Healthcare workers’ level of adherence to infection prevention and control and its impact on puerperal and neonatal sepsis among delivering women and neonates in Central Tanzania: a protocol for a prospective cohort study

Laura Edward Marandu,1,2 Golden Mwakibo Masika 3

ABSTRACT

Introduction Delivering women and neonates are at a great risk of acquiring infections due to a lack of adherence to infection prevention and control (IPC), a low level of immunity and extended exposure to care procedures that can lead to infections. This prospective cohort study aims to assess the level of adherence to IPC among healthcare workers and its impact on puerperal and neonatal sepsis in the Dodoma region. Methods and analysis The level of adherence to IPC is examined cross-sectionally among healthcare workers (HCWs) in contact with delivering women and their neonates. A prospective cohort approach is used to assess the level of exposure of 294 delivering women and their neonates to poor hygienic practices of HCWs through an observation checklist. Outcomes, including the incidence of puerperal and neonatal sepsis, are evaluated clinically 2 days later before discharge. Laboratory culture and sensitivity confirmatory tests of blood samples are done on positive cases. Data analysis for level of adherence to IPC practices, incidence of puerperal and neonatal sepsis, and relative risk among the exposed women and neonates will be performed. Ethics and dissemination The University of Dodoma Research Ethics Committee approved this study (ref no. MA.84/261/4/25). Findings of this study will be published in international peer-reviewed journals and disseminated at international conferences to the participating hospitals, the University of Dodoma and the Tanzanian Ministry of Health for informing practice and policy.

BACKGROUND AND RATIONALE

Globally, infection prevention and control (IPC) practices and maternal outcomes remain a great challenge, especially in the low/middle-income countries, due to a low level of technology, understaffing and limited medical supplies.1 Worldwide, 15 out of 100 patients or clients who receive care in healthcare facilities develop infections that are related to poor adherence to IPC standards, including maternal and neonatal infections.2 Maternal infections before or during childbirth contribute to approximately 1 million newborn deaths annually. These deaths are contributed by postpartum infection; pre-existing maternal conditions such as malnutrition, diabetes, obesity, anaemia, bacterial vaginitis and group B streptococcal infections; and spontaneous or provider-induced conditions during labour and childbirth such as premature rupture of membranes, multiple vaginal examinations, manual removal of the placenta and caesarean section.3 In reaching the Alma Ata Declaration and ensuring health for all, healthcare standards, including adherence to the IPC standard, must be followed to achieve a better outcome and to minimise the risk of puerperal and
neonatal sepsis. Adherence to IPC standards during labour and childbirth can reduce the risk of acquiring puerperal and neonatal sepsis. On the contrary, failure to adhere to IPC standards in labour wards can result in healthcare-associated infections (HCAIs) among delivering women, newborns and healthcare workers (HCWs). This, in turn, may result in morbidity and mortality among patients and increased treatment costs for both patients and the healthcare system due to an increased length of hospital stay and additional investigations ordered.

In African settings where financial and/or healthcare resources to combat or manage HCAIs among delivering women and their neonates are scarce, adherence to IPC standards is vital in the prevention of such infections from occurring. Thus, practice-related factors such as hand washing using soap and running water before and after any procedure, appropriate use of personal protective equipment, frequency of per vaginal examinations (PVEs), control for labour duration and membrane rupture, use of sterile, clean or highly disinfected equipment, environmental cleaning, and waste and linen management must be considered in the prevention of infections in the healthcare facilities as they have shown to reduce the risk mortality related to puerperal and neonatal sepsis. In addition, service-related factors such as the number of antenatal clinic visits, minimising delivery by caesarean section, the presence of infection control committees and routine maternal audits in the health facilities have also been shown to reduce the risk of mortality related to puerperal and neonatal sepsis.

Nevertheless, researchers have identified a number of factors that heighten the rate of puerperal and neonatal sepsis. Such situations include inadequate compliance with IPC standards during caesarean section. Other factors that have been linked to puerperal sepsis include poor personal hygiene, rural living, a lack of proper equipment sterilisation, postpartum haemorrhage, anaemia, prolonged labour and bacterial infection. In addition, inadequate training on IPC and stockout of basic consumables and equipment, such as surgical gloves and elbow tap, have shown to contribute to poor adherence to IPC standards and increase the risk of infection to mothers and their newborns especially in sub-Saharan Africa.

The relationship between these variables and the risk of puerperal and neonatal sepsis can be best explained by the epidemiological triad theory, which explains the development of a disease as a result of interaction between the agent and the susceptible host in an environment that supports transmission of the agent from a source to the host. Changes in the balance and interactions among the three components must occur so that the host’s susceptibility and the presence of an environment that exposes the host to an agent are critical for infection or disease to occur. In the context of obstetric care, delivering women and neonates are susceptible to various nosocomial infections and from the community settings due to suppression immunity during pregnancy, whereas neonates have immature immune system to fight infections in the microbial-rich environments. Figure 1 illustrates the interaction of the variables of the epidemiological triad as explained by Johnson-Walker and Kaneene.

In Tanzania, adherence to IPC standards in obstetric care has additional variables that contribute to the complexity of the issue. For example, a Star Rating Assessment in Tanzania reveals that with only 31% prevalence of adherence to IPC standards, the private healthcare facilities have better adherence compared with the public healthcare facilities. Also, tertiary and secondary health facilities have better adherence to IPC standards compared with primary healthcare facilities. Despite literature providing a clear link between poor adherence to IPC standards in the context of obstetric care and the risk of puerperal and neonatal sepsis, it is to the best of our knowledge that the amount of risk attributed to exposure to the incidences of non-adherence to IPC standards and the magnitude of risk of puerperal and neonatal sepsis among delivering women and their neonates in Tanzania have never been studied. Therefore, this study uses a descriptive cross-sectional approach to examine the pattern of HCWs’ adherence to IPC standards and a prospective cohort design to examine the risk of exposure to HCWs’ non-adherence to IPC standards on puerperal and neonatal sepsis among delivering women and their neonates in Dodoma.

**Aim**

This prospective study aims to assess the level of adherence to IPC among HCWs and its impact on puerperal and neonatal sepsis in the Dodoma region. The specific objectives are:

1. To determine the level of adherence to IPC standards in labour and postnatal wards among HCWs in the Dodoma region.
2. To determine the incidence of puerperal sepsis from the day of admission to the day of discharge among postnatal women.
3. To determine the incidence of early neonatal sepsis among neonates.
4. To examine the risk of puerperal sepsis among post-delivery women attributed to exposure to HCWs’ poor IPC practices.
5. To examine the risk of neonatal sepsis among neonates attributed to exposure to HCWs’ poor IPC practices.
6. To determine other risk factors independently associated with the development of puerperal and neonatal sepsis.

METHODS AND ANALYSIS

Study design

This study adopts a cross-sectional approach for the first objective to examine the level of adherence to IPC standards in labour and postnatal wards among HCWs, and a prospective cohort design for examining the incidence of puerperal and neonatal sepsis and the amount of risk of developing puerperal and neonatal sepsis. After the baseline demographic data are taken, a woman and her neonate begin to be followed up on all the points of possible exposures to infection immediately after admission to labour ward and postnatal ward. Thus, an observation checklist is used to assess the practice of HCWs and score practice events where IPC standards are not followed. This will enable gauging the level of adherence to IPC standards required at the labour and postnatal wards as prescribed in the national guidelines. Another observation checklist is used at baseline to score all events that a woman and her neonate are exposed to in practice incidents where IPC standards are not followed. Each of those events is scored and ultimately used to compute the magnitude of exposure, the incidence rates, and the relative risk of puerperal and neonatal sepsis across different levels of exposure to poor IPC practices. The recruitment of participants began in April 2022 and is expected to end in December 2022.

Study settings

The study is being conducted in the Dodoma region and involves three hospitals. Dodoma Regional Referral Hospitals (DRRH), St Gemma Designated District Hospital (DDH) and Makole Municipal Health Centre are all situated in Dodoma city. Dodoma region is the capital city of Tanzania. Projection data for 2019 from the National Bureau of Statistics show that Dodoma has a total population of 2,492,989 with an annual growth rate of 2.1%.

Due to the fact that Dodoma city is fast growing as a result of the high number of immigrants following the shift of government activities (ministries) from Dar es Salaam to Dodoma, there has been a tremendous increase in the demand for healthcare services, including obstetric care services. Even with this demand, Dodoma is one of the regions that perform poorly in star ratings as evaluated by the Ministry of Health, where IPC adherence was one of the domains assessed. Due to these alarming data, it is justifiable to conduct this study in Dodoma and provide empirical evidence for future directions towards interventions to curb this problem.

Study population

This study involves HCWs, delivering women and their neonates as study populations. HCWs in the labour wards and postnatal wards are targeted for assessing the level of adherence to IPC standards related to their practices. Their practices determine exposure to infectious agents among delivering women and neonates; thus, they are studied for adherence to IPC standards during interaction with delivering women. Women and neonates are the target populations who are subject to the outcomes of adherence or non-adherence to IPC standards in HCWs’ practices. Delivering women are studied starting from baseline based on their level of exposure to HCWs’ poor IPC practices from the day of admission to the labour ward until postnatal discharge. The neonates are studied immediately after birth until discharge.

Inclusion and exclusion criteria

Inclusion criteria

For HCWs

HCWs who work in the labour ward and postnatal ward are included.

For women

Women who deliver by spontaneous vaginal delivery (SVD) at a respective research site during the time of research are included.

For neonates

All neonates delivered by women who are studied are also included.

Exclusion criteria

Healthcare providers who meet the inclusion criteria but refuse to consent are excluded. Delivering women who present with conditions or complications such as a preterm baby, premature rupture of membranes, signs of existing infection, postpartum haemorrhage or fever are excluded as they can bias the evaluation of outcomes. Women who delivered by SVD before arriving (birth before arrival) to the facility of a respective study area are also excluded. A neonate is excluded from the study if seriously sick of other conditions not related to puerperal sepsis.

Sample size determination

The sample size for cohort study is calculated based on the following formula as adopted from Kelsey (1996):
taking assumptions of one cohort group where some of the subjects will be exposed to poor IPC practices of HCWs and others not exposed.

\[ N_{\text{Kelsey}} = \frac{(Z_\alpha^2/2 + Z_\beta^2) \times P_0 \times (1-P_0) \times (1+1)}{nP_0 - P_1)^2} \]

Where:

<table>
<thead>
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<th>Descriptions</th>
<th>Value</th>
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<tr>
<td>( \alpha )</td>
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<tr>
<td>( \beta )</td>
<td>Probability of type II error</td>
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</tr>
<tr>
<td>( P_0 )</td>
<td>Proportion of the unexposed group</td>
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<tr>
<td>( P_1 )</td>
<td>Proportion of the exposed group</td>
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<td>( r )</td>
<td>Ratio of unexposed to exposed</td>
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<td>( P_1/P_0 )</td>
<td>Calculated relative risk (RR)</td>
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</tr>
<tr>
<td>( N )</td>
<td>Sample size</td>
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</tbody>
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Based on Kelsey’s formula, the sample size will be 295 delivering women. Every neonate of a woman recruited in the study will also be recruited. Thus, if all women have singleton pregnancy, 295 neonates will be included in the study.

As HCWs working in the labour and postnatal wards are few, the sample size calculation for this group is not warranted. Instead, all available HCWs were asked to participate.

Sampling procedure
The sample is being drawn from three healthcare facilities that were purposively selected because they have a large volume of deliveries per day and represent three levels: a regional referral hospital, a district hospital and a health centre. Thus, the healthcare facilities include DRRH, St Gemma DDH and Makole Municipal Health Centre.

Proportional sampling is used when a stratum sample size is allocated in proportion to the population size within the stratum, that is, \( n_b = n_b N \). This procedure is done to determine the proportional samples for women and then their newborns. Women are being recruited following a systematic random sampling procedure until a daily sample size is reached. As for DRRH and Makole Municipal Health Centre, both with a maximum number of 20 SVDs per day, the daily sample of 10 is enrolled by recruiting every second mother giving birth in the delivery room; whereas in St Gemma DDH, with a maximum of 10 deliveries per day, five women are recruited using the same systematic random sampling procedure. Neonates of women are also included in the study and are recruited after they are born. As for HCWs, all those available at the labour and postnatal wards who interact with delivering and postpartum women at the facilities under study were invited to participate at the beginning of the study.

Variables and measurements
Outcome variables
Two outcome variables are considered in this study. We measure the incidence of puerperal sepsis for post-delivery women and the incidence of neonatal sepsis for neonates as outcome variables. The two outcome variables are measured as follows:

Puerperal sepsis
The doctor evaluates puerperal sepsis based on clinical signs and symptoms. A woman is diagnosed with puerperal sepsis if she has lower abdominal pain, abnormal vaginal discharge with a foul odour and a fever of more than 38°C. If the signs and symptoms persist after the administration of antibiotics, laboratory investigations, including culture and sensitivity testing, are performed to isolate the specific microorganism responsible for the infection. This diagnostic approach is the gold standard for the diagnosis of puerperal sepsis in Tanzania and is considered reliable for this study. During coding, the measure of puerperal sepsis is dichotomised into (1) puerperal sepsis, coded as 1, and (2) no puerperal sepsis, coded as 0.

Neonatal sepsis
Neonatal sepsis is evaluated by a doctor using clinical signs and symptoms. A neonate is considered to have neonatal sepsis if he or she is found to have a temperature >38°C, a foul-smelling cord stump, discharge from the cord, be lethargic, jaundiced, and/or conscious or unconscious. If the signs and symptoms persist after the administration of antibiotics, laboratory investigations are done, where blood culture and sensitivity are done to rule out any of the microbial agents from the child’s blood sample. This diagnostic approach is the gold standard for the diagnosis of neonatal sepsis and is routinely used in Tanzania. Similar to puerperal sepsis, the measure of neonatal sepsis is dichotomised into (1) neonatal sepsis, coded as 1, and (2) no neonatal sepsis, coded as 0.

Predictor variables
Baseline demographic characteristics
For HCWs, demographic characteristics including age, sex, marital status, occupation, profession and working experience are collected. As for delivering women, demographic characteristics collected at baseline include age, marital status, level of education, occupation and residence.

As for neonates, demographic data collected at baseline include birth weight, feeding status, gestational age, Apgar score and sex.

Level of adherence to hygienic practices among HCWs
The level of adherence to IPC standards among HCWs is measured using an observation checklist; the observation IPC checklist was adapted from the Ministry of Health’s standard Hospitals Assessment Tool on Standards-Based Management and Recognition for improving IPC. The checklist has seven domains with a total of 65 items that are measured; each item is scored as yes (1) or no (0). The highest score for all items is 65, and the lowest is 0, with a higher score indicating adherence to IPC standards.

Level of exposure to HCWs’ unhygienic practices
Immediately after admission to labour ward, women are examined for signs of infection by history taking and observation to rule out any infection before inclusion.
in the study. Those who are not infected are included and begin follow-up through observation for the level of exposure to unhygienic HCW practices. The observation checklist was developed by the research team comprising of 4 domains with 12 items. Observation points indicating a woman is subjected to infection are captured by the checklist as ‘baseline exposure’. These include the following domains: (1) hygiene of the bed into which a woman is transferred (three observation items); (2) during PVEs (four items); (3) during injections (one item) and (4) during placenta delivery (four items).

As for the neonate, exposure to HCWs’ unhygienic practices as a baseline measure is based on 5 domains with 22 items captured from observation checklist points that include contact with an HCW (1) during delivery (six items); (2) during resuscitation (six items); (3) during comprehensive neonatal assessment (four items); (4) during immunisation (three items) and (5) during skills training to a woman on how to properly breast feed (three items). These items are formulated based on summarising the activities of the routine labour ward and postnatal ward practices and directives of the obstetric care guidelines in the context of Tanzania.

Items in both women’s and neonate’s checklists are scored as ‘observed’ and given a score of 1 when an HCW shows a deviation from the recommended IPC standard, and are scored as ‘not observed’ and given a score of 0 when they practise according to the recommended standard. The checklist for a woman, therefore, has scores ranging from 0 to 12, whereas that for a neonate has scores from 0 to 22. The higher the score, the higher the level of exposure to unhygienic practices by HCWs.

Data collection procedure

Observations

After they consent to participate in this study, HCWs in each facility are observed for their adherence to IPC standards during practice in labour and postnatal wards. Data are collected by trained nurses who work in other health-care facilities other than the study sites. On the first day, observation of all HCWs’ practices was conducted and data were recorded. However, those data are assumed to have been influenced by Hawthorne effect, which could lead to observation bias due to the observer’s presence on the first occasion when they are informed that they are being observed. Thus, these data will be excluded from the analysis. Actual observation of practice and data collection began on the second day. Multiple events of the HCWs while attending patients are being observed, and data are abstracted in the checklist.

The same nurses who collect data from the HCWs also observe and abstract data for women’s and neonates’ exposure to poor IPC practices using a different checklist. Every encounter between a woman and an HCW is observed. It is recorded as ‘observed’ and given the score of 1, when an HCW shows a deviation from the recommended IPC standard; or ‘not observed’ and given the score of 0, when they practise according to the recommended standard.

Procedure for collection and transport of blood sample for culture

Trained nurses collect blood samples from the mother and/or neonate who show signs of infection for investigation by observing IPC standards and standard operating procedures for blood sample collection and transportation. They collect 1–2 mL in an EDTA tube with a vacutainer needle and send it to the laboratory for a full blood picture, which is processed in three-part or five-part differential machines. They also collect 5–10 mL of blood into two blood culture bottles (aerobic and anaerobic bottles) for culture and sensitivity as per hospital protocol and the manufacturer’s instructions. The blood culture is incubated at 37°C for 7–14 days. Therefore, if significant growth is seen, the isolation, identification and drug sensitivity of microorganisms are examined.

Data management and analysis plan

Data collected are checked for quality and kept confidential per the University of Dodoma’s (UDOM) policies. They are kept safe under the computer with a password, accessed only by the researchers. After the study is completed and the findings are published, the checklists and questionnaires with individual data will be destroyed, and the electronic data set will be kept by the researchers per UDOM’s policies.

After all the data are collected, analysis will be performed using SPSS V.25.0. Descriptive analyses will be used to summarise the demographic characteristics of HCWs, women and neonates. The pattern of HCWs’ adherence to IPC standards in their practice is set to be analysed using descriptive statistics of mean or median and analysis of variance to compare the overall mean score per IPC domain for each of the three hospitals, and logistic regression, where the association between adherence and demographic characteristics will be examined. The incidence of puerperal sepsis and neonatal sepsis will be computed using the number of cases of puerperal sepsis per person-time obtained from the number of people followed up and the sum of time each one contributed before developing puerperal sepsis. The same approach will be used for the calculation of the incidence of neonatal sepsis. As for the risk of exposure to HCWs’ poor IPC practices and the development of puerperal sepsis, rating categories defined by the Ministry of Health as determined by adherence scores will be used to determine the threshold for high exposure and low exposure groups. Then, the risk ratio will be calculated to compare the risk of developing puerperal sepsis among those with high exposure to HCWs’ poor IPC practices and those with low risk. A similar approach will be used to calculate the risk ratio for developing neonatal sepsis. Otherwise, to examine the influence of various factors, including adherence to IPC practice, on the development of puerperal and neonatal sepsis and control for potential confounders, an overall multivariate logistic regression analysis will be performed. Results will be considered statistically significant at p<0.05 using...
two-tailed tests, and estimates will be presented with their 95\% CIs.

Ethics and dissemination
This study obtained ethical approval from the UDOM Research Ethics Committee. Permission to conduct this study has been sought from the President’s Office, Regional Administration and Local Government Authority, and the Dodoma Regional Administrative Secretary. Each participant who is being recruited for this study signs the informed consent form, and those who cannot read or write receive oral information about the study and then provide thumbprint on the consent form. As for the neonates, assent by the parent is obtained. To enhance anonymity and confidentiality of participants’ information, each questionnaire and checklist are identified with codes and numbers instead of participants’ names. All data are kept secured by the principal investigator in a locked cupboard until the time allowed for discarding per UDOM’s policies.

The findings of this study will be disseminated through the following avenues: first, the findings will be disseminated to the participating hospitals for self-reflection and action to improve IPC practices by the HCWs. Second, the findings will be disseminated to the UDOM for academic purposes. Third, the findings will be shared with the Ministry of Health for policy and guideline reviews. Lastly, the findings will be disseminated at international conferences and published in peer-reviewed journals for an international audience.

Patient and public involvement
Due to budgetary constraints, it was not possible to involve patients or the public in the design of our research protocol. Thus, patient and public involvement was not implemented. However, we sought guidance from the guidelines of the Ministry of Health to design this protocol.

Author affiliations
1 Department of Clinical Nursing, The University of Dodoma, Dodoma, Tanzania, United Republic of
2 Department of Health Quality Assurance, Ministry of Health, Dodoma, Tanzania, United Republic of
3 Department of Clinical Nursing, School of Nursing and Public Health, The University of Dodoma, Dodoma, Tanzania, United Republic of

Twitter Golden Mwakibo Masika @MasikaGolden

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Contributors LEM conceived the study, developed the study plan/protocol and supervised acquisition of data, will do data analysis and draft the manuscript. GMM conceptualised and shaped the study idea, reviewed the study plan/protocol, reviewed the research tools and provided intellectual technical guidance for the study.

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Competing interests None declared.

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ORCID iD
Golden Mwakibo Masika http://orcid.org/0000-0003-0581-5797

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