance of the data will be tested.<sup>25</sup> Thematic content analysis will be used to identify emerging themes and document barriers and facilitators to promoting HPV vaccination and VMMC through FMP from project documents, deliberations of the sessions and study team members' experiences.<sup>26</sup>

### Project Timeline, Monitoring and Evaluation

This will take into consideration the length of the FMP program, i.e., 5 weeks for implementing the intervention and a booster session 6 months later.<sup>18</sup> HPV vaccination is also given over a 6 months' period.<sup>8</sup> Moreover, HPV and VMMC services will be available for free at selected public health facilities for a 7 months period from the beginning of the FMP sessions. The study timeline is shown in [figure 1](#). Implementation lessons will be documented and shared during debrief sessions and later prepared for publication.

### Ethical Considerations

Written informed consent will be obtained from parents/guardians of the participants and assent from the minors. The informed consent process will be administered in the language the participants and guardians feels most comfortable, in English, Kiswahili or Dholuo. They will also be informed of the referral procedures as described in the intervention. A detailed description of all procedures including period of study will be provided.

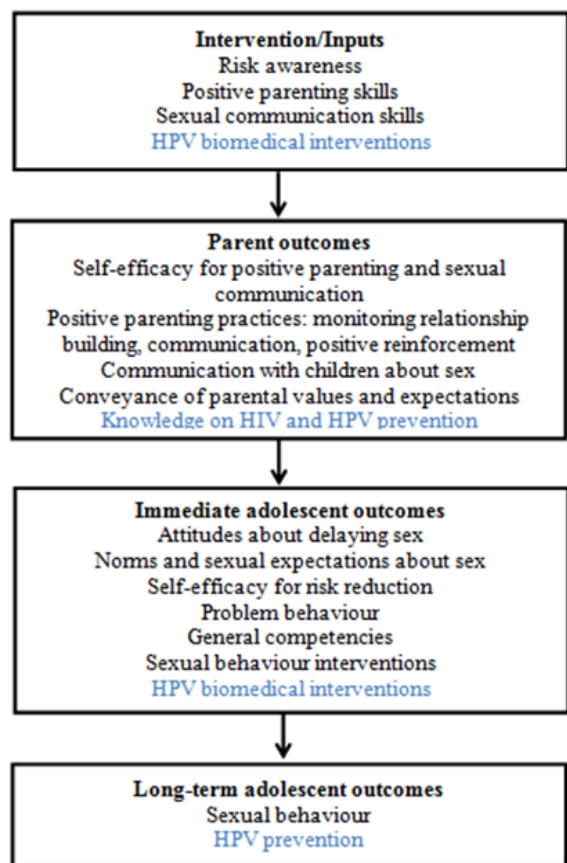
No personal identifiers will be collected and all collected information shall remain private. All data collected will be kept secured, in locked storage spaces or in password-protected files and computers for the digital files. Furthermore, all staff will be



**FIGURE 1: Gantt Chart For Study Implementation**

Activity	Number of Months															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
IRB approval	█	█	█	█												
Inception meetings					█											
FMP recruitment						█										
FMP implementation & booster							█	█	█	█	█	█	█	█		
VMMC at health facilities							█	█	█	█	█	█	█			
HPV vaccination at health facilities							█	█	█	█	█	█	█			
Debrief, dissemination & closure														█	█	█

**FIGURE 2: Inputs and Outputs of the Adapted FMP Program**



Source: Dittus P, Miller KS, Kotchick BA, Forehand R. Why Parents Matter!: The Conceptual Basis for a Community-Based HIV Prevention Program for the Parents of African American Youth. *Journal of Child and Family Studies*. 2004;13(1):5-20.

trained in ethical procedures and measures to protect confidentiality; they will also be required to sign confidentiality agreements. Ethical approval for the conduct of this study will be sought and obtained from the Jaramogi Oginga Odinga Teaching and Referral Hospital (JOTRH) Ethics Review Committee that cater for research projects in Kisumu County. Study approval will only commence following liaison and approval with the County government of Kisumu, officials from the ministry of education and the heads of the participating school and health facility.

**Dissemination of study findings:** Study findings will be disseminated internally to participants in a debrief session, staff of the participating schools, county government officials and externally in national stakeholder forums, international conferences and in peer-reviewed publications.

**Expected application of results:** It is anticipated that the intervention will enhance parental-child communication about sexual matters, promote safe sexual practices and overall reproductive health among the pre/early-adolescents and the uptake of biomedical HIV and HPV prevention interventions. Figure 2 shows the proposed inputs and expected outputs of the adapted FMP (black font) that includes HPV prevention (blue font).<sup>27</sup>

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