Hand hygiene, glove use and avoiding recontamination before aseptic procedures at birth: a multi-centre time-&-motion study conducted in Zanzibar

Giorgia Gon (MSc)1, Marijn de Bruin (PhD)2, Mícheál de Barra (PhD)3, Said M. Ali (MSc)4, Oona M. Campbell (PhD)1, Wendy J. Graham (DPhil (Oxon))1, Mohammed Juma (PGD)4, Stephen Nash (MSc)1, Claire Kilpatrick (MSc)5, Loveday Penn-Kekana (MA)1, Sandra Virgo (PhD)1, Susannah Woodd (MSc)1

1London School of Hygiene and Tropical Medicine, Faculty of Epidemiology and Population Health, London, UK
2University of Aberdeen, Institute of Applied Health Sciences, Aberdeen, UK
3Brunel University London, Department of Life Sciences, Uxbridge, UK
4 Public Health Laboratory-Ivo de Carneri, Chake Chake, Pemba, Zanzibar
5 Consultant for the World Health Organisation IPC Global Unit, Service Delivery and Safety Department, Geneva, Switzerland
Corresponding author: Giorgia Gon, email: Giorgia.gon@lshtm.ac.uk; Address: Keppel Street, WC1E 7HT, London, UK; Phone number: 020 7927 2098

ABSTRACT

Objectives

To assess the hand hygiene (HH) compliance before aseptic procedures among birth attendants in the10 highest-volume facilities in Zanzibar. We also examined the extent to which recontamination contributes to poor HH; recording exact recontamination occurrences is not possible using the existing World Health Organisation HH audit tool.

Methods

In this time-&-motion study, three trained coders used the WOMBATv2 software to record the hand actions of all birth attendants present in the study sites. The percentage compliance and 95% confidence intervals for individual HH behaviours and for behavioural sequences during labour and delivery were calculated.

Results

We observed 104 birth attendants and 781 HH opportunities before aseptic procedures. Compliance to hand rubbing/washing was 24.6% (CI:21.6-27.8). Only 9.6% (CI:7.6-11.9) also donned gloves and avoided glove recontamination. Half of the time when rubbing/washing or glove donning was performed, hands were recontaminated prior to the aseptic procedure.

Conclusions

In this study, HH compliance by birth attendants was poor before aseptic procedures. To our knowledge this is the first study in a LMIC to show the large contribution to poor HH compliance from hand and glove recontamination before the procedure. Recontamination is an important driver of infection risk from poor HH and should be understood for the purposes of improvement and therefore included in HH monitoring and interventions.

KEY WORDS

Maternal health, newborn health, hand hygiene, behavioural medicine, labour ward, Tanzania

INTRODUCTION

Healthcare associated infections (HAIs) in low and middle-income countries (LMICs) affect an estimated 15% of patients; five times more than in Europe.(1) For mothers and newborns in LMICs, where infection is already a leading cause of death,(2,3) the risk of HAIs could escalate with increasing healthcare facility newborn deliveries as well as substandard infection prevention standards.(4)

Hand hygiene (HH) is deemed the single most important behaviour for preventing HAIs.(5) Historical evidence suggests the importance of HH in reducing maternal infections in European hospitals and recent studies support its value for newborns in LMICs.(6) The World Health Organization (WHO) recommends five moments for hand hygiene (5MHH) during patient care.(7) Among these, Moment 2 – HH before clean/aseptic tasks when there is potential contact with patient's mucous membranes or non-intact skin – is considered the most significant for preventing bacterial transmission to patients including the bloodstream that could result in infection. During birth, this primarily occurs before and during a vaginal examination or delivery, and related procedures.

Before these aseptic procedures, the WHO guidelines require attendants to hand rub or wash, avoid recontaminating their hands, don gloves and avoid recontaminating those gloves before starting the procedure.(7) The current WHO HH audit tool does not distinguish whether the

failure to comply with the 5MHH stems from not hand rubbing/washing or from, for example, subsequently touching potentially unclean surfaces (7) making the initial HH action redundant. Although successful multimodal interventions exist to improve hand hygiene, they require in-depth understanding of the context and achieve variable long-term success.(5,7–9) Determining whether birth attendants comply with any of the steps in the prescribed behavioural sequence and more specifically within the workflow in our context – Zanzibar, a region of Tanzania – is important to inform successful improvement interventions.

Our study therefore aims to examine the complex workflow and HH behaviours undertaken by birth attendants in multiple high-volume labour wards in Zanzibar. Our specific research questions were:

- 1. What is the compliance with hand rubbing/washing (and then avoiding hand recontamination) and donning gloves (and then avoiding glove recontamination)?
- 2. Is variability of these behaviours primarily greater *between* birth attendants or *within* birth attendants across different hand hygiene opportunities?
- 3. To what extent does failure to avoid recontamination (vs. not hand rubbing/washing before a procedure) contribute to poor hand hygiene?
- 4. What behaviour sequences do birth attendants undertake most often before aseptic procedures when compared to the behaviour sequence prescribed by the WHO guidelines?

METHODS

The context

The current study is part of the larger HANDS project (Hand-hygiene of Attendants for Newborn Deliveries and Survival): a mixed-methods study investigating drivers of birth attendant HH. HANDS ran between November 2015 and April 2017 in the 10 highest-volume labour wards in Zanzibar, with average monthly delivery volumes ranging from 75-930 (Appendix A from <u>https://doi.org/10.17037/DATA.00000778</u>). The project was a partnership between the London School of Hygiene and Tropical Medicine, the University of Aberdeen and the Public Health Laboratory of Pemba. Previous work in eight of these maternity wards found the majority had policies and basic infrastructure to perform HH but only 50% received HH training in the previous year.(10)

Study design and data collection

Within HANDS, we conducted a time-&-motion study wherein three observers recorded the hand actions (e.g. procedures, hand touches on surfaces) of birth attendants 24 hours per day (one data collector per 8-hour shift – morning, evening and night), for a mode of 6 days (range: 5-14 days) per labour ward. Results are reported using the STROBE guidelines.(11) All observers were trained midwives. Birth attendants were all staff involved in assisting deliveries, irrespective of cadre, including midwifes and orderlies. Details of the tool, training and data collection protocols can be requested from the authors.

To estimate a HH compliance of 10% with an absolute precision of +/-3%, 768 HH opportunities were required. For the sample size calculation, we used the formula for estimating a proportion from a cross-sectional survey, with $\alpha = 0.05$ and a design effect of 2 based on a survey in Benin of facility quality indicators.(12) Using the reported number of deliveries in the 10 study facilities overall, we calculated the length of observation required to achieve this sample size.

Data were collected via tablets, pre-coded using WOMBATv2 software.(13,14) An observation session began when an attendant started assisting a labouring woman. All observed hand actions were recorded as they occurred, and the time of each was automatically logged. A set of mutually exclusive actions was pre-coded and used specifically this study. One attendant was observed per observation session, but multiple patients or procedures could be included. Multiple observation sessions were usually captured in one shift. To minimise the Hawthorne effect, attendants were told that the observation was about overall quality of care, not specifically HH, in all facilities but the one where the pilot occurred.(15)

We trained on and piloted the observation tool over two-weeks following the WHO guidelines.(7,16) During the first month of data collection we also assessed inter-observer agreement between pairs of data collectors (on 49 or 50 behaviours for each pair) and calculated kappa statistics. We provided tailored feedback to the data collectors based on these results.

Ethics

The project was approved by the Zanzibar Medical Research and Ethics Committee and the London School of Hygiene and Tropical Medicine Research Ethics Committee. Consent was gathered from women (patients) either in writing in the antenatal ward prior to observation, or verbally in the labour ward, with written consent gathered before discharge. Women were informed that the person being observed was the birth attendant, and that we would not collect information on them. Consent to observe the birth attendants was granted by the Ministry of Health Zanzibar and obtained verbally from the birth attendants when the data collectors first visited the facility. All observed healthcare worker information was anonymised.

Definitions

HH opportunity

HH compliance is calculated as the number of times hand hygiene is performed, divided by the number of opportunities when HH ought to occur. The opportunities in this study were procedures at birth which ought to be aseptic (listed in Table 1). We termed a 'delivery flow' as any sequence of these procedures occurring one after the other without a break and considered as *one* opportunity for HH. We defined these opportunities using available guidelines(16–18), unstructured observations in four of the study wards, and expert consultation. This aimed to capture realistic workflows within our setting and to observe HH to be accurately observed according to WHO recommendations.

Table 1.	List o	f asentic	procedures	during a	'deliverv	flow'
Table L	List	n aseptie	procedures	uuring a	uchvery	110 W

Aseptic procedures				
Wiping the vagina				
Vaginal examination				
Artificial rupture of membranes				
Episiotomy				
Catching the baby (delivering the baby)				
Cord cutting and clamping				
Cord traction				
Manual removal of placenta*				
Post-delivery vaginal examination				
Suturing of the perineum*				
Wiping baby clean				
Urinary catheter insertion or removal				

*We allowed manual removal of placenta or suturing to be considered within the 'delivery flow' when these occurred before or after a vaginal examination, post-delivery examination, or vaginal wiping; or when manual removal of the placenta occurred after cord traction.

During a 'delivery flow', a birth attendant was permitted to undertake hand actions within the *patient zone*, defined for this study as the woman's perineal area and thighs, any clean or sterile equipment being used and the newborn as it was caught and wiped (Table 2). The patient zone includes the patient and some surfaces and items that are temporarily and exclusively dedicated to her, limiting the risk of transmitting pathogenic organisms.(17) We excluded the delivery bed and trolley from the patient zone because previous work in Zanzibar found these surfaces were often contaminated with bacteria.(10) A break in the 'delivery flow', indicating a new hand hygiene opportunity, arose if an activity occurred that was not exclusive to the patient zone e.g. inserting an IV line, touching the patient beyond the zone, or leaving the room.

Table 2. Types of hand actions that did NOT indicate a new opportunity for HH

Hand Actions
Touching the patient thighs or perineal area, and the newborn after birth
Touching her own (the attendant's) body*
Touching a clean** delivery surface – cloth or macintosh
Touching equipment contaminated only with the woman's own body fluids during the
procedure
Touching other sterile or clean material e.g. cotton swabs, drying material already available
in the area for patient care***
Performing an injection (oxytocin) or supporting breastfeeding
Carrying the placenta to be disposed i.e. 'dragging' the patient zone

Removing or adding gloves, or rinsing hands with water **** as per WHO

recommendations

*Unconscious touches e.g. touching briefly her own face are allowed by the WHO guidelines(7). During the training we did not differentiate between this type of unconscious gesture and a longer behaviour e.g. standing with hands on hips for minutes. This recommendation assumes overall cleanliness and health of the birth attendant. These "permitted touches" did not include the birth attendant's clothes or gown.

Usually a delivery surface was a large rectangular sheet of cloth or plastic (also called macintosh) brought by the woman from her own household. The surface was presumed to be clean, provided it was not contaminated e.g. with a woman's facees or after falling on the floor. When the observer could not see what happened to the sheet, it was presumed to be clean *If these items were collected outside the patient zone, they were also allowed as long as the birth attendant did not touch any other surface whilst collecting these items. Any other hand touch was recorded as a separate action, and would indicate a new opportunity.

****We allowed for the donning or removal of gloves, and rinsing hands with water only during the 'delivery flow' (after the first procedure) without indicating a new HH opportunity. This is because the WHO Guidelines for Pregnancy and Childbirth suggest that birth attendants should change their gloves before cord cutting and clamping, without needing HH, or that they should wash their gloved hands (18) while this is not a recommendation within the WHO HH Guidelines.

Hand hygiene, glove use and recontamination

Before a 'delivery flow', a birth attendant should perform four behaviours sequentially, defined in our study as follows:(7)

- Rub hands with alcohol-based handrub or wash hands with soap and water (soap use was presumed if the observer couldn't see the action)
- Avoid hand recontamination after rubbing/washing until gloves are donned (or until the procedure if gloves are not worn);
- 3) Don at least one glove,
- 4) Avoid glove recontamination before starting the 'delivery flow'.

We defined recontamination of hands or gloves, as touching an unclean delivery surface (e.g. a sheet that was in contact with the floor or with the woman's faeces), unclean hand-drying material (e.g. re-usable material), the woman and newborn outside the defined patient zone, the woman's bed, trolley, unclean objects used during HH (e.g. the sink tap, the bin) and *other* unclean surfaces, .unless classified as outside the workflow (full list of activities outside the workflow in Appendix B available from

https://doi.org/10.17037/DATA.00000778). These touches were distinguished from a deliberate new activity outside the workflow that would lead to a new HH opportunity as per the 5MHH (e.g. leaving the room or measuring blood pressure following completion of the aseptic procedure; see Appendix B available from

https://doi.org/10.17037/DATA.00000778).

Where none of the four behaviours were implemented, we described the sub-optimal glove related behaviours practised instead.

Data cleaning and analyses

One author cleaned and checked the data for consistency. Where multiple actions were recorded simultaneously we used the actions related to the hygiene behaviours and procedures of interest above other actions (e.g. leaving the room) leading to some loss of information. When contradictory information was reported about the same action (e.g. if observers recorded that both soap was used and that they did not see soap being used), we coded the data as *inconsistent information*. For software interruptions during data collection, we followed the WOMBAT guidelines to clean time data.(14) We censored opportunities with insufficient information on hand hygiene, glove use and recontamination because they occurred too close to the start of a time-&-motion observation session.

We estimated percentage compliance (behaviour performed over number of opportunities) and 95% confidence intervals for the entire recommended behaviour sequence (1-4), for partial completion of the sequence, and for each of the four hygiene behaviours individually. Behaviours 2 and 4 (avoid hand and glove recontamination) were, respectively, contingent on hand rubbing/washing (behaviour 1) and donning gloves (behaviour 3) (see Appendix C for numerators and denominators for each combination available from https://doi.org/10.17037/DATA.00000778).

We calculated frequency of adequate rubbing/washing technique (right palm over left dorsum with interlaced fingers and *vice versa(16)*) and duration (\geq 10s, following the Zanzibar infection prevention guidelines). We also described surfaces touched during hand/glove recontamination. Finally, we described within- and between-individual variation for the four behaviours using bar charts and intracluster correlation coefficients (ICC), restricted to attendants with \geq 5 opportunities. The ICC is a measure of the relatedness of data. It accounts for this relatedness by comparing the variance within clusters with the variance between clusters.(19) The ICC was calculated on the log odds scale from univariate logistic regression models accounting for individual level clustering at the birth attendant level.

GG coded all outcomes and SW checked the coding. Analyses were performed using STATA v14.

DATA SHARING

Anonymised data at the opportunity level is available in Appendix F available from <u>https://doi.org/10.17037/DATA.00000778</u>.

RESULTS

The dataset

We observed a total of 7893 hand actions (including procedures, touches, hand hygiene etc.). After cleaning, the final results present the actions of 104 birth attendants across 10 facilities with 4 to 18 attendants per facility. These data were collected during 336 observation sessions ranging from 13 minutes to 6 hours 45 minutes, with a median time of 1 hour and 41 minutes. Each attendant was observed between one and nine times (observation sessions). The kappa statistic calculated for pairs of data collectors was good for two out of three pairs at 93% and 90%, but was below the optimal level of 85% for one of the pairs, at 73%.(14) Tailored feedback was provided to data collectors based on these results.

Hand hygiene opportunities

There were 914 HH opportunities, of which 127 (13.9%) were censored because they occurred too close to the start of the observation period. Six HH opportunities were dropped because they had inconsistent information on HH. Our final dataset contains 781 HH opportunities.

Hand hygiene compliance

Birth attendants hand rubbed/washed in 24.6% (CI: 21.6-27.8; 192/781) of opportunities and 6.3% (12/192) of these instances were hand rubbing. Compliance to hand rubbing/washing did not vary much by observer or by shift – the CIs overlap (Appendix D available from <u>https://doi.org/10.17037/DATA.00000778</u>). Hand rubbing/washing was performed with adequate technique 30.7% (59/192) of the time and 14.6% (160/192) of the time lasted \geq 10seconds (Appendix E available from <u>https://doi.org/10.17037/DATA.00000778</u>). Birth attendants avoided hand recontamination after rubbing/washing in 68.8% (CI: 61.7-75.2; 28/192) of opportunities.

In 63.0% (CI: 59.5-66.4, 492/781) of opportunities, attendants added at least one glove before the procedure (with or without prior hand washing/rubbing). Of these, 61.8% (CI: 57.3-66.1, 304/492) avoided glove recontamination. Overall, birth attendants risked recontaminating their hands or gloves in 45.3% (CI: 40.9-49.8; 227/501) of the opportunities when rubbing/washing or glove-donning occurred.

Consider now the actions that led to failures in avoiding glove or hand recontamination (Table 3). On average there were 1.3 unclean touches after hand washing/rubbing (s.d.= 0.7, range 1-4) and the most commonly touched surfaces were the glove packs and unclean hand-drying material. While, on average, there were 1.5 unclean touches after adding gloves (s.d.= 0.5, range 1-7); the most commonly touched surfaces were the patient outside the defined patient zone and unclean delivery surfaces.

Type of surface touched	After hand	After adding
	rubbing/washing	gloves
	% (n)	% (n)
	N*=78	N*=275
Gloves pack	47.4 (37)	0
Unclean material when drying hands	20.5 (16)	0
Other unclean touches	16.7 (13)	16.4 (45)
Patient touched in areas which are not within the	9.0 (7)	56.0 (154)
defined zone (i.e. the pelvis and thighs, or the		
newborn)		
Personal bag	5.1 (4)	2.2 (6)
Unclean delivery surface (cloth or macintosh)	1.3 (1)	20.0 (55)
Patient bed	0	5.1 (14)
Waste bin	0	0.4 (1)

Table 3. Surfaces touched risking recontamination after hand rubbing/washing or glove use

*Overall number of touches performed when birth attendants did not avoid hand or glove recontamination. These touches are spread across 60 opportunities when birth attendants did not avoid hand recontamination; whilst these touches are spread across 187 opportunities when birth attendants did not avoid glove recontamination.

Between-person and within-person variability

The 65 individuals with \geq 5 hand hygiene opportunities contributed to the individual-level analyses of hand rubbing/washing (behaviour 1) and glove donning (behaviour 3) (Figure 1). However, recontamination could only be examined amongst 11 individuals who rubbed/washed and 44 individuals who donned gloves \geq 5 times.

Fifteen attendants never rubbed/washed, one had 100% compliance, whilst the rest ranged between 5% and 85.7% compliance. The ICC indicates that most of the variation lies within (72%; CI:0.57-0.84) rather than between individuals (28%; CI 0.16-0.43). One attendant always avoided hand recontamination. The rest ranged between 28.6% and 83.3%. Most of the variation is within individuals, rather than between individuals (ICC=10%; CI: 0.01-0.59%).

Two individuals never added new gloves before an aseptic procedure and five individuals always did. The rest ranged between 10.5% and 88.2%. Almost all of the variation lies within individuals (96%; CI:0.86-0.99) compared to between individuals (4%; CI:0.01-0.14). After glove donning, two individuals always avoided recontamination. The rest ranged between 14.3% and 88.2%. Only 8% (CI:0.03-0.22) of the variation lies between individuals and most of the variation is within individuals (92%; CI:0.78-0.97). All ICC analyses were also carried out with all 104 individuals and yielded remarkably similar results.

Figure 1. Distribution of individuals' compliance for hand rubbing/washing, glove use and recontamination





Note on Figure 1: Only individual with more than five opportunities were included in each of these graphs.

Behaviour sequences

Figure 2 presents the specific behaviour sequences of birth attendants. Sequence 1, the WHO recommendation, was only followed in 9.6% (CI:7.6-11.9) of opportunities. The most common practice, sequence 9, was to perform none of the four behaviours (35.8%;CI:32.5-39.3), followed by donning gloves without hand rubbing/washing and avoiding glove recontamination (24.8%;CI:21.9-28.0), or not avoiding recontamination (14.7%;CI:12.3-17.4); (Appendix F available from <u>https://doi.org/10.17037/DATA.00000778</u>).

In the majority of opportunities in sequence 9 (55.0%; CI:49.0-61.0, 154/280) attendants wore gloves used in a previous delivery flow. Other patterns are described in Appendix G which is available from <u>https://doi.org/10.17037/DATA.00000778</u>.



Figure 2. Behaviour sequences for 781 hand hygiene opportunities*

Note on Figure 2: This Figure describes the 781 opportunities available in the dataset. For each opportunity it outlines whether each of the four behaviours was performed. *Percentages refer to the number of opportunities in the last column e.g. in the first sequence: 9.6% refers to 75/781.

DISCUSSION

In a time-&-motion study of 104 birth attendants across the 10 highest-volume labour wards in Zanzibar, we observed 781 hand hygiene opportunities before aseptic procedures. Compliance to hand rubbing/washing occurred in a quarter of opportunities; but only 9.6% also donned gloves and avoided hand and glove recontamination before the procedure in accordance with WHO guidelines.(16) Half the time attendants either rubbed/washed hands or donned gloves they subsequently touched surfaces that could recontaminate their hands, contributing substantially to poor HH compliance. The variation in behaviour was much larger within than between individuals, suggesting these behaviours are not habitual.

Our findings of poor compliance are similar to the few other studies from LMICs. Low HH compliance (21%) before aseptic procedures was recently reported in a Nigerian hospital.(20) In Indian labour wards, compliance before delivery was 10.6%(21) and one study from Iran report similar levels during the second stage of labour.(22) Evidence from one labour ward in Ghana reports compliance ranging between 21% and 27% before aseptic procedures,(23) whilst in Zimbabwe one study found 62% of midwives never washed hands before procedures.(24). Hand hygiene definitions vary in these studies making direct comparison with our results challenging. However, all studies highlight extremely poor hand hygiene behaviour.

Although, for the majority of opportunities birth attendants did not rub/wash hands, in twothirds of opportunities they did wear at least one new glove for the procedure. Among the remaining one third, birth attendants adopted suboptimal glove-use behaviours that are not recommended(7) but may imply an attempt at placing a barrier between the birth attendant's hands and the patient. The most common was to attend different patients and procedures using the same gloves, consistent with other studies on the misuse of gloves.(15,25)

This is the first paper to our knowledge that seeks to quantify the contribution of avoiding recontamination to HH compliance while delineation between patient zones to address recontamination was studied in Vietnam.(26) Our findings are supported by studies in the UK and Australia where healthcare workers were observed to touch privacy curtains between HH or glove donning and patient care.(15,27) Loftus and colleagues demonstrated microbiological recontamination of hands at the point of care despite high levels of self-reported hand hygiene compliance, indicating the relevance of recontamination in infection transmission.(28) Recontamination may be an indication that there is a lack of understanding of the definition WHO 5MHH in its attempt to direct an approach to HH action at times when recontamination risk within or between patients has been established. Future versions of the WHO HH audit tool could add a recontamination option for the "missed" hand hygiene opportunities (when compliance was not met); this would allow for recontamination to be monitored for both implementation and research purposes.

The contribution of avoiding recontamination to overall HH compliance in our study calls for further research, to investigate its importance in other contexts, its drivers, and its direct

contribution to HAIs.(7) Acknowledging the avoidance of recontamination as a distinct behaviour and incorporating its measurement into existing tools for observing compliance, such as the WHO HH audit tool, would help quantify this problem and inform interventions to tackle it.

Our analyses revealed that variation in behaviour was much larger within than between individuals, suggesting that varying factors such as availability of materials and workload may be more important drivers than individual psychological determinants and behaviour change strategies need to be tailored to actual practices and contexts.(29,30) It is important to note that these findings were generated in settings with limited resources, hence, in settings with more stable resources hand hygiene practices may be more habitual. Future studies could further investigate this.

We monitored healthcare workers behaviour using state-of-the-art time-and-motion methods, rarely employed in low-resource settings.(31) This allowed us to investigate compliance to both the complete HH sequence prescribed by WHO, plus each individual behaviour and behaviour sequence. It also reduced the risk of observer bias because HH opportunities were identified retrospectively in a standardised way rather than relying on observer judgement. Our study has some potential limitations. Residual Hawthorne effect may have caused overestimation of compliance, despite blinding attendants to the study purpose in all but one facility. The 13% of opportunities with incomplete HH information might not be random, as they may have occurred when procedures were rushed and HH more difficult – leading us to over-estimate compliance.(32) In 5/336 observation sessions we did not have data on attendance of new patients and assumed the same woman was attended throughout, potentially under-estimating opportunities for HH and over-estimating compliance.

In conclusion, in this time-&-motion study of HH practices in the 10 highest-volume labour wards in Zanzibar, we found – like in previous studies – low compliance to the WHO HH guidelines. The major addition of this study is that it reveals the potential impact of recontamination, after initial washing/rubbing and donning gloves, on infection risk and the importance of including this as a separate item in HH measures. Additionally, variability in this behaviour seems to primarily reside within the individuals across opportunities. Reducing the threat of HAIs in mothers and newborns calls for further research into drivers of recontamination and effective behaviour change strategies to tackle it.

CONFLICT OF INTEREST AND ACKNOWLEDGEMENTS

We declare no potential conflict of interests.

The project was funded by the Medical Research Council – PHIND scheme. Award number MR/N015975/1. The Soapbox Collaborative also contributed by funding staff involved in this project. The writing up of this paper provided part of the background needed for the CLEAN Study funded by the UK Joint Global Health Trials (Wellcome, MRC, DFID and DOH) Award number: MR/R019274/1.

We thank the Ministry of Health of Zanzibar for their participation and engagement in the study. A special thanks to Rukaiya M Said, Mwanafatima Ali Mohammed, Bijuma Mkubwa Abdallah, and Asya Hati Vuai who collected all the data. We also thank Marina Daniele for participating in the consultation exercise aimed at refining the definition of opportunity. Finally, we thank Daniel Powell and David Macleod for the support in data management.

REFERENCES

- Allegranzi B, Nejad SB, Combescure C, Graafmans W, Attar H, Donaldson L, et al. Burden of endemic health-care-associated infection in developing countries: systematic review and meta-analysis. The Lancet. 2011 Jan;377(9761):228–41.
- Kassebaum NJ, Bertozzi-Villa A, Coggeshall MS, Shackelford KA, Steiner C, Heuton KR, et al. Global, regional, and national levels and causes of maternal mortality during 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. The Lancet. 2014 Sep 19;384(9947):980–1004.
- Oza, S, Lawn, JE, Hogan, DR, Mathersb C, Cousens SN. Neonatal cause-of-death estimates for the early and late neonatal periods for 194 countries: 2000–2013. Bulletin of the World Health Organization [Internet]. Available from: http://www.who.int/bulletin/online_first/BLT.14.139790.pdf
- Campbell OMR, Calvert C, Testa A, Strehlow M, Benova L, Keyes E, et al. The scale, scope, coverage, and capability of childbirth care. The Lancet [Internet]. 2016 [cited 2016 Oct 21]; Available from: http://www.sciencedirect.com/science/article/pii/S0140673616315288

- Luangasanatip N, Hongsuwan M, Limmathurotsakul D, Lubell Y, Lee AS, Harbarth S, et al. Comparative efficacy of interventions to promote hand hygiene in hospital: systematic review and network meta-analysis. The BMJ. 2015 Jul 28;351:h3728.
- Blencowe H, Cousens S, Mullany LC, Lee ACC, Kerber K, Wall S, et al. Clean birth and postnatal care practices to reduce neonatal deaths from sepsis and tetanus: a systematic review and Delphi estimation of mortality effect. BMC Public Health. 2011;11 Suppl 3:S11.
- WHO. WHO Guidelines on Hand Hygiene in Health Care: First Global Patient Safety Challenge Clean Care is Safer Care. WHO; 2009.
- Gould DJ, Moralejo D, Drey N, Chudleigh JH, Taljaard M. Interventions to improve hand hygiene compliance in patient care. Cochrane Database Syst Rev. 2017 01;9:CD005186.
- WHO. Evidence of hand hygiene as the building block for infection prevention and control [Internet]. WHO; 2017. Available from: http://www.who.int/infectionprevention/tools/core-components/evidence.pdf?ua=1
- 10. Gon G, Ali SM, Towriss C, Kahabuka C, Ali AO, Cavill S, et al. Unpacking the enabling factors for hand, cord and birth-surface hygiene in Zanzibar maternity units. Health Policy Plan [Internet]. 2017 Aug 22 [cited 2017 Aug 22]; Available from: https://academic.oup.com/heapol/article/doi/10.1093/heapol/czx081/3957928/Unpackin g-the-enabling-factors-for-hand-cord-and
- 11. STROBE Initiative Group. STROBE checklist for cohort, case-control, and crosssectional studies (combined) [Internet]. 2007. Available from: https://www.strobestatement.org/index.php?id=strobe-group0
- Rowe AK, Lama M, Onikpo F, Deming MS. Design effects and intraclass correlation coefficients from a health facility cluster survey in Benin. Int J Qual Health Care. 2002 Dec 1;14(6):521–3.
- 13. Zheng K, Guo MH, Hanauer DA. Using the time and motion method to study clinical work processes and workflow: methodological inconsistencies and a call for standardized research. J Am Med Inform Assoc JAMIA. 2011 Oct;18(5):704–10.

- Westbrook J. Work Observation Method By Activity Timing: A guide to the installation and use of WOMBAT V2. Sydney: Centre for Health Systems and Safety Research, Macquarie University; 2016 Aug.
- 15. Wilson J, Prieto J, Singleton J, O'Connor V, Lynam S, Loveday H. The misuse and overuse of non-sterile gloves: application of an audit tool to define the problem. J Infect Prev. 2015 Jan;16(1):24–31.
- 16. WHO. Hand Hygiene Technical Reference Manual [Internet]. WHO; 2009. Available from: http://apps.who.int/iris/bitstream/handle/10665/44196/9789241598606_eng.pdf;jsession id=C23CC7AC25035E11B1F80D3012E835E4?sequence=1
- WHO. Hand Hygiene in Outpatient and Home-based Care and Long-term Care Facilities. Geneva: WHO; 2012.
- 18. WHO. Pregnancy, Chilbirth, Postpartum and Newborn Care: A guide for essential practice 3rd edition. WHO, UNICEF, UNFPA and The World Bank; 2015.
- Killip S, Mahfoud Z, Pearce K. What Is an Intracluster Correlation Coefficient? Crucial Concepts for Primary Care Researchers. Ann Fam Med. 2004 May;2(3):204–8.
- Shehu N, Onyedibe K, Mark O, Gomerep S, Isa S, Ibrahim C, et al. Assessment of hand hygiene compliance among health care workers in a Nigerian Tertiary Hospital. Vol. 6(Suppl 3). 2017. 57 p.
- 21. Spector JM, Agrawal P, Kodkany B, Lipsitz S, Lashoher A, Dziekan G, et al. Improving Quality of Care for Maternal and Newborn Health: Prospective Pilot Study of the WHO Safe Childbirth Checklist Program. PLoS ONE. 2012 May 16;7(5):e35151.
- 22. Simbar M, Ghafari F, Zahrani ST, Majd HA. Assessment of quality of midwifery care in labour and delivery wards of selected Kordestan Medical Science University hospitals. Int J Health Care Qual Assur. 2009;22(3):266–77.
- Yawson AE, Hesse AAJ. Hand hygiene practices and resources in a teaching hospital in Ghana. J Infect Dev Ctries. 2013 Apr 17;7(4):338–47.

- 24. Danda G, Dube K, Dube P, Mudokwenyu-Rawdon C, Bedwell C. An observational study of midwives' practices to prevent peripartum sepsis in Zimbabwe. Afr J Midwifery Womens Health. 2015 Jan 2;9(1):17–21.
- 25. Picheansanthian W, Chotibang J. Glove utilization in the prevention of cross transmission: a systematic review. JBI Database Syst Rev Implement Rep. 2015 May 15;13(4):188–230.
- 26. Salmon S, Pittet D, Sax H, McLaws ML. The "My five moments for hand hygiene" concept for the overcrowded setting in resource-limited healthcare systems. J Hosp Infect. 2015 Oct;91(2):95–9.
- 27. Stewardson AJ, Stuart RL, Egerton-Warburton D, Marshall C, van den Driesen M, Havers S, et al. Determinants of hand hygiene behavior in Australian emergency departments. In Antimicrobial Resistance and Infection Control; 2017. (Meeting Abstracts; vol. 6(Suppl 3):52).
- Loftus RW, Muffly MK, Brown JR, Beach ML, Koff MD, Corwin HL, et al. Hand contamination of anesthesia providers is an important risk factor for intraoperative bacterial transmission. Anesth Analg. 2011 Jan;112(1):98–105.
- Pittet D, Simon A, Hugonnet S, Pessoa-Silva CL, Sauvan V, Perneger TV. Hand hygiene among physicians: performance, beliefs, and perceptions. Ann Intern Med. 2004 Jul 6;141(1):1–8.
- 30. Huis A, Achterberg T van, Bruin M de, Grol R, Schoonhoven L, Hulscher M. A systematic review of hand hygiene improvement strategies: a behavioural approach. Implement Sci. 2012 Sep 14;7(1):92.
- 31. Lopetegui M, Yen P-Y, Lai A, Jeffries J, Embi P, Payne P. Time Motion Studies in Healthcare: What are we talking about? J Biomed Inform. 2014 Jun;0:292–9.
- 32. Srigley JA, Furness CD, Baker GR, Gardam M. Quantification of the Hawthorne effect in hand hygiene compliance monitoring using an electronic monitoring system: a retrospective cohort study. BMJ Qual Saf. 2014 Dec;23(12):974–80.

APPENDICES

All appendices are available from https://doi.org/10.17037/DATA.00000778

Appendix A – Facilities description

Appendix B – Actions that indicated a new hand hygiene opportunity & were outside of the workflow

Appendix C – Numerator and denominator definitions for each outcome combination reported in the methods

Appendix D – Hand hygiene compliance by observer and shift

Appendix E – Duration and technique of hand rubbing/washing

Appendix F – Sequence of actions preceding the first aseptic procedure in the "delivery flow"

Appendix G –Patterns of glove behaviour under sequence 9 (from Figure 2 in manuscript)