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Impact of a low-cost bundle of interventions on infection prevention and control during labour and delivery in rural health centres in Zambia: results from a quasi-experimental study

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Abstract

Infection remains an important cause of maternal and newborn morbidity and mortality globally despite evidence that it can be reduced with adherence to infection prevention and control (IPC) practices. The implementation of IPC has been especially challenging in rural health centres. This pilot study used a non-randomised quasi-experimental design to examine the impact of a low-cost intervention bundle at five rural health facilities in Southern Province of Zambia. We used the Infection Control Assessment Tool (ICAT) and surveyed the incharge nurse, observed deliveries and reviewed logbooks to collect pre- and post-intervention data on healthcare worker IPC practices and maternal and newborn outcomes. The intervention bundle included education sessions, provision of alcohol hand rubs (AHRs), short message service (SMS) text messages and poster reminders, and monthly study visits. The overall ICAT score did not significantly increase after the intervention (64.0 vs. 71.8, maximum score 133, P = 0.28). There was a significant increase in the labour and delivery practices module score (12.5 vs. 16.6, maximum score 27, P = 0.04) and a trend towards improvement in the hand hygiene module (9.1 vs. 13.6, maximum score 23, P = 0.08). There were no differences in pre- or post-intervention outcomes amongst the 654 mothers who delivered and the 655 newborns during the study period. In conclusion, a low-cost bundle of interventions did neither overall improve healthcare workers' IPC practices in rural Zambia nor significantly change the rates of newborn and maternal complications. Identified challenges included inconsistent supplies of AHRs, protective and sterile equipment, as well as heavy workload for healthcare workers, which inhibited preventative behaviours.

Keywords: infection control; public health; rural health; hand hygiene; childbirth; peripartum period; Zambia

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In low- and middle-income countries (LMICs), postpartum infections are an important cause of morbidity and mortality for both mothers and newborns. In 2016, postpartum sepsis was the third most common cause of maternal death worldwide; the burden of disease may be even higher due to the difficulty of diagnosing maternal sepsis (1). Severe infection is estimated to contribute 25% of newborn mortality and remains one of the most common causes of childhood death in sub-Saharan Africa (2).

The high prevalence of maternal and neonatal infection in LMICs exists despite evidence that these infections can be reduced with consistent adherence to basic infection prevention and control (IPC) practices such as hand hygiene, clean delivery practices and use of sterile equipment (3–5). The implementation of IPC practices has been noted to be particularly challenging in rural health centres (RHCs) in LMIC as demonstrated by observational studies conducted in India and Nigeria (6, 7).

Studies conducted on improving newborn outcomes and healthcare worker's (HCW) hand hygiene through bundles of low-cost interventions have demonstrated modest success (8). In Uganda, a bundle of training,

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Trial registration: Clinical Trials NCT03809741.

posters and supply of alcohol hand rub (AHR) was associated with a 9% improvement in hand hygiene compliance (9). In Zambia, there was a 24% reduction in hospital-associated mortality in a neonatal intensive care unit following implementation of an IPC bundle (10). Most IPC trials have been performed in hospitals, so little is known about the potential for interventions to improve IPC practices in primary health centres and other healthcare settings where access to water and soap for handwashing can be inconsistent (11). Despite the value of intervening at the rural primary care level of the health system, there are limited data on the impact of improved IPC at RHCs on maternal and newborn mortality where a large number of deliveries take place (12, 13).

We investigated the impact of a low-cost bundle of interventions on IPC practices at five RHCs in Southern Province of Zambia. In addition, a comprehensive evaluation of IPC in rural settings was performed to elucidate future targets for improvement, in order to reduce maternal and newborn health complications in rural community settings. Finally, the data collected will shed further light on health outcomes of mothers and newborns who receive intrapartum care in RHCs.

Methods

Study design

This pilot study used a non-randomised, non-blinded, quasi-experimental design to examine the impact of an IPC intervention bundle at five RHCs. The allocation was not randomised or blinded due to logistical and financial limitations of a pilot study. Each of the five RHCs served as its own control rather than using aggregate mean, to reduce the impact of variation in this study with a small sample size. IPC practices and outcomes were assessed before and after introduction of a bundle of IPC interventions.

Setting and participants

This study was performed at RHCs in Choma District of Southern Province of Zambia. The sites were chosen by convenience sampling in a geographic area of the country where the research team had extensive prior experience. The RHCs were located between 30 min to 2 h distance from a town centre and general hospital. According to the most recent Zambia Demographic and Health Survey at the time of the study, 55.9% of the women in Southern Province delivered at a health facility (14). Whilst some of the facilities had capacity to administer parenteral antibiotics to mothers and newborns, none performed the full set of basic emergency obstetric and neonatal care (15). Each facility was staffed with a nurse incharge, clinical officers and midwives. Each facility also had an environmental health technician whose responsibilities included oversight of that facility's IPC in coordination with the charge nurse.

Women were eligible for the observation portion of the study if they presented for childbirth and were at least 18 years old or under 18 with a guardian present. Exclusion criteria included presenting in second stage of labour or later.

Study outcomes and data sources

The primary outcome was a score determined by the modified Infection Control Assessment Tool (ICAT), developed by the Rational Pharmaceutical Management plus Infection Control Project team (16). ICAT was developed to evaluate and improve IPC in LMICs based on guidelines and recommendations from international organisations like the World Health Organization (WHO). This tool was field tested and validated in the Philippines and Uganda and has been used in studies to evaluate IPC in settings such as South Africa and Pakistan (17). The six ICAT modules used for this survey consisted of general facility characteristics and demographics, existing IPC systems of monitoring and education, general IPC behaviours and supplies, hand hygiene, labour and delivery (L&D) specific behaviours and systems, and postpartum practices. This tool was designed to standardise approaches for improving IPC practices in various healthcare settings including L&D units. The L&D sections of the original ICAT included questions about Caesarean section and peri-operative IPC practices, but these were removed from final data analysis as surgical procedures were not practiced at any RHC. The ICAT data collection had two components: a survey that was completed with the unit administrator and observation of HCWs during L&D. Prior to data collection, research assistants (RAs) were trained by the study team to standardise the use of ICAT, HCW's observation and methods of logbook review by one of the study authors (JHP). Pilot testing was performed in December 2018.

Secondary outcomes included maternal and neonatal healthcare outcomes (discharge, transfer and death), and postpartum maternal or neonatal infection. Only complications that happened whilst at RHC or necessitated a return visit were included. Secondary outcomes were collected from facility logbooks, which included data from the maternal admission, delivery and postnatal registries. Complications were defined as healthcare outcomes leading to death or transfer to a higher level of care.

Data collection

Retrospective pre-intervention data were collected by review of all deliveries recorded in the logbooks at each clinic from September to November 2018. Prospective observational data were collected from December 2018 to on postnatal events as described earlier. During data collection, RAs were present at each RHC to interview the incharge nurse using the questionnaire portion of the ICAT, complete childbirth observations and perform logbook review. Each antepartum woman at the RHC was assessed for observation eligibility via chart review and then consented prior to going into labour. If an eligible woman presented in first stage of labour, the facility HCW determined whether there were clinical or psychosocial barriers to informed consent before the RA began any discussions of the study and consent process. For consented participants, the RA accompanied the HCW during their provision of care and patient contact during first, second and third stages of labour for observation and assessment of IPC practices using the ICAT. Observed hand hygiene practices were categorised according to the WHO's 5-Moments of Hand Hygiene (18). Hand hygiene after toilet use could not be verified as the location of latrine precluded sufficient observation, so was deleted from ICAT.

No identifiable information or demographic information was obtained to protect participants' confidentiality, and all data were collected on paper instruments before being transferred to a password-protected electronic device at the end of each week.

Intervention bundle

The intervention bundle was implemented from April to June 2019 and consisted of four components, which are described as follows.

Infection control training

All RHC staff attended IPC training during the first 2 weeks of the intervention phase, structured as 2 half-day sessions. The curriculum was adapted from the US Agency for International Development (USAID) infection prevention training curriculum for HCWs in resource-limited settings with a mixture of didactic, multimedia activity and quiz content (19). The modules were taught by a study team member and included topics such as hand hygiene, L&D IPC practices and postpartum care. To reinforce IPC techniques and address possible staff turnover, a refresher course was held during weeks 6–7 of the post-intervention phase.

Alcohol hand rub production

AHR was made according to a WHO-recommended formulation for local production (20). The study team collaborated with the district pharmacist, who oversaw the production and distribution of AHR to the study sites.

Reusable, heat-resistant bottles were used for AHR dispensing to reduce the costs of bottle replacement. The bottles were thermally decontaminated after use at the district pharmacy by boiling the bottles, as per WHOrecommended practice (21). The cost of initial non-perishable production supplies including mixing, measuring and storage equipment was 4,350 Zambian Kwacha (365 USD at the time of the study), and the monthly cost to each RHC for AHR was estimated around 43 Zambian Kwacha (3.6 USD at the time of the study).

Infection control reminders via posters and short message service texts

Posters promoting hand hygiene, L&D IPC practices and postnatal care were placed on prominent display around the RHC. This study also harnessed the ubiquity of cell phones amongst Zambian HCWs to reinforce IPC concepts. De-identified phone numbers of HCWs were entered into the study's bulk short message service (SMS) texting directory. SMS texts were sent to HCWs daily during weekdays, consisting of various IPC reminders, including hand hygiene, standard precaution and postnatal care.

Monthly study visits

Each RHC was visited once a month for updates on the intervention bundle. During the first study visit after pre-intervention data collection, centre-specific areas of improvement from the results of ICAT were provided. These results were discussed with the leadership in charge of IPC of each RHC, which included both the charge nurse and the environmental health technician. During each visit, monthly AHR use was tracked, and AHR supply was restocked if running low. Maternal and neonatal infection surveillance was done by performing logbook review to detect any outbreaks.

Statistical analysis

The primary and secondary outcomes were compared between pre- and post-intervention periods at each study site independently to account for site-to-site variation using the Wilcoxon signed-rank test. This non-parametric method was used since ICAT score distribution could not be presumed to be normally distributed due to the small sample size. Descriptive statistics were used to cumulatively assess change in each ICAT module's score between pre- and post-intervention periods.

Results

A total of 654 mothers and 655 newborns were evaluated over the entire study period (Fig. 1). After excluding

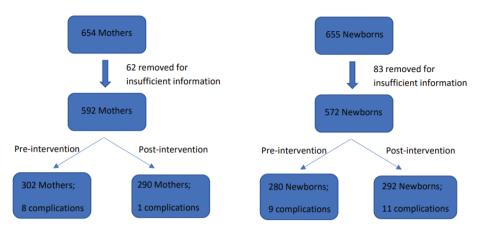


Fig. 1. Logbook review participants.

Table 1. I	Descriptive	information	of	participants
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		Maternal ir	nformation	
	Pre-interven	tion (<i>n</i> = 302)	Post-interver	ntion (<i>n</i> = 280)
	Mean	Std. dev.	Mean	Std. dev.
Length of stay (h)	15.7	11	21	13.3
Duration of labour (h)	7.2	2.7	8.1	4.5
Duration of rupture of membrane (min)	15.4	42.9	21.1	44.4
		Maternal	outcomes	
Transfers (number)	8	N/A	I	N/A
Deaths (number)	0	N/A	0	N/A
		Newborn ir	nformation	
	Pre-interven	tion (<i>n</i> = 302)	Post-interver	ntion (<i>n</i> = 280)
	Mean	Std. dev.	Mean	Std. dev.
Length of stay (h)	11.9	7.6	17.7	11.9
Gestational age (weeks)	37.4	2.8	37.9	3.1
Birth weight (kg)	2.9	0.5	2.8	0.6
		Newborn	outcomes	
Transfers (number)	5	N/A	9	N/A
Deaths (number)	4	N/A	2	N/A

births for which no outcome information was recorded, 592 births were included (302 mothers and 280 newborns during the pre-intervention period and 290 mothers and 292 newborns during the post-intervention period). There were no clinically relevant differences for mothers in length of stay, duration of labour or proportion with prolonged rupture of membranes for mothers between pre- and post-intervention periods. There were no clinically relevant differences for newborns in length of stay, gestational age or birth weight between the two phases (Table 1). There were 12 observed childbirths amongst the five RHCs during each of pre- and post-intervention periods.

Assessment of infection control practices

The median ICAT score on the L&D practices module increased from the pre- to post-intervention period (12.5 vs. 16.6, max score 27, P = 0.04). There was a trend towards improvement in the score on the ICAT hand hygiene module (9.1 vs. 13.6, max score 23, P = 0.08). There was no significant change in ICAT score before and after the intervention in the other modules. When overall ICAT scores were compared between before and after intervention periods, there was a non-significant increase after the intervention (64 vs. 71.8, max score 133, P = 0.28) (Table 2).

Each ICAT module's subsections were analysed before and after intervention. In the hand hygiene module, the

Table 2. Mean Infection Control Assessment Tool scores for five rural health centres

	Pre-intervention $(n = 5)$	Post-intervention $(n = 5)$	P-value	Maximum score
Total ICAT score	64	71.8	0.28	133
Module 1: Facility	7.4	7.2	0.32	16
1.1: Facility demographic information	5	5	N/a	10
1.2:Water supply	2.4	2.2	0.32	6
Module 2: IPC program	9.6	9.2	0.89	30
2.1: IPC program	7	7.6	0.79	13
2.2: IPC activities	2.6	1.6	0.88	17
Module 3: IPC – general	16.8	16	0.16	23
3.1: IPC supplies	4.8	4.4	0.32	9
3.2:Waste	2.6	2	0.27	4
3.3: Injection practices	7.6	7.8	0.56	8
3.4: Sharps safety	1.8	1.8	N/a	2
Module 4: Hand hygiene	9.1	13.6	0.08	23
4.1: Hand hygiene supplies	7.1	12.4	0.06	16
4.2: Hand hygiene practices	2	1.2	0.14	7
Module 5: L&D practices	12.5	16.6	0.04	27
5.1: General issues	1.2	2.6	0.04	3
5.2: Cleaning and general hygiene	0.8	1.8	0.27	4
5.3: Glove use for vaginal deliveries	3.8	4	0.16	4
5.4: Barriers worn for vaginal deliveries	3.5	4.2	0.5	9
5.5: Invasive devices in L&D	I	I	N/a	3
5.6: L&D procedures	2.1	3	0.06	4
Module 6: Postpartum care	8.6	9.1	0.89	14
6.1: Newborn care	2.2	3.2	0.09	5
6.2: Cord care	3.2	3.1	0.32	4
6.3: Postpartum care	3.2	2.8	0.49	5
IPC system	19.6	22	0.68	41
IPC supply	24.7	31.1	0.04	47
IPC behaviour	19.7	18.7	0.5	45

Bolded values are statistically significant (p < 0.05) or trend towards significance (p < 0.10)

trend towards improvement was driven by the increase in hand hygiene supplies (7.1 vs. 12.4, P = 0.06). In the L&D practices module, increase in score was due to increased education on general issues of L&D IPC (1.2 vs. 2.6, P = 0.04). There was also a non-significant increased use of protective equipment that was available but not previously used such as gloves, eyewear, masks, and gowns and aprons (3.8 vs. 4, P = 0.16; 3.5 vs. 4.2, P = 0.5). Although there was no significant change in the postpartum care module, analysis of the subsection on newborn care revealed a trend towards improvement from increased use of clean facility linen and having dedicated space for cleaning the newborn after birth (2.2 vs. 3.2, P = 0.09).

ICAT scores were compared by question categories, pertaining to the IPC system, supply or behaviours. There was a significant increase in ICAT scores to questions related to supply category (24.7 vs. 31.1, max score 47, P = 0.04). There were no significant differences in ICAT scores for system and behaviour before and after the intervention.

Hand hygiene compliance

Hand hygiene compliance was measured during the 12 observed deliveries. During pre-intervention, there were 160 total hand hygiene opportunities observed with 56 events of hand hygiene (35% compliance). During the post-intervention period, there were 135 opportunities with 32 hand hygiene actions (24% compliance, P = 0.41) (Table 3). None of the WHO's 5-Moments of Hand Hygiene had compliance greater than 50%, and there was no significant change in compliance for any of the moments. Amongst all hand hygiene moments, compliance was highest before patient contact during both periods.

Newborn and maternal outcomes

There were six newborn deaths and 14 newborns transferred to higher level of care during the study period (Fig. 2). Prematurity was the most common neonatal complication (2.3%, 13/572) of newborns during the study period. Other common complications were cord

Hand hygiene moment	Pre-intervention $(n = 12)$	Post-intervention $(n = 12)$	Р
Overall	35% (56/159)	24% (32/131)	0.41
Before patient contact	50% (14/28)	32% (10/31)	0.22
After patient or environment contact	34% (13/38)	23% (7/31)	0.4
Before touching medical device	32% (10/31)	26% (5/19)	0.35
After touching contaminated surfaces	28% (11/39)	31% (9/29)	0.89
After removing gloves	35% (8/23)	5% (1/21)	0.17

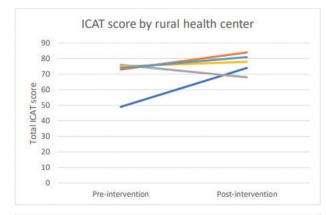
Table 3. Hand hygiene compliance during observed deliveries, before and after intervention

asphyxia (0.5%, 3/572) and stillbirth (0.5%, 3/572). Postpartum haemorrhage was the most common maternal complication at 1.2% (7/582), followed by breach birth (0.7%, 4/582) and eclampsia (0.5%, 3/582). Not all mothers with complications were transferred to a higher care centre, as some women with postpartum haemorrhage were managed at the health centre and subsequently discharged.

Discussion

The implementation of a bundle of low-cost interventions focused on education, feedback and reminders to encourage behavioural changes, and AHR provision did not improve overall infection control practices in RHCs in Zambia. Overall, aspects of IPC in L&D settings in RHCs in Zambia that were lacking included infection prevention systems like surveillance and education, WHOrecommended hand hygiene practices and reliable supply of protective equipment and AHR. There were trends towards improvement in hand hygiene supplies, L&D education and behaviours. Hand hygiene both before and after the interventions remained inadequate with no significant change in compliance rates. The presence of hand hygiene supplies was a major problem at all RHCs in the study, as the lack of AHR was one of the reasons for low hand hygiene practices. The results were limited by the small number of deaths, and no infection cases amongst newborns or mothers in peripartum period diagnosed at the RHCs during the study period, but the rates of maternal and newborn complication did not significantly change after interventions.

Many of the studies focusing on IPC interventions to reduce newborn sepsis have been implemented in hospitals, even in rural settings (10, 22). In addition, as larger trials implementing low-cost IPC interventions done at hospitals were able to ascertain patient outcomes, there is a relative lack of studies looking at the improvement and measurement of IPC practices. Thus, it is difficult to ascertain whether the lack of improvement in IPC after the interventions in our study has been seen at other



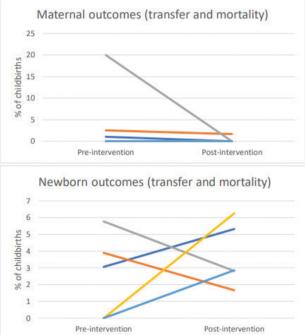


Fig 2. Pre- and post-intervention results. Note: Each coloured line represents one rural health centre.

RHCs or is specific to our study. There is a possibility that the acuity of patients' clinical status seen in RHCs and rural hospitals differs enough that the impact of improving IPC on patient outcomes would be different. This is difficult to ascertain as literature on the prevalence of infectious diseases, clinical acuity and transfer demographics in rural Zambia is limited.

Our bundle of interventions, which included education, visual reminders and provision of easily accessible AHR, did not result in improvement in hand hygiene during childbirth. There may have been contextual factors such as night-time or urgent deliveries that inhibit proper hand hygiene, and longer study periods and larger sample size could have mitigated these circumstances. It is also worth noting that a Cochrane review article in 2017 found that despite many studies on interventions on improving hand hygiene, there is currently great variability in the certainty of evidence, methods and interventions (23). It is also worth noting that our bundle of interventions was not focused solely on hand hygiene and did not fully implement WHO's recommended multimodal strategy to improve hand hygiene; specifically, we did not focus on system change or institutional safety climate (24). This is compounded by the studies mostly being conducted in hospitals or long-term care facilities, leaving RHCs in a study gap. The great variability in methods, contexts and settings means improving hand hygiene in rural settings is still a field that requires further research.

Considering the above comparisons to existing literature, we conclude that, based on this pilot study, the bundle of low-cost interventions has potential to improve some aspects of IPC in RHCs but is not sufficient to significantly improve overall IPC. The aspects of IPC that were lacking included systemic surveillance due to lack of human capital, inconsistent supply of protective and cleaning equipment, and difficulty practicing sterile behaviours due to challenges in time and supply. These challenges are hard to improve with one-time interventions focused on education, training and reminders. Even with monthly study visits intended to provide feedback about the gaps in IPC and support in IPC duties, some of these systemic and supply challenges were difficult to overcome. Whilst provision of easy-to-use AHR improved the supply of hand hygiene equipment, integration into frequent hand hygiene in settings where the staff are not used to them was more difficult.

Whilst some specifics may differ, general issues of the IPC infrastructure and supply deficiencies such as the lack of peripartum infection surveillance, regular IPC education or stable supply of AHR would apply to other RHCs in Zambia as they are systemic issues. The specifics of IPC at other RHCs in sub-Saharan Africa may differ from the results of our study. However, the difficulty of improving IPC at RHCs in LMICs may have similar challenges, including improving behaviours like hand hygiene and using consistent barriers when there is a shortage of necessary equipment and difficulty practicing IPC due to time and resource constraints. Further research of IPC in RHCs in other LMICs is needed to identify these gaps.

Future interventions to improve IPC in RHCs in Zambia should focus on improving systemic aspects such as implementing regular annual IPC training that involves all RHC staff, including clinical officers, nurses and community health workers, and having consistent supply of protective equipment and AHR so their use can become more ingrained in daily workflow. Improving antenatal care service and outreach with interventions such as maternal waiting homes could also reduce rates of emergency or late-stage presentation of childbirth, which would also improve IPC behaviours (25). Finally, improving the quality of medical documentation and storage of medical record data at RHCs are needed in order to improve future data collection activities in these settings.

There were some limitations to this study. First, logbooks remain an insufficient source of clinical information in RHCs, and being able to correlate interventions with patient-centred outcomes remains difficult in these settings without accurate charting information. This was a challenge seen in a pilot study in rural healthcare in other areas of sub-Saharan Africa such as eastern Uganda, and improved documentation would be beneficial for systemic quality improvement as well as future studies (26). This was further limited by the lack of information on outcomes that occurred outside of RHCs. We attempted to bypass this problem by making that a secondary outcome, but future research may benefit from better information being able to be gathered from logbooks. The Hawthorne effect and selection bias remain possible sources of bias in observational data gathering of behaviours. The former was mitigated by planning out the RAs' vantage points to reduce their presence during observations. The small sample size of five RHCs and 24 delivery observations is also a major limitation of this study. This was attempted to be mitigated by using statistical methods that are designed to reduce effect of variability in small sample sizes. As the pre- and post-intervention data collections occurred at different times of the year, infectious outcomes could have been impacted by seasonality of infections. However, there is no known seasonality to peripartum infections in this region unlike other parasitic infections, and therefore, we would not expect this to impact our primary outcome of ICAT scores. Finally, the choice of RHCs for this study is a source of bias, as their prior experience with research studies may have meant their infrastructure and behaviours were different than other RHCs who were research naïve. This could mean that some of the findings may not be generalisable. However, the direction of bias here would mean that they were more prepared than other RHCs, thus minimising the impact of interventions, and other more naïve RHCs could see greater benefit from similar interventions.

In conclusion, a low-cost bundle of interventions did not improve IPC at RHCs in Southern Province of Zambia. Potential next steps include improving the supply and consistent availability of protective equipment and AHR; increasing human capital support to improve IPC surveillance, education and oversight; and structural support so that the clinical staff would not be overwhelmed and not be able to practice IPC. Hand hygiene compliance did not improve with provision of AHR and a one-time education session. There was not a significant change in rate of newborn and maternal complication after our interventions, with prematurity the most common newborn complication and postpartum haemorrhage the most common maternal complication in Zambian RHCs.

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Conflict of interest and funding

This study was supported by the Fogarty International Center and National Institute of Mental Health, of the National Institutes of Health under Award Number D43 TW010543. The authors report no conflict of interests.

Ethical approval

This study was conducted according to the applicable US and Zambian government regulations and institutional policies provided by Boston University Medical Center IRB (H-37813) and University of Zambia Biomedical Research Ethics Committee (REF. No. 005-11-19). Prior to beginning this study, approval was received from the Zambia National Health Research Authority, Choma district health office and study site RHCs. A written-informed consent was obtained from all observed participants. Consent exception for HCWs was approved by both domestic and international IRBs.

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