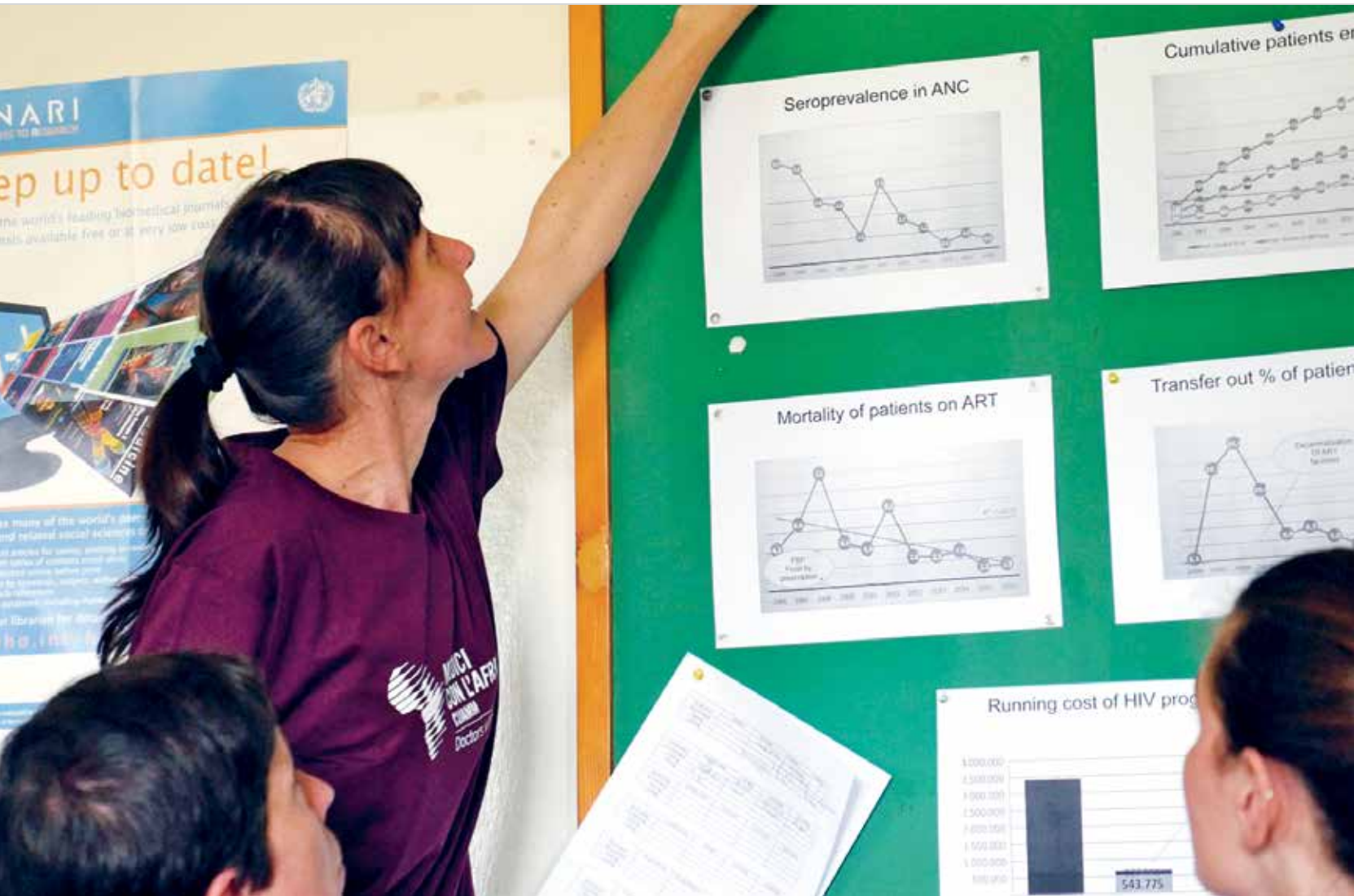
Field research

Scientific papers from cooperation activities in Africa – 2020

MEDICI CON L'AFRICA
CUAMM
Doctors with Africa



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Doctors with Africa

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Padua, March 2021

«I must confess that research and the resolve to get to the bottom of matters, refusing to passively accept possible truths as absolutes, were constant, very fruitful companions during my time as a tropical doctor».

«Devo confessare che la ricerca, il desiderio di andare a fondo, la non accettazione supina di eventuali verità assunte come assolute, furono una presenza costante e molto produttiva nella mia attività di medico tropicalista».

Giovanni Baruffa,
L'uomo dei tre sì, 2012

BACK TO BASICS

IL RITORNO A CIÒ CHE CONTA

And so comes to a close 2020, the *annus horribilis* of the Covid-19 pandemic, but also a record year for CUAMM in terms of both the quantity and quality of our scientific output: 37 studies published in prestigious international journals. We would like to greet 2021 by attempting to "read" all that is going on around us through a series of questions: How does health bind people to one another and strengthen communities? What are the pillars upholding those health systems best able to withstand crises like the current one? As an on-the-ground NGO, what is the best way to fit our own work into this framework?

The pandemic has turned it back to the devastating power of infectious diseases, bringing to light a series of systemic weak points that are particularly evident in the West. The most important concern the gaps and fragmentation of territorial healthcare, which, after being progressively weakened over the years, has proven incapable of containing Covid-19 at the community level; the inequalities that have put at risk the most vulnerable categories within given populations (the elderly in Italy, and the poorest in the global South); and the indissoluble, but too-often unacknowledged or understood, link between health factors and social and economic ones.

Yet epidemics are a constant, even in recent history, just as emergencies are becoming increasingly common, too; in Africa alone we are now seeing at least two every year, whether they be climate events (cyclones, droughts, etc.), humanitarian emergencies, or public health crises like the current one. Thus we are called on to continue to hone our emergency preparedness skills; indeed, being prepared for crises of any nature is essential not only for being able to tackle and overcome them, but for doing so while also ensuring the smooth functioning of everything else. If we lacked this capacity, the development work that we at Doctors with Africa CUAMM, like so many others, have engaged in for so long would have to be deferred every time an emergency occurs.

Thus as we contemplate what is happening from our privileged vantage point in Africa, we are getting back to basics, and using the paradigm to help guide our vision of development cooperation, of our work on the ground, and of research as a driver of quality.

What does this mean in practice? Firstly, there is a clear need to leverage communities everywhere, including in Africa. It is communities that fill the gaps when government is inadequate or absent altogether, and where initiatives of resistance are first sparked; this makes it crucial to breathe new life into them. This has long been evident to us at CUAMM; indeed, in recent years communities have often been at the center of our research (for example, financing health services in Uganda's rural district of Oyam, or using the precious work of activists in Beira to respond to the cyclone in Mozambique)[1] as spaces in which awareness can be raised to generate health as well.

At the same time, though, such solutions "from below" are often insufficient on their own. They need to take place within

Chiudiamo il 2020, annus horribilis *della pandemia di Covid-19, con 37 ricerche pubblicate su riviste internazionali, sicuramente la produzione più consistente e anche prestigiosa che Cuamm abbia avuto finora. E apriamo il 2021 con uno sguardo che desidera leggere ciò che sta accadendo intorno a noi: in che modo la "salute" lega le persone tra di loro e rende forti le comunità? quali sono i pilastri di un sistema sanitario capaci di reggere l'onda d'urto delle emergenze come questa? e come può inserirsi in questa cornice il nostro lavoro di una ong "da campo"?*

Questa epidemia torna ad accendere i riflettori sulle infezioni e la loro potenza, portando a galla tutte le fragilità del sistema, particolarmente evidenti nel nostro Occidente: nella maggior parte dei casi una medicina territoriale inconsistente e frammentata, che non ha saputo "contenere" Covid-19 con la medicina comunitaria perché troppo impoverita negli anni; le diseguaglianze che hanno messo a rischio le categorie più fragili – da noi gli anziani, nel sud del mondo i più poveri; e infine quel legame indissolubile tra gli aspetti sanitari e quelli sociali ed economici, che troppo spesso però non viene compreso.

Eppure le epidemie sono una costante nella storia anche recente, così come sempre più frequenti sono le emergenze: solo nella "nostra" Africa ne contiamo ormai almeno due all'anno tra eventi climatici come cicloni o siccità, crisi umanitarie o ancora fenomeni di natura sanitaria. È la preparazione – preparedness *per usare un termine ormai sempre più in voga – ciò su cui dobbiamo riflettere e affinarci: si rende necessaria infatti la capacità di essere preparati alle crisi, di qualunque natura esse siano, per poterle gestire e superare, ma al tempo stesso è fondamentale farlo mantenendo il buon funzionamento di tutto il resto. Se così non fosse, emergenza dopo emergenza si bloccherebbe quella capacità di sviluppo su cui noi di Medici con l'Africa Cuamm – e come noi tanti – lavoriamo da anni.*

Ed è così che dal nostro osservatorio privilegiato che è l'Africa, raccogliamo oggi delle riflessioni su quanto accade e che ci riportano "ai fondamentali", back to basics, *per recuperare quel senso alla base di tutto che possa guidarci nella nostra visione della cooperazione, dell'intervento sul campo, della ricerca come motore di qualità.*

Innanzitutto risulta evidente la necessità di tornare alla comunità, anche in Africa. Sono le comunità che riempiono gli spazi dove lo Stato è assente o insufficiente, è dalle comunità che partono iniziative di resistenza e per questo si rende necessario animarle e rivitalizzarle. Sicuramente è un aspetto conosciuto per noi del Cuamm, anche tra le ricerche di questi ultimi anni ci sono stati studi che hanno messo la comunità al centro per esempio in tema di finanziamento dei servizi nel distretto rurale di Oyam in Uganda o di risposta al ciclone con gli attivisti di Beira in Mozambico[1] *come luogo che può creare consapevolezza e diventare a sua volta spazio che genera salute.*

Ma le risposte che arrivano "dal basso", dalle sole comunità, rischiano di essere insufficienti da sole e vanno sposate con

a broader framework bolstered by an inclusive, pluralistic health system (whether public or private) based on the principles of universal access to quality care and supportive financing mechanisms, a space that makes it possible to reconcile the international and local development agendas to create real development momentum. This is the balance that must continue to guide our own work.

And here the issue of inequality, the extent to which cultural and social factors are determinants of people's health, surfaces once again. Although many were already well aware of it, the pandemic has laid it bare for all to see in terms of direct and indirect mortality. And it is here that we must continue to laser-focus our efforts; indeed, economic and social inequalities determine not only whether people have access to treatment, but their very risk of falling ill to begin with. Added to this is a sort of "African paradox", where the indirect consequences of the pandemic in terms of extreme hunger and poverty, and the subsequent avoidable morbidity and mortality, will be worse than those of the pandemic itself. Then there is the issue of "vaccine apartheid", where exclusive intellectual property rights and monopolies vis-à-vis patents will force Africa to vaccinate itself far later, and at a much greater cost, than wealthier parts of the world – a prospect labelled "a catastrophic moral failure" by the Director-General of the World Health Organization.

It is against this backdrop, which demands that we keep our feet firmly on the ground as we continue to support communities and systems, that we reaffirm our belief in the importance of research. Research can provide tools to help us better familiarize ourselves with and interpret the facts, potentially bringing us even closer to communities as we respond to their needs, and pointing the way to innovations – sometimes unexpected and inexpensive, yet key, ones. As we move into a new year of research, this is our mindset, together with a sense of humility and awareness of the unprecedented times we are living in.

una dimensione più ampia, sorretta da un sistema sanitario inclusivo, pluralistico, sia esso pubblico o privato, improntato a un accesso universalistico alle cure di qualità e a meccanismi solidali di finanziamento. E che possa conciliare l'agenda internazionale con quella locale, per riuscire a creare davvero un movimento di sviluppo. È proprio su questo equilibrio necessario che dobbiamo continuare a orientare il nostro lavoro.

Ancora una volta emerge il grande tema delle diseguaglianze e quanto siano i fattori culturali e sociali a determinare la salute delle persone: lo sappiamo bene ma l'attuale pandemia lo riporta davanti a tutti in termini di mortalità diretta e indiretta ed è su questo che ancora dobbiamo strenuamente lavorare. Le diseguaglianze economiche e sociali determinano non solo la possibilità di cura ma, ancor più a monte, il rischio di ammalarsi. In questo quadro poi si inserisce anche una sorta di "paradosso africano"*, dove i danni indiretti della pandemia avranno conseguenze peggiori del Covid stesso in termini di fame e povertà estrema con il loro strascico di mortalità e morbilità evitabili. Per non parlare dell'*"apartheid vaccinale" *dove a causa dei diritti esclusivi, della proprietà e dei monopoli sui brevetti l'Africa sarà costretta a vaccinarsi in grande ritardo e a prezzi molto più elevati rispetto ai paesi ricchi.* "Un catastrofico fallimento morale" *lo ha definito il segretario generale dell'OMS.*

Ecco, in questo quadro dove ci viene richiesto di stare ben ancorati a terra e "servire" le comunità e i sistemi, vogliamo continuare a credere anche nel ruolo della ricerca. La ricerca può permettere di avere chiavi di entrata e interpretative dei fatti, può creare percorsi di coesione per rispondere alle necessità delle popolazioni e può diventare un modo per fare innovazione, anche frugale dove meno te l'aspetti. Con questo sguardo alto ma anche con grande consapevolezza e umiltà di fronte al tempo che stiamo vivendo ci incamminiamo verso le ricerche del nuovo anno.

don Dante Carraro
Director, Doctors with Africa CUAMM

Giovanni Putoto
Head of planning and operational research,
Doctors with Africa CUAMM

don Dante Carraro
Direttore Medici con l'Africa Cuamm

Giovanni Putoto
Responsabile della programmazione
e della ricerca operativa, Medici con l'Africa Cuamm

[1] *HIV continuity of care after Cyclone Idai in Mozambique*, Pozniak A, Atzori A, Marotta C, Di Gennaro F, Putoto G., in Lancet HIV, 2020 March; *Assessing the feasibility of community health insurance in Uganda: A mixed-methods exploratory analysis. Biggeri M, Nannini M, Putoto G. in Social Science & Medicine, 2018 March.*

RESEARCH IN TIMES OF COVID-19

37 original research papers by CUAMM published in international journals, and another 7 that mention our interventions and/or contributions: that's our operational research round-up for 2020, and it's a record. In fact, although our scientific output has been steadily on the rise since 2015, never before have we had a greater number of our studies published in a single year, many of which – as in the past – in prestigious journals including those of *The Lancet* group, the *British Medical Journal* (BMJ) and *BioMed Central* (BMC), as well as the *American Journal of Tropical Medicine and Hygiene* and The *International Journal of Infectious Diseases*.

This steady rise demonstrates CUAMM's resolve to continue to invest in research as a tool with which to hone our understanding of the settings in which we work, identifying the most effective interventions and validating good practices in order to improve our work at every level of a given health system. Indeed, as we never tire of repeating, research guarantees the quality of interventions, and CUAMM knows that quality development cooperation is the only kind that matters.

The Covid-19 pandemic inevitably helped shape this year's scientific output: eight of the published articles focus on the topic, reflecting our organization's wish to draw attention to the huge impact the virus is having in the most vulnerable settings both across the African continent and in Italy. One piece published in the Correspondence section of *The Lancet Global Health* (*"COVID-19 in Italy: momentous decisions and many uncertainties"*) underscored the importance of public access to data and information in order to plan the most effective interventions to curb the spread of the pandemic, while other research focused on describing the pandemic's impact on health services, particularly vis-à-vis women and children, but also especially at-risk groups such as migrants (see, for example, our *"Situational brief: deportations and irregular migrants during the Covid-19 pandemic"* published on the Lancet Migration research platform).

Yet Africa continues to experience other emergencies in addition to the crisis brought by the pandemic: both natural disasters, such as the cyclones that hit Mozambique, and humanitarian tragedies, including refugees fleeing from conflict zones. CUAMM conducted research in 2020 on these topics as well, assessing the health impact of such events in order to make health systems stronger and more resilient in the face of future emergencies.

We also focused much attention this year on the care of critically-ill patients both at the district and hospital levels, especially that of mothers and infants (indeed, 19 of our 37 published pieces have to do with maternal and child health). At the territorial level, emergency transport systems were a priority topic: two of our published studies focused on the National Emergency Medical Service (NEMS), a prehospital referral system in Sierra Leone co-managed by CUAMM and the Novara-based Research Center in Emergency and Disaster Medicine (CRIMEDIM), describing both the

LA RICERCA AI TEMPI DI COVID-19

37 pubblicazioni scientifiche a firma Cuamm e altri 7 articoli in cui Cuamm viene menzionato per descriverne l'intervento e il contributo: questo è il "bottino" della nostra ricerca operativa nel 2020. È il numero più alto di ricerche pubblicate in un anno, a conferma del costante aumento di produzione scientifica dal 2015 a oggi. Come gli scorsi anni, numerosi lavori sono stati pubblicati su riviste prestigiose del gruppo Lancet, BMJ – British Medical Journal *o* BMC*, così come su* American Journal of Tropical Medicine and Hygiene *e* International Journal of Infectious Diseases.

Questo costante aumento indica come Cuamm intenda continuare a investire nella ricerca come strumento per capire meglio i contesti in cui lavora, per identificare le azioni più efficaci e validare buone pratiche per migliorare il proprio intervento a tutti i livelli del sistema sanitario. Perché, non ci stanchiamo di ripeterlo, la ricerca garantisce qualità di intervento ed è di qualità la cooperazione che noi desideriamo fare.

La pandemia da Covid-19 ha inevitabilmente influenzato anche la produzione scientifica nel corso dell'anno. Con 8 pubblicazioni su questo tema, il Cuamm ha voluto contribuire a porre l'attenzione sul grande impatto che Covid-19 ha avuto nei contesti più fragili, non solo nel continente africano, ma anche nel territorio italiano. Con la corrispondenza su Lancet Global Health "COVID-19 in Italy: momentous decisions and many uncertainties" si è voluta sottolineare l'importanza dell'accesso a dati e informazioni durante l'epidemia per poter meglio programmare gli interventi per limitarne la diffusione. Altri lavori si sono invece focalizzati sul descrivere l'impatto dell'epidemia sui servizi sanitari, in particolare su donne e bambini, con un'attenzione anche a categorie particolarmente a rischio come i migranti (ad esempio "Situational brief: deportations and irregular migrants during the Covid-19 pandemic" pubblicato su Lancet Migration*).*

L'Africa tuttavia continua a vivere condizioni di emergenza che vanno al di là della pandemia da Covid-19. Catastrofi naturali, come ad esempio i cicloni che hanno colpito il Mozambico, o drammi umanitari, come quello dei rifugiati in fuga dalle zone di conflitto: anche su questi temi il Cuamm ha portato l'attenzione attraverso la ricerca, per cercare di avvicinarsi con una prospettiva di studio a questi fenomeni, in particolare per valutare l'impatto che hanno avuto sulla salute nell'ottica di rafforzare il sistema sanitario e renderlo più resiliente a futuri eventi emergenziali.

Grandissima attenzione è stata data nel corso di quest'anno alla cura del malato critico, in particolare della mamma e del neonato, sia a livello distrettuale, sia ospedaliero (19 delle 37 pubblicazioni appartengono all'area tematica della salute materno-infantile). A livello territoriale, un ruolo prioritario di interesse scientifico lo ha avuto il sistema di trasporto delle emergenze. Sono stati pubblicati due lavori sul progetto National Emergency Medical Service (NEMS) in Sierra Leone condotti insieme a CRIMEDIM, dove vengono descritti sia l'implementazione di un sistema di trasporto nazionale (Designing, Implementing and Managing a National

implementation of the system (*"Designing, Implementing and Managing a National Emergency Medical Service in Sierra Leone"*) and the impact of the pandemic on it (*"The National Emergency Medical Service Role During the COVID-19 Pandemic in Sierra Leone"*).

With regard to in-hospital care, we published 9 studies on the care of newborns in critical conditions, based primarily on our work in Ethiopia and Mozambique, and 3 others investigating epidemiology and the management of mothers in the high-dependency unit, an intensive care section set up by CUAMM in Sierra Leone's main maternity hospital.

Complementing our 2020 operational research was an online training course dedicated to implementation research and the skills needed for conducting it in low-resource settings; participants received an overview of research strategy and learned about its multiple dimensions.

Year after year CUAMM continues to build up its wealth of know-how, tools, resources and partnerships – a path we set out on long ago, when our organization was first founded, and still travel proudly along today.

Emergency Medical Service in Sierra Leone) *sia l'impatto che la pandemia ha avuto sul servizio (The National Emergency Medical Service Role During the COVID-19 Pandemic in Sierra Leone).*

Per quanto riguarda le cure intraospedaliere, 9 sono stati i lavori pubblicati sulla cura del neonato in condizioni critiche condotte principalmente in Etiopia e Mozambico, che si aggiungono ai 3 condotti per approfondire epidemiologia e gestione delle madri nella High Dependency Unit, reparto di cure intensive creato dal Cuamm nella principale maternità della Sierra Leone.

A completare il quadro della ricerca operativa, si è aggiunto nel 2020 il corso di formazione dedicato proprio alla Implementation Research *e alle competenze necessarie per fare ricerca in contesti con poche risorse: in modalità virtuale, il corso ha dato una lettura complessiva della strategia di ricerca, trasmettendo ai partecipanti le molte dimensioni che la compongono.*

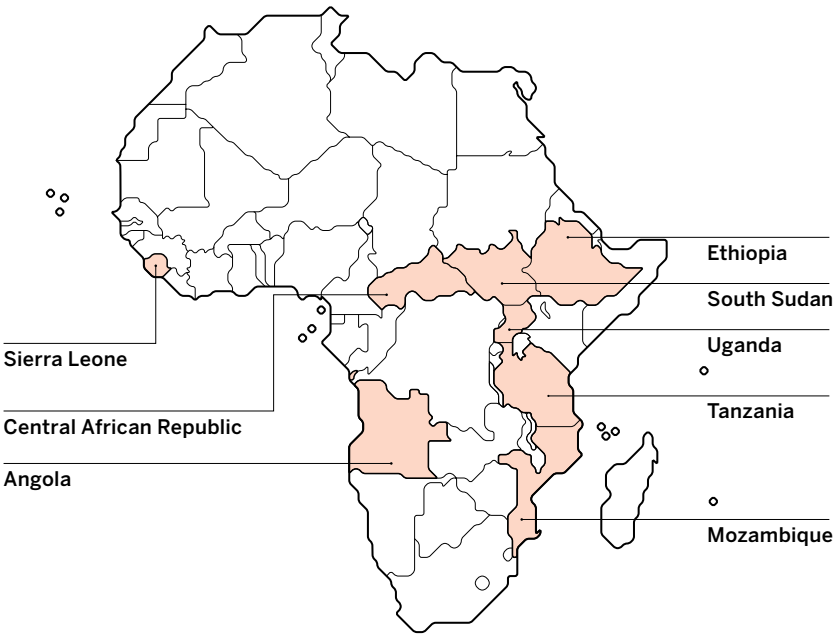
Un panorama, quello che stiamo costruendo anno dopo anno, che si arricchisce di competenze, strumenti, risorse e collaborazioni: una strada iniziata da lontano, fin dagli albori della storia del Cuamm, e che con orgoglio continuiamo.

Chiara Di Benedetto e Francesca Tognon
Implementation Research Unit

Chiara Di Benedetto e Francesca Tognon
Implementation Research Unit

Doctors with Africa CUAMM

Medici con l'Africa Cuamm



Doctors with Africa CUAMM is the largest Italian NGO working to **improve the health of vulnerable communities in Sub-Saharan Africa**. CUAMM carries out **long-term projects in 8 countries** in the region and partners with **universities and research centers** in Italy and abroad to raise awareness about people's right to health care. CUAMM also organizes **courses on global health** for medical students and health professionals and conducts **research** with international partners, convinced that such endeavors are vital to developing **quality international healthcare programs**.

*Medici con l'Africa Cuamm è la più grande organizzazione italiana per la **promozione e la tutela della salute delle popolazioni africane**. Medici con l'Africa Cuamm realizza **progetti a lungo termine in 8 paesi** dell'Africa Sub-sahariana e collabora con **università e centri di ricerca in Italia e in Europa**. Organizza inoltre **corsi di Salute Globale** per studenti di Medicina e professionisti sanitari e lavora con partner internazionali a **progetti di ricerca**, nella convinzione che questi sforzi siano necessari per lo sviluppo di **programmi sanitari internazionali di qualità**.*

Doctors with Africa CUAMM currently operates in Angola, Central African Republic, Ethiopia, Mozambique, Sierra Leone, South Sudan, Tanzania and Uganda. / *Medici con l'Africa Cuamm attualmente lavora in Angola, Etiopia, Mozambico, Repubblica Centrafricana, Sierra Leone, Sud Sudan, Tanzania e Uganda attraverso:*

23
hospitals / *ospedali*

127
districts (for public health activities, mother-child care, the fight against HIV/AIDS, tuberculosis and malaria, training) / *distretti (iniziative per la salute pubblica, assistenza e cure per la salute materna e infantile, lotta contro l'HIV/AID, la tubercolosi e la malaria)*

3
nursing schools / *scuole per infermieri e ostetriche*

1
university (Mozambique) / *università (Mozambico)*

4,777
health workers, including / *collaboratori sanitari, che includono:*

434
from Europe and abroad / *europei e internazionali*

Operational research in 2020
Ricerca operativa nel 2020

37 articles published by CUAMM in prestigious international journals and another 7 that mention our organization's work: even as the COVID-19 pandemic raged, CUAMM's operational research carried on, enabling us to continue building up know-how and designing projects in low-resource countries. 178 researchers from 66 research centers in Italy, Africa and elsewhere around the world partnered with our organization, together taking the path of quality development cooperation.

37 ricerche pubblicate su riviste prestigiose e 7 articoli internazionali che citano il lavoro del Cuamm: nell'anno della pandemia di Covid-19 la ricerca operativa non si è fermata, ha continuato a costruire conoscenza e sviluppare progetti per i paesi a risorse limitate. 178 ricercatori e ricercatrici, appartenenti a 66 differenti centri di ricerca italiani, africani o internazionali, hanno lavorato in sinergia percorrendo la strada della cooperazione di qualità.

Maternal and child health
Salute materna e infantile

Infectious and tropical diseases
Malattie infettive e tropicali

Universal coverage and equity
Copertura sanitaria universale ed equità

Nutrition
Nutrizione

Chronic diseases
Malattie croniche

OUR RESEARCH PARTNERS

The 66 research centers, universities and other organizations – in Africa, Europe (including Italy), and other countries around the world – with which Doctors with Africa CUAMM partnered on research in 2020.
I 66 centri di ricerca, università e organizzazioni con cui Docotrs with Africa Cuamm ha collaborato per produrre la ricerca nel 2020

AFRICA

1. Ministry of Health and Sanitation, Freetown, Sierra Leone
2. University of Freetown, Sierra Leone
3. Princess Christian Maternity Hospital, Sierra Leone
4. Partners In Health, Sierra Leone
5. UNFPA, United Nations Population Fund, Freetown, Sierra Leone
6. Military Hospital, Freetown, Sierra Leone
7. Ministry of Health, Tanzania
8. National Institute for Medical Research, Tanzania
9. Tosamaganga Hospital, Tanzania
10. Bugando Medical Centre, Mwanza, Tanzania
11. Central Hospital of Beira, Mozambique
12. Ministry of Health, Angola
13. Ministry of Health, Kampala, Uganda
14. School of Medicine, College of Health Sciences, Makerere University, Uganda
15. Department of Obstetrics and Gynecology, St Kizito Hospital, Uganda
16. World Health Organization, Uganda
17. Makerere University Lung Institute, Uganda
18. USAID Mission, Uganda
19. University Research Co, LLC (URC) & Center for Human Services (CHS), Uganda
20. St. Luke Catholic Hospital, Wolisso, Ethiopia
21. Italian Agency for Development Cooperation, Sudan
22. Department of Public Health Technology, Federal University of Technology, Imo State, Nigeria
23. Faculty of Medicine and Health Sciences, University of Stellenbosch, South Africa
24. Department of Paediatrics, University of Witwatersrand, South Africa
25. Department of Physiotherapy, School of Health Sciences, University of KwaZulu-Natal, South Africa

ITALY

1. Bocconi University, Centre for Research on Health and Social Care Management (CERGAS), Milan, Italy
2. Università Cattolica del Sacro Cuore, Rome, Department of Pediatrics, Italy
3. Università Cattolica del Sacro Cuore, Rome, Institute of Endocrinology, Italy
4. University of Bari, Department of Emergency and Organ Transplantation, Italy
5. University of Bari, Clinic of Infectious Diseases, Italy
6. University of Padova, Department of Woman's and Child's Health, Italy
7. University of Padova, Department of Surgery and Organ Transplantation, Italy
8. University of Padova, Epidemiology and Public Health Department, Italy
9. University of Palermo, Department of Science for Health Promotion and Mother to Child Care, Italy
10. University of Trieste, Department and legal and language sciences, Italy
11. University of Udine, Department of Medicine, Italy
12. University of Verona, Department of Neonatal and Pediatric Critical Care, Italy
13. Mater Dei Hospital, Bari, Italy
14. Policlinico Hospital of Abano Terme, Department of Obstetrics and Gynaecology, Italy
15. Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy
16. CRIMEDIM - Research Center in Emergency and Disaster Medicine, Università del Piemonte Orientale, Italy
17. WHO Collaborating Center, Institute for Maternal and Child Health - IRCCS Burlo Garofolo, Trieste, Italy
18. Organizational Unit Prevention and Public Health, Veneto Region, Italy
19. SUEM 118, Veneto Region, Italy
20. Primary Care Department, Unità Locale Socio Sanitaria 3 'Serenissima', Venice, Italy

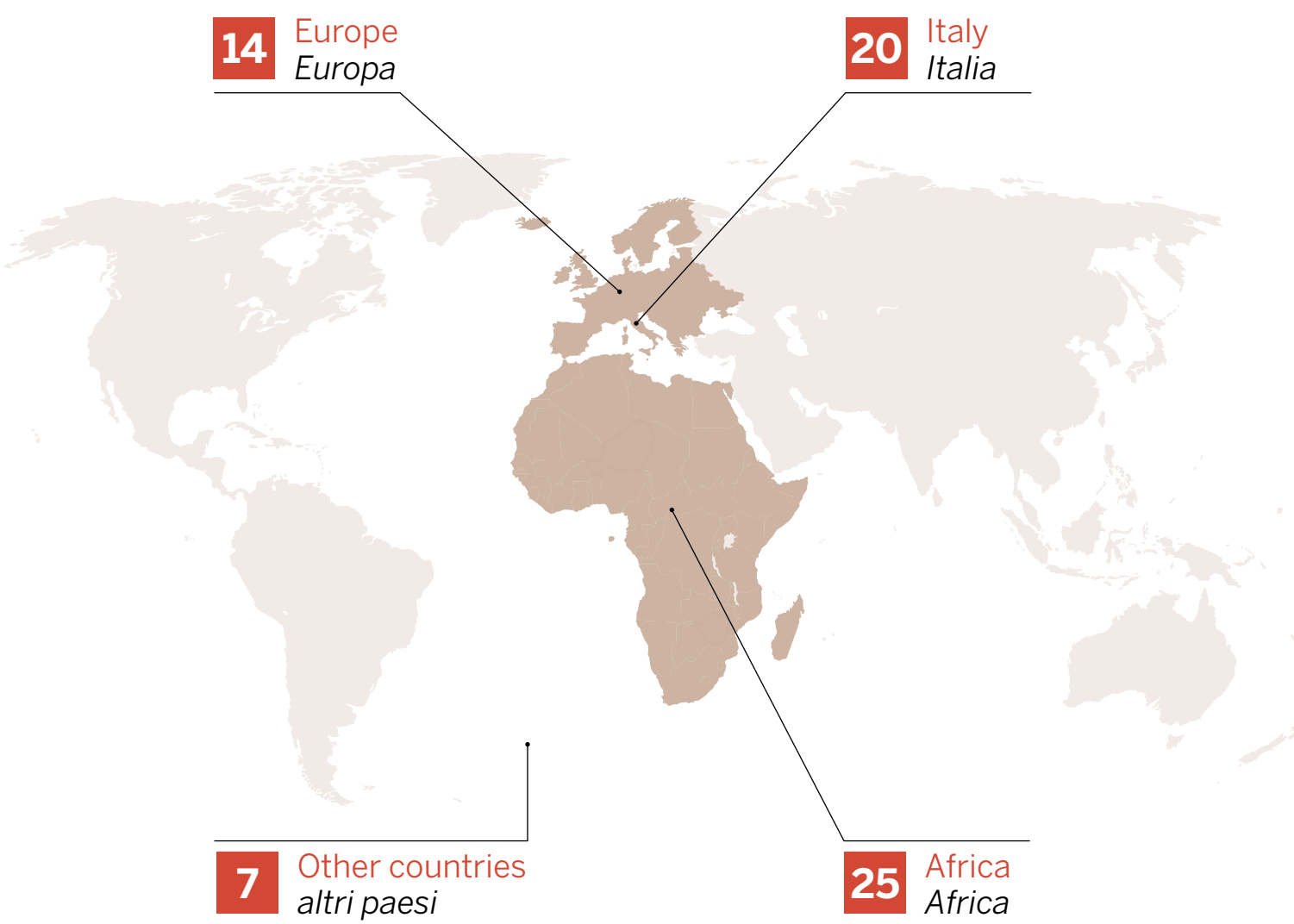
EUROPE

1. Directorate-General for Parliamentary Research Services, European Parliament, Brussels, Belgium
2. King's Centre for Global Health and Health Partnerships, King's College London, UK
3. Institute for Global Health, University College London, UK
4. London School of Hygiene and Tropical Medicine, UK
5. Nuffield Department of Medicine, University of Oxford, UK
6. Chelsea and Westminster Hospital NHS Foundation Trust, London, UK
7. Amsterdam University, Department of Intensive Care, The Netherlands
8. Maastricht University, Department of International Health, The Netherlands
9. Amsterdam Institute for Global Health and Development, The Netherlands
10. Amsterdam University Medical Centers, Department of Intensive Care, The Netherlands
11. Amsterdam University Medical Centers, Department of Internal Medicine, The Netherlands
12. Service de Néonatologie - Centre d'Etudes Périnatales Océan Indien (CEPOI), Centre Hospitalier Universitaire Sud Réunion, SaintÐ Pierre Cedex, France
13. World Health Organization, Switzerland
14. University of Bergen, Centre for International Health, Norway

OTHER COUNTRIES

1. Harvard Medical School, Department of Global Health and Social Medicine, Boston, USA
2. Thomas Jefferson University Hospital, Philadelphia, Pennsylvania, USA
3. University of California, Department of Pediatrics, USA
4. University of Michigan, Department of Pediatrics and Communicable Diseases, USA
5. Hospital Israelita Albert Einstein, Department of Critical Care Medicine, São Paulo, Brazil
6. Center for Global Health, The Chinese University of Hong Kong, Hong Kong
7. Mahidol University, Bangkok, Tropical Medicine Research Unit, Thailand

66 Research partners
partner di ricerca



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PAPERS

Chronic diseases

PAPERS

Below is a list of seven research papers published in prestigious journals that cited CUAMM's work in 2020 (although none of the authors are part of our organization).
Qui di seguito riportiamo le ricerche che nel corso del 2020 hanno citato il lavoro del Cuamm, sebbene nessuno degli autori appartenga all'organizzazione.

A)
TITLE: **Perspectives of health workers on the referral of women with obstetric complications: a qualitative study in rural Sierra Leone**
AUTHORS: Proos R., Mathéron H., Vas Nunes J., Falama A., Kamal P.S., Grobusch M. P., van den Akker T.
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B)
TITLE: **Use of a participatory quality assessment and improvement tool for maternal and neonatal hospital care. Part 1: Review of implementation features and observed quality gaps in 25 countries**
AUTHORS: Tamburlini G., Bacci A., Daniele M., Hodorogea S., Jeckaite D., Siupsinskas G., Pessa Valente E., Stillo P., Vezzini F., Bucagu M., Lincetto O.
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C)
TITLE: **Use of a participatory quality assessment and improvement tool for maternal and neonatal hospital care. Part 2: Review of the results of quality cycles and of factors influencing change**
AUTHORS: Tamburlini G., Bacci A., Daniele M., Hodorogea S., Jeckaite D., Maciulevicius A., Pessa Valente E., Siupsinskas G., Uxa F., Vezzini F., Lincetto O., Bucagu M.
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TITLE: **Improving mental health and psychosocial wellbeing in humanitarian settings: reflections on research funded through R2HC**
AUTHORS: Tol W. A., Ager A., Bizouerne C., Bryant R., El Chammay R., Colebunders R., García-Moreno C., Usman Hamdani S., James Leah E., Jansen Stefan C. J., Leku Marx R., Likindikoki S., Panter-Brick C., Pluess M., Robinson C., Ruttenberg L., Savage K., Welton-Mitchell C., Hall B.J., Harper M., Harmer A., van Ommeren M.
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E)
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Maternal Caesarean Section Infection (MACSI) in Sierra Leone: a case control study

PAPER

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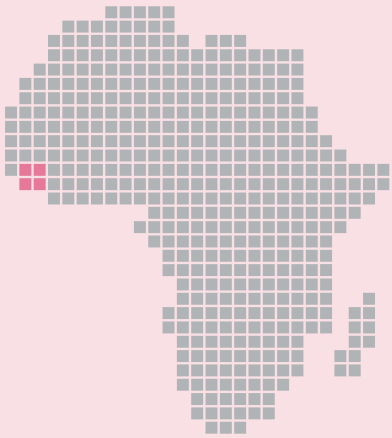

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Maternal caesarean section infection (MACSI) in Sierra Leone: a case–control study

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Abstract

Sierra Leone is the country with highest maternal mortality and infections are the underlying cause in 11% of maternal deaths, but the real burden remains unknown. This study aims to determine the incidence and risk factors of surgical site infection (SSI) post-caesarean section (CS) in women admitted to Princess Christian Maternity Hospital (PCMH) in Freetown, Sierra Leone. A prospective case–control (1:3 ratio) study was implemented from 1 May 2018 to 30 April 2019 and 11 women presenting with suspected or confirmed infection post-CS were screened for inclusion as a case. For each case, three patients undergoing CS on the same day and admitted to the same ward, but not presenting with SSI, were selected as controls. The post-CS infection rate was 10.9%. Two hundred and fifty-four clinically confirmed cases were enrolled and matched with 762 control patients. By multivariable analysis, the risk factors for SSI were: being single (odds ratio (OR) 1.48, 95% confidence interval (CI) 1.36–1.66), low education level (OR 1.68, 95% CI 1.55–1.84), previous CS (OR 1.27, 95% CI 1.10–1.52), presenting with premature membranes rupture (OR 1.49, 95% CI 1.18–1.88), a long decision–incision time (OR 2.08, 95% CI 1.74–2.24) and a high missing post-CS antibiotic doses rate (OR 2.52, 95% CI 2.10–2.85).

Introduction

Two-thirds of the global maternal deaths in 2017 occurred in sub-Saharan Africa (SSA), and Sierra Leone was one of the countries with the highest maternal mortality ratios (MMRs) with 1360 deaths per 100 000 live-births in 2015 [1, 2]. The country also ranks 184th out of 189 countries on the human development index and has the third lowest life expectancy in the world [3, 4]. These maternal and neonatal mortality indices are lagging behind the United Nations Sustainable Development Goals for 2030 of an MMR of less than 70 deaths per 100 000 live-births and a neonatal mortality rate of less than 12 deaths per 1000 live-births [5].

Infections are the underlying causes in 11% of maternal, and one-fourth of newborn deaths, but the true burden of maternal infections and related complications remains unknown [6, 7]. Among maternal infections, surgical site infections (SSIs) play a dominant role. Caesarean section (CS) delivery is one of the most common operative procedures performed in SSA, and accounts for as much as 80% of the surgical workload with accompanying high morbidity and mortality rates [8, 9]. Notably, CS is the most important risk factor for infections in the immediate postpartum period, with a 5- to 20-fold increased risk compared to vaginal birth [10, 11]. Up to one in five women in Africa who deliver their baby by CS develop a wound infection, but reliable data are lacking from low resource settings, and in particular from Sierra Leone, where the incidence and risk factors for CS SSIs are still unexplored [6].

Although largely preventable, SSIs represent a considerable burden for health-care systems, particularly in low- and middle-income countries [12, 13]. In order to reduce the burden of maternal and neonatal infections, there is a need to improve our understanding of clinical, epidemiological and contextual factors impacting CS-related SSIs. Therefore, the aim of this 12-month prospective case–control study was to determine the incidence, risk factors and predictors of negative outcome of such infections in women admitted to a high-volume urban referral centre in Freetown, Sierra Leone.

Table 1. Baseline characteristics of the 1016 enrolled patients

	Total (no. 1016; 100.0%)	SSI (no. 254; 25.0%)	Controls (no. 762; 75.0%)	*P*-value
Age (mean; s.d.)	25.5 (0.5)	26.4 (0.7)	25.9 (0.4)	0.53
BMI *n* (%)				
Low (<18)	90 (8.8)	57 (22.6)	33 (4.4)	**<0.0001**
Normal (18–25)	798 (78.5)	137 (53.8)	661 (86.8)	
High (>25)	128 (12.7)	60 (23.6)	68 (9.0)	
Status, *n* (%)				
Married	799 (78.6)	178 (70.3)	621 (81.5)	**<0.0001**
Single	247 (21.4)	76 (29.7)	141 (19.5)	
Occupation, *n* (%)				
Employed	224 (78)	41 (16.0)	183 (24.0)	**0.04**
Unemployed	792 (22)	213 (84.0)	579 (74.0)	
Education, *n* (%)				
Illiterate	87 (8.5)	61 (23.7)	26 (3.4)	**<0.0001**
Primary education level (<8 years)	829 (81.5)	170 (67.1)	659 (86.5)	
High education level (>8 years)	100 (10)	23 (9.2)	77 (10.1)	
Gravidity, *n* (%)				
Gravida 1	316 (31.1)	73 (28.9)	243 (31.9)	**<0.0001**
Gravida 2–4	632 (62.2)	141 (55.3)	491 (64.6)	
Gravida >4	67 (6.7)	40 (15.8)	27 (3.5)	
Comorbidity, *n* (%)	240 (23.6)	134 (52.7)	106 (13.9)	**<0.0001**
Referred from other health facilities *n* (%)	575 (56.6)	73 (28.9)	502 (65.9)	**<0.0001**
Presence of premature rupture of membranes, *n* (%)	330 (32.5)	174 (68.4)	156 (20.5)	**<0.0001**
Previous CS, *n* (%)	678 (66.7)	183 (72)	495 (65)	**0.03**
Time decision–incision, median (IRQ) (min)	80 (55 −120)	101 (90–160)	68 (55–94)	**<0.0001**
Duration of CS, mean (s.d.) (min)	32 (1.0)	36 (0.8)	28 (0.3)	0.10
Type of incision, *n* (%)				
Transverse	839 (82.5)	191 (75.0)	648 (85.1)	**0.04**
Midline	177 (17.5)	63 (25.0)	114 (14.9)	
Suture used for skin closure, *n* (%)				
Absorbable	896 (88.2)	214 (84.2)	682 (89.5)	**0.02**
Non-absorbable	120 (11.8)	40 (15.8)	80 (10.5)	
% Missing post-CS Antibiotic doses (not given/prescribed), *n* (%)				
Day of CS				
0–50%	87 (8.6)	75 (29.3)	12 (1.6)	**<0.0001**
51–100%	929 (91.4)	179 (70.7)	750 (98.4)	
Day 1 post-CS				
0–50%	101 (10)	74 (29.3)	27 (3.5)	**<0.0001**
51–100%	915 (90)	180 (70.7)	735 (96.5)	
Day 2 post-CS				
0–50%	101 (10)	89 (34.9)	12 (1.6)	**<0.0001**
51–100%	915 (90)	165 (65.1)	750 (98.4)	
Maternal death, *n* (%)	14 (13.8)	13 (5.3)	1 (0.1)	**<0.0001**

Methods

Study design

This was a prospective matched case–control (1:3 ratio) study carried out from 1 May 2018 to 30 April 2019 at Princes Christian Maternity Hospital (PCMH) in Freetown, Sierra Leone. It is the largest urban maternity referral hospital in the country, serving a population of 1.5 million inhabitants. It has approximately 9000 admissions and 6000 deliveries per year of which around 30% are CSs [14]. The study protocol is registered on Clinicaltrials.gov with the reference number NCT03929991. Ethical approval of the protocol was obtained from the Ministry of Health of Sierra Leone Ethical Committee.

Study population

All pregnant women undergoing a CS in the hospital during the study period were enrolled, and all those admitted or already hospitalised with suspected or confirmed infection after CS were screened for inclusion as potential cases. Case confirmation was established by a daily detailed physical examination of all hospitalised women by an infectious disease specialist. All the post-caesarean surgical incision as well as the body temperature and other available clinical parameters were evaluated. Complex clinical cases were discussed in a multidisciplinary teamwork and diagnosis of SSIs was made according to current guidelines [15]. For each case, three patients undergoing a CS on the same day and admitted to the same ward, but not presenting with SSI from the day of enrolment until the end of hospital stay, were selected as controls.

Data collection

Clinical data, such as body mass index (BMI), gravidity, comorbidity, presence of premature rupture of membranes and breastfeeding, were recorded at the onset of SSI, and whether infections occurred post-CS or within the hospital stay for cases, and on the day of examination for controls. Socio-demographic data (age, occupation, level of education and referral from other health facilities) and information about the CS (i.e. previous, clinical indication, elective or emergency, antibiotic prophylaxis, time 'decision to incision', duration of operation, type of incision, type of anaesthesia, suture used for skin closure and closure style) was also recorded at the same time point. Time 'decision to incision' was calculated as the time elapsed between the gynaecologist's indication for urgent CS and the time of the incision. Both were recorded according to the study protocol.

The missing post-CS antibiotics dose rate was calculated as doses not given/doses prescribed, and recorded on day and then on the first and the second day post-CS. Information on the administration of antibiotic prophylaxis and operating procedures was recorded on the patient's file, and reviewed by an infectious disease specialist.

For cases only, the SSI was classified according to the CDC definition [15] as: superficial incision; deep incision and organ/space infection. Data were also collected on the interval; post-CS and onset of infection; the type of treatment and final outcomes.

Patients and newborns were assessed at hospital discharge, together with the length of hospital stay. The incidence of SSI post-CS was determined retrospectively from the operating theatre register for the total number of CS performed during the study period; data were cross checked with the labour ward register.

Table 2. SSI characteristics of the 254 enrolled cases

Classification, *n* (%)	
Superficial	90 (35.5)
Deep	98 (38.2)
Organ	66 (26.3)
Days from the CS to the onset, mean (s.d.)	4.4 (1.8)
Type of treatment, *n* (%)	
Antibiotics	81 (31.9)
Antibiotics + opening of the wound at the bedside	99 (39.0)
Antibiotics + minor surgery[a]	51 (20.1)
Hysterectomy	23 (9.0)
Final outcome, *n* (%)	
Complete resolution	241 (94.7)
Death	13 (5.3)

[a]Internal cleaning of uterus.

Statistical analysis

Data were reported as means and standard deviations (s.d.) for continuous variables. Absolute and relative frequencies (percentages) were used for categorical variables. Independent *t* test was used to compare groups for continuous variables, whilst a χ^2 test (with the Fisher's correction if less than five cases were present in a cell) was applied for categorical variables. A logistic regression model was implemented as follows. SSI was considered as a dependent variable and each one of the available factors at the baseline evaluation as independent variables (univariate analysis). In the multivariate analysis factors with a *P*-value <0.10 by univariate analysis were included. Multicollinearity among covariates was assessed through the variance inflation factor, taking a value of 2 as cut-off to exclude a covariate. However, no variable was excluded according to this pre-specified criterion. Odds ratios (ORs) as adjusted odds ratios (adj-ORs) with 95% confidence intervals (CIs) were used to measure the strength of the association between factors at the baseline (exposure) and treatment failure (outcome). The R^2 value to quantify the variability of the dependent variable was also determined. All statistical tests were two-tailed and statistical significance was assumed for a *P*-value <0.05. Analyses were performed using SPSS 21.0 for Windows (SPSS Inc., Chicago, Illinois).

Results

Overall, 254 clinically confirmed SSI post-CS were enrolled in the study as cases, these were matched with 762 control patients, accounting for a total of 1016 patients (mean age 25.5 years, s.d. 5.6). Baseline characteristics for cases and controls are presented in Table 1. HIV, HBV or HCV infections, diabetes, hypertension and other chronic diseases were recorded and considered comorbidities. Over the study period, 2323 CS interventions were registered at PCMH, giving an SSI incidence of 10.9%.

Table 2 shows that of the 254 cases of SSI, 90 (35.5%) were classified as superficial, 98 (38.2%) deep and 66 (26.3%) as organ/space. The onset of the infection was on average on the 4th day (1.8%). Treatment by antibiotic therapy alone was given for 81 (31.9%) patients, antibiotic plus opening of the wound at

Table 3. Predictors of the SSI onset in the 1016 enrolled women undergoing to CS

	Unadjusted analysis of SSI risk		Adjusted analysis of SSI risk	
Characteristics	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value
Age (years)	1.02 (0.98–1.04)	0.53	–	0.46
Single	1.32 (1.01–1.52)	**<0.0001**	1.48 (1.36–1.66)	**<0.0001**
Low BMI (<18)	1.80 (1.42–2.02)	**<0.0001**	1.42 (1.18–1.72)	**<0.0001**
High BMI (>25)	1.50 (1.28–1.74)	0.05	1.85 (1.02–2.68)	**<0.0001**
Referred from other health Facilities	1.34 (1.10–1.66)	**<0.0001**	2.35 (2.18–2.59)	**<0.0001**
Gravida >4	0.51 (0.43–0.70)	0.04	0.64 (0.59–0.83)	**0.19**
Unemployed	1.85 (1.35–2.45)	0.04	1.74 (1.24–2.21)	**<0.0001**
Low education	2.02 (1.27–2.53)	**<0.0001**	2.19 (1.71–2.33)	**<0.0001**
Presence of premature rupture of membranes	1.20 (0.84–1.85)	**<0.0001**	1.49 (1.18–1.88)	**<0.0001**
Time decision–incision, median (IRQ)	1.76 (1.45–2.25)	**<0.0001**	2.08 (1.74–2.24)	**<0.0001**
Suture used for skin closure absorbable	0.90 (0.65–1.15)	0.02	0.98 (0.88–1.19)	0.06
Missing post-CS Antibiotic doses (>51%)	1.80 (1.50–2.00)	**<0.0001**	2.52 (2.10–2.85)	**<0.0001**
Previous CS	1.34 (1.19–1.54)	0.03	1.27 (1.10–1.52)	0.02

*$P < 0.05$.

the bedside for 99 (39.0%), antibiotic plus re-operation for 51 (20.1%) and hysterectomy for 23 (9.0%) patients. Complete resolution of the SSI was observed in 241 (94.7%) patients, while 13 (5.3%) women died.

Cases more frequently had an abnormal BMI (low or high), were more often unemployed and with a lower educational level than the control group, and less frequently referred from other health facilities. Cases also presented with a higher incidence of premature rupture of membranes and comorbidities, as well as a higher rate of missing antibiotic doses over the first 3 days post-CS. Regarding factors related to surgical intervention, bivariate analysis showed that a midline CS incision and the use of non-absorbable sutures for skin closure were more frequently associated with infection ($P < 0.05$). There were no differences regarding the anaesthesia received, the type of suture and the closure style. All patients were administered prophylactic antibiotic therapy pre C/S section. (Complete information on cases and controls is shown in Supplementary Material.)

By multivariable analysis, several factors were found to be independently associated with an increased risk of SSI (Table 3). These were being single (OR 1.48, 95% CI 1.36–1.66), having an abnormal BMI (low (OR 1.42, 95% CI 1.18–1.72); high (OR 1.85, 95% CI 1.02–2.68)), admitted from home (OR 2.35, 95% CI 2.18–2.59), unemployed (OR 1.74, 95% CI 1.24–2.21), low education level (OR 1.68, 95% CI 1.55–1.84), presenting with premature rupture of membranes (OR 1.49, 95% CI 1.18–1.88), a long decision–incision time (OR 2.08, 95% CI 1.74–2.24), frequent missing post-CS antibiotic doses (OR 2.52, 95% CI 2.10–2.85) and previous CS (OR 1.27, 95% CI 1.10–1.52).

Discussion

The primary findings of this study were that (1) one in 10 women undergoing CS at PCMH developed an SSI that led to death in 5.3% of them; (2) the predictors of SSIs were social and demographic i.e. being single, being unemployed, with low education level, having an abnormal BMI, both low and high, health-system related (coming from home instead of being referred from a health facility), obstetric (previous CS, presenting with premature membranes rupture, a long decision–incision interval) and clinical (a high rate of missing post-CS antibiotic doses).

Many of these demographic variables reflect a common scenario for a large proportion of the Sierra Leone population. Similarly, low BMI, low socio-economic status or educational levels predispose patients to be less aware of their clinical condition. Likewise, they are less able to buy drugs for their comorbidities, or lack confidence in hospital care and thereby increasing their risk of acquiring SSIs. Hence, these variables serve as proxies of discomfort experienced by such populations in Sierra Leone which has undergone a prolonged civil war (1991–2002) followed by Ebola virus disease outbreak (2014–2016). These events have profoundly affected the already fragile healthcare system, leading to significant worsening of maternal health indicators [16, 17].

The post- CS SSI rate of 10.9% reported in our cohort is comparable with some reports from Ethiopia and Gambia [2, 18, 19], but was markedly lower than the 15.6% incidence found in SSA [20]. However, many context-related factors, such as urban *vs.* rural hospital settings, make direct comparison of infection rates in different countries difficult. Nevertheless, it is important to note that despite the relatively moderate infection rate found in this series, maternal deaths (5.3%) and hysterectomies (9%) represent an important disability especially in the African context.

Among all predictors of mortality, the role of antibiotics deserves special attention. According to hospital guidelines and local clinical practice, the antibiotic prophylactic schedule was: 2 g of ampicillin IV 15–60 min before the skin incision and continued for 48 h after the CS with empiric therapy [21]. Also, it is noteworthy that as antibiotic prophylaxis was a key factor for the prevention of surgical infections, this – together with a possible indirect study effect – could explain the universal pre-operative antibiotic coverage observed, which is generally uncommon in low-income contexts. Nevertheless, despite the high coverage rate of prophylactic antibiotics, the SSI cohort had a higher frequency of missing antibiotic doses over the first 2 days post-CS

compared to the controls. It is known that prophylactic antibiotics work synergistically with the appropriate antiseptic measures before and during surgery [22, 23], so such factors might also have impacted the observed low SSI rate. Indeed, it is widely recognised that infection prevention requires the integration of a range of control procedures before, during and after surgery [24–27].

We found that the high rate of incomplete antibiotic dosing was an important predictor of infection, resulting in a two and half fold increase of infection risk for each missed dose. It is worth noting that the WHO no longer recommends a prolonged antibiotic prophylaxis strategy, especially in a context of low resources [28, 29]. Indeed, the lack of antibiotics is a serious concern in this setting, where despite being an irreplaceable weapon against infections, frequent misuse facilitates the development of multi-drug-resistant bacteria [30–32]. The data on the missing antibiotic doses prompted us to reflect on antibiotic prescribing practice. In low resource settings such as Sierra Leone where there is a significant lack of drugs, antimicrobials must be prescribed accurately and following the international guidelines. In this regard, the current protocol of prescribing an antibiotic for 48 h post-caesarean should be reviewed. We suggest that antibiotic prophylaxis should be limited to 24 h post-caesarean which in turn would lead to a better use of these drugs and also reduce the rate of missing doses with a resulting reduced infectious risk.

A second interesting study finding was the role of time and duration of the CS. It is recommended that CS should be performed in less than 30 min to reduce the risk of SSI [33], and long decision–incision time has been shown to double the risk of infection [34–38]. As suggested by the American College of Obstetrics and Gynecology (ACOG) guidelines, the CS defined as 'urgent' should activate a rapid protocol that takes the patient to the theatre as soon as possible, and within half an hour [39]. However, the achievement of this high-quality standard requires important and significant investment in terms of public health organisation, surgical team training and structural improvements, all of which require a coordinated approach. Moreover, patients with low socio-economic status remain the most vulnerable in terms of post-caesarean infections and will always need more medical attention and follow-up [40–42].

This study had several limitations. Since the study site was a tertiary referral hospital, it is possible that it served to centralise cases of the most complicated pregnancies at higher risk of infection, thereby limiting the applicability of our results to the district hospital setting. In this perspective, a comparison with primary or secondary level of care would be important to achieve. Likewise, the lack of microbiological confirmation of cases and scarcity of post-discharge patient information is an important limitation from an epidemiological viewpoint and which we hope to address in further investigations.

In conclusion, the key message from our findings is on the role of antibiotics in ensuring universal coverage. This requires appropriate administration and dosing and in selecting eligible patients for treatment, in order to avoid resource waste and the development of antibiotic-resistance. These aspects have a key role in national infection control and antibiotic stewardship programmes and should be prioritised in the national health strategy particularly in low resource countries, where the availability of antimicrobials is very limited and the emergence of multi-drug-resistant bacteria is a reality [42, 43]. Understanding the determinants and predictors of SSIs and their outcomes involves wider interventions that go beyond the patients themselves in order to reduce the burden of diseases in mothers and children. Our findings from Sierra Leone highlight the need to urgently tackle SSIs more stringently.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S0950268820000370.

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Considering the gender narrative in the mirror of reality. How women consider and manage their right to health in some pastoralist tribes of South Omo Zone (Ethiopia)

PAPER

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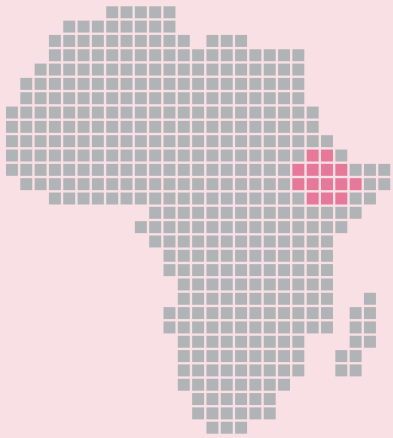

ILARIA MICHELI

Considering the gender narrative in the mirror of reality

How women consider and manage their right to health in some pastoralist tribes of South Omo Zone (Ethiopia)[1]

ABSTRACT

This paper is one of the outcomes of the International Cooperation project "*Mothers and Children First: newborn, children and women's health care among the pastoralist communities of the South Omo Zone, Ehtiopia*" funded by AICS and carried out by the Italian NGO *Doctors with Africa CUAMM* in 2016-2017. Despite the project's main objective was the implementation of the primary health care services delivered to women and children in the Hospitals and HCs of the Zone, it included a preliminary socio-anthropological investigation in the Hamar and Dhaasanach (Dasenech[2]) woredas, where the women's response to the services offered seemed to be much lower than in the other areas of the Zone. The research was carried out during two periods and with two different approaches: 1) the first one, in August 2016, visiting 5 households and 5 villages respectively in the Hamar and Dasenech woredas, doing observation and carrying out lexical mappings and semi-structured interviews with young wives, widows, husbands and elders focussing on maternal and newborn care and health; 2) the second one, in December 2017, carrying out an extensive survey based on the outcomes of the previous year. The data emerged from the comparison of the two parts of the research revealed that, despite women are aware of their unfair conditions with respect to their husbands, their need of support based on social/family ties seems to be still so strong that it generally prevents them from taking public positions and stand up for their rights.

Keywords: Anthropological Linguistics, Gender studies, Maternal Health, Ethiopia, Dasenech, Hamar.

Introduction

Despite by now already 30 years have passed since the publication of Marylin Strathern's masterpiece *The gender of the Gift* with its focus on the social and cultural construction of gender, referring to Africa (or to developing countries in general), scholars seem still to struggle very hard with the need to deconstruct, once and for ever, a colonial, Western-centered, monolithic view of what many people continue to brush off as patriarchal, backward societies.

The picture that comes out from such a simplistic approach prevents a true understanding of the different dimensions implied in the gender discourse: i.e. power, role, economy, exchanges, contacts as well as, of course, all the dynamics already analyzed in Bourdieu's theory of *practice* and in his conceptualization of *habitus*. Bourdieu himself with his theory of practice left the door open to change, despite the binding force of *habitus*, and more recent philosophical and anthropological theories on *normativity* (Copp, Post, Vogelstein), *morality* (Zigon) and *resilience* have had the credit to shed a new and more fruitful light on gender studies.

With this premises, living aside the licit, even tough sometimes too pervasive, feminist approach, I will try to discuss how women consider and manage their right to health in some Hamar and Dasenech pastoralist tribes of the South Omo Zone in Ethiopia with a holistic and multi-dimensional perspective. I will try to demonstrate how the adherence to the *habitus* can be seen not only as a passive choice, but also, in some cases, as a consciously, – even though hardly – adopted resilience strategy allowing women to keep and strengthen their social capital[3], made of a chain

[1] This paper was presented and discussed at the ECAS2019 Conference *Africa: Connections and Disruptions*, held in Edimburgh on June 12-14, 2019.

[2] Despite the more correct linguistic form for the ethnonym is Dhaasanach, we will use in this paper the graphic form commonly used in literature and other documents: Dasenech.

[3] See Grootaert & Van Bastelaer 2002 on the relevance of social capital.

of relationships, support and reciprocity. In a context where women's education and economic conditions are very limited, these relationships seem indeed to represent the only resource they can rely on.

This paper is one of the outcomes of the International Cooperation project "*Mothers and Children First: newborn, children and women's health care among the pastoralist communities of the South Omo Zone, Ehtiopia*" funded by AICS and carried out by the Italian NGO Doctors with Africa CUAMM in 2016-2017. Despite the project's main objective was the implementation of the primary health care services delivered to women and children in the Hospitals and HCs of the Zone, it included a preliminary socio-anthropological investigation in the Hamar and Dasenech woredas, where the women's response to the services offered seemed to be much lower than in the other areas of the Zone.

The research was carried out during two periods and with two different approaches: 1) the first one, in August 2016, during which 5 households (2 in Besheda, 2 in Shango and 1 in Dambayte) and 3 villages (Cies, Ocholoch, Libemuket) were visisted, respectively in the Hamar and Dasenech *woredas*, doing observation and carrying out lexical mappings, semi-structured interviews and focus group discussions with young wives, widows, husbands and elders focussing on maternal and newborn care and health; 2) the second one, in December 2017, during which an extensive survey based on the outcomes of the previous year was carried out in the two woredas. The data emerged from the comparison of the two parts of the research revealed that, despite women are aware of their unfair conditions with respect to their husbands, their need of support based on social/family ties seems to be still so strong as to generally prevent women from taking public positions and stand up for their rights.

This study will focus on the traditional and cultural factors hindering the Dasenech (Afro-Asiatic, Cushitic, East, Western Omo-Tana) and Hamar (Hamar-Banna, Afro-asiatic, Omotic, South) peoples to look for and take advantage of the MNCAH services offered.

Dasenech and Hamar are patrilineal nomad pastoralists.

In both societies women are in a position of submission to their fathers and husbands and they usually get married very early after their first menstruation[4].

The Hamar and Dasenech traditional culture admits polygamy and, therefore, a man's resources and attention have to be shared among 2-6 different family units. This element is crucial in understanding the dynamics which push women to look first and foremost for social approval. The quasi-perfect adherence to *tradition*, which leads to the impossibility to take actions and make autonomous decisions also when their children's life is at stake, is part of this mechanism that we could easily call "the power of *normativity*".

In holistic societies in general, *normativity*, seen as the indirect pressure of the community on the single person in terms of expectations about his/her social behavior is extremely high and this brings sometimes to a true paralysis. In most cases this paralysis is outdone through the establishment of informal ties based on self-help and reciprocity networks among different transversal groups of people inside the community itself. Crucial for a better understanding of the actual condition of women in the Hamar and Dasenech context is thus the identification (if present) of their informal networks of relationships and reciprocity within their social environment.

Despite both Hamar and Dasenech people are pastoralists and live in a more or less similar ecological context, their customs in terms of solidarity networks inside and outside the family (both nuclear and extended) are very different, being definitely lesser meaningful among the Hamar, where women are usually alone also in the moment of delivery, and much stronger among the Dasenech, where, on the contrary, women can rely on a specific first wives' council, parallel to the men's one (*arra*) in order to make their voices heard in front of their community.

[4] Child marriage is still very common also in less remote areas in Ethiopia. See Erulkar & Mathengi 2009; Gurmu & Dejene 2012.

The Hamar live usually in isolated households (HHs), while the Dasenech, despite their mobility, live mostly in village-like settlements, where different lineages or clans share the same space, building a true community. This implies that once a Dasenech girl becomes a bride it is sometimes possible for her to remain to live in the same settlement of her original family.

As a consequence, the possibilities and modalities of intervention on the one or the other context are very different and must be very carefully considered.

From the preliminary project baseline assessment made by CUAMM in the South Omo Zone, it was noticed that poor education, the lack of money, together with poor infrastructures and long distances from the HC are currently the main factors impeding the women's access to MNCAH services[5] and this is of course true.

Nevertheless, this study will focus on other, too often neglected, culture- and context-bound elements that interfere with a correct process of *Behavioral Change*.

In other similar studies elsewhere in Africa (Holten 2013, Roth-Allen 2004) this point has already been proved and described, but each specific culture has its specific characteristics which deserve due attention.

Before discussing the research outcomes and going to my conclusions, I will briefly try to describe the conditions of women in the traditional Hamar and Dasenech contexts (see Brüderlin 2012 and Elfmann 2005).

Being a woman in the Hamar context

Being a woman in the Hamar, patrilineal and patrilocal context means to be always subjected to the wish and will of men. First the father and then the husband are those who can decide a woman's destiny. The birth of a girl in a family is a positive event, because it represents the occasion, for the father, to get the bride-price as soon as she is ready for marriage. Hamar girls are considered a precious good to "*sell*", so to say, to the better tenderer. The price of a bride in the Hamar tradition is fixed, but the fathers of the most beautiful girls, as well as those belonging to the most respected and rich lineages, can obtain more advantageous conditions during the bride-price negotiations in terms of lesser deferments and delays in the payment.

Considering the life-stages of a woman, three passages are marked by a change in terminology, which correspond to consequent changes in her expectations, activities, socail roles and position according to tradition. These three passages are:

1. the first menstruation (*doobi*);
2. marriage;
3. the birth of the first child.

A baby girl, until her first menstruation is called *naanu*, and is considered a child.

It is, however, possible that, already as a *naanu*, a girl is promised to a man as a bride.

After the *doobi*, which is underlined by a family ceremony, the girl is called *ansanu* and from this very moment she can get married, since Hamar do not practice any FGM. Celebrating a daughter's marriage represents for the father an occasion to get cows and/or money and therefore, Hamar girls usually get married at a very early age. After her marriage, the girl becomes a true woman and is called *uta*. At the birth of her first baby she is addressed to as *gul*.

A marriage is decided by the bride's and the groom's fathers during specific negotiations. Once the girl's father has given his consent to the marriage, the girl cannot refuse to marry. A marriage can be decided also when a girl has not had the *doobi*. In this case she remains in her father's HH until the *doobi* comes and, only after this, she must join her husband's compound.

Despite the average age for a woman's marriage in the Hamar context is around 18, during the fieldwork for this research I met many girls younger than that who were breastfeeding their babies and, therefore, I guess they got married at least a couple of years earlier.

According to B.L., my gatekeeper in the Hamar *woreda*, the average age for marriage is diminishing both for male

[5] See also Birmeta 2013 for Ethiopia and more in general Gabrysch & Campbell 2009.

and females due to the fact that Hamar people are becoming richer.

If Hamar girls and young men had traditionally the custom to get married respectively around 18 and 20, nowadays their age at the moment of their marriage falls down at 15 and 18 respectively.

According to the men gathered for our FGD, the bride-price for a Hamar girl implies that the boy's family pays to the girl's father 28 goats, 10 or 20 oxen (depending on the bride's family prestige) and 3 calabashes of honey (nowadays just symbolic).

Given the structure of the Hamar settlements, and the rule of extra-clanic marriages, it is very common that when a girl gets married, she goes to live quite far away from her original family. Solidarity networks with her blood relatives are thus *de facto* most of the times abruptly broken. Divorce is something quasi-impossible in the Hamar culture. Indeed, a woman can go back to her original family only if she does not bear babies. Even in case of an extremely violent husband, a wife is never allowed to leave her husband's house with her children. Children, in fact, belong to their fathers and can never be taken away from their clan. Therefore, children represent the true tie which obliges a woman to stay with her husband, no matter how badly he behaves towards her.

Only in documented, extremely violent cases, when a man beats his wife too hard and too often, the woman's original clan can try to do something and the woman can temporarily leave her husband's *delo* (HH) and go back to her parents.

In this case, the men of the woman's clan can either decide to take initiative and beat the violent husband, or wait for him to come and reclaim his wife, profiting of this occasion to make him pay a meaningful fine as a means to have his wife back home. This is obviously impossible if the woman is married too far away from her original village and this is the reason why a Hamar man usually looks for wives far from home, while, whenever possible, a father prefers to marry his daughters to men in a close-by settlement.

Since she lives far from her original family, it is self-evident that usually a Hamar woman cannot rely on the *natural* solidarity networks with her blood relatives and, therefore, she is completely subjected to her husband's will. In a word, her degree of autonomy, above all in the first times of her marriage and, for example, during her first pregnancy, is equal to zero.

In fact, both the face to face interviews I recorded with Hamar women in their own huts, and the FGD we held in the village of Shango, reflected a picture of extreme loneliness.

A Hamar woman spends most of her time alone in her hut, at the extreme point that she is often alone even when the moment of labour and delivery comes.

Even though in the same compound usually there are at least two co-wives, despite what is reported in literature and despite the traditional narrative usually refers to a state of mutual care and support between the co-wives, in reality most of the times they see each other as a menace to their own marriage. Therefore, they usually do not trust each other very much and, in case of need, each of them prefers to rely on her own children or on the neighbors.

This puts the Hamar women in an extremely weak social position.

Of the 13 women attending the FGD in Shango, who had an average of 5 children each, only 2 declared to have given birth, at least one time in their life, at the presence of a TBA (traditional birth attendant), while all of them admitted to have delivered alone in their hut at least one time.

None of them declared to have ever delivered in a HC or HP[6].

However, the co-wives, in a sense, still help each other, as emerged from a face to face interview in HH4 in Besheda, since the majority of them admitted that the presence of more wives in a family means at least lesser work for each one of them. From the husbands' point of view a second/third or even fourth wife is necessary when the lineage is poor and it needs to grow in number and resources.

[6] From my field diary: "How many children have you born? In the group of the elder women, the answer was: a) 7ch, b) 4ch, c) 5ch, d) 6 ch. In the group of adult/young women the answer was: aa) 4, bb) 4, cc) 5, dd) 3, e) 7, f) 2, g) 5, h) 4, i) 3. This means that a Hamar woman in her lifecycle has approximately between 5 and 7 children, and this is confirmed from what we saw during our visits to the HHs". Of course we do not consider here those children who eventually died at a very early age.

As far as money is concerned, most of the men I met on the field declared that a Hamar woman has always a little pocket money, which comes from what she can earn selling sorghum, eggs or vegetables at the local market. In the men's narrative, women could use this money as they prefer, even for the purchase of beauty products (necklaces, soap and the like).

Indeed, the women told us another story. Most of them declared that they do not possess any private pocket money. Everything they can earn selling vegetables grown in their own gardens is perceived as belonging to their husband and it is their opinion that the husband only – in very few cases in agreement with his wife/wives – can decide what to do with it.

Of all the women met on the field, only widows dared to manage autonomously their own money and this point is specifically meaningful if we consider its implications on the health of mothers and children. Indeed, both from the interviews and the FGDs it emerged that only the father/husband or one of his male closest relatives can decide if and when to refer a pregnant woman or a sick child to hospital and, despite a woman could collect money from her neighbors, "*the husband is the leader of the house and if he says "no", that's "no"... "A woman must just sit here and wait*"[7].

A barren woman is called *gali* and people usually say she is *wèidi*, literally "useless"[8]. Her condition does not imply that she is chased away from her husband's HH, nor that her family has to pay her bride-price back to the husband's family. She must, instead, remain in her husband's *delo* where she is destined to spend her whole life caring for the other wives' children and serving her husband more than her co-wives.

When I asked to the men what they thought and how they considered a barren woman, they always answered that, since they pay the same price for a barren and for a fertile woman, they treat the two in the same way. Nevertheless, some of the women admitted in private that the treatment reserved in the compound to barren women is not at all similar to the treatment reserved to fertile ones.

The first wife, in the Hamar context, is not only the eldest one, but also the most respected since she is in charge of the spiritual pureness of all her co-wives and their children.

The sexual and fertile life of the Hamar wife is strictly bound to the concepts of *mingi* and *barjo*.

To be *barjo*, i.e. *blessed*, people must avoid anything that could cause a baby to be or to become *mingi*, i.e. *impure*.

In order to be *barjo* a baby must be born after a series of pre- and post-natal rites (*gilo*)[9], some of which are celebrated by a male ritual figure (the *baje*), and some others by the first wife (*geshono gembo*).

The *gilo* which must be performed before the mother gets pregnant is the *gungulo gilo*, which has the aim to give the baby a *barjo*, a good destiny. If a woman gets pregnant before the *gungulo gilo*, the baby has to be aborted.

If the *gungulo gilo* has been done correctly and the baby is born safe, after his/her birth, it's up to the first wife to lead two other rites before the baby's mother can get pregnant again. These two *gilos* are the *gali gilo* (the name-giving ceremony) and the *gore gilo* (the band tying ritual, which has the aim to *tie* the baby to his/her family). If these two rites are not performed, the mother cannot go through a new *gungulo gilo* and, therefore, she cannot get pregnant again.

According to Brüderlin 2012, if the *gilo* are not performed before the birth of a second baby, both the newborn and the previous one have to be killed. However, even though this should be the general rule, according to my informants, at the proof of reality, the only baby who is considered *mingi* and, therefore, aborted or killed, is the last one.

As the responsible for all the *gilo* of her co-wives, the first wife is thus the one who can exert a specific control over the births of the whole family and over the number of children of all the other wives. In simpler words, the family planning of a Hamar compound lays in the hands of the *geshono gembo*.

The *geshono gembo* is recog-

[7] From my field diary – Besheda HH2.

[8] The same expression, *wèidi*, is used referring to a child's death.

[9] See Brüderlin 2012 for a detailed descriptions of all the *gilo*.

Fig. 1. A Hamar geshono gembo *with her* binjere *necklace.*

nizable in that she is the only one in the compound who wears the *binjere*, a big, black, heavy, necklace, made of metal and leather, which she can take off only when her first daughter gets married or she goes through the ceremony of the bull jumping.

Being a woman in the Dasenech context

The life of a woman in the Dasenech context is marked by four principal events (cf also Elfmann 2005):

1. the *neyra*;
2. the *d'immi*;
3. the marriage;
4. the birth of her first child.

Each one of these passages implies a change in terminology.

Before the *neyra*, i.e. the FGM implying the ritual cutting of the clitoris and of the *labia majora*, the girl is just a baby. After the *neyra* she becomes a *marti*, and this means that, as soon as her father takes part to the *d'immi* ceremony, she can get married.

The *d'immi* ceremony is a community event during which the fathers of all the girls who have gone through the *neyra* together pay goats and beverages for a feast for the whole village.

Immediately after this, the *marti* can get married.

After her marriage, a *marti* becomes a *nyakhataran*, i.e. a bride, and only after the birth of her first baby she becomes a true woman, a *minni*.

The term *minni* means at the same time "woman" and "wife".

Both the *neyra* ritual cutting and the *d'immi* ceremony can take place before the girl's first menstruation. As a consequence, a Dasenech girl can get married when she is *de facto* still a child. However, in this case, the child-bride remains in her father's hut until her first menstruation comes. Only after this, she joins her husband in his own hut (*bil)* and starts having sex with him.

For the *neyra*, usually all the girls of the same *lol* (generational class) gather together and go for a ritual washing to the Omo river. Once there, they take a ritual bath and, after that, the *min gal id michwa*, the FGM ritualist, cuts them with the *fadi* knife. Before the cutting, the *fadi* is neither cleaned nor washed, and the same knife is used on all the girls.

No traditional or biomedical remedy is used to help the cuts heal up.

The *d'immi* ceremony is usually celebrated a couple of months after the *neyra*.

Concerning marriage, despite a Dasenech girl has no right to choose her groom, in most cases nowadays she can actually refuse a partner she really doesn't like.

In the Dasenech culture, the steps which characterize the marriage negotiations are three: *abunna*, *garr* and *galim*. During the *Abunna*, lit. "coffee", the groom clan's delegate asks for the girl's hand. During the *garr*, the elders of the two families meet again in order to seriously discuss the issue and come to an agreement. The final step is *gali*, which represents the ritual seal of the marriage, marked by the slaughtering of a goat.

When a boy and a girl fall in love (or when a boy *wants* a girl, even against her will), they can try to force their marriage, leaving the village together for some days and having sex. Once they come back to the settlement after this rupture of a true taboo, the two families are obliged to negotiate and let them marry. However, in this case, if the girl's family does not accept the negotiations, the boy's family usually shall pay 8 cows and the girl is set free to marry another boy.

Contrary to what happens in the Hamar culture, in the Dasenech context, even though exogamous marriages are privileged, a girl can marry a man of a different clan who,

however, lives in the same village of her own. Therefore, in this case the solidarity networks with her blood relatives are not so abruptly broken as it happens in the Hamar society.

Moreover, the Dasenech bride-price is not fixed and it is paid step by step at the birth of any new babies. At the moment of the marriage, the husband just pays one cow (the so-called mother's cow), to the girl's mother and one goat to each of the girl's stepmothers. Afterwards, for each new baby the woman bears, all her relatives, both on her father's and mother's sides, receive their share, be they male or female. There is no difference in the price paid if the baby born is male or female.

This is probably the reason why a Dasenech woman can easily divorce and abandon her husband until the birth of her first child. Indeed, until she is a *nyakhataran*, a girl can decide to go back to her original family if her husband mistreats her, and her original family doesn't have to pay-back a bride-price which, *de facto*, has not yet been paid. A *nyakhataran* who decides to go back to her original family can anyway get married again and it usually happens very soon. In this case, in fact, on the one hand the new husband will not have to pay the ritual mother's cow, and the girl will thus result lesser expensive than a virgin. On the other hand "she has demonstrated to be a woman" (from my field diary – Ocholoch, meeting with men).

This type of procedure for the payment of the bride-price represents at the same time a guarantee for both parts. If, on the one hand, the bride is free to go back to her original family in case of mistreatments by her husband, on the other hand her husband is free to send her back if she does not generate an offspring.

When I asked the elders of Ocholoch if a barren woman is treated as equal to a fertile one by her husband, the discussion got animated.

In the end the answers proposed in the men's narrative were two:

1. if a woman is barren, but her husbands loves her, because she is loving and takes good care of him, he can pay 5 cows to her family and keep her in his HH, treating her like the other wives;

2. if a woman is barren and the husband doesn't love her in a special way, the two can divorce and the woman must go back to her original family.

If a barren woman remains with her husband she is supposed to take care of the other wives' children and, if she is a first wife, she takes the name of the second wife's first child and her role as peacekeeper in the house is respected.

Even though the traditional narrative provides that barren women should not be blamed, it is instead very common that, even though they remain in their husband's *d'èyo*, they live there as servants of the other co-wives and their children.

A barren woman will always be called *nyakhataran*, what means that her evolution towards *woman-hood*, i.e. towards becoming a *minni*, is, maybe unconsciously, considered impossible.

While a Dasenech girl is often in the graze-land following the cows, once she gets married and she bears her own children, her place is her husband's *d'èyo*. She stops herding and dedicate herself to the fields or, eventually, to the market.

A Dasenech woman can never refuse sex to her husband.

With respect to their economic possibilities, Dasenech women usually sell only coal or wood at the local market, being their sorghum or beans harvesting sufficient only for the family. According to the traditional narrative, the money they earn selling these goods could be used for their own needs. However, again, women see it differently and most of them usually think that only their husband can decide how to use great part of this money, for example when a child or one of the co-wives is sick. If an accident happens when the husband is not in the village, only one of his closest male relatives can decide what to do on his behalf.

Concerning polygamy, the Dasenech can have up to six wives. The elders I met during my fieldwork had an average number of 5 wives. Each woman has usually 4-7 children. Therefore, it is very common that an elder has a number of

children which goes from 20 to 30.

The husband is always the leader of the *d'èyo* and, *if needed* (again an interesting point of view!), he can punish his wives and children with extreme violence. The men gathered for the meeting I held in Cies, in fact, agreed that:

> Husbands have the right to punish their wives beating them with a traditional whip (*lotch*). If the woman is pregnant they will avoid the whip and beat her with their shoes, being careful not to hit her womb. Dasenech fathers also use to beat children with a stick (*lotch*), but only on their legs (not on the head or upper part of the body). Dasenech can use also a stronger whip for beating women and animals, which is made of a hippo skin. The name of this whip is *iye* (lit. hippo). They buy this whip from the fishermen (dies).

However, if a woman has too serious problems with her husband, she can refer to the men's *arra* (elders' council) with or without the mediation of the first wives' council, and ask the elders' support in order to obtain her divorce from him. Usually the men's *arra* tries first to negotiate with the husband, letting him pay fines and asking him to modify his behavior, in order to bring the peace in the *d'èyo*. If the negotiations do not come to a good solution, the *arra* can decide to let the woman go back to her original family. According to J. and M., my gatekeepers, this happens, however, very rarely (in one case out of hundreds).

The first wife is called *min gudwa*, the big wife. The second one is called *minni na* (lit.: little wife), while the last one is the *min' kara* (lit. *the woman of the chair*, since she is the one in whose hut the husband usually sits).

As it is typical in the narratives referring to most polygamous contexts, also in the Dasenech case, the ethnographic literature speaks of a good cooperation and positive attitudes of the co-wives towards each other, in children rearing and, in general, in everything that has to do with the well being of the whole family. Contrary to what I could record in the Hamar *woreda*, all the women I met during my fieldwork in the Dasenech villages agreed on this point and what I could witness with my eyes goes exactly in this direction. In this case *narrative* seems to coincide with *reality*.

Indeed, in my field diary, about a meeting held in Ocholoch, I wrote:

> According to the women co-wives usually really help each other. One of the elder women raises her hand and asks to speak. She tells me that her husband has three wives, and all of them live together in the same compound, even though each one has her own hut. Anyway, the children of each of them are the children of everybody, there is no difference among the ones she has born and the ones the other wives have born in their turn. They live peacefully and help each other. The husbands treats all of them in the same way and they three, together, must take care of (and can use) their husband's goats and cows as they like. She then tells me that one of her co-wives is present in the hut and I notice that they are sitting close to each other, and really seem to be in a good relationship. When, during the meeting, we speak of the TBAs' job, both of them, who declared to be TBAs, co-operate in order to show me the right position for a woman to deliver etc. The husband of this two women is dead, but they say that they still go on helping each other like when he was still alive. The solidarity network of a Dasenech woman in her village goes beyond the compound and, in case of need, «also the neighbors can help… if I do not have anything to cook and my neighbor prepares, then we all will eat together».

Concerning migration, the Dasenech usually move in a group of 20 to 30 people, belonging either to the same family or to the neighborhood. These migrations happen only during the rainy seasons. The Dasenech, however, see their villages as their home-towns. When the adult and strong population migrates to the graze-lands, the elders remain in the village, together with some of the women with their children. If a woman is pregnant and the time of delivery is approaching, she also remains at the village and, in case of need, she can refer to one of her husband's male closest relatives (his father or one of his

Fig. 2. The two Dasenech co-wives showing me the right position for a woman during delivery.

brothers or uncles). If even a pregnant woman follows her husband in the graze-land during the rainy season, when the time for her delivery approaches, she goes back to the village, where a TBA is always at hand.

A short excursus is needed here, in order to speak of the Dasenech taboos concerning children and death.

No Dasenech woman likes, in fact, to speak of her children and in the Dasenech villages I visited it was very hard to meet women walking around with very small babies on their back, as it is so common everywhere else in Africa. The babies I met, even those who were still breastfed, were never younger than one year.

Even though Dasenech women do not have to respect a period of seclusion after delivery, they usually remain in their *bil* (hut) as long as possible, and their babies are kept hidden from foreigners at least until they start to crawl. When mothers go out, they "envelop" their babies in a kind of a leather bag, in order that no one can see them and, until the babies start to walk, only the members of the family (cognates and agnates) can see them. What their mothers fear the most is, in fact, the *ma ill gwa*, the wicked eye of people outside the family, which could cause the babies to get ill or even to die.

Also death is a taboo for the Dasenech people. When a father dies, only his first son participates to his burials, and when a woman dies, it is up to her husband to bury her. If the husband is no longer in this world, then it is up to the first son of the couple to bury his mother.

During a burial, nobody can stand by. If the dead is an old man, he is buried in his compound and the people of the compound just move with their *bil* a bit further. If it is an adult man or woman, his/her first son brings him/her out of the village and bury him/her in the desert.

If the dead is a baby who has not left the hut yet, he is buried inside the hut, very close to the firestones, where also his placenta had been buried when he/she was born. If the baby who dies is already able to walk, then he/she is buried outside the village like an adult.

Data from the field. The attitude of women and their possibility to take action

Despite the adult literacy rate in Ethiopia is growing and in 2017 it was attested at 39% in general, with males at 49,13% and females at 28,92[10], according to Ethnologue in 2014 the average literacy rate in L2 (i.e. the language of the school) for the Hamar was 1%, while for the Dasenech it reached 2%. This means that formal education is *de facto* absent in the two *woredas* we are considering. Indeed, despite the fieldwork had been very well organized by the CUAMM staff in advance, it was impossible to find at least one woman in the Hamar context to be employed as an interpreter, while in the Dasenech area I had the possibility to work with M., a young Dasenech woman, who could get her bachelor, could speak a quite acceptable English and lived alone with her children and her partner (it is interesting that she did not refer to him as to her *husband*) in Omorate far from her native village and from the social control the village implies.

This extremely low literacy rate, together with the very low age of both women and men at marriage, lay at the basis of the dramatically poor degree of emancipation of both Hamar and Dasenech women.

Despite women, above all in the Hamar *woreda*, expressed fatigue and in many cases unhappiness, together with a sense of pervasive loneliness

[10] https://countryeconomy.com/demography/literacy-rate/ethiopia.

and disenchantment towards their duties and their possibilities inside their homes, only very few of them showed a true will and a real engagement in change, if not for themselves, at least for their daughters.

Probably not by chance the most courageous and active women in this sense were widows.

In both context, in fact, despite the tradition of levirate marriage, when a widow is in her menopause and/or she has an adult son who can take care of her, she can remain to live with him. This implies that, from that moment on, she reaches an otherwise unexpected degree of independence, being free to save a little pocket money for herself and, above all, being free to decide (eventually discussing the issue with her son) wether or not to let her younger children study.

As a matter of fact, among the Hamar women I met on the field, only three women (all of them widows) had had the possibility to enroll at least one of their daughters in primary school.

By the way, widows and elder women have also been individuated as the probably most reliable referents for community based project at the moment, because we realized that they could probably be the only ones with a certain real possibility of agency also outside their own HH or village.

It is now self evident that, at least at present, the acknowledgement of equitable opportunities to young girls and boys is something still impossible to envisage both in the Hamar and in the Dasenech communities.

As well as women are trapped by traditional morality and *normativity* in a position of inferiority and dependance, men are trapped in their role of extreme masculinity, power and violence and many wives who should be happy not to be mistreated by their husbands, refer to fear that their husbands "do not love" them, since they usually do not beat them.

Emblematic in this perspective is the attitude of joy with which young Hamar girls not only accept, but really desire to be hardly whipped by their brothers during the rite of passage of the bull jumping, in order to demonstrate their femaleness, their strength and their devotion. The more they appear resistant in that occasion, the more possibilities they have to be chosen as brides by good, rich and powerful partners. The same is true with respect to their patience and strength in suffering the labour pains and getting on with the birth of their babies on their own. Crying or fading during the act of delivery is considered a shame in both communities and, when it happens at the presence of elder women, the new mother is beaten and insulted by them, losing, in a way, the right to their respect and support. This is probably why, in the Hamar context, women prefer to deliver on their own, alone in their hut and far from indiscreet eyes and ears.

For all these reasons, in my opinion this choice is not to be seen as a passive acceptance of traditional rules, but as a conscious strategy performed in order not to lose their, already precarious, social status.

In both communities, Hamar and Dasenech, I had the occasion to discuss a number of similar little strategies indicating a high degree of self-consciousness and agencies on the part of women, even though very limited in their outputs.

During one of my visit in Besheda, I met a young, apparently very modern family. When I arrived at their HH, husband and wife were there, sitting together in their hut. The husband was about 25 years old, while the wife was around 18. For the moment she had no co-wives. The couple had two babies, one of 3 and the other a toddler of 1. The youngest had still not grown all his teeth, and this was for me the starting point from which I could "test" their perception and hypothetical behavior toward *mingi*-ness. I first congratulated them for their babies and then I introduced the issue, asking them what they would do if one of their children would ever be born as *mingi*. The two looked intensely at each other and finally the father answered: "*to avoid killing babies and all these* mingi *things, it suffice to hide in the family the signs of* mingi-*ness. If people do not know, then they do not ask you to kill your baby*".

I found this answer quite

revolutionary and at the same time relevant for the objective of the present work. Indeed, the young father's words revealed two things:

1. *Normativity* and *Social control* do not characterize and influence only the women's agency, since also men seem to be in the same condition, sharing the same burden – in our case, if it is true that the husband can decide to go against tradition, he declares anyway that he would do it trying to hide his action in front of the community;

2. despite the high degree of social conditioning, there is always a way to negotiate or to find an alternative exit strategy.

Going on discussing with the couple, I then asked their opinion about polygamy. The husband declared without hesitation that as soon as he would be rich enough to *buy* (I asked the perfect translation of the term to my interpreter and the man really used the verb *to buy* and not *to marry*) another woman, he would do it without asking his first wife's opinion, because it is also for the first wife's sake that a rich man *buys* other women, so that she can relax and share her duties with the others. On her side, the wife supported her husband's words and declared to look forward the day in which he would really bring home a new girl, so that her status will finally be recognized and appreciated.

What prevents Hamar women to stand up for their rights is also their difficulty in meeting each other. Living usually in semi-isolated HHs, in a condition of economic and relational poverty, is of course not at asset and the only occasion of meeting they have is during the market days.

On the contrary, the situation is different in the Dasenech *woreda*.

Despite the Dhaaanach land is even more hostile in ecological terms, than the Hamar one, the fact of living in a village and, above all, the possibility to organize themselves in the first wives' council, undoubtedly represents a strong tool for their self-determination.

In line with the Dasenech tradition, the existence of the women's council allows Dasenech women:

1. to gather and discuss their issues freely and far from the men's ears;

2. to decide a common strategy, e.g. wether or not to accept the visit of external NGOs (of course only after that these foreigners have obtained the *arra's* allowance to meet the village women);

3. to organize themselves in self help groups for economic, educative, or emancipatory actions.

During a couple of meetings with the women council, extended to all the women and girls of the village of Ocholoch, I had the possibility to explain them the activities of CUAMM and ask them how CUAMM could respond to their needs.

The discussion went on both times for longer than two hours and it was very exciting to witness the animation and interest of all the women present. The discussions were sometimes interrupted by songs and personal narratives, and the context was extremely relaxed. I noticed that, when some young adult males tried to join the group, the eldest women felt free to chase them away: our meeting could go on without their unwelcome observation and the women had no consequences for this.

At the end of our two meetings, the traditional midwives, who, in a way, represented the group spoke-persons, asked for a handy-phone, in order to have the possibility to call for help in case of need for the sake of pregnant women or of their newborn babies.

The women attending those meeting were very attentive, questioning, excited and participative. They did not fear speaking with us and telling us their opinions or sharing with us their fears, their personal opinions or their wishes. Indeed, I had the neat impression that from there we could start a good cooperation, what revealed itself true.

On the contrary in the Hamar *woreda* it was impossible to speak with a group of women alone, far from the eyes and ears of their men. Even during the FGD in Sango, men were present and no woman, except for a couple of widows, had the courage to expose herself expressing her thoughts in front of the males.

Isolation and the lack of female solidarity networks is thus really the key element to consider when trying to approach women and stimulate their will of emancipation and agency.

During the second period of fieldwork, the sociologist Riccardo Occa with the CUAMM team based in Jinka, submitted 111 surveys to 59 Hamar and 52 Dasenech women regarding very specific points of their experience as pregnant women and mothers of very young children.

Besides confirming many aspects of the conditions of these women which emerged both from literature and from the qualitative research carried out in 2016 (their very early age at marriage, the impossibility to choose their partner, the high number of children, the impossibility to take decisions regarding their own health as well as that of their babies without their husband's consent or going contrary to a suggestion by the husband's mother[11]), the answers to the surveys in the two *woredas* confirmed also, in a way, a different attitude with respect to certain traditional behaviors reputed unsafe for the babies' health.

I give here just two examples.

Both in the Hamar and Dasenech traditions it is unthinkable, for a mother with a scarce possibility to breastfeed due to a lack of milk, to rely on other mothers of the family who could breastfeed their babies. The reasons rooted in traditions and indicated by the

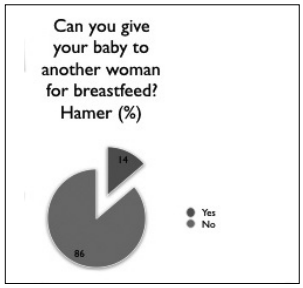

TABLE 1A

TABLE 1B

women are usually three: 1) because of the family blood-type; 2) because another woman's milk makes the baby sick; 3) another woman's milk would not be sufficient and it could transmit diseases.

Even admitting that, from a medical point of view, in some cases breastfeeding can be risky, because diseases as HIV or other infections could be transmitted to the baby, if the nanny is healthy, her milk is definitely better than the milk of a cow or even better than artificial milk, when diluted in polluted water, as it would be the rule in these contexts where people are neither used to boil water before using it for alimentary purposes, nor is the purchase of bottled water so easy for many families.

In the Hamar context only 4 out of 59 women accepted the idea of relying on a nanny for their baby. On the contrary, in the Dasenech context, more that the double, 11 women out of 52, admitted it could be a resource, even though with some reluctance.

In this case a great role is probably played by the different perception of the other women's reliability. In addition, the strong and very elaborated normative behavior surrounding motherhood and characterized by the fear of *mingi-ness* in the Hamar context is probably a major impact factor (table 1).

The second example refers to a quite dangerous practice, very common to both areas, but, this time, much more pervasive in the Dasenech society.

In the Dasenech tradition, immediately after birth and before the first breastfeeding, the baby is given liquified butter in order to "*cleanse its stomach*". The same practice is repeated every day from the baby's birth and until it "*is strong enough*". According to the WHO guidelines on weaning and nutrition, giving a baby anything different from maternal milk in the first 5 months is very dangerous, since a newborn baby has still not developed a proper immune system.

Now, what emerged from the survey on this specific point was that:

1. 22% of Dasenech women (11 out of the 50 who answered this question) declared to have avoided the traditional cleansing of the baby's stomach because, in the words of 5 of them "*after education I won't give my baby anything before the 6th month*";

[11] On the role of elder women or of mothers in law in issues regarding babies' health, see also Brezner *et al.* 2008; Holten 2013.

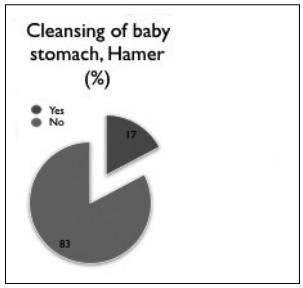

TABLE 2A

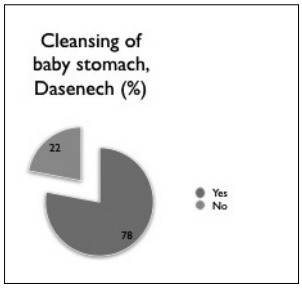

TABLE 2B

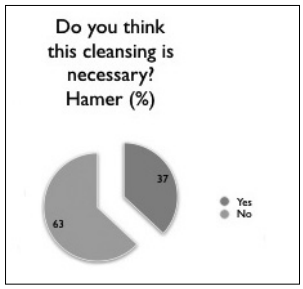

TABLE 2C

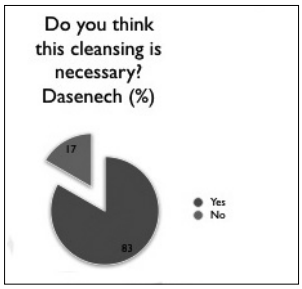

TABLE 2D

2. 78% of them, however, not only did the stomach cleansing, but they also added that "*it prevents constipation and it is useful for the baby's growth*"[12] (table 2).

Despite these answers clearly indicate that the path towards emancipation for Hamar and Dasenech women is still very long, at least they let us think that:

1. the educative campaigns promoted by the Government or other NGOs[13] previously active on the field had had in the Dasenech context at least an initial greater success than in the Hamar one;

2. Due to its different traditions in terms of settlements, proximity to the women's original families and possibility to have a voice expressing common needs in front of the community, the Dasenech society is at the moment probably more ready to accept and participate in cooperation projects regarding women than the Hamar one.

Conclusions

The gender issue is not new to Ethiopia and despite both feminist and homosexual activisms have already appeared on the Ethiopian political stage, as described by Blystard *et al.* 2014; Tedele 2011; Thubauville & Gabbert 2014 and White 2011, the most remote rural communities of the country live in a condition of negation of even the most basic human rights in terms of gender expression.

In the mirror of reality – and of such extreme realities as those discussed in this paper –, the gender narrative cannot but leave aside its idealistic, western-born attitude. If the final objective remains equity and the respect of human rights for all, the points of departure of each society is different from that of the other and it is impossible to inject a social and behavioral change from the outside without understanding the reasons underlying the actual limitations of the one or the other specific group.

Sometimes it is possible to start from advocacy campaigns directed to everybody, but many times it is necessary to start from scratch and help local people first of all to create solidarity networks on which to build in the future, stimulating at least the will of finding an alternative way with respect to very basic resilience strategies stacked and trapped in the usual traditional dynamics as those here described.

Refusing to *cleanse* the baby's stomach with butter a few hours after their birth, going against tradition and sometimes against the will of grandmothers or first wives, is for a Dasenech woman an achievement which could be paralleled with the possibility to strive for a very high managerial position in a space agency in a Western country.

In traditional, rural, fragile contexts, as those here described, characterized by patrilinearity and by patriarchal power relations, no true change for women can be obtained starting from women only. Education for all, and for males in particular, should be the first step on which to build a new horizon for future

[12] About non exclusive breastfeeding in Ethiopia see also Tadesse *et al.* 2016.

[13] On maternal health care in this and in other zones of Ethiopia see also Birmeta 2013; Mengesha *et al.* 2013; Prata & Summer 2015; Shiferaw *et al.* 2013; Sonalkar *et al.* 2013; Tolo Østebø & Østebø 2014; Tsegay *et al.* 2013.

generations. A necessary, even though not sufficient step, unfortunately.

I report here the case of B.L., my interpreter in the Hamar *woreda*.

B.L. has obtained a bachelor in anthropology and he has been working since some years, more or less regularly, as an interpreter and mediator for researchers in Turmi and its surroundings. B. is thus a very educated man. Nevertheless, he is circumcised, he has done the bull jumping and he is currently married in the traditional way. His wife, H., who in 2016 was around 24 years old, had been chosen for him by his father. B. and H. had never lived together because B. had always refused to stay with H., since he had not fallen in love with her and declared to find this traditional marriage unbearable. Nevertheless, as it is the rule in the Hamar culture, he didn't divorce from her, but "gave" her to his younger brother. With this brother of B., H. gave birth to 2 children, one boy and one girl, who were respectively 8 and 3 years old in 2016. The two children are classificatorily and socially considered as being B.'s children, as well as any other children to which H. may give birth in the future. What surprised me a lot was the total lack of interest and sense of responsibility that B. felt towards this "wife" or these children, which he even did not considered as members of his own "family".

Indeed, I would have expected the deployment of troublesome sentiments in a young man, with a bachelor in anthropology, i.e. with the possibility to reflect at a theoretical level on his society and traditions. On the contrary, he told me his story without a quiver and without any apparent profound reconsiderations of his position as a "modern" male in front of a tradition which, in his words, he refused, but which he actually *de facto*, tolerated.

In conclusion, putting the gender narrative in front of the mirror of reality, the fieldwork in the Hamar and Dasenech *woredas* demonstrated at least three things:

1. Adhering to traditional behavior and to one's community expectations in a world in transition could represent for rural, fragile and very poor communities a conscious strategy of survival, both for women and men.

2. Going against tradition requires a high degree of courage, because in many cases it represents the subject's social exclusion from his original environment.

3. When people do not have high educative, social and economic resources, it is even more difficult for them to react and stand up for their rights.

21 ottobre 2019

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Heart Rate Determination in Newborns at Risk for Resuscitation in a Low-Resource Setting: A Randomized Controlled Trial

PAPER

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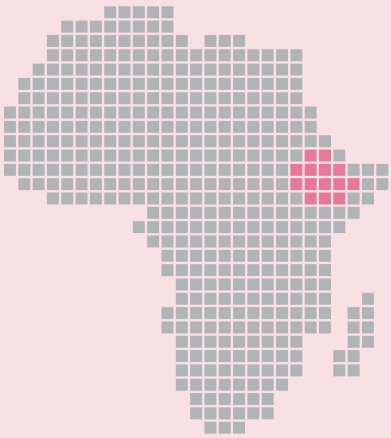

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Factors associated with mortality among asphyxiated newborns in a low-resource setting

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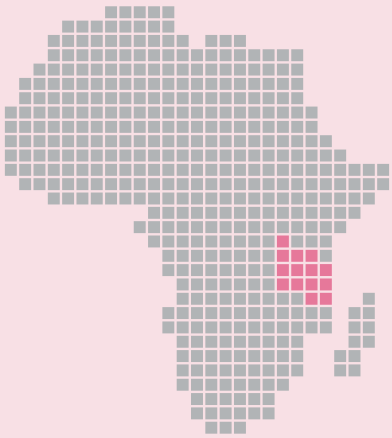

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Quality of health care for children with severe acute malnutrition in a refugee setting: cross sectional study in West Nile Region, Uganda

PAPER

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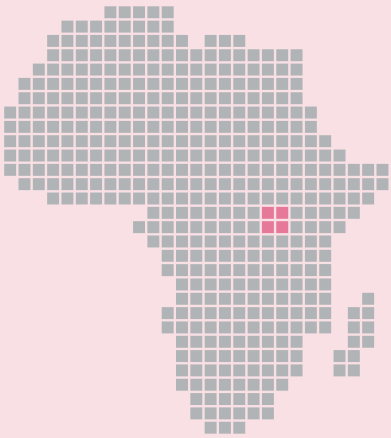

Open access Original research

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Quality of healthcare for children with severe acute malnutrition in a refugee setting: cross-sectional study in West Nile Region, Uganda

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ABSTRACT

Objectives 5.0 million annual deaths in low-income and middle-income countries are due to poor quality of care (QOC). We evaluated the QOC provided to malnourished children in West Nile Region in Uganda.

Design Cross-sectional study.

Setting West Nile Region, an area hosting over one million refugees.

Participants Among 148 facilities providing nutritional services, 30 randomly selected facilities (20%) and the records of 1467 children with severe acute malnutrition (100% of those attending the 30 facilities during last year) were assessed.

Outcomes The national Nutrition Service Delivery Assessment (NSDA) tool was used to assess capacity areas related to QOC. Case management, data quality and health outcomes were assessed from official health records. Multivariate analysis was performed to explore factors significantly associated with better cure rates.

Results Of 305 NSDA scores allocated to 30 participating centres, 201 (65.9%) were 'good' or 'excellent'. However, 20 (66.7%) facilities had 'poor' 'quality improvement mechanisms' and 13 (43.3%) had 'poor' 'human resources'. Overall data quality in official records was poor, while recorded quality of case management was overall fair. Average cure rate was significantly lower than international Sphere standards (50.4% vs 75% p<0.001) with a higher default rate (23.2% vs 15% p<0.001). Large heterogeneity among facilities was detected for all indicators. Refugee-hosting and non-refugee-hosting facilities had a similar cure rate (47.1% vs 52.1%) though transfer rates were higher for those hosting refugees (21.5% vs 1.9%, p<0.001) despite better 'equipment and supplies'. 'Good/excellent' 'equipment' and 'store management' were significantly associated with better cure rates in outpatient therapeutic centres (+55.9, p<0.001; +65.4, p=0.041, respectively) in multivariate analysis.

Conclusions Though most NSDA capacity areas were rated good or excellent, health outcomes of malnourished children in West Nile Region, both in refugee-hosting and non-refugee-hosting facilities, are significantly below international standards. Effective and sustainable approaches to improve malnourished child health outcomes are needed.

Strengths and limitations of this study

- This study explored the quality of care delivered to malnourished children in a refugee-hosting setting, an area which has been very poorly investigated in previous literature.
- The study assessed multiple indicators in each facility—including indicators related to the overall service capacity to deliver high quality care, process indicators on quality of case management, quality of data and health outcomes—thus exploring several different dimensions of quality of care.
- Limitations of the study mostly relate to poor data quality in official administrative records, from which most data were extracted.
- However, documenting poor data quality in official administrative records is a critical finding in its own right, and advocates for more investment to strengthen existing routine systems for data collection and analysis, in line with the WHO Global Strategy for Mothers and Children recommendations.

INTRODUCTION

Poor quality of care (QOC) has been implicated as a major risk factor for excess mortality across conditions, especially in low-income and middle-income countries (LMICs). Globally, an estimated 5.0 million deaths in LMICs are directly linked to poor QOC, while an additional 3.6 million excess deaths are due to non-utilisation of health services.[1]

Achieving high QOC may be even more challenging in humanitarian settings, such as West Nile Region in Uganda. According to a recent report from the United Nations High Commissioner for Refugees, since 2017 over one million refugees have fled to Uganda, currently is the third largest refugee-hosting country in the world with 1.36 million refugees.[2] Wars, violence and persecution in the Horn of Africa and Great Lakes region were the main drivers of forced displacement into Uganda, specifically South Sudan's conflict,

insecurity and ethnic violence in the Democratic Republic of the Congo, and political instability and human rights violations in Burundi.[2] About 92% of refugees live in settlements alongside local communities, and the largest number of refugees (over one million) are located in the West Nile Region in Northern Uganda.[2]

More than 60% of Uganda's refugees are children, with implications for protection and prevention services.[2] A survey conducted in October 2017 in refugee-hosting areas in Uganda revealed that the prevalence of global acute malnutrition in children ranged from 4% to 12% among refugee communities, and from 5% to 11% in hosting communities.[3] These data are in line with other studies conducted in similar settings which report high rates of malnutrition among children both in refugee camps[4–6] and in hosting communities, with large variations among districts.[2 4–7]

While previous studies in LMICs such as Kenya, Benin and Brazil reported substandard QOC for malnourished children,[8–10] very little is known about QOC delivered to children with malnutrition in refugee-hosting areas. A recent survey conducted in the district of Arua in West Nile Region reported an average cure rate for children with malnutrition of 52.9%.[11] However, the study included only a small sample of facilities, none specifically dedicated to refugees and none providing inpatient care.

In order to provide a more comprehensive assessment of QOC offered to malnourished children in West Nile Region, the present study was designed to include a larger, more geographically representative sample of facilities, including facilities of different levels providing both inpatient and outpatient care and facilities dedicated to both refugees and the local community. The study aimed to assess the overall service capacity to deliver high-quality care, the quality of case management, the quality of data and health outcomes at each facility. It also aimed to explore health facility-level factors associated with better cure rates. This study contributes to evidence on current QOC for children with severe acute malnutrition in LMICs and particularly in refugee settings, and may be used by researchers and policy-makers to design tailored interventions to improve the quality of nutritional services in Uganda and other similar settings.

METHODS

Study design and setting

This was a cross-sectional study, and the Strengthening the Reporting of Observational Studies in Epidemiology guidelines for reporting on cross-sectional studies were applied.[12] The study was conducted between 20 August and 7 September 2018 in the West Nile Region of Uganda. The region has a population of approximately 2 180 947,[13] with an estimated number of refugees at the time of the study between 1 074 000 and 1 200 000.[2 14]

Levels II, III and IV health centres (HCs) and hospitals provide nutritional care in Uganda. Based on the current national regulations, level II HCs should serve about 5000 people and be headed by a nurse working with other nurses and midwives to provide care for common conditions (eg, malaria, antenatal care). Level III HCs should be led by a senior clinical officer, serve about 20 000 people and have a functioning laboratory. Level IV HCs should have a senior medical officer and at least another doctor, be able to admit patients and carry out emergency operations and serve about 100 000 people.

In Uganda, outpatient care to children with severe malnutrition is provided in outpatient therapeutic centres (OTCs), which are usually located at HCs and, in rare cases, in hospitals.[15] Inpatient therapeutic centres (ITCs) are most often located in hospitals, with some in higher level HCs (level III or IV). Given the large number of refugees, some facilities for outpatient care are specifically located in refugee camps and are designated as refugee-hosting OTCs. Inpatient care for refugees is provided in the same facilities used by local community members (eg, 'non-refugees').

Health facility sample size and selection

Five refugee-hosting districts in West Nile region—namely Arua, Koboko, Yumbe, Moyo and Adjumani (see map in online supplementary appendix 1)—were selected for the study.

Out of the 148 facilities providing nutritional services in the five districts under study, a sample of 30 (20%) facilities was determined to be adequate to detect a 52.9% cure rate (identified as primary outcome), with a type I error of 5%, a 95% CI from 36.9% to 68.9%. The anticipated cure rate and its 95% CI were estimated based on the most recent relevant literature.[11]

Before randomisation, facilities were stratified in order to ensure geographical coverage, including a representative sample of about 20% of the total facilities in each district, with at least one centre providing inpatient care in each district, to include facilities from lowest level II HCs, to level III and IV HCs and hospitals, and to include at least 20% of all refugee OTCs (online supplementary appendix 2). Facilities offering either ITC or OTC services where health facility staff agreed to participate were eligible for inclusion in the study, while facilities with emerging security concerns impeding participation and those without staff assigned to be responsible for nutrition service delivery were excluded. Three districts had only one facility providing inpatient care, which were automatically included in the sample.

Study variables, data collection tools and procedures

Service capacity to deliver high-quality care

The evaluation of the quality of nutritional services was performed at each participating facility using the Nutrition Service Delivery Assessment (NSDA) Tool,[16] the official national instrument for assessing performance of nutritional services in Uganda. The tool assesses the following 10 capacity areas for OTC (see online supplementary appendix 3 for details): (1) general information on service implementation, assessing the existence

a person in charge of the nutrition service and a quality improvement team; (2) adequate human resources, evaluating the number, type and percentage of staff trained in six key courses; (3) provision of nutritional services, assessing all steps related to nutrition assessment of the patient, nutrition counselling and micronutrient supplementation; (4) community linkage, assessing links with community-based health workers and community groups, and effective referral; (5) quality improvement activities, investigating availability of a functional quality improvement team; (6) materials and supplies, assessing availability of guidelines, counselling cards and many other job aids; (7) facility nutrition equipment, assessing a list of 17 key items, including weighting scales, glucometers, and so on; (8) store management, evaluating conditions of the storage room and its management; (9) logistics management for commodities, assessing specifically logistical aspects, such as correct and regular use of order forms; (10) monitoring and evaluation (M&E), assessing five items, including the availability of a designated person for health management information system data, data collection and data use. The same 10 capacity areas were assessed for ITCs, plus requirements for inpatient care such as kitchen equipment and ingredients for therapeutic foods.[16]

Data were collected using predefined checklists and data sources including direct observation, document review and interviews with health workers, as indicated by the NSDA tool. Each area was scored based on the results of the checklists and according to predefined criteria, with four possible score categories: 'poor', 'fair', 'good' and 'excellent'. For example, to achieve a score of good under 'facility nutrition equipment', 12 out of 17 items need to be available. Similarly, to achieve a score of good under 'Store management', at least 13 out of 17 items in the checklist need to be available.[16]

Quality of case management, quality of data and health outcomes

Data on quality of case management, quality of data and health outcomes of children were extracted at each facility from the official 'Integrated Nutrition Register'. Each case of a child diagnosed with severe acute malnutrition and discharged in the period covering the financial year 2017/2018, which in Uganda covers the period July 2017 to June 2018, was reviewed. Integrated Nutrition Registers are the official documents at health facility level where all information on each malnourished child is recorded according to a standard format. Aggregate level data were collected using field-tested data collection tools (online supplementary appendix 4-6) developed based on national guidelines[15] and previous experience from similar evaluations.[11 17] The case definition of severe acute malnutrition was based on national guidelines, as follows: weight-for-height zeta-score < −3 SD, mid-upper-arm circumference (MUAC) <11.5 cm (6–59 months), or bilateral pitting oedema.[15]

Quality of case management was measured with the following five process indicators, using national guidelines as reference standards[15]: (1) correct diagnosis of malnutrition based on weight-for-height Z-score or MUAC; (2) correct treatment of malnutrition evaluated as correct ready to use therapeutic food dosage according to national guidelines[15]; (3) correct evaluation of HIV as per the national guideline[15]; (4) correct counselling of care givers on nutrition, ready-to-use therapeutic foods (RUFT) administration, hygiene and HIV; (5) correct exit outcome assignment as per national guidelines[15]; see online supplementary appendix 7 for more details.

Data quality was assessed using the following two predefined indicators: (1) data completeness (presence of 15 key items in Integrated Nutrition Registers); and (2) internal consistency (consistent visit dates and child height measurements over time (see online supplementary appendix 7 for more details).

Findings on case management and data quality were compared against predefined targets of at least 75% correctness, data completeness and internal consistency.

Health outcomes were determined for each child with severe acute malnutrition admitted during the study period following predefined categories indicated by the national guidelines[15]: (1) died (while in the programme); (2) cured (weight for height ≥ −2 SD or MUAC of ≥12.5 cm with no bilateral pitting oedema for 2 weeks and clinically well); (3) non-responders (not reaching discharge criteria after 3 months, or 4 months for patients with HIV/tuberculosis); (4) defaulters (absent for two consecutive follow-up visits); (5) transferred to inpatient care (ITC); (6) transferred to another outpatient care facility (OTC; see online supplementary appendix 7 for more details). Health outcomes were compared with SPHERE indicators, which represent the internationally recognised minimum standards for management of severe acute malnutrition in humanitarian response.[18] According to SPHERE standards, the acceptable cure rate should be at least 75%, default rate should always be below 15% and the death rate should be below 10% at inpatient level and below 3% at outpatient level.[18] Cases not classifiable due to missing information or to misclassification were labelled as 'missing outcome information' and, in line with SPHERE standards,[18] were not considered for the calculation of health outcomes.

Data quality assurance procedures

The study team included a senior paediatrician, a nutritionist, a public health expert and six data collectors, all experienced in using the national guidelines for the Integrated Management of Acute Malnutrition (IMAM),[15] and the NSDA tool.[16] Before data collection, data collectors were provided refresher training on the key concepts of the IMAM guidelines, as well as training on data collection using predefined study tools and standard operating procedures (SOPs). Training included tests in the field, where data collection performance was evaluated and improved until considered sufficient.

All data collection tools included explicit case definitions on each page of the tool based on national IMAM

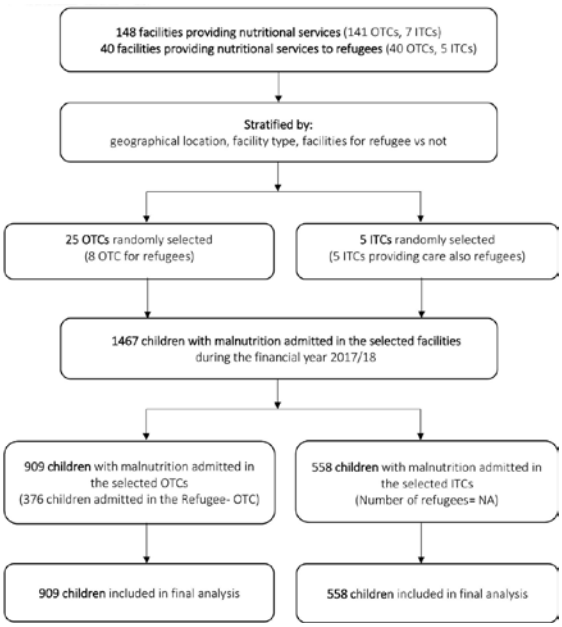

Figure 1 Study flow diagram. ITCs, inpatient therapeutic centres; NA, not applicable; OTCs, outpatient therapeutic centres.

guidelines.[15] All tools were predefined and field tested, and staff was trained in the SOPs, and routinely supervised. Data collection was routinely monitored by two senior supervisors on site. Hard copies of data collection forms were checked daily for completeness and accuracy with inconsistencies discussed and corrected as needed prior to data entry. Data were cleaned, coded and double entered into an Excel database. Range, consistency and validity checks were built into the entry programme to minimise errors. Entered data were double checked for completeness and internal consistency and any problems (such as missing data) were discussed and solved in real time. The dataset was monitored remotely at regular intervals by a senior paediatrician.

Data analysis

First, we conducted a descriptive analysis of findings of the assessment. Data were presented as frequencies with respective proportions for categorical parameters and as median and range for continuous non-normally distributed variables.

We looked at variation of outcomes across single facilities by conducting exploratory subgroup analyses comparing outcomes between OTCs and ITCs and between refugee and non-refugee OTCs, as ITCs provide care both to refugees and to residents. We tested for differences in outcome distribution between groups using a χ^2 test or Fisher's exact test as appropriate.

Lastly, we performed a multivariate analysis with a general linear model using Gaussian family with identity link function to assess the association between the cure rate of children in OTCs (analysed as a continuous variable) and the following independent variables: health facility level; district; refugee facility status; number of admissions; the areas assessed by the NSDA tool. Findings were presented with β coefficients and 95% CIs, representing change in cure rate. We could not fit a multivariate model of cure rate in ITCs, given the low number of this type of facility (n=5). In all analyses, a p value of <0.05 was taken as statistically significant. Stata 14 was used for data analysis.

Patient and public involvement

In each facility, a formal written informed consent (online supplementary appendix 8) was sought before data collection from health workers. All communication was conducted in English and Lugbara, Madi or Kakwa local languages. The study did not involve patient interaction and therefore patient consent was not needed. The study did not include direct patient participation. However, selection of the study outcomes carefully took into consideration outcomes that are of primary importance for patients, such as child health outcomes.

RESULTS

Characteristics of the sample

Out of all 148 facilities in the five selected districts in West Nile Region, 30 (20%) were identified by random selection; none presented exclusion criteria. Among the 30 selected facilities, 8 (32% of total OTCs) were refugee-hosting OTCs. All facilities were evaluated for quality of nutritional services with the NSDA tool.

A total of 1467 children with severe malnutrition were admitted to the 30 selected facilities during the financial year 2017/2018. All cases were reviewed to asses quality of case management, quality of data and child health outcomes (figure 1).

Characteristics of health facilities are reported in table 1. A high percentage (44.6%) of children was enrolled in Arua district, which also is the most populated district, and the one with the highest number of facilities (online supplementary appendix 2). Most of the included OTCs were level III HCs, which is the facility type most often providing outpatient nutritional care in the region.

The median (range) number of yearly admissions was quite variable, with 81 (21–288) in ITCs and 32 in (6–77) OTCs. There was no significant difference between the average number of children admitted to OTCs when comparing refugee to non-refugee OTCs (p=0.3), or when looking at the HC level (p=0.1). Districts of Adjumani and Moyo admitted more children in refugee-hosting OTCs than non-refugee (p≤0.001 and p=0.01, respectively) while the number of children admission in Arua and Yumbe was higher in non-refugee OTCs (p=<0.001 and p=0.041, respectively). Other characteristics of refugee-hosting versus non-refugee-hosting OTCs were not significantly different (table 1).

Quality of nutritional services

The frequency of NSDA scores in each of the 11 capacity areas assessed in all 30 participating facilities is reported

Table 1 Health facility characteristics

Facility characteristics	Health facility type			OTC facilities	
	Overall (n=30)	OTC (n=25)	ITC (n=5)	Non-refugee (n=17)	Refugee (n=8)
Health facility level, n (%)					
II	4 (13.3)	4 (16.0)	0	2 (11.7)	2 (25.0)
III	18 (60.0)	18 (72.0)	0	13 (76.5)	5 (62.5)
IV	3 (10.0)	2 (8.0)	1 (20.0)	1 (5.9)	1 (12.5)
Hospital	5 (16.7)	1 (4.0)	4 (80.0)	1 (5.9)	0
Children admitted, n (%)*	1467 (100)	909 (62.0)	558 (38.0)	533 (58.6)	376 (41.4)
Children admitted by district, n (%)*					
Adjumani (# facilities=4, population=113 404)	141 (9.6)	117 (12.9)	24 (4.3)	0	117 (31.1)
Arua (# facilities=14, population=429 185)	654 (44.6)	366 (40.3)	288 (51.6)	282 (52.9)	84 (22.3)
Koboko (# facilities=3, population=118 868)	208 (14.2)	127 (14.0)	81 (14.5)	77 (14.5)	50 (14.3)
Moyo (# facilities=4, population=76 388)	100 (6.8)	79 (8.7)	21 (3.8)	32 (6.0)	47 (12.5)
Yumbe (# facilities=7, population=310 288)	364 (24.8)	220 (24.2)	144 (25.8)	142 (26.6)	78 (20.8)
Admissions per facility, median (range)	33.5 (6–288)	32 (6–77)	81 (21–288)	30 (6–77)	48.5 (20–71)

Data on population in each district derive from the National Population and Housing Census 2014.
*Percentage calculated on the total number of children admitted in the 30 selected facilities (n=1467).
ITC, inpatient therapeutic care; OTC, outpatient therapeutic care.

Table 2 Nutrition Service Delivery Assessment (NSDA) scores

	Score assessed with the NSDA tool (30 facilities) N (%)			
Capacity area	**Poor**	**Fair**	**Good**	**Excellent**
1. General information*	0	6 (20.0)	3 (10.0)	21 (70.0)
2. Human resources	13 (43.3)	9 (30.0)	6 (20.0)	2 (6.7)
3. Provision of services	0	1 (3.3)	11 (36.7)	18 (60.0)
4. Community linkage	2 (6.7)	12 (40.0)	0	16 (53.3)
5. Quality improvement	20 (66.7)	4 (13.3)	4 (13.3)	2 (6.7)
6. Materials and supplies	4 (13.3)	17 (56.7)	6 (20.0)	3 (10.0)
7. Nutrition unit requirements†	0	2 (40.0)	0	3 (60.0)
8. Facility nutrition equipment	0	7 (23.3)	21 (70.0)	2 (6.7)
9. Store management	0	4 (13.3)	19 (63.3)	7 (23.3)
10. Logistics management for nutrition commodities	0	0	22 (73.3)	8 (26.7)
11. Monitoring and evaluation	2 (6.7)	1 (3.3)	2 (6.7)	25 (83.3)

*This area includesdifferent key items, from human resources to key aspects of quality improvement mechanisms and supportive supervision.
†Domain to be assessed only for inpatient care (n=5).

in table 2. Looking at the overall distribution of the 305 assessed scores, 107 (35.1%) were excellent, 94 (30.8%) good, 63 (20.7%) fair and only 41 (13.4%) were poor.

Overall, 25 (83.3%) and 21 (70%) facilities had excellent 'monitoring and evaluation' and 'general information' scores, respectively. 'Provision of service' was scored as excellent in 18 (60%) facilities and as good in 11 (36.7%). 'Nutritional equipment', and 'logistics management' were most often scored as good (70%, and 73.3% of total facilities, respectively). 'Materials and supplies' was scored as either fair, good or excellent in 26 (86.6%) facilities. Six capacity areas were never scored as poor, namely: general information; provision of services; 'nutrition unit requirements' (evaluated only in ITCs); 'facility nutrition equipment'; store management and 'logistics management for nutrition commodities'.

On the other hand, two capacity areas were frequently scored as poor: 'quality improvement mechanism' in 20 (66.7%) facilities and 'human resources' in 13 (43.3%). Scores for 'community linkage' were variable, excellent in 16 (53.3%) facilities but only fair in 12 (40.0%).

When comparing NSDA scores between ITCs and OTCs (online supplementary appendix 9), significant differences were observed in materials and supplies (significantly better in ITCs, exact p=0.029), and in community linkage (significantly better in OTCs, exact p=0.005). Refugee-hosting compared with non-refugee-hosting OTCs received overall higher scores in materials and supplies (exact p ≤0.001; online supplementary appendix 9).

When looking at data by single facility, among the 30 facilities assessed, about one-third (26.7%, two of which were ITCs) did not score poor in any of the 11 capacity areas, while a maximum of four capacity areas were scored as poor in any single facility (observed in two facilities).

Quality of data

Overall, data quality was poor (table 3): only 43.1% of admitted children had all essential data present in registers, and only 62.6% of cases had consistent height and date data over time (most of these being related to inconsistent height measurement in subsequent visits).

Both data completeness and consistency were significantly better in ITCs compared with OTCs (48.4% vs 39.8%, p=0.044for completeness and 80.1% vs 51.8% p=0.001 for consistency). Data quality was not significantly different between refugee-hosting and non-refugee-hosting OTCs. Overall, only 4 (13.3%) facilities (1 ITC) had more than 75% record completeness, and 7 (23.3%) facilities (three ITCs) had more than 75% internally consistency of records.

Process indicators of case management

Four out of five process indicators of case management—specifically diagnosis, evaluation of HIV status, caregiver counselling and evaluation of exit outcome—were recorded as correctly performed in ≥75% of children (table 3). Treatment was correctly performed in 68.4% of total cases.

Significant differences were observed by facility type: according to records, caregiver counselling was less well performed in ITCs compared with OTCs (57.9% vs 88.8%, p=0.001); moreover, fewer ITC cases were correctly assigned an exit outcome (55.9% vs 74.9%, p=0.001).

Process indicators of case management also significantly varied between refugee-hosting and non-refugee-hosting OTCs, although different indicators varied in different directions: for example, caregiver counselling and correct treatment were better performed in refugee-hosting compared with non-refugee-hosting OTCs

Table 3 Quality of data and case management

Variables	Health facility type					OTC facilities		
	Overall N=1467	OTC N=909	ITC N=558	P value		Non-refugee N=533	Refugee N=376	P value
	n (%)	n (%)	n (%)			n (%)	n (%)	
Data quality								
Data completeness								
Yes	632 (43.1)	362 (39.8)	270 (48.4)	0.044		210 (39.4)	152 (40.4)	0.756
No	835 (56.9)	547 (60.2)	288 (51.6)			323 (60.6)	224 (59.6)	
Internal consistency								
Yes	918 (62.6)	471 (51.8)	447 (80.1)	0.001		267 (50.0)	204 (54.3)	0.421
No	359 (24.5)	268 (29.5)	91 (16.3)			165 (31.0)	103 (27.4)	
Not classifiable*	190 (13.0)	170 (18.7)	20 (3.6)			101 (19.0)	69 (18.3)	
Quality of case management								
Correct diagnosis†								
Yes	1212 (82.6)	723 (79.5)	489 (87.6)	0.223		430 (80.7)	293 (78.0)	0.139
No	193 (13.2)	159 (17.5)	34 (6.1)			84 (15.8)	75 (20.0)	
Missing	62 (4.2)	27 (3.0)	35 (6.3)			19 (3.6)	8 (2.0)	
Correct treatment								
Yes	1004 (68.4)	605 (66.6)	399 (71.5)	0.393		334 (62.7)	271 (72.1)	0.012
No	250 (17.0)	213 (23.4)	37 (6.6)			140 (26.3)	73 (19.4)	
Missing	212 (14.5)	91 (10.0)	122 (21.9)			59 (11.0)	32 (8.5)	
Evaluation of HIV status								
Yes	1181 (80.5)	722 (79.4)	459 (82.3)	0.663		461 (86.5)	261 (69.4)	<0.001
No	56 (3.8)	56 (6.2)	0			8 (1.5)	48 (12.8)	
Missing	230 (15.7)	131 (14.4)	99 (17.7)			64 (12.0)	67 (17.8)	
Caregiver counselling								
Yes	1130 (77.0)	807 (88.8)	323 (57.9)	0.001		446 (83.7)	361 (96.0)	<0.001
No	15 (1.0)	15 (1.7)	0			15 (2.8)	0	
Missing	322 (21.9)	87 (9.6)	235 (42.1)			72 (13.5)	15 (4.0)	
Correct assignment of exit outcome								
Yes	1035 (70.6)	725 (79.8)	310 (55.5)	<0.001		413 (77.5)	312 (83.0)	0.001
No	307 (20.9)	113 (12.4)	194 (34.8)			58 (10.9)	55 (14.6)	0.001
Missing	125 (8.5)	71 (7.8)	54 (9.7)			62 (11.6)	9 (2.4)	

*Cases of children presenting only with one visit could not be assessed for consistency.
†At enrolment.
ITC, inpatient therapeutic centres; OTC, outpatient therapeutic centres.

Table 4 Health outcomes

Variables	Overall	Health facility type			OTC facilities		
		OTC	ITC	P value	Non-refugee	Refugee	P value
Available data	N=1035	N=725	N=310	<0.001	N=413	N=312	0.042
Dead, n (%)*	109 (10.5)	16 (2.2)	93 (30.0)	<0.001	7 (1.7)	9 (2.9)	0.28
Cured, n (%)*	522 (50.4)	362 (49.9)	160 (51.6)	0.62	215 (52.1)	147 (47.1)	0.188
Non-responders, n (%)*	18 (1.7)	18 (2.5)	0	0.005	6 (1.4)	12 (3.9)	0.04
Defaulters, n (%)*	240 (23.2)	221 (30.5)	19 (6.1)	<0.001	151 (36.6)	70 (22.4)	<0.001
Transferred to OTC, n (%)*	106 (10.2)	75 (10.3)	31 (10.0)	0.867	8 (1.9)	67 (21.5)	<0.001
Transferred to ITC, n (%)*	40 (3.9)	33 (4.6)	7 (2.3)	0.08	26 (6.3)	7 (2.2)	0.01

*Percentage calculated on the total number of available data.
ITC, inpatient therapeutic centre; OTC, outpatient therapeutic centre.

(p=0.001), while correct evaluation of HIV status was less frequent in refugee-hosting OTCs (p=0.001).

Large heterogeneity in outcomes was observed across facilities. Correct diagnosis rates ranged from 33.3% to 100% in OTCs and from 82.3% to 98.6% in ITCs, with 15 (60%) OTCs having correct diagnosis rates greater than 75%. Correct treatment rates ranged from 14.3% to 100% in OTCs and from 45.7% to 97.2% in ITCs. Overall, 10 (33%) facilities had correct treatment rates of greater than 75%.

Health outcomes

Overall health outcomes could be evaluated in 1035 (70.6%) children; 432 (24.4%) cases were excluded due to missing information on final health outcome (table 3). Based on data recorded in official forms, the average cure rate was 50.4%, significantly lower than SPHERE standards of ≥75% (p<0.001), without significant differences between OTCs and ITCs (table 4). The average death rate was 10.5% (table 4), with a death rate of 2.2% in OTCs and 30.0% in ITCs, the latter being significantly higher than SPHERE standards of <10% (p<0.001). The overall default rate was 23.2%, significantly higher than SPHERE standards of <15% (p<0.001), and with significant more defaulters at OTCs (30.5%) compared with ITCs (6.5%, p<0.001). The prevalence of other health outcomes assessed was overall low.

Refugee-hosting compared with non-refugee-hosting OTCs (table 4) had a similar cure rate (47.1% vs 52.1%, p=0.188) with a significantly higher rate of children transferred to OTCs (21.5% vs 1.9%, p<0.001) and a lower rate of default (22.4% vs 36.6%, p<0.001) and transfer to ITC (2.2% vs 6.3%, p=0.010). Non-response rate was also higher in refugee-hosting compared with non-refugee-hosting OTCs (3.9% vs 1.4%, p=0.040), however with low absolute numbers.

Large heterogeneity in health outcomes was detected between single facilities. Death rates ranged from 0% to 11.1% in OTCs and from 0% to 59.1% in ITCs, with 7 (23.3%) facilities having a rate above the SPHERE standard, specifically 3 OTCs exceeded the OTC target level of 5% and 4 ITCs the ITC target level 10%. Cure rates ranged from 28.3% to 85.7% with only 3 (10%) facilities within SPHERE standards of ≥75%. Default rates in OTCs ranged from 0% to 100%, with 21 (84%) of OTCs recording a rate within the acceptable SPHERE standards of 15%.

Multivariate analysis

In multivariate analysis (table 5), a score of 'good/excellent' under the NSDA capacity areas of 'availability of facility nutrition equipment' (+55.9, 95% CI 25.2 to 86.6, p=<0.001), and 'store management' (+65.4, 95% CI 2.7 to 128.1, p=0.041) were significantly associated with a better cure rate at the OTC level. 'Good/excellent' scores on 'availability of materials and supplies' were significantly associated with lower cure rates (−74.7), although with very large CIs (95% CI −130.1 to −19.2, p=0.008).

DISCUSSION

This study showed that in the West Nile Region, an area hosting over 1 million refugees in Northern Uganda, average cure rates for severe acute malnutrition in children were significantly below the minimum SPHERE standards (50.4% vs 75%, p<0.001). This was despite overall good scores on the capacity to provide nutrition services as assessed by the national NSDA tool, and good process indicators as recorded in official patient charts. Previous studies from other LMICs have reported low QOC for malnourished children, highlighting that poor health outcomes and problems in data quality are frequent findings in these settings.[2–4 11] The current study adds to this previous knowledge as it is the first to our knowledge to assess QOC and health outcomes of malnourished children in refugee settings. Acute malnutrition is considered a condition of public health importance in Uganda,[19] and as such, the findings of this study also strongly advocate for further actions to monitor and improve health outcomes of malnourished children in West Nile region across all facility types.

Some findings of this assessment deserve further discussion. First, this study highlighted that good health service 'capacity' as assessed by the NSDA tool and good process

Table 5 Factors independently associated with a better cure rate at outpatient therapeutic centres level (N=25)

Variable	Beta coefficient (95% CI) (difference in cure rate)	P value
Health facility level		
HCII	Reference	
HC III	−40.5 (−81.4 to 0.4)	0.052
HC IV	−18.2 (−40.4 to 76.7)	0.543
Hospital	68.4 (−21.5 to 158.3)	0.136
District		
Arua	Reference	
Adjumani	57.9 (−0.8 to 116.7)	0.053
Koboko	−10.7 (−75.7 to 54.2)	0.746
Moyo	−33.4 (−68.8 to 2.0)	0.065
Yumbe	−22.3 (−59.6 to 15.0)	0.241
Refugee facilities		
No	Reference	
Yes	18.8 (−15.9 to 53.5)	0.289
Total number of admissions		
≤50	Reference	
>50	18.0 (−33.8 to 70.0)	0.494
Area assessed by NSDA tool*		
1. General information†		
Poor or fair	Reference	
Good or excellent	23.7 (−6.3 to 53.7)	0.121
2. Human resources		
Poor or fair	Reference	
Good or excellent	−40.3 (−73.4 to 7.3)	0.117
3. Provision of services		
Poor or fair	Reference	
Good or excellent	34.8 (−21.7 to 91.3)	0.228
4. Community linkage		
Poor or fair	Reference	
Good or excellent	34.9 (−0.8 to 70.6)	0.056
5. Quality improvement mechanism		
Poor or fair	Reference	
Good or excellent	−6.8 (−37.5 to 23.9)	0.662
6. Materials and supplies		
Poor or fair	Reference	
Good or excellent	−74.7 (−130.1 to −19.2)	0.008
8. Facility nutrition equipment		
Poor or fair	Reference	
Good or excellent	55.9 (25.2 to 86.6)	<0.001
9. Store management		
Poor or fair	Reference	
Good or excellent	65.4 (2.7 to 128.1)	0.041
11. Monitoring and evaluation		
Poor or fair	Reference	
Good or excellent	10.4 (−33.2 to 54.1)	0.64

*Two Nutrition Service Delivery Assessment (NSDA) domains were not included: the domain # 7 Nutrition unit requirements, which is pertinent only to inpatient therapeutic centres, and the domain # 10 Logistics Management for nutrition commodities, where no facility scored as either poor or fair.
†This area includes including different key items, from human resources to key aspects of quality improvement mechanisms and supportive supervision.

indicators as recorded in patient files may not directly translate into good health outcomes. This has been observed in other studies,[11 16] and underscores the importance of including 'hard outcomes' such as child health indicators in any evaluation, in order to analyse the actual output of nutritional services in addition to inputs and processes.

Second, some of the apparent discrepancies between NSDA tool findings and data quality and internal consistency and final health outcomes may be explained by the nature of the NSDA tool. For example, the finding that most (83.3%) facilities were rated as excellent in 'M&E' seems incongruous with the fact that both data completeness and internal consistency were found to be below SPHERE standards. This may be because the current version of the NSDA tool allocates an excellent score for M&E when a person is designated to record data and records them, with no consideration of the quality of resulting data available for analysis. As a consequence, the NSDA tool may overestimate the real quality of the M&E. In general, low effectiveness of routine M&E systems is a well-documented problem in LMICs.[20 21] According to the current system of M&E in Uganda, supportive supervision should be performed quarterly.[15] In practice, however, supervision is often weak due to multiple barriers including lack of funds and physical resources (internet access, vehicles and fuel for conducting supervision visit), lack of leadership and coordination, and low supervisory capacity.[11] Existing literature,[22–24] including randomised controlled trials,[17] indicates that supportive supervision delivered by trained staff at fixed intervals can significantly increase cure rate and QOC for children.

Similarly, materials and supplies availability may not be properly estimated by the NSDA tool, as several items like the availability of ready-to-use therapeutic foods are only assessed as 'present at the moment of the assessment', while availability in the previous 2 years is only assessed indirectly. Existing literature[11 17] showed that frequent stock-outs are related to higher default rates, and people aware of stock-outs tend not to come back for follow-up visits, as they assume they will not receive therapeutic foods. This may at least partly explain a high default rate in areas with frequent stock-outs.[11 17]

Findings of this study are in line with previous studies,[11] but differ from those of routine monitoring data.[25] This may be due to multiple factors, including different time periods and samples of facilities and children, and different data sources, for example, the use of dispensing logs rather than nutrition registers. In addition, differences in case definitions and discharge criteria likely led to different findings. Once again, this discrepancy highlights the need to strengthen and standardise routine data collection systems, data validation procedures and mechanisms of effective M&E.

High heterogeneity in outcomes among facilities has been reported in other quality assessment studies.[11 24 26 27] Research has indicated that applying quality improvement interventions can significantly reduce this heterogeneity among facilities.[17 24]

Other findings such as the observation of poor availability of human resources are not surprising.

The latest WHO strategy on health workforces recognises that global investment in the health workforce is lower than is often assumed,[28] despite literature showing that the density of human resources is significantly related to maternal, infant and under-five mortality rates.[29]

The exploratory finding that cure rates were similar in refugee-hosting and non-refugee-hosting OTCs (47.1% vs 52.1%) is plausible, given the low-resourced context and the fact that more resources are often available in LMICs for managing emergencies than for maintaining the national health system.[30] Interestingly, refugee-hosting facilities had a high rate of children transferred to other OTCs (21.5%), despite the finding that overall they are better equipped with materials and supplies when evaluated with the NSDA tool. This high transfer rate may potentially overload other facilities and indicates the need for better coordination and a systematic approach to caring for malnutrition among children in these settings.

While findings of the multivariate analysis require further confirmation in other studies, it is plausible that capacity areas identified as significantly associated with better cure rates (ie, 'facility nutritional equipment' and store management) may indeed contribute to better health outcomes. However, it is also plausible that many other aspects may contribute to better health outcomes of children, including, as already discussed, regular availability of therapeutic foods. Although measures of these items were included in our multivariate models, the accuracy and validity of these measures could be improved, as discussed previously.

Limitations of this study include the retrospective nature of the data collected. Poor quality of official health records may have affected the reported cure rate, as well as other indicators, such as correct diagnosis, although we cannot know in which direction. Poor quality of data is per se an interesting finding, certainly worth documenting for advocating for better quality data, as pointed out in previous studies.[11 20 21] Similarly, process indicators relied on recorded information, and may actually overestimate the quality of case management (eg, caregiver counselling was almost always recorded as 'performed', but we cannot be sure whether this was actually performed in reality, and with what quality).

Another limitation of the study is that we did not collect individual patient information in each facility (such as HIV status) so we cannot exclude that differences in cure rate among facilities may be due to some extent to difference in the case mix of children. However, following major investments in prevention and control, HIV prevalence among children in Uganda is currently estimated to be relatively low (0.5%),[31] with an observed prevalence in malnourished children in West Nile Region of around 2.4%,[17] significantly lower than that reported in other nearby countries.[32] Additionally, studies have reported that the health status of refugees can be quite variable even within nearby areas, and volatile within a short time frame, due to multiple factors including population type and place of origin, local conditions like water and hygiene sanitation, existing protection services like distribution of food rations, and treatment services such as access to healthcare and availability of drugs and therapeutic foods.[2 4–7] The influence of all these factors on the final outcomes of refugee children with malnutrition should be better evaluated in future prospective studies.

Lastly, according current regulations, refugees with registered status have the right to access any existing health facility.[2] As such, it is possible that some of the children admitted to non-refugee-hosting facilities were actually refugees. We believe this does not undermine the general message of the study, which indicates that improving QOC for malnourished children in West Nile Region is a priority, regardless of their refugee status.

Findings of this study cannot be directly generalised to other refugee settings. However, they do suggest that more evaluation of the QOC delivered to children in these settings is needed.

CONCLUSIONS

This study shows that health outcomes of malnourished children admitted to both refugee-hosting and non-refugee-hosting facilities in West Nile Region were significantly below international Sphere standards, despite the fact that NSDA ratings of the majority of the service capacity areas were good or excellent. Effective and sustainable approaches to improve child health outcomes should be promoted, with more investment clearly needed to strengthen existing routine systems of data collection and analysis, in line with the WHO Global Strategy for Mothers and Children recommendations.[33]

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Re: Incidence and characteristics of pregnancy-related death across ten low- and middle-income geographical regions: secondary analysis of a cluster randomised controlled trial: The underestimated scourge of eclampsia in low-income countries

PAPER

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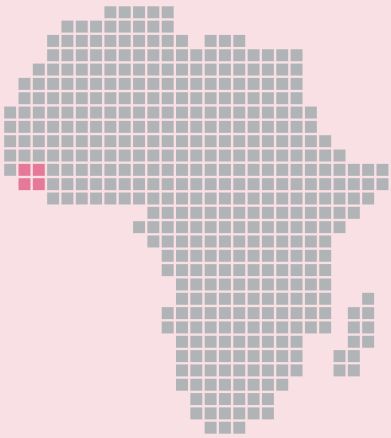

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Management of mothers and neonates in low resources setting during covid-19 pandemic

PAPER

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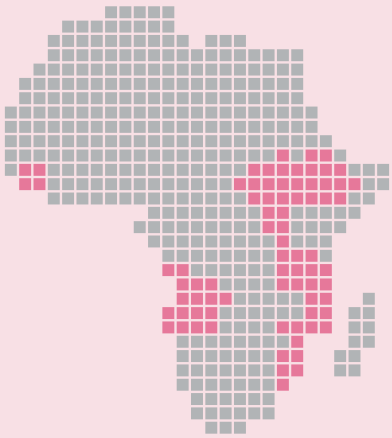
Focus country
Multi-countries



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OTHER

Management of mothers and neonates in low resources setting during covid-19 pandemia

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ABSTRACT

The coronavirus disease (COVID-19) epidemic started in the Hubei province of China, but is rapidly spreading all over the world. Much of the information and literature have been centered on the adult population while a few reports pertaining to COVID-19 and neonates have been published so far. Actual guidelines are based on expert opinion and show significant differences among the official neonatal societies around the world. Recommendations for the care of neonates born to suspected or confirmed COVD-19 positive mothers in low-resource settings are very limited. This perspective aims to provide practical support for the planning of delivery, resuscitating, stabilizing, and providing postnatal care to an infant born to a mother with suspected or confirmed COVID-19 in low-resource settings where resources for managing emergency situations are limited.

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Introduction

The novel coronavirus-related infection has rapidly spread from its origin in Wuhan City, Hubei, China in December 2019 to the rest of the world [1]. On 11 March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic [2].

Initially defined as the 2019-novel coronavirus (2019-nCoV) [3], the pathogen is now officially named severe acute respiratory syndrome corona virus 2019 (SARS-CoV-2019), while its related disease is called COVID-19 (coronavirus disease 2019) [4].

With an impressive rate of global spread, 6 416828 confirmed cases of COVID-19 have been reported across the world as of 5 June 2020 with 382 867 confirmed deaths. At the same date, 115 639 confirmed cases and 2 858 deaths have been documented in Africa [5].

The disease is primarily transmitted *via* respiratory droplets or direct contact (0–2 meters), and the incubation period ranges from 2 to 14 days (median 5 days) [6,7]. Although intrauterine and transplacental transmission appear to be unlikely, they cannot be completely ruled out based on the current evidence [7–12]. A small case series from Wuhan, China does report early onset post-natal transmission to 3 neonates born to a cohort of 33 mothers with COVID-19 [9]. Another 4 infected neonates, 30 h to 17 days old, were recently reported [12].

In adults, clinical features range from an asymptomatic state to an influenza-like illness with fever, cough, fatigue and myalgia. The infection may progress to severe pneumonia and fatal acute respiratory distress syndrome (ARDS). The greatest risk of serious complications and mortality is in the elderly and those with comorbidities [13–15]. In neonates, symptoms appear

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Due to the urgent and developing nature of the topic, this paper was accepted after an expedited peer review process. For more information about the process, please refer to the Instructions for Authors.

to be milder and associated with better outcomes compared with adults [7–12,16,17].

Several documents for high and low-resource settings have been made available from official international institutions in order to prevent transmission of the infection in the general population and among healthcare workers and to ensure the best possible care for affected people [18–20].

Recommendations for caring for pregnant women with suspected or confirmed COVID-19 and their newborns before, during and after delivery have also been released. These guidelines include different recommendations, reflect different interpretations of the scientific evidence, are based on expert opinion, and are mainly relevant to high-resource settings [21–29]. Furthermore, only a few of these guidelines have focused on the appropriate planning for neonatal resuscitation after birth [30,31].

Compared to other countries, Africa has been faced with more epidemics, such as HIV, malaria, tuberculosis, and Ebola, in the past. On one side, this could be an advantage during the present pandemic because previous global initiatives have strengthened health systems to manage these national emergencies [32]. On the other side, African health systems have many weakness, including an extreme shortage of intensive care beds, overcrowded and understaffed health facilities, and barriers for poor people accessing care due to inadequate roads and transportation systems. Moreover, people frequently live together in limited spaces making prevention based on maintenance of spatial distance very difficult to implement. Frequent handwashing is one of the most important recommendations for preventing the spread of infection, but access to clean running water is impracticable for millions of Africans [33]. Specific protocols aimed to contain the impact of this new epidemic in low-resource settings are needed [34].

This perspective aims to provide a stepwise approach to resuscitating, stabilizing, and providing postnatal care to an infant born to a mother with suspected or confirmed COVID-19 in low-resource settings where resources for managing emergency situations may be limited.

Since knowledge about SARS-CoV-2019 is rapidly evolving, these guidelines are likely to evolve.

Before delivery

Both the general population and, especially, healthcare workers must be aware that SARS-CoV-2019 is transmitted *via* respiratory droplets when an infected person coughs, sneezes or speaks or by touching contaminated surfaces and then touching your own eyes, mouth or nose [6,7]. 2019-nCoV was isolated from a stool specimen, suggesting the possibility of fecal-oral transmission [35]. Increasing the public's knowledge of these routes of transmission may help to reinforce correct behaviors and control spread of the infection. Observing the following rules has been demonstrated to reduce viral transmission [6,18–20]:

1. Strict hand hygiene. Standard hand-washing techniques should be followed by healthcare providers and patients. Wash hands with soap and water for at least 20 s, especially after going to the bathroom; before and after eating; and after blowing the nose, coughing, or sneezing. If soap and water are not available, use an alcohol-based sanitizer with at least 60% alcohol.
2. Spatial distancing. Avoid crowded spaces and keep adequate space (minimum 2 meters) between yourself and others.
3. Covering mouth and nose. Cover the mouth and nose with a flexed elbow or tissue when coughing or sneezing. Immediately dispose used tissues.
4. Cleaning. Frequently clean surfaces and objects that have been touched and potentially infected.

Currently, there is no evidence that pregnant women present with different signs or symptoms or are at higher risk of severe illness [21,27–29].

Antenatal care (Figure 1)

Antenatal care for COVID-19 positive or suspected women should be offered as per established schedules. While providing antenatal care, healthcare workers should wear personal protective equipment (PPE) such as a medical mask, gloves, eye protection (goggles or face shields) and perform hand hygiene after removing their mask. Pregnant mothers should be invited to wear a medical mask or cloth mask and should be kept preferably in the open spaces of the health facilities near the designated antenatal clinic. If a waiting room is used, it must have wide, open windows that allow natural ventilation from all sides. Spatial distance, a minimum of 2 meters, between persons should be maintained. (Figure 2(a,b))

Clinicians should offer a single course of antenatal steroids, ideally at least 24 h before birth, to all women at risk of preterm delivery from the time when pregnancy is considered potentially viable until 34 weeks' gestation [36]. Although the well-established

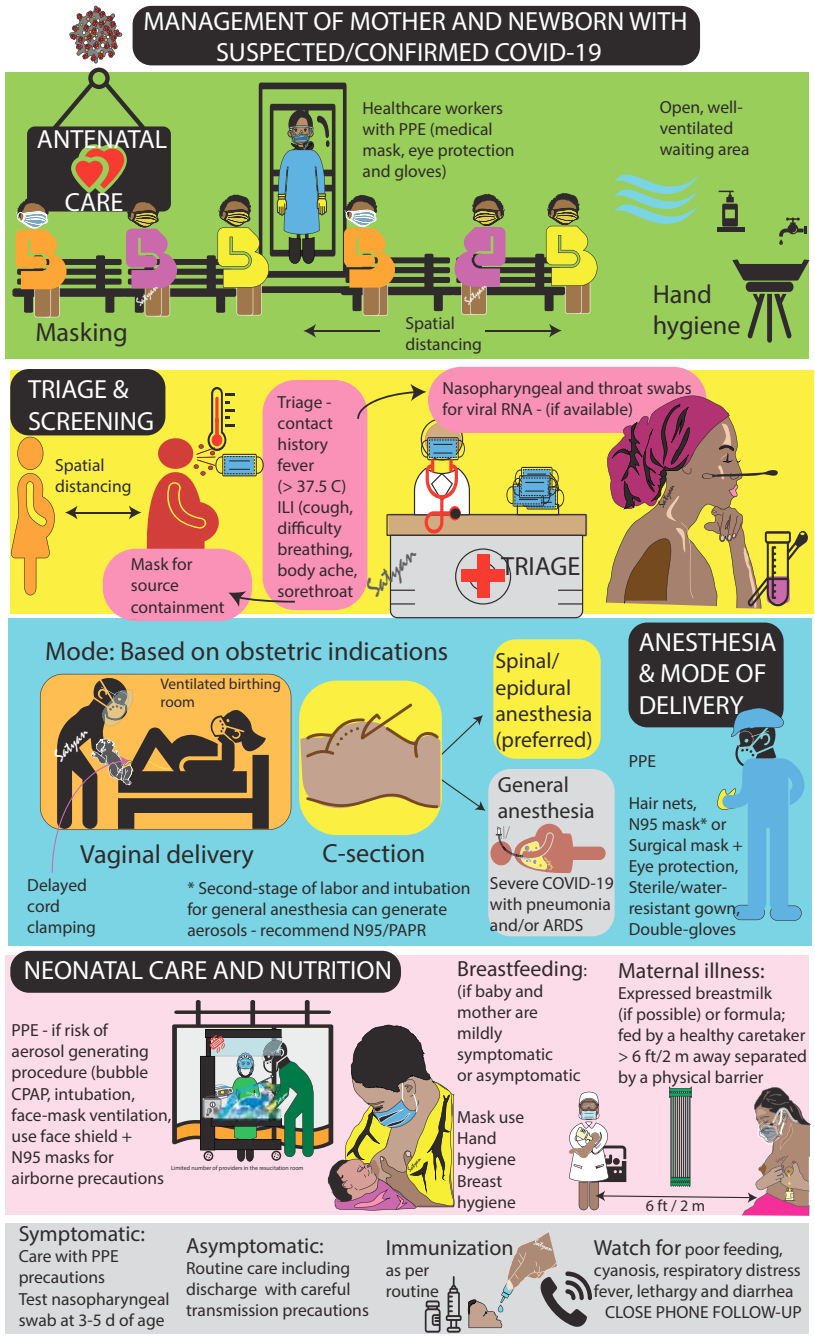

Figure 1. Infographic showing the approach to neonates born to mothers with suspected or confirmed COVID-19. ARDS, acute respiratory distress syndrome; ILI, influence-like illness; PAPR, powered air-purifying respirator; PPE, personal protective equipment; SARS-CoV-2, severe acute respiratory syndrome–coronavirus 2. Image Courtesy: Satyan Lakshminrusimha.

Figure 2. Organization of waiting area of antenatal clinic at (a) Tosamaganga Hospital, Tanzania and (b) Matani Hospital, Uganda.

beneficial effects of antenatal steroids documented in high-resource settings were not confirmed in low-income and middle-income countries [37], the World Health Organization (WHO) recommends antenatal corticosteroid therapy for women at risk of preterm birth from 24 to 34 weeks of gestation when there is no clinical evidence of maternal infection [38]. Studies on the use of corticosteroids in patients with COVID-19 are inconclusive and some of them showed potential harm [39]. Steroids could lead to an immunosuppressive response to infection in pregnant women with COVID-19. As evidence on the benefit-harm ratio for the use of steroids in women with confirmed COVID-19 is inconclusive, a shared decision should be made by the attending caregiver and woman after reviewing the relevant information.

Triage (Figure 1)

To prevent potential transmission to other patients and staff, maternity departments with direct entry for patients and the public should have a system in place for identifying potential cases as soon as possible. This should occur at the point of first contact, either near the entrance or at reception, to ensure early recognition and infection control. The choice of location will determine the challenges that may be encountered. For this reason, every facility must identify an entry site capable of ensuring safe patient flow. (Supplementary Figure 1).

Each reception or triage booth should be clearly labeled and identified to avoid mistakes in patient flow [40]. Patients must maintain a distance of 2 meters while waiting to be triaged or seen by a healthcare provider.

Triaging patients at hospital admission (i.e. healthy mothers, suspected asymptomatic COVID-19 mothers with close contacts, suspected symptomatic COVID-19 mothers, and proven COVID–19 mothers) is important during an outbreak [18–20,34]. Triage is based on three pillars: (i) history of close contact with suspected/infected persons; (ii) presence of "influenza-like illness" (fever, myalgia, sore throat, malaise) or respiratory symptoms (cough or difficult breathing); and (iii) checking temperature (higher or lower than 37,5 °C). In suspected cases, nasopharyngeal and oropharyngeal swabs should be collected and placed in viral transport medium for RNA detection (typically real-time polymerase chain reaction [RT-PCR]) [6]. However, nasopharyngeal and oropharyngeal swabs are not available in all hospitals and the results of the RT-PCR test would not be immediately available even with routine screening at admission. Therefore, history and clinical status will determine the management of pregnant women during maternity ward admission [28,30,31]. However, it is important to note that a relevant percentage of women may be infected but asymptomatic or pre-symptomatic at the time of obstetrical triage. A recent study, in fact, showed that 29 out of 33 (87 ·0%) of COVID positive women presenting in labor had no symptoms [41].

Suspected women should be invited to wear a medical mask and should be cared for in an isolated room by a dedicated team wearing appropriate PPE during labor and delivery. If a suspected or confirmed case is identified, hospital infection control or other appropriate authorities should be immediately informed, as per local requirements.

If possible, dedicated equipment (e.g. stethoscopes, blood pressure cuffs and thermometers) should be used, but if equipment needs to be shared among patients, it must be cleaned and disinfected between each patient use with appropriate products.

Delivery (Figure 1)

Rooms for managing suspected or confirmed COVID-19 pregnant women during labor, vaginal delivery, and cesarean section should be identified and prepared in all maternity departments. If possible, these rooms should be adequately ventilated. Decisions regarding the mode of delivery should be made by the attending staff and should be based on standard obstetric protocols. COVID-19 infection itself does not represent an indication for delivery, unless there is a need to improve maternal respiratory insufficiency and oxygenation. In this case, general anesthesia could be considered; otherwise, spinal/epidural anesthesia remains the first choice. Given that materials will be in short supply during an epidemic, the minimum number of staff required for each procedure and limiting the "time of contact" with the patient should be planned to minimize the risk of exposure and reduce the use of PPE [30,31,34,39].

The staff should wear appropriate PPE including goggles or a face shield, mask (possibly N95 respirators); disposable latex gloves; and a clean, non-sterile, long-sleeved gown. Hand hygiene should be done before and after any contact, as per local guidelines. Staff need to be instructed on the correct procedure for donning and doffing PPE [42].

The delivery room should be immediately cleaned with 500 mg/L chlorine-containing disinfectant and all supplies and equipment (i.e. surgical instruments, face masks, self-inflating bag, tube, laryngoscopes) must be disposed or sterilized, as per protocol. Waste produced during the care of patients with suspected or confirmed should be safely disposed.

Resuscitation

In a retrospective review of 9 patients, Chen et al. showed that intrauterine transmission from SARS-CoV-2-positive mothers seems to be unlikely [8], but two other studies suggest further research is needed to better estimate the risk of vertical transmission [9,10]. Current protocols should guide the management of neonates at birth, as COVID-19 infection does not represent an indication for changing established guidelines on neonatal resuscitation/stabilization [43,44]. However, all aerosol-generating interventions (i.e. face-mask ventilation, tracheal intubation) should be provided by using appropriate PPE, ideally, with N95

respirators or at minimum surgical mask with a face shield.

Delayed cord clamping (DDC) and skin-to-Skin contact (SSC)

Delayed umbilical cord clamping has been demonstrated to improve cardiovascular transition from intra- to extra-uterine life, iron stores in childhood and neurodevelopment in infancy [45–47]. It is likely that these advantages are more important in neonates born in low-resource settings. International scientific institutions recommend delayed cord clamping (DCC) for longer than 30 s in both term and premature infants who do not require resuscitation in order to assure placental transfusion [43,48–51]. Babies born to mother with suspected or confirmed COVID-19 who don't need resuscitation can continue to receive DCC and SSC, as per local protocol, but mothers should wear medical mask and wash hands before and after touching the baby. Also caregivers must adopt all the prevention measures, including hand washing, use of medical mask, face shields or goggles aimed to avoid viral transmission.

After delivery (Figure 1)

All pregnant women with COVID-19 or who have recovered from COVID-19 should be provided with information and counseling on safe infant feeding and appropriate prevention control measures to prevent viral transmission [34,52,53].

Given that there is no evidence to show that SARS-CoV-2019 can be transmitted through breast milk, the WHO recommends that "a woman with COVID-19 should be supported to breastfed safely, hold her newborn skin-to-skin and share a room with her baby" [53]. However, necessary precautions to limit viral spread to the baby must be taken and mothers with suspected or confirmed COVI-19 should be instructed on the correct procedure. It includes: hand washing and breast hygiene before and after touching the baby; avoiding coughing or sneezing on the baby while feeding at the breast; wearing a face mask while breastfeeding; following recommendations for pump cleaning after each use and disinfecting contaminated surfaces. Stable neonates exposed to COVID-19 infection from mothers or other relatives should roomed-in with their mothers. If rooming-in is not possible because of the mother's or newborn's illness, the baby should be fed the mother's expressed breast milk by a nurse or family member who has not been in contact with the mother or other suspected/proven cases.

Symptomatic neonates

Three out of 33 neonates born to confirmed COVID-19 mothers tested positive for SARS-CoV-2 by RT-PCR on the 2nd day of life [9]. One of them was a preterm infant born at 31 weeks' gestation. All presented with pneumonia, while other clinical features including fever, respiratory distress syndrome, shortness of breath, cyanosis and feeding intolerance were registered only in the preterm infant. This infant required mechanical ventilation and received antibiotics. It remains to be demonstrated whether symptoms were due to the viral infection or to complications of prematurity [9]. In another small series including four Chinese COVID-19 positive neonates, two had fever, one had shortness of breath, one had cough and one was asymptomatic. Supportive treatment was provided for all of them, but none required intensive unit care or mechanical ventilation [12].

Symptomatic neonates born to a mother with suspected or proven COVID-19 infection should be managed by a dedicated staff in closed incubators in a separate special care unit. The staff should wear appropriate PPE. If isolation room is not available, a distance of at least 1 m should be maintained between neonatal beds [30,31,54]. Nasopharyngeal and oropharyngeal swabs should be tested in sick neonates at 3–5 days of life.

Asymptomatic neonates

Late-onset SARS-CoV-2 infections have been reported in neonates after hospital discharge supporting evidence that human-to-human transmission appears to be the most important route of disease spread. In a nationwide case series of 2 135 pediatric patients with COVID-19 reported to the Chinese Center for Disease Control and Prevention, clinical manifestations of children's COVID-19 cases were generally less severe than those of adult patients, but infants (less than 1 year-old), were more vulnerable to infection [55]. Therefore, it is imperative to educate the mother and the family living with COVID-19 positive cases on the importance of respecting rules for preventing spatial transmission of the infection.

Asymptomatic COVID-19 positive mothers and her baby should be discharged home as soon as possible, but the family should be instructed on recognition of early clinical features (i.e. fever, shortness of breath, cyanosis, feeding intolerance, diarrhea) in order to be referred to a health care center without delay. (Figure 3). If possible, early discharge to home would

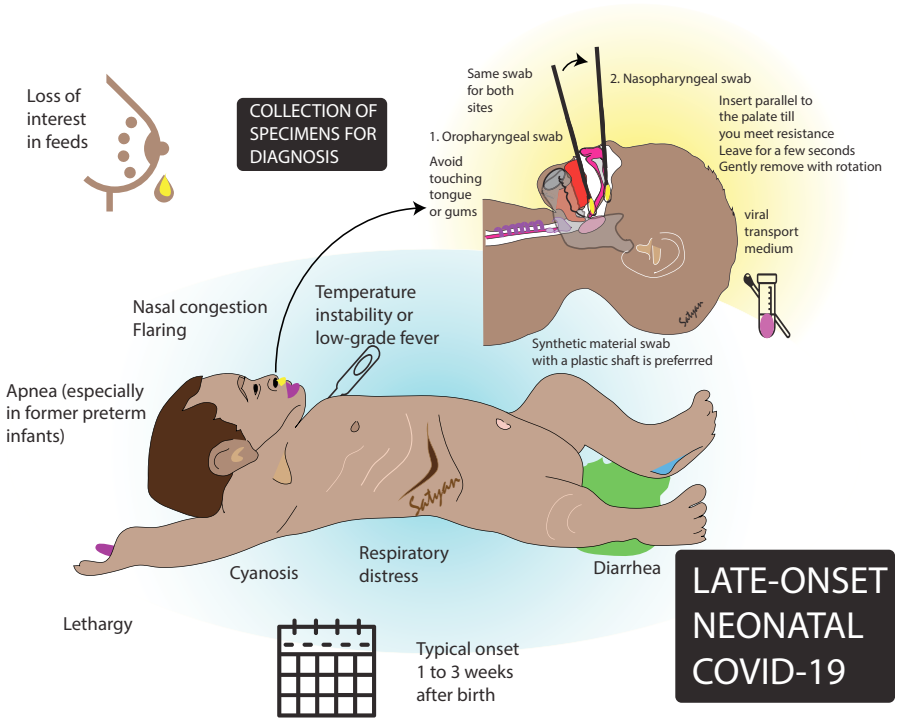

Figure 3. Late-onset neonatal COVID-19–warning signs and diagnostic measures. *Image Courtesy: Satyan Lakshminrusimha.*

be followed by telephonic follow-up or home visit by a designated healthcare worker [30,31,54].

All pregnant women and mothers with or recovering from COVID-19 should be provided with psychosocial counseling and information related to the potential risk of infection and its consequences.

Immunization

Routine immunization policy should be provided to neonates born to mothers with suspected or confirmed COVID-19 infection [52,54].

Personal protection equipment (PPE)

In high-resource settings, the procurement of appropriate PPE has been one of the most important difficulties during the actual epidemic [39], but it is likely that this problem will be even more relevant in LRS [34]. For this reason, the rational use of different types of PPE should be appropriately addressed in relation to the procedure to be performed and the setting.

Respiratory protection

There are three modalities of respiratory protection with different indications: (a) cloth face covering/cloth masks; (b) surgical mask and (c) N-95 respirators.(a) The simple cloth face covering reduces the spread of the virus from infected people and should be used in public settings where other spatial distancing measures are difficult to maintain, especially in areas of significant community-based transmission. Cloth face coverings can be washed for sufficient cleaning and sterilization [56]. The CDC advises that cloth face coverings are not surgical masks or N-95 respirators because they have a lower protective capabilities compared to surgical masks [53,54]. However, they can be considered as last possible alternative if a supply of commercial face masks is not available [56]. Hand-made masks made with local cloth (e.g. Kitenge) have been prepared in many limited-resource hospitals during the actual pandemic (Supplementary Figure 2). Ideally, every healthy caregiver must have at least two cloth face coverings/cloth masks to allow cleaning one while continuing use.

(b) Surgical masks are designed to protect against splashes and sprays. During periods of severe surgical mask shortages, they could be used beyond the manufacturer-designated shelf life during patient care activities. When surgical masks are not available, healthcare providers can consider to work with home-made masks that must be ideally used in combination with a face shield [57].

Table 1. Suggested cleaning & disinfection options for healthcare settings.

	Healthcare settings
Surfaces	• Neutral detergent AND • Virucidal disinfectant OR 0·05% sodium hypochlorite OR 70% ethanol
Toilets	• Virucidal disinfectant OR 0·1% sodium hypochlorite
Textiles	• Hot-water cycle (90 °C) AND regular laundry detergent • Alternative: lower temperature cycle + bleach or other laundry products
Cleaning equipment	• Single-use disposable OR non disposable disinfected with: • virucidal disinfectants OR 0·1% sodium hypochlorite
PPE for staff	• Surgical mask • Disposable long-sleeved water resistant gown • Gloves • FFP2 or 3 or N95 when cleaning facilities where aerosol generating procedures have been performed
Waste management	• Infectious clinical waste category B (UN3291)

From: European Center for Disease Prevention and Control. TECHNICAL REPORT (ref #58)

Those are critical supplies that must continue to be reserved for healthcare workers and other medical first responders, as recommended by current CDC guidance.

(c) Respirators (FFP2 or N95 equivalent and FFP3) are recommended only for use by healthcare workers who need protection from both airborne and fluid hazards, such as splashes or sprays. In times of extreme shortage, respirators should be restricted to staff dealing with suspect or confirmed case COVID patient or exposed to aerosol generating procedures performed on symptomatic persons [58].. Extended use has been recommended as an option for conserving respirators during previous respiratory pathogen outbreaks and pandemics [59,60].

Eye protection

Health care givers must wear plastic goggles or, preferably a face shield that covers the entire front (that extends to the chin or below) and sides of the face. Face shields can be re-used following the standard disinfection procedures. If a face shield is indicated but it is unobtainable, it could be built by using a soda bottle [61].

Hand protection

Disposable gloves should be used for every procedure and should be safely discarded after.

Body protection

Personnel assisting suspected or known COVID-19 positive women during labor and delivery and their babies immediately after birth should wear a water-resistant complete gown. As such supply may not available in local markets during the pandemic, some hospitals have started to produce gowns made out of cotton and nylon (Supplementary Figure 3).

Cleaning and disinfection

Handwashing with soap and water is still the best way to prevent transmission of the virus [6]. Cleaning refers to the removal of germs and reduction of their numbers from surfaces. It reduces the risk of spreading infection, but does not kill germs. Disinfecting refers to using chemicals to kill germs on surfaces [62]. Cleaning staff should wear surgical mask, gown and disposable gloves. Gloves and gowns should be discarded after each cleaning or disinfecting a room or area occupied by ill persons and hands must be washed immediately after the procedure [62].

Rooms where aerosol generating procedures have been performed (bag-valve ventilation, intubation, administration of nebulized medicines, bronchoscopy, etc.) need to be ventilated with fresh air for 1–3 h, if they are not functioning under negative pressure, before cleaning and admitting new patient(s) [63].

In many parts of sub-Saharan Africa, particularly in hard to reach areas or fragile states (i.e. South Sudan, Central African Republic, etc.) where sterilization machines or alcohol-based disinfectants or even soap may not fully available in the health care setting, sodium hypochlorite (chlorine or bleach), if properly prepared and used, could be a viable option for hand washing, cleaning, surface, toilets, textiles, medical equipment, PPE and waste management as recommended by CDC, ECDC and WHO. This should be applied also for staff and medical equipment dealing with neonatal care [62–64] (Table 1).

Conclusions

Since the end of 2019, an outbreak of the 2019 novel coronavirus disease (COVID-19) has spread at unprecedented speed around the world. Management of women with suspected or confirmed COVID-19 and postnatal care of their infants is based on standard

Table 2. Main concerns/questions and suggested solutions.

Main concerns/questions	Suggested solutions
Structure	
Overcrowded waiting areas	Use open spaces and identify well ventilated rooms (with large, open windows).
Risk of transmission through surface contact	Identify paths and rooms devoted to the care of COVID positive women and try to manage them in the same room for labor, delivery and post-natal care of the baby. Cleaning and disinfection of surfaces and equipment (with appropriate disinfectants) at every staff shift and when the patient leave the room.
Person-to-person transmission	
Risk of transmission among patients	Women should wear a mask (i.e. cloth mask) during triage and maintain distance of 2 meters among them. Identify 2 areas (one for healthy mothers and one for suspected/proven COVID-19 positive mothers.
Risk of transmission for health caregivers	PPE (goggles or a face shield, mask, disposable latex gloves, and a clean, non-sterile, long-sleeved gown) should be worn by staff during all procedures (assistance to labor and delivery) with a suspected or confirmed COVI positive woman. The same precautions have to be taken when managing a symptomatic baby in the NICU.
Risk of transmission to the baby	From mother: mother should wear a medical mask, wash hands before and after touching the baby, clean the breast before and after feeding, disinfect surfaces and equipment. From staff: staff should wear medical mask and wash hands before and after touching; the baby and manage the ill neonates in a closed incubator. From the environment: cleaning and disinfecting surface and equipment as indicated.
Visitors or support people in the hospital or delivery area	
Are visitors or support people allowed to stay at the delivery area?	Visitors are not allowed entering in the delivery area; one relative can just access the isolation room area twice a day for taking food to his/her patient.
Supply shortage	
Limited supply of material (i.e. masks, swabs, thermometers, fetal monitoring, stethoscope, …)	Consider cloth face coverings, but at least a surgical mask with face shield must be used when managing infected patients. Cleaning and disinfecting equipment immediately after use.
Infant nutrition	
How to feed the baby?	Breastfeeding must be supported with appropriate prevention measures (hand washing and breast cleaning before breastfeeding and use of mask). Expressed breast milk may also be considered in unwell mothers with help of staff or one COVID-19 negative family member who respects prevention measures.
Cleaning and disinfection	
How to do cleaning and disinfection?	Cleaning: use soap and water solutions before disinfection. Disinfection: at least once per shift and after a patient discharge. Choice of disinfectant products and their use based on specific indications and available resources.
Discharge to home and follow-up	
When mother and baby should be discharged?	Discharge to home of asymptomatic COVID-19 positive mothers should be based on routine protocol. Mother and family members should be instructed on recognition of dangerous clinical features (i.e. fever, shortness of breath, cyanosis, feeding intolerance, diarrhea) in order to refer the baby to health care center on appropriate time. Phone contact with mother should be considered.
Immunization	
When to vaccinate a baby born to COVID-19 positive mother?	Based on routine immunization policy.

rules, but all measures have to be directed to prevent transmission between the mother-infant dyad and among healthcare providers (Table 2). Knowledge and application of simple rules including maintenance of spatial distance, frequent hand-washing, identification and isolation of suspected or known cases, rationale use of PPE and disinfectant products represent the most effective barriers to combat the epidemic. Programs aimed to optimize structural, instrumental and human resources remain a crucial objective in this difficult time, especially in settings where the resources are limited.

Disclosure statement

The authors have no conflicts of interest to disclose. D.T., G.W., and S.V. are scientific experts associated with the Neonatal Task Force of the International Liaison Committee On Resuscitation and S.L. is a member of the steering committee of the American Academy of Pediatrics Neonatal

Resuscitation Program. The views expressed in this article are individual opinions of the authors and do not reflect official recommendations of these organizations. The other authors have no conflicts of interest to disclose.

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Limited agreement between clinical assessment of infant colour at birth and oxygen saturation in a hospital in Ethiopia

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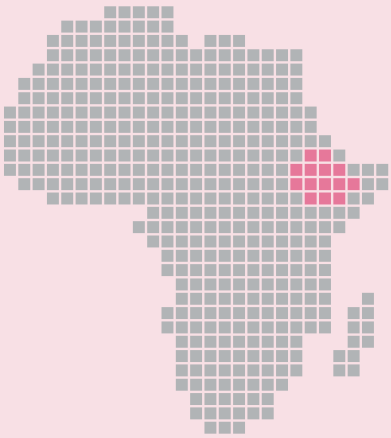

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A simplified diagnostic work-up for the detection of gestational diabetes mellitus in low resources settings: achievements and challenges

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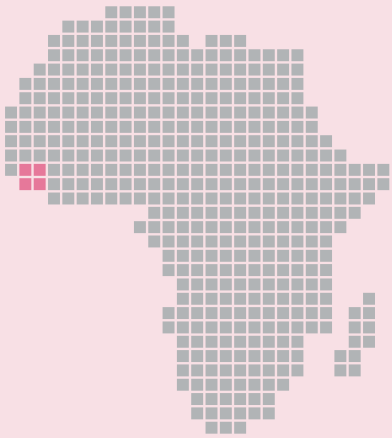

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MATERNAL-FETAL MEDICINE

A simplified diagnostic work-up for the detection of gestational diabetes mellitus in low resources settings: achievements and challenges

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Abstract

Purpose Modern strategies for the screening and diagnosis of Gestational Diabetes Mellitus (GDM) rely on universal Oral Glucose Tolerance Test (OGTT). However, they are unsustainable in low-income countries. In this study, we aimed at assessing the feasibility of a simplified diagnostic policy.

Methods The study took place in an urban referral hospital in Freetown, Sierra Leone. During an 11-month period, pregnant women were offered capillary blood test for glucose assessment. They could be screened at any time during pregnancy. GDM was diagnosed if fasting glucose was ≥ 92 mg/dl or if the OGTT was positive. The latter was prescribed only to women presenting after 24 weeks' gestation with at least one risk factor for GDM and fasting capillary glucose between 85 and 91 mg/dl. A definitive diagnosis required confirmation to this aim, women with values above the thresholds were invited to refer the next working day for repeating the test after fasting overnight.

Results Overall, 7827 women were referred for screening, of whom 6872 (87%) underwent at least one capillary glucose assessment. However, 895 of those who had a positive test did not return for confirmation. Overall, a definite assessment could be done in 5799 subjects corresponding to 76% (95% CI 75–77%) of those eligible. GDM was diagnosed in 128 women (1.9%, 95% CI 1.6–2.2%). Based on an expected confirmation rate of 22% (calculated from those who referred for confirmation) in the 895 women who did not come back, one could infer that GDM would have been diagnosed in additional 197 women, raising the prevalence to 4.7% (95% CI 4.2–5.3%).

Conclusion Three quarters of subjects could be assessed with our approach. Data also suggest that GDM is not rare even if identification of affected cases remains challenging.

Keywords Gestational diabetes mellitus · Screening · Low-resource setting · Glucose

Introduction

There has been a remarkable progress in health status in low-resource countries over the past two decades. However, additional important efforts are required to improve health and reduce mortality, particularly maternal and newborn mortality [1].

Gestational Diabetes Mellitus (GDM) in low-resource settings is neglected and has been poorly studied [2, 3]. However, improving the management of this condition may represent a valuable action to further tackle maternal and neonatal mortality and morbidity. Indeed, GDM is associated with obstetrical and neonatal complications that may expose women and their children to short- and long-term risks [4–7]. The hyperinsulinism can cause excessive

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foetal growth with metabolic consequences that can persist in childhood and adult life [5]. In the short term, the overgrowth of the foetus can cause complications at birth (traumatic injury, shoulder dystocia, obstructed labour and caesarean section). In addition, GDM increases the risk of preeclampsia and puerperal sepsis [4, 6, 8]. Of relevance is that pivotal randomized-controlled trials (RCTs) consistently showed that a prompt identification and treatment of GDM can effectively prevent these complications [9, 10]. On these bases, the main international scientific societies advocate universal screening of GDM with Oral Glucose Tolerance Test (OGTT) [11]. Specifically, based on the International Association of Diabetes in Pregnancy Study Groups (IADPSG) criteria, GDM is diagnosed if at least one of the three peripheral blood assessments of the 75 g OGTT overcomes the thresholds (baseline fasting ≥ 92 mg/dl, 1-h ≥ 180 mg/dl and 2-h ≥ 153 mg/dl) [12].

On the other hand, inferences of evidence obtained in western world to low-resource countries are challenging. Gold standards of management are actually unsustainable in these settings. Main obstacles include the lack of infrastructures, the scant awareness of the condition and of the possible preventive interventions, the low compliance and adherence of patients and the lack of financial resources to cover the costs [13, 14]. In addition, the clinical relevance of GDM in low-income countries remains uncertain. However, one may hypothesize that GDM-related complications could be more devastating because access to caesarean section and intense neonatal and adult care is hindered or significantly delayed. In addition, the strict monitoring of foetal conditions that is generally advocated for GDM women to prevent overgrowth or metabolic consequences is more complicated.

In this cross-sectional study, we aimed at assessing the feasibility of a simplified policy for the detection of GDM in Sierra Leone. The country is an underprivileged area of Sub-Saharan Africa ranking 184 out of 189 on the Human Development Index [15], with a under-5 mortality rate of 110 deaths per 1000 live births and a maternal mortality rate of 1,360 per 100,000 live births [16, 17]. More specifically, consecutive women referring for antenatal visits in a referral urban hospital were offered to be screened with mere capillary testing, regardless of the gestational age. OGTT was prescribed after 24 weeks' gestation exclusively to women with risk factors and borderline glucose values at baseline evaluation. The primary aim was determining the rate of women that could be assessed with this policy.

Methods

The study took origin from a comprehensive 2 years lasting project specifically dedicated to improving the management of GDM in the Republic of Sierra Leone. The project was supported by the World Diabetes Foundation (WDF) and implemented by the Italian non-governmental organization (NGO) Doctors with Africa CUAMM. The present cross-sectional study reports on part of the program, more specifically on the screening of GDM performed at the Princess Christian Maternity Hospital, a public referral hospital located in Freetown (the capital of the Republicof Sierra Leone). The study was approved by the local Institutional Review Board. An informed consensus was not requested because the study was planned after the implementation of the project and data were collected retrospectively.

The Princess Christian Maternity Hospital receives referrals for obstetrics complications from a catchment area of 1,606,145 inhabitants, corresponding to an annual number of expected pregnancies of 64,246. In 2018, the hospital ensured 22,542 antenatal visits, of whom 9440 were first visits. The total number of deliveries in the year was 7367, corresponding to 19% of all institutional deliveries in the area (data inferred from Sierra Leone 2015 Population and Housing Census, 2015) [18].

The main idea of the project was to determine the effectiveness and validity of GDM screening and diagnosis in low-resource settings, taking into utmost consideration the issues of sustainability and feasibility. The main views included the potential clinical relevance of GDM in low-resource settings [2] as well as the idea that glucose intolerance in pregnancy is not a "yes or no" condition but, instead, a situation characterized by a linear gradient between the grade of glucose intolerance and the frequency and severity of GDM-related obstetrics complications [5]. In other words, we did not aim at blindly transferring the western world modality of GDM detection, but, conversely, we aimed at implementing a sustainable screening that could detect the most worrisome cases. The project initiated in April 2017 and lasted 2 years. Data reported herein were collected starting some months after the implementation to allow the system to properly run. Specifically, data were retrieved from March 3, 2018 to January 30, 2019 with a 2-week interruption at the end of March because of the accidental loss of the dedicated registers.

A team of expatriated gynaecologists and midwifes with expertise in both western world and low-income settings implemented the project and performed the teaching and tutoring. Since the beginning of the project, a service specifically dedicated to GDM management and run by two trained nurses was implemented at the hospital. The criteria used for the diagnosis of GDM are illustrated in Fig. 1. Specifically, all women referring to the antenatal ward for obstetrical care were offered to be screened twice, one before and one after 24 weeks' gestation. No further specific restrictions for gestational age were given. The cut-off of 24 weeks' gestation was chosen because there is a general consensus that screening for GDM should be done

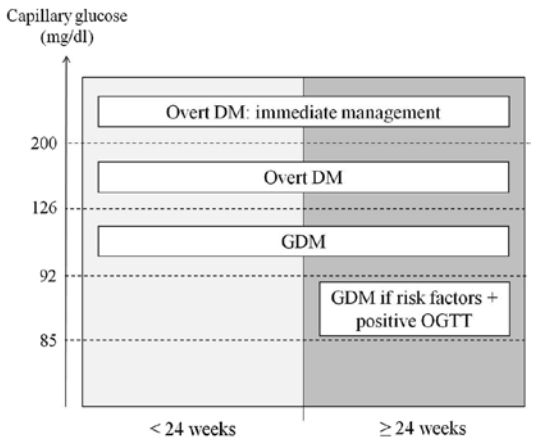

Fig. 1 Criteria for GDM diagnosis. Women were tested before and after 24 weeks' gestation. Diagnosis of GDM was done if fasting capillary glucose levels were ≥ 92 mg/dl (overt DM was diagnosed for levels ≥ 126 mg/dl). Women with levels exceeding 200 mg/dl were promptly referred for immediate clinical management. To rule out false positive results, women with positive findings were invited to refer the following working day after fasting overnight for confirmation ("come back tomorrow"). In addition, after 24 weeks' gestation, the subgroup of women presenting with risk factors for GDM and borderline fasting capillary glucose levels (85–91 mg/dl) underwent a 75 gOGTT. Criteria for diagnosis with OGTT were the detection of at least one value above the thresholds of 92, 180 and 153 mg/dl at baseline, and one and two hours after the glucose load, respectively. *GDM* gestational diabetes mellitus, *DM* diabetes mellitus, *OGTT* oral glucose tolerance test

after this gestational age [8–10]. However, given the elevated proportion of women referring for antenatal care only once during pregnancy in our setting, we could not restrict the time for screening only to the second part of pregnancy. We, thus, deemed important to perform the GDM assessment regardless of gestational age. Women accepting to perform the screening were referred to the GDM room to be managed by the dedicated nurses. The presence of risk factors was actively and systematically investigated. They included a first-degree relative with diabetes mellitus, BMI > 30 kg/m^2, age > 35 years, history of GDM, repeated miscarriages (≥ 3), previous stillbirth and previous macrosomia (neonatal weight > 4 kg). In women reporting fasting, a capillary blood sample was obtained and immediately tested for glucose concentration using a glucometer. Women denying fasting and those with values exceeding the stated limits (Fig. 1) were invited to refer the next working day for re-check capillary glucose concentration ("come back tomorrow") underlying the crucial importance of overnight fasting. This strategy was decided soon after the initiation of the project when it became evident that information regarding fasting was poorly reliable. It was, thus, decided that only women whose values exceeded the stated thresholds at the second assessment were diagnosed with GDM and continued in the diagnostic and therapeutic work-up. The unique exception to the "come back tomorrow" rule was the finding of capillary glucose exceeding 200 mg/dl at the first assessment; these women were straight referred to medical doctors for prompt management. In addition, women at gestational ages > 24 weeks' gestation with at least one risk factor for GDM and confirmed fasting capillary glucose between 85 and 91 mg/dl underwent a 75 g OGTT. They were diagnosed with GDM if at least one of the three assessments overcame the thresholds of 92 (basal), 180 (1 h) and 153 (2 h) mg/dl. Testing for OGTT was also done using capillary blood assessments. The idea to limit the OGTT exclusively to this subgroup of women rather than to the whole population was taken to avoid overburdening the antenatal care service.

In case of GDM diagnosis, women were invited to refer weekly. At first assessment, they were invited to increase physical activity if sedentary and to restrict food assumption if overweight. They also received a dietary consultation to improve their diet and were given a specific informative flyer. At each weekly visit, women presented after overnight fasting and capillary glucose were assessed before eating and 2 h later. The values obtained were used to tailor treatment and to decide on the need for medical therapies (metformin, glyburide or insulin).

Gestational age was calculated based on last menstrual period. In case of major discrepancy between gestational age and uterus measurement, an ultrasound examination was performed and, if indicated, gestational age was adjusted. Women referring to the antenatal care service did not routinely undergo ultrasound scanning. However, this examination was done in case of suspected pregnancy complications. Conversely, women who were diagnosed with GDM were systematically scanned at the time of GDM diagnosis and subsequently at every referral to monitor foetal growth and well-being. Elective caesarean section was planned in case of estimated foetal weight above 4500 g. Foetal growth exceeding the 90th percentile was an indication for induction of labour if the woman had reached at least 38 weeks' gestation.

Capillary glucose assessments were generally done using the glucometer On Call Plus II® (San Diego, CA, US). The HemoCue® glucose 201 RT (Angelholm, Sweden) was used for the OGTT and for GDM monitoring.

All diagnostic steps were for free. They include the capillary assessments, the consultations and the ultrasound scans if needed. Conversely, medical treatments were not supported by the project (subjects had to pay for the drugs). Women requested to come back the following working day after a fasting overnight were refunded of the costs of the journey.

Follow-up of affected women was done by consulting patients' charts at the hospital.

Data analysis was done using the Statistical Package for Social Sciences software (SPSS version 25.0, IL, USA). The recruited sample size was deemed sufficient to provide an estimate of the frequency of tested women and GDM diagnoses with a 95% Confidence Interval (CI) of less than 2%. The 95% CIs of proportions were calculated using a binomial distribution model. The Kaplan–Meier method was used to obtain the survival curve on the cumulative risk of GDM with gestational age. The frequency of risk factors between affected and unaffected women was compared using the Fisher's exact test. For this analysis, missing data were equated to absence of risk factor. The database is available on request. The described intervention ended in August 2019 and further evaluations are not foreseen.

Results

The flow diagram of the studied women is shown in Fig. 2. Overall, during the study period, 7827 women were referred for screening. In 955 of them, capillary testing could not be done because they reported to have just eaten and, despite being invited to refer again the following working day, they never came back. They were judged non-informative. Overall, data were available for 6872 women, corresponding to 87% of those eligible. Nulliparity was reported in 2689 subjects (39%); 2270 (33%) had one previous delivery, 1084 (16%) had two previous deliveries and 790 (12%) had three or more previous deliveries.

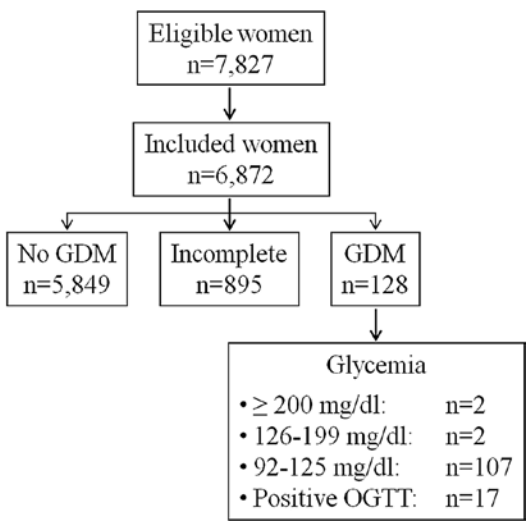

Fig. 2 Flow diagram of the study. Women were classified as "incomplete" when they were requested to come back the following day for re-assessment because of fasting capillary glucose levels exceeding 92 mg/dl but they never came back

One-thousand and nine-hundred sixty women (29%) were screened exclusively before 24 weeks' gestation, 3744 (54%) exclusively after 24 weeks' gestation and the remaining 1168 (17%) underwent both assessments. Overall, 4912 women were screened in the second part of pregnancy. OGTT was required in 32 women.

GDM was diagnosed in 128 women while the screening resulted negative in 5849 women. The remaining 895 women with initial positive capillary testing requiring confirmation did not perform it; 864 of them did not return despite the recommendation to come back the following day without providing explanations (drop-outs), while in 31 cases, this was due to the violation of the clinical protocol, i.e., they came back but did not undergo the test. Overall, definite information on GDM was, thus, available in 5977 women (128 + 5,849), corresponding to 87% (95% CI 86–88%) of those included and 76% (95% CI 75–77%) of those eligible. The diagnosis was exclusively based on fasting testing in 111 women (in four cases values were above 126 mg/dl) corresponding to 87% of the identified cases, whereas OGTT was required in the remaining 17 (13%). Forty seven out of 128 cases (37%) were diagnosed before 24 weeks' gestation; the remaining 81 (63%) were identified after 24 weeks' gestation.

Risk factors for GDM were more common in affected cases with the exception of a history of GDM and recurrent miscarriages (Table 1). Seventy six affected women (59%) had at least one risk factor compared to 1,404 controls (21%, $p < 0.001$).

To assess the importance of confirmation and its possible confounding effect on the estimation of the prevalence of GDM, we did a subgroup analyses on all women

Table 1 Risk factors for GDM in women with and without a diagnosis of GDM

Characteristics	GDM	Controls	*p*
Totale number	128	6744	
Age ≥ 35 years	19 (15%)	548 (8%)	0.02
BMI > 30 kg/m^2	28 (22%)	986 (15%)	0.04
Previous GDM	3 (2%)	50 (1%)	0.15
First degree relatives with DM	10 (8%)	55 (1%)	< 0.001
Recurrent miscarriages	3 (2%)	48 (1%)	0.07
Previous stillbirths	10 (8%)	66 (1%)	< 0.001
Previous macrosoma	22 (17%)	70 (1%)	< 0.001

Missing values were considered as negative

GDM gestational diabetes mellitus, *DM* diabetes mellitus, *BMI* body mass index

who attended for confirmation ($n=577$). The frequency of women who were diagnosed GDM ($n=128$) was 22%.

Overall, the prevalence of GDM in our cohort was 1.9% (95% CI 1.6–2.2%) (128/6,872). Figure 3 illustrates the cumulative rate of GDM with gestational age. Based on an expected confirmation rate of 22% in the 895 women who did not come back, one could infer that GDM would have been diagnosed in additional 197 women. The inferred prevalence of GDM in our cohort would raise to 4.7% (95% CI 4.2–5.3%) (128 + 197/6872).

Among women with GDM, the rate of referral for subsequent monitoring was 77%, 72%, 65%, 55% and 44% at 1st, 2nd, 3rd, 4th and 5th weeks, respectively. Insulin was immediately prescribed in the 4 women with overt Diabetes Mellitus. Twenty additional women were prescribed metformin or glyburide because diet was insufficient. None of the women who referred regularly were given insulin. Data on pregnancy outcome were available in 50 out of the 128 GDM cases (39%). One maternal death occurred in a woman because of eclampsia. Six stillbirths were documented (including the one associated to the maternal death). Among women delivering viable foetuses ($n=44$), the rate of macrosomia (foetal weight > 4 kg) was 32% ($n=14$, of whom seven underwent caesarean section). The rate of caesarean section was 18% ($n=8$).

Discussion

GDM is not rare in low-income countries but identification of affected cases is challenging. Our protocol was shown to be acceptable by the local population since the vast majority of women accepted the screening. Overall, definite data on GDM were available in three quarters of eligible subjects (76%) and six of seven included women (87%). However, we detected less than half of the potentially affected cases, i.e., 1.9% rather than a projected 4.7% that would have occurred if adherence to our confirmation policy was optimal. In addition, given the increase in prevalence with gestational age [19], the number of detected cases could have been higher if women referred more frequently in the second part of pregnancy. Indeed, the cumulative prevalence of GDM in our cohort overcomes 5% at the end of pregnancy. In fact, 29% of women in our cohort could be tested only in the first part of pregnancy. To note, based on a theoretical simulation that we run hypothesizing to overcome these two pitfalls (i.e., all women returned for confirmation and all were tested in the second part of pregnancy), the cumulative prevalence of GDM would reach 12% at the end of pregnancy (data not shown).

Even if there is currently a general consensus on the criteria to be applied for GDM diagnosis [12], their use in low-resource settings remain challenging and mostly inapplicable. The time required to perform an OGTT, the need for a specific gestational age for testing (24–28 weeks' gestation) and the need for blood rather than capillary assessments hamper its universal application. In a recent systematic review, Behboudi-Gendevani et al. identified seven main strategies for GDM screening [3]. The most appealing for low-resource countries is the 75 g OGTT with a single assessment at 2 h and a threshold for diagnosis set at 140 mg/dl. The pros include the possibility to perform the test also in non-fasting women and the need for a single rather than multiple assessments. The cons are the needs to prolong antenatal visits for at least 2 h and the necessity for a blood rather than a capillary assessment. This latter aspect actually hinders its use in peripheral basic care facilities that rarely have the possibility to perform blood tests. As a matter

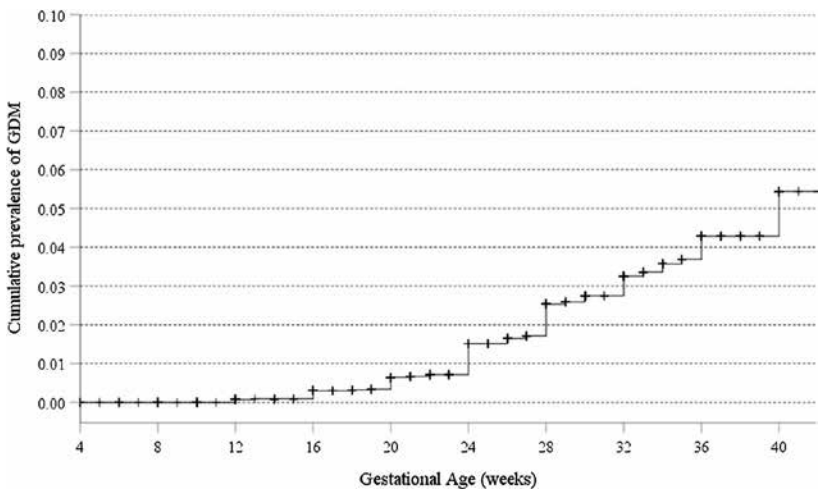

Fig. 3 Survival curve on the cumulative risk of GDM according to gestational age. The Kaplan-Meyer method was used to draw the curve. The prevalence of GDM at 24, 32 and 40 weeks' gestation was 1.5%, 3.3% and 5.4%, respectively

of fact, albeit attracting, this option appears inappropriate for universal application. If validated in other contexts, a screening approach exclusively using capillary assessments like the one proposed in the present study could be more sustainable.

In general, our study shows that GDM is not rare and screening may be worthwhile. To the best of our knowledge, the present study represents the first population-based evidence on the prevalence of GDM in the Republic of Sierra Leone and one of the few in sub-Saharan countries [2, 3]. To note, previously reported prevalence in this geographical area varied between 0 and 14% [2, 3], and thus in line with our findings. However, reliable epidemiological comparisons with other countries cannot be done. The use of peculiar and arbitrarily set criteria of diagnosis rather than the referral 75 g OGTT at 24–28 weeks hampers meaningful comparisons. On the other hand, it should be underlined that a population-based study applying the standard criteria of diagnosis in sub-Saharan countries is currently utopian. The few available evidence adopting these criteria in low-resource settings was obtained in experimental contexts [20, 21]. In addition, the authors had to face a consistent proportion of drop-outs (close to 50%), a situation that exposes the results to potential confounders [21]. In this regard, our study better reflects real-life situations. We actually opted to favour sustainability rather than methodology. However, our arbitrary criterion for definition of GDM is a weakness of the study and validation is warranted. Of particular concern is the reliability of capillary compared to plasma assessments of peripheral glucose. This aspect remains debated in general and the use for OGTT is not validated [22–24].

The Hyperglycaemia and Adverse Pregnancy Outcome (HAPO) study showed that there is a linear relation between hyperglycaemia in pregnancy and obstetrics complications [8]. The International Association of Diabetes in Pregnancy Study Groups (IADPSG) criteria for GDM diagnosis were set based on the wise but arguable statement that an increase in risk of complication of 1.75 would be relevant [12]. Therefore, so far, any thresholds for diagnosis could be viewed as arbitrary. In addition, one has to underline that, in the HAPO study, the increase in risk with the increase in hyperglycaemia was documented for all the three assessments of the OGTT (baseline, 1 h and 2 h). Using three measurements rather than only the basal one increased the sensitivity but not the specificity. In fact, 55% of cases were captured exclusively with the basal assessment (and this rate overcame 70% in some of the participating centers) [8]. On this basis, one may wonder whether the OGTT could be completely omitted in the diagnostic work-up in low-resource settings (at least in the initial phase of implementation), in particular if one aims at universal coverage and, thus, needs to include Peripheral Health Centers. Performing OGTT also requires fasting and makes the screening more complex and expensive. In addition, our data show that confirmation could be more fruitful in the identification of additional cases than OGTT. To note, this may also be due to our protocol that gave the indication to OGTT only in women with risk factors, a situation that was not very common (Table 1). In this regard, it has also to be pointed out that previous GDM was inevitably rare given that a policy of systematic screening was not in place. In addition, the relatively high proportion of nulliparous (39%) hinders the relevance of risk factors, such as previous stillbirths, previous GDM and previous macrosoma. Of interest here is also that differences in the frequency of risk factors markedly differ between affected and unaffected cases only for rare exposures (previous GDM, previous stillbirths and previous macrosoma) (Table 1), thus confirming the scant validity of a strategy based on risk factors for the identification of GDM cases. In fact, risk factors were present in only 3 out of 5 cases.

Overall, we believe that the main point of discussion is not whether or not our strategy identified all GDM cases (it did not) but, conversely, whether we captured those at highest risk of complications. We are confident that this might be the case, but we have to recognize that this opinion is speculative and more evidence is needed. In this regard, it is interesting to highlight that we identified four cases of overt Diabetes Mellitus (DM). These cases were presumably pre-pregnancy unnoticed cases of DM rather than frank GDM, but their identification underlines the interest of a simplified policy of glucose-intolerance screening. Indeed, if not identified, women with such severe glucose intolerance are exposed to life-threatening complications.

Our study also highlights some pitfalls of our intervention. First, the proportion of women who did not return for confirmation is too high. Reasons for drop-out were not actively investigated. However, we speculate that this may be mainly due to cultural reasons because the common local attitude is to overlook the importance of antenatal care. Most women in the studied settings refer only once during pregnancy. To note, the high proportion of nulliparous despite being in a high-fertility area also suggests that antenatal care was not perceived as crucial in the population (multiparae presumably skip any assessment during pregnancy). In addition, we cannot also rule out that logistic and financial constraints may have also played a role. This latter point is particularly concerning since the study refers to a period that was financially supported (tests and consultations were for free and women requiring confirmation were refunded for the costs of the journey) and the situation may worsen once external support will terminate. On the other hand, we are confident that the notion that fasting before performing an antenatal care consultation can progressively diffuse in the community so that, in the future, one may foresee to delete this step (or to reduce the proportion of women requiring to return). So far, our results show that confirmation is still a crucial aspect (only 22% of cases

remains positive at confirmation) but also suggest that the parallel awareness campaign made during the project gave some good results given that confirmation was needed in a minority of women, specifically 27% (984 + 842/6641).

Second, the high rate of obstetrics complications in detected cases is troublesome. On the one hand, it confirms the idea that the strategy could have identified cases at worse prognosis, while on the other hand, it clearly underlines that clinical management has to be improved. Even if the diagnosis of GDM may be per se a therapeutic achievement because affected cases are aware of the increased risk of complications (obstructed labour, preeclampsia or neonatal maladaptation) and could refer earlier and to more equipped centers, efforts should be taken to improve prevention of complications with more effective life-habit consultations and with the increased use of the pharmacological armamentarium (metformin, glyburide or insulin). Referral for weekly monitoring was low and we did not attempt to actively investigate the adherence to diet and therapeutic prescriptions. The project did not foresee sufficient attention to this important but challenging part of the management of GDM. Planning specific training at the hospital and in the community and implementing a dedicated team for therapy could fill this gap.

Some limitations of the study deserve to be commented. First, inference made on the prevalence of GDM is theoretical and should be interpreted with caution. Even if we did not show significant differences in the available baseline characteristics between women who did and did not return for confirmation (data not shown), we cannot exclude some other relevant selection bias. Second, even if the study was implemented within an everyday clinical activity of antenatal care, there is a need for validation in other contexts. In particular, one has to investigate the acceptability and effectiveness in rural areas. Third, economical evaluations were not done. Implementation of any policy needs to be supported by in-depth and reliable cost–benefit analyses, in particular in remote settings. Unfortunately, our study was not designed to address this issue. We calculated that the crude costs for running the service (including consumable, salaries, refunds for confirmation-related journeys and costs of the glucometers) corresponded to 170 Euros per identified case of GDM (data not shown) but we were unable to quantify the benefits. Much larger samples with precise information on the outcomes are necessary. To note, given the difficulties in designing such studies, one may consider theoretical rather than real-life economic analyses.

Conclusion

GDM is not rare in low-resource countries and may deserve consideration in public health interventions. Our protocol of diagnosis has some pros and cons but merits consideration, in particular if validated in other contexts. However, the strategy needs to be improved and several challenges remain. Priorities include the need to enhance sensitivity without increasing costs and the diffusion of the clinical know-how among healthcare givers.

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Compliance with ethical standards

Conflict of interest None of the authors have any conflict of interest to declare.

Ethical approval The study was accepted by the local Institutional Review Board.

Informed consent An informed consensus was not requested because the study was planned after the implementation of the project and data was collected retrospectively.

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Cost-Utility of Intermediate Obstetric Critical Care in a Resource-Limited Setting: A Value-Based Analysis

PAPER

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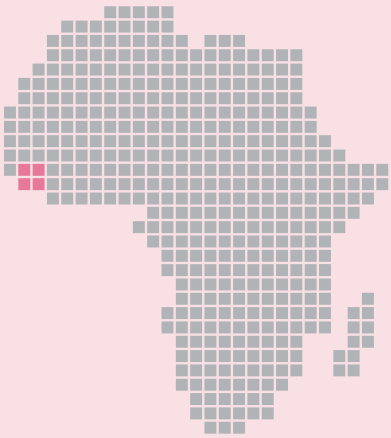

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ORIGINAL RESEARCH

Cost-Utility of Intermediate Obstetric Critical Care in a Resource-Limited Setting: A Value-Based Analysis

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Background: Sierra Leone faces among the highest maternal mortality rates worldwide. Despite this burden, the role of life–saving critical care interventions in low–resource settings remains scarcely explored. A value-based approach may be used to question whether it is sustainable and useful to start and run an obstetric intermediate critical care facility in a resource–poor referral hospital. We also aimed to investigate whether patient outcomes in terms of quality of life justified the allocated resources.
Objective: To explore the value-based dimension performing a cost-utility analysis with regard to the implementation and one-year operation of the HDU. The primary endopoint was the quality-adjusted life-years (QALYs) of patients admitted to the HDU, against direct and indirect costs. Secondary endpoints included key procedures or treatments performed during the HDU stay.
Methods: The study was conducted from October 2, 2017 to October 1, 2018 in the obstetric high dependency unit (HDU) of Princess Christian Maternity Hospital (PCMH) in Freetown, Sierra Leone.
Findings: 523 patients (median age 25 years, IQR 21–30) were admitted to HDU. The total 1 year investment and operation costs for the HDU amounted to €120,082 – resulting in €230 of extra cost per admitted patient. The overall cost per QALY gained was of €10; this value is much lower than the WHO threshold defining high cost effectiveness of an intervention, i.e. three times the current Sierra Leone annual per capita GDP of €1416.
Conclusion: With an additional cost per QALY of only €10.0, the implementation and one-year running of the case studied obstetric HDU can be considered a highly cost-effective frugal innovation in limited resource contexts. The evidences provided by this study allow a precise and novel insight to policy makers and clinicians useful to prioritize interventions in critical care and thus address maternal mortality in a high burden scenario.

Background

As international commitments in the health sector become more complex in the face of increasingly constrained aid resources, funding stakeholders increased the demand for value-for-money (VfM) assessments of global health interventions [1–3]. This holds true also for maternal and newborns health [4, 5]. Community based, antenatal care packages, and other primary care interventions to reduce maternal mortality have been demonstrated to be highly cost-effective [6]. This also applies to most hospital-based interventions, irrespective of their resource-intensiveness. In fact, with accessible and good quality clinical services, most maternal deaths may be averted—e.g., with skilled attendance to allow recognition and treatment of complications, along with a timely referral to hospitals for more complex care [6]. This hospital-based care includes various forms of obstetric intensive care support.

In a resources-limited setting, up to 15% of pregnant women suffer from some form of critical illness [7], conditions such as eclampsia, hemorrhage, coagulopathy, and sepsis, which may benefit from a more intensive setting of care. In high–income settings, this is provided by intensive care units (ICUs) [8, 9]. However, ICUs require significant technological, human, and technical investments, seldom affordable in resource constraints contexts. In poorer settings, high dependency units (HDUs) may

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represent frugal innovations incorporating few but essential lifesaving interventions to critically-ill women [9, 10]. These include a high patient to nurse ratio, close monitoring of vital signs, a personalized intravenous fluid, and vasopressor therapy management, rational use of oxygen and antibiotics, a fundamental point of care laboratory [11], adequate pain management, blood transfusions, and renal output monitoring in the early postoperative period, may impact outcomes for critical pregnant women in a referral Comprehensive Emergency Obstetric Care Service (CEmOC).

However, there are no accurate estimates of health effects and costs sustained by services providing intermediate obstetric critical care in resource-limited countries.

In particular, Sierra Leone is the country with highest maternal mortality ratio (MMR) worldwide – accounting 1.360 deaths per 100.000 live births in 2015, and healthcare system has been strongly proved by a prolonged civil war (1991–2002) followed by Ebola virus disease outbreak (2014–2016). These events have profoundly affected the already fragile healthcare system, leading to a significant worsening of maternal health indicators [11–13].

The case of the HDU of an urban, high-volume maternity referral hospital in Freetown, Sierra Leone, maybe paradigmatic in order to assess the cost-utility of such intervention. In this study, we hypothesized that the value of the extra cost per QALY gained from the implementation and one-year running of the HDU in a large maternity hospital would amount to less than three times the country's average per capita gross domestic product (GDP) at purchasing power parity. This cutoff follows suggested benchmarks for adequate value for money (VfM) in global health interventions [14].

This study aimed to evaluate from a value-based perspective whether it is sustainable, economic, and 'useful' to introduce an obstetric intermediate critical care setting in contexts with high morbidity and mortality coupled to limited resources to face these challenges. We also questioned whether the outcomes obtained in terms of quality of life justify the investment of the expected costs.

Methods

Study design

We performed a retrospective cost-utility analysis for the implementation and one-year (2nd October 2017 to 2nd October 2018) operation of the HDU of a large maternity hospital in an African urban context (Princess Christian Maternity Hospital [PCMH], Freetown, Sierra Leone). The study received ethical approval and a waiver of informed consent from the Sierra Leone Ethics and Scientific Review Committee (on December 18, 2018). The study was registered on ClinicalTrials.gov (study identifier NCT04121234).

Study Setting

With 129 beds, the PCMH is the largest maternity referral hospital in Sierra Leone, with a reference population of 1.5 million inhabitants. PCMH is a primarily obstetric institution with approximately 9,000 admissions and 6,500 deliveries per year [15, 16]. One-third of the parturients develop major obstetric emergencies, including peripartum haemorrhage, sepsis, and pre-eclampsia [15, 16]. Theatre and anesthetic facilities are essential. The only public ICU in Freetown with a very basic setup is located at the nearby Connaught Hospital.

Intervention

The intervention assessed was the implementation and one-year operation of a nurse-based HDU in a high-volume urban referral maternity hospital. The HDU was set up to centralize at-risk patients, or patients with established organ failures, especially after lifesaving surgery and anesthesia. The HDU aimed to ensure the maximal level of assistance possible in this context in order to reduce maternal mortality – or guarantee a dignified terminal phase in case of death. The HDU is a 4-bed medium care unit, with an additional four step–down beds, with a nurse to patient ratio of 1:2 available 24/7. Common interventions include close monitoring of vital signs and organ function, intravenous fluids, vasopressor therapy, antibiotics, rational use of oxygen, and a very basic point of care laboratory [17]. Electricity and clean water were continuously available, while oxygen was generated through bedside oxygen concentrators with a maximal output of 10 l/min and maximal purity of 96%. The basic setup of a typical HDU bed in PCMH is shown in **Figure 1**. No mechanical ventilators or dialysis apparatus were available in the unit or hospital at the moment this study ran. A basic neonatal ICU was available as a separate entity. Physicians performed a clinical round twice a day and were called when needed. The HDU is supported by 'Doctors with Africa – CUAMM' (DwA – CUAMM), an Italian non–governmental organization. A central room of the hospital was chosen and renovated with independent water and power system. Specific training was done to a selected pool of nurses with the collaboration of trainers from the Network for Intensive Care Skills Training [18].

Study endpoints

The primary endpoint was the quality-adjusted life-years (QALYs) of patients admitted to the HDU during the study period, against direct and indirect extra costs of the HDU admission. Secondary endpoints included key treatments received during HDU stay.

Data collection

The study included all women during pregnancy or up to 42 days after the termination of pregnancy [19], admitted to the hospital, and HDU in the one-year study time-frame. The primary data source was the HDU patient chart, with data crosschecked with the hospital patient charts and the HDU admission book for quality control purposes. Data on hospital deliveries, admissions, and mortality were taken from the hospital register and the maternal mortality hospital database. The data was collected by a dedicated researcher (CM) and included patient demographics, admission date, and source, main reasons for admission to hospital, defined as by the WHO handbook on Monitoring emergency obstetric care [19], (detailed in Supplementary Table 1); the main reason for admission to the HDU, classified as haemodynamic instability or haemorrhage; sepsis; acute renal failure; neurological impairment; respiratory distress; severe malaria; coagulopathy; other diagnoses.

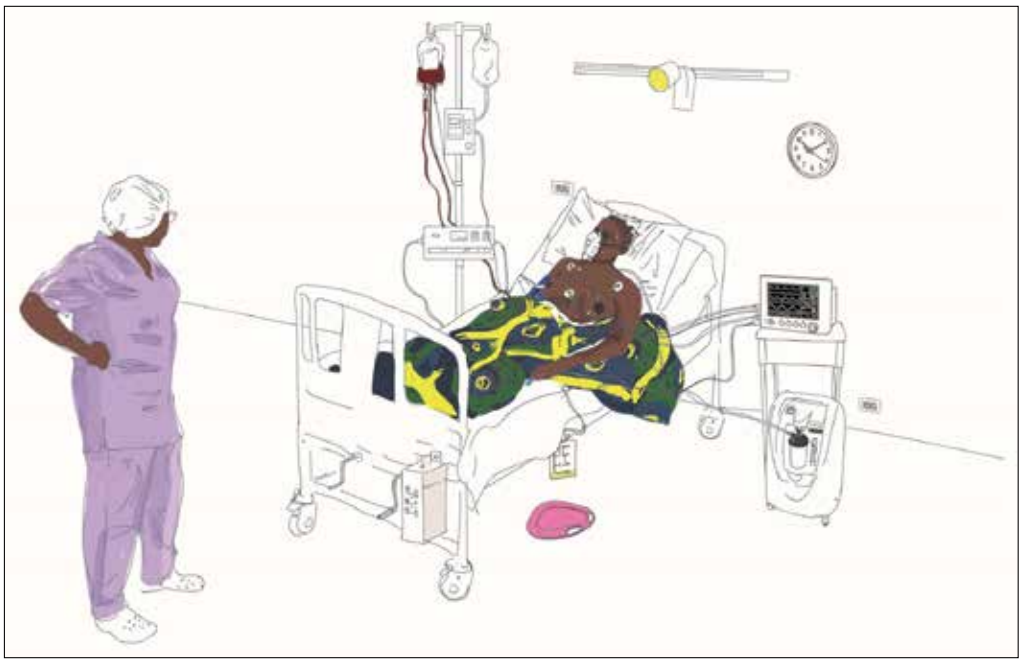

Figure 1: Overview of a PCMH HDU bed with essential standards of care provided (see text).

These were system–based diagnoses based on the clinical assessment of the attending physician rather than strict research definitions.

Specific treatments received at any point during HDU stay included: oxygen supplementation, use of vasopressors, blood transfusions, antibiotic therapy, eclamptic seizures prevention with intravenous or intramuscular magnesium sulphate and anti–hypertensive treatment with intravenous hydralazine. Time from hospital admission to HDU admission was calculated. Length of stay (LOS) and patient outcomes at discharge (classified as a death in HDU, discharge to ward, or transfer to other facilities).

Assessment of Value

Among the variety of methods to assess value, we used QALY [20]. QALYs are a composite measure of health outcomes, which combine the length of time spent in a health state with the quality of life experienced in that health state. Specifically, the estimation of QALYs multiplies two variables, namely:

(a) *Years of life gained due to the health intervention*: calculated as the difference between the age of the woman when the critical health event occurred and the life expectancy in Sierra Leone at that time (53.8 years) [21–23].
(b) *Health-related quality-of-life weights*: health-related quality-of-life weights associated with each health state in the model – on a cardinal scale of 0–1, where 0 indicates death and 1 indicates full health – were derived from the peer-reviewed literature (**Table 1**), and age-specific baseline quality-of-life estimates for reproductive health.

Costs

Direct and indirect costs were included and classified as implementation cost (drugs, equipment, medical materials and consumable, human resources, renovation, training, and other – e.g., this included an electricity generator) and running costs (drugs, medical materials and consumable, human resources, maintenance, training). Custom import taxes were also included. No adjusting of unit costs for inflation was performed.

We analysed only *extra expenditure for HDU implementation and one-year running*, calculated as the amount of direct and indirect cost provided by the NGO in addition to the Free Health Care Initiative provided by the National Health System and to the hospital infrastructures already available. Thus by using the term '*cost*,' we refer to the *extra cost* in addition to the current funding. Neither hospital budget nor specific government expenditure for HDU information was available – even upon request – and for this reason, the total expenditure for HDU could not be estimated.

We undertook a retrospective costing review using as primary data source the DwA-UAMM project budget and accountability, including invoices. As for the pharmaceutical expenditure, the DwA-CUAMM pharmacy register was used, and data were crosschecked with the HDU pharmacy request book. The financing spectrum for the first year was mixed: DwA–CUAMM mainly financed renovation, training, and material procurement, while the nurse pool and drugs were financed both by hospital budget

Table 1: Health-related quality-of-life weights.

Quality of Life weights	Health-related reasons
0.0	Deaths
0.30	Referral to Intensive Care Unit
0.40	Hysterectomy in patients <30 years
0.80	B-Lynch surgical procedure in patients <30 years
0.90	Uterine ruptures in patients <30 years
0.90	Sepsis (29)
0.95	Pre-eclampsia/eclampsia (30)
0.50	Other severe diagnosis (disseminated intravascular coagulation, emiparesis)
1.0	Full recovery at discharge

and DwA–CUAMM. A pool of 13 nurses was trained and dedicated to HDU and received an allowance from DwA–CUAMM for the extra working hours in addition to their former salary. Similarly, drugs from the hospital pharmacy were assigned to the HDU as for the other hospital wards, and extra drugs provision was supplied from DwA–CUAMM.

Cost-Utility Analysis

Cost per QALY was calculated by dividing the total costs of the intervention (investment and operations) by the number of patients treated in the study time window. The cost per QALY was also analyzed according to the main admission diagnosis. In order to provide an estimation of running costs, the cost per QALY was also calculated, excluding the investment costs.

The cost-utility of the intervention was evaluated from a Value for Money (VfM) point of view, verifying if each QALY gained had an extra cost less than three times the country's average per capita gross domestic product (GDP) at purchasing power parity, as suggested from WHO in global health interventions [14]. The Sierra Leone GDP in 2018 was $4 billion [20], with a GDP per capita of 523 US dollars ($) or 472 euros. This ranks Sierra Leone 187th among 196 censed countries [21]. Thus an intervention yielding a QALY for <$523 is considered *very cost-effective*. Interventions yielding a QALY at a cost greater than three times GDP per capita (>$1569) are considered *not cost-effective*, while those falling between $523 and $1569 are considered *cost-effective*.

Results

Patients Characteristics and Clinical Outcomes

From the 2nd October 2017 to 30th September 2018, 523 patients (median age 25 years, IQR 21-30) were admitted, an average of 44 patients a month. Patients' clinical profile and specific fatality rates are objects of a separate analysis. Fifty-five patients died in HDU (10.5%). Four out of five patients (n = 428, 81.9%) improved and were transferred to the ward after a median stay of two days (IQR 1-3). Thirty-three patients (6.3%) were transferred to an external ICU or to other hospitals after a median stay of two days (IQR 1-4), and seven patients (1.3%) were discharged directly at home after a median stay of five days (IQR 4-6). Key procedures and treatments administered in both dead and alive cases are reported in **Table 2**.

Costs

Values for investment and one-year running costs are detailed in **Table 3**. The total cost summing investment with operation costs was of €120,082. Total investment costs accounted for approximately half of the total costs, with one quarter spent on equipment, one quarter for renovation work, 14% for the electricity generator, 13% for the nurse training, and only 11% for medical materials and drugs. Instead, most of the one-year running costs were explained by medical materials and consumables, followed by maintenance, human resources, and training. Detailed costs per each category are available in Supplementary Table 2, while the drugs available are listed in Supplementary Table 3.

Values of QALY

The estimation of the years of life gained with the intervention was 28.8 years (median, range 8.8–39.8). The total of years gained was 14,160.6 years resulting in a cost for a year of life gained value of €8.4.

The value of QALY gained on the overall sample was 22.8. The mean values of QALY gained for each of the main admission diagnosis are reported in **Table 4**. The category "others" – disseminated intravascular coagulation (DIC), sickle cell disease, severe malaria – had the highest cost per QALY of €12.5, followed by puerperal sepsis (€10.9) and PPH (€10.6); on the contrary, complications of abortion had the lowest cost per QALY value (€8.8).

Cost-Utility Analysis

Dividing the total costs by the total number of patients admitted, the extra cost per admitted patient was €230, equalling a cost per QALY of €10.0. This resulted in being much lower than both thresholds defining 'cost-effective' and 'very cost-effective' interventions for Sierra Leone (**Figure 2**). Considering only the running costs, the cost per admission/patient was of €107, equalling a running cost per QALY of €4.7.

Table 2: Use of key procedures and treatments provided in the HDU compared between survivors and non-survivors.

Treatment	All patients (n = 523)	Alive cases (n = 468)	Dead cases (n = 55)
Oxygen	116 (22.2%)	84 (72.4%)	32 (27.6%)
Vasopressors	68 (13.0%)	45 (66.2%)	23 (33.8%)
Transfusions	263 (50.3%)	241 (91.6%)	22 (8.4%)
Antibiotics	109 (20.8%)	103 (94.5%)	6 (5.5%)
Magnesium Sulphate protocol	72 (13.8%)	63 (87.5%)	9 (12.5%)
Hydralazine protocol	74 (14.1%)	68 (91.9%)	6 (8.1%)

Table 3: Values for investment and one-year running costs of the HDU in the study.

	Value in €	%
INVESTMENT COSTS	**64.064,65**	**100**
Drugs, medical materials and consumable	6.763,50	11
Equipment	16.355,31	26
Human resources	7.644,44	12
Other – extra generator	9.182,12	14
Renovation work	15.971,35	25
Training	8.147,92	13
ONE-YEAR RUNNING COSTS	**56.017,28**	**100**
Equipment, medical materials, and drugs	33.956,54	61
Human resources	5.094,95	9
Maintenance	13.182,83	24
Training	3.782,95	7
TOTAL COSTS	**120.081,93**	

Table 4: Values of QALY and cost per QALY per main admission diagnosis in the HDU.

Main Admission Diagnosis	n. patients n (%)	QALY (mean)	Cost per QALY (€)
Ante-Partum Haemorrhage (APH)	85 (16.3)	23.4	9.8
Post-Partum Haemorrhage (PPH)	66 (12.6)	21.7	10.6
Pre-Eclampsia (PE)/eclampsia	117 (22.4)	23.6	9.7
Complications of abortion	12 (2.3)	26.2	8.8
Ectopic Pregnancy	53 (10.1)	25.5	9.0
Obstructed labour	28 (5.4)	25.2	9,1
Puerperal Sepsis	49 (9.4)	21.0	10.9
Uterine Rupture (UR)	55 (10.5)	24.3	9.4
Others	58 (11.1)	18.3	12.5
Overall	**523**	**22.9**	**10.0**

Discussion

This study analyzed the sustainability of an obstetric HDU in a resource-limited setting. The cost-utility analysis yielded the following value-based findings: (1) the total cost for starting and running an HDU for more than 500 patients was of €120,082 – resulting from 53% of investment costs and 47% of one-year running costs; (2) the extra cost per admission was of €230, with an overall cost per QALY of €10; (3) the intervention can be defined as *highly cost-effective*, as the value of cost per QALY gained resulted in being much lower than the Sierra Leone annual per capita GDP.

To the best of our knowledge, no other similar research experiences have been reported in the literature. So, the strength of this analysis lies in being the first value-based evaluation of an obstetric HDU from limited resources

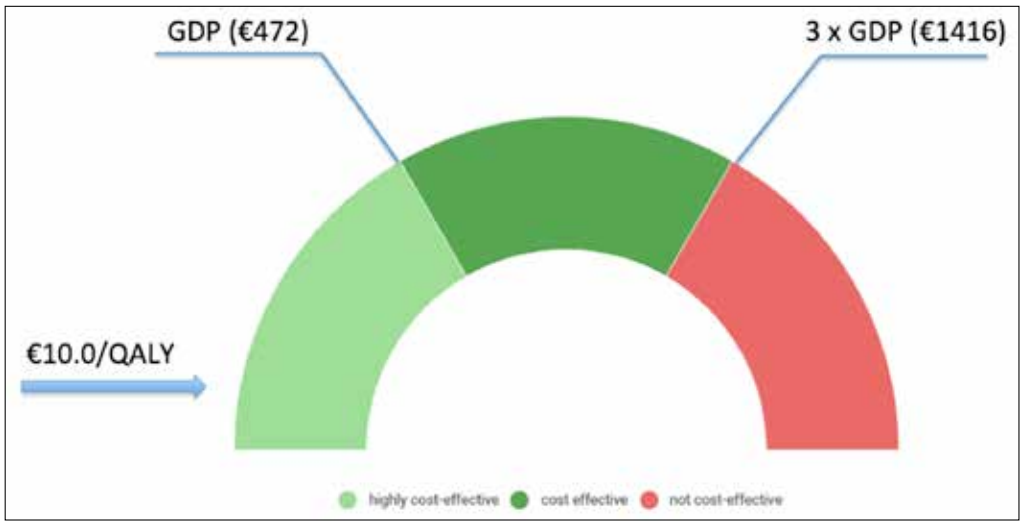

Figure 2: Cost for QALY of the implementation and one-year running of HDU within the framework of the World Health Organization interpretation of the cost-effectiveness of health care interventions. *If the value of cost per QALY is less than the Country's GDP per capita, then the intervention is considered very cost-effective. If the value of cost per QALY falls between one and three times GDP per capita, then the intervention is cost-effective, and if the cost per QALY is more than three times GDP per capita, the intervention is considered not cost-effective* [12].

setting with extreme maternal mortality, even if direct comparison with analogue experiences and benchmarking could not be performed. Real-world data is instrumental in informing decision-makers for resource allocation processes while defining fields of action where the greatest health gains can be achieved. In this way, it is directly related to Universal Health Coverage, since shifting from a less to a more cost-effective set of health, activities is equivalent to raising new finance.

Just above a hundred thousand euros were sufficient to start and run an HDU serving more than 500 patients. The investment cost amounted to half of this figure required for renovation and basic equipment. Most of the one-year running costs were explained by medical materials and consumables and by maintenance cost. This total figure is not excessive if we consider that ICU admission costs for advanced therapies in high–income countries may reach 80 thousand euros for a single patient [24].

The total extra cost per admission/patient in our study was €230, and this value drops to roughly €100 when accounting only for the running costs. Being intermediate – and not full ICU care, this compares favorably to the total cost per ICU admission day in India of around the US $ 200 found in one of the rare costing analyses of an ICU from a low or middle-income country [25, 26]. In high-income countries, the median *daily* cost of a non-ventilated patient was recently estimated in German ICUs to euro 999 [26], thus, twenty times higher the running cost per day found in this cohort (considering a median HDU stay of two days). We were unable to assess the share of the HDU costs in the overall hospital stay costs since we lacked a precise estimation of out of HDU hospital costs. However, it is known that critical care absorbs the highest quota of hospital budgets [26, 27]. This holds true also in low and middle-income countries despite these have lower ICU costs than high–income countries and thus more conservative cost-effectiveness ratios [28–30].

The cost per QALY gained was extremely low, i.e., €10.0 were spent for every year of life gained in perfect health. This value is very low also for a limited resource setting [14], and is surely facilitated by the young age of the patients [26] and high reversibility of obstetric conditions [8]. QALYs are a measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. Being much lower than the WHO threshold of one time, the annual per capita GDP – the extra effort spent to implement and run the HDU can be considered highly cost-effective [14]. Among the variety of methods to assess value, we decided to use QALY since the study was based on the evaluation of a single intervention without direct comparison, and also because this is recommended for intensive care settings [20, 31, 32]. In our sample, the HDU intervention allowed an estimated average gain of 22.8 years of life in perfect health for the woman who had benefited from it. The number of life-years gained per patient is similar to the one found in an economic evaluation of a low-resource ICU in Sarajevo, where however the cost of treatment per QALY saved was higher and varied between 100 and 2514 US $ [29].

This analysis also offers a reflection in a donor 'exit strategy' perspective to ensure that the benefits of the intervention are not lost once the external support finishes. After the first year, the investment costs are zeroed. Hence considering only the running costs and maintaining the same volume of activity and the same

patient case-mix of the year in the study, the cost per admission/patient would be only just above €100, with a cost per QALY below $5. Also, according to our results and the high morality ratio in Sierra Leone, it could be suggested to set up a national needs assessment of obstetric HDU beds and their appropriate distribution between the government district hospital of the country [31–33].

Our study has some notable limitations. We analysed only extra expenditure for HDU implementation and one-year running, calculated as the amount of direct and indirect cost provided from the external partner in addition to the Free Health Care Initiative provided by the NHS and to the hospital infrastructures already available. For example, surgical procedures and related costs were not included in the analysis as these are provided independently of the HDU service and are part of the routine treatment of several obstetric critical illnesses. However, it is obvious that effective supportive critical care needs fast surgical etiological treatment. Secondly, the generalizability of the findings is limited to similar settings, being this monocenter study from a single African urban setting. Finally, the retrospective nature made it impossible to examine health-related quality of life (HRQoL) after the HDU discharge, and its comparison to age-appropriate reference values from the general Sierra Leonean female population. Integrating such indicators in future investigations could allow a comprehensive value-based evaluation including also the personal value. In conclusion, our data contribute to tackling the scarcity of costing analyses regarding obstetric critical care in limited-resource settings. The obstetric HDU under study resulted in being a low-cost and highly cost-effective intervention. These findings allow a precise insight to policymakers, donors, and hospital managers that wish to consider critical care frugal interventions to address maternal mortality in low–income settings.

Additional Files

The additional files for this article can be found as follows:

- **Supplementary Table 1.** Operational definitions of major direct obstetric complications according the WHO Handbook Monitoring emergency obstetric care. DOI: https://doi.org/10.5334/aogh.2907.s1
- **Supplementary Table 2.** Detailed investment and one-year running costs. DOI: https://doi.org/10.5334/aogh.2907.s2
- **Supplementary Table 3.** List of drugs used in HDU during the first year of operations. DOI: https://doi.org/10.5334/aogh.2907.s3

Competing Interests

The authors have no competing interests to declare.

Author Contributions

All authors contributed to the conception and design of the study. CM, GP, LP, FDG contributed to the interpretation of data. VP, LP, FA, EB, has also contributed to the design of the study and analysis. The manuscript has been approved by all authors.

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Epidemiology, outcomes, and risk factors for mortality in critically ill women admitted to an obstetric high-dependency unit in Sierra Leone

PAPER

Authors
Marotta C., Pisani L., Di Gennaro F., Cavallin F., Bah S., Pisani V., Haniffa R., Beane A., Trevisanuto D., Hanciles E., Schultz M.J., Koroma M.M., Putoto G.

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Emergency paediatric blood transfusion practices in Mozambique

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Authors
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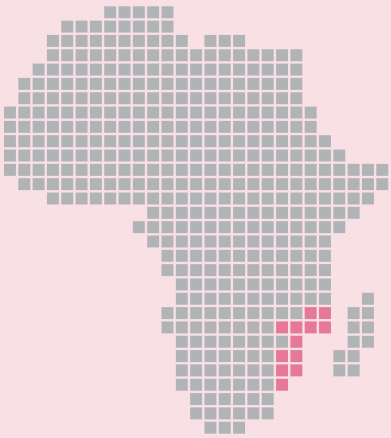

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Neonatal Intensive Care Unit Evacuation and Care During a Natural Disaster: The Experience of Cyclone Idai in Beira, Mozambique

PAPER

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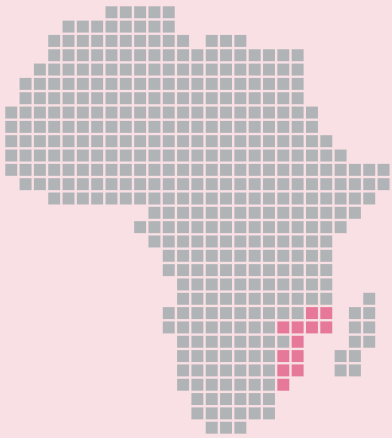

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Neonatal Intensive Care Unit Evacuation and Care During a Natural Disaster: The Experience of Cyclone Idai in Beira, Mozambique

Serena Calgaro [1,2], Martina Borellini [1,2], Amir Hussein Abubacar Seni [3], Maria Concetta Tirzi [2], Antonio Marcos Dias Gimo [3], Bonifacio Rodriguez Cebola [3], Giovanni Putoto [2] and Daniele Trevisanuto [1]*

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Global warming has increased the frequency of natural disasters, such as cyclones. Mozambique is considered one of the most vulnerable countries to extreme weather events. Natural disasters particularly affect vulnerable people, including preterm and critical ill infants of Neonatal Intensive Care Units (NICUs). Literature on NICU evacuations in the case of a natural disaster has been reported in high-resource settings, but it is lacking in low-resource settings. On the 14th of March 2019, a tropical cyclone (Idai) hit Mozambique. This report is a descriptive analysis of the experience of the NICU evacuation and care during and after cyclone Idai at Beira Central Hospital, Beira, Mozambique.

Keywords: NICU, neonatology, cyclone, natural disaster, Mozambique

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INTRODUCTION

During natural disasters Neonatal Intensive Care Units (NICU) patients are potentially the most vulnerable in a hospital structure. Despite this fact, literature on NICU evacuations remains very limited dealing with the experiences in high-resource settings (1–4). Barkemeyer published a descriptive report of NICU evacuation during Hurricane Katrina at the University Hospital of New Orleans in 2006 (1). After 5 years, he analyzed how the lessons learned from that experience were implemented, concluding that health care system preparation is the key component for facing extreme events (2). The presence of an evacuation plan allowed safe NICU evacuation in New York during Hurricane Sandy in 2012 (3). In 2017 Iwata et al. reported the first experience of a NICU evacuation after an earthquake in Japan, highlighting the urgency to develop a specific emergency plan for vulnerable infants (4).

Experience with NICU evacuations during natural disasters in low-resource settings, remains a knowledge gap.

On March 14, 2019, category 4 cyclone Idai struck Mozambique, Malawi, and Zimbabwe affecting 3 million people. In Mozambique alone, Idai killed at least 602 people, injured 1,641 and left an estimated 1.85 million people in need (5). In Beira, Mozambique, the cyclone and subsequent flooding severely damaged infrastructure and roads leaving the population isolated without electricity or communication for many days. All 17 health centers and the hospital were affected (3).

We report the events and the lessons learned from our experience at Beira Central Hospital in order to inform best practices in neonatal emergency care during future disasters.

Hospital and NICU Background

The Central Hospital of Beira is a 1,040 bed referral hospital, located at 200 m from the coast. Every year, CHB records about 6,000 births. The hospital has a neonatal intensive care unit (NICU), the second biggest in Mozambique, service of reference for three provinces. Neonates aged 1–28 days of life are admitted to the NICU, with the lower level of viability around 28 weeks' gestation and/or birth weight around 900 g. Survival of extremely low birth weight infants is very rare. At CHB, structured plans for evacuation in case of emergency situations (i.e., natural disasters or fire) were not available.

In 2018, 2,176 newborns were admitted to the NICU, 49% of them were <2,500 g. The NICU is staffed by a local medical team of two residents and two general doctors, directed by a pediatrician from Cuba. A neonatologist and a pediatric fellow of Doctors with Africa CUAMM (an Italian non-governmental organization) continuously support the staff. Twenty-six local nurses and six local health workers complete the team. The neonatal ward is located on the 1st floor of the main building, near the Gynecology and Obstetrics Unit. It is organized in two sub-units: a 14 beds NICU and a 19 beds Kangaroo Mother Care (KMC) Unit. In the NICU there were seven incubators and six infant warmers, even if the bed capacity was often exceeded. The NICU offers the possibility of non-continuous monitoring of vital signs, respiratory assistance limited to non-invasive support (oxygen via nasal cannula, bubble continuous positive airway pressure - CPAP), intravenous hydration in peristaltic and syringe pump (even if not in sufficient number for all patients), umbilical and peripheral venous catheterization, phototherapy, enteral nutrition with gavage. A portable ultrasound machine is also available. There is no possibility to offer parenteral nutrition, invasive ventilation or therapeutic hypothermia.

Pre-landfall

The population of Beira was alerted about 1 week before the cyclone's landfall, but no emergency plans were specifically organized. On March 14th, there were 13 sick infants in the NICU and 17 stable infants in the adjacent Kangaroo Mother Care (KMC) unit. One patient was receiving respiratory support with bubble CPAP, and other five were treated with supplemental oxygen.

The outer bands of the cyclone arrived on the morning, many hours before the Idai's eye impact. Because of logistic difficulties to reach the hospital, the nurse staff was reduced. Finally, that night the staff was composed by a doctor and a health care worker, as usual, but only by one nurse instead of three. None of them had previously received training on management of emergency situations or evacuation plans.

Landfall

Time line of events and interventions are reported in **Figure 1**.

6:00 p.m.–0:00

In the afternoon of March 14th, Idai's eye made landfall on Mozambique's coast with winds that reached 121 miles/h. Shortly afterward, electrical power, water and telephone services failed. A generator briefly provided electricity but it was damaged by water. While functioning, the staff used their mobile phones for light and communication. The lack of electricity signified that incubators and radiation lamps usually used to keep warm the newborns didn't work; moreover, infusion and syringe pumps were out of action.

00:00–2:00 a.m.

Later that evening, a portion of the roof and windows were torn apart and rain entered the NICU (**Figure 2**). Neonates who were feeding with formula milk, didn't receive it during the night until 12:00 of the following day. Fortunately, all the NICU were receiving intravenous hydration and the infusions were administered without electric pumps.

At 2:00 a.m., the NICU patients were moved to the KMC unit where mothers helped care for the additional babies by wrapping them in dry sheets. Only one oxygen source was available and no cardiorespiratory monitors. Unfortunately, during the evacuation, a preterm suffered severe hypothermia. This likely contributed to his death on 15th March morning.

2:00–7:00 a.m.

Fortunately, the area of KMC was not excessively damaged, except for some broken windows. The patients remained stable in this area, receiving only intravenous hydration and being kept warm with dry cloths, waiting for the improvement of the weather conditions. At 4:00 a.m. the cyclone's strength started to shrink, and subsided at 6:00 a.m.

7:00–12:00 a.m.

As the NICU was severely damaged, two pediatric intensive care unit (PICU) rooms were adapted to care for NICU patients in an adjacent building (**Figure 3**). The evacuation was coordinated and performed by the doctor and the nurse who were on duty that night.

Babies were carried to the PICU in providers' arms because transport incubators were not available. Current medical records were rescued, but the NICU document archive was destroyed. Lacking communication equipment, the staff didn't know about the condition of their own families or when relief would arrive. In the NICU, a nurse had to work for 26 h continuously. Medical shift came at 12:00. Unfortunately, the number of kangaroo beds was considerably reduced, from 20 to 8.

Recovery

The majority of hospital departments were severely damaged. In the "new" NICU, the staff faced challenges due to limited space, oxygen, and supplies for hygiene and thermoregulation. It was necessary to place more than one baby in each bed. Because there were only two oxygen sources, an improvised distribution system was created using multiple "Y" -connectors and tubing so each source could provide oxygen to 3–5 infants. As incubators were damaged, radiant lamps were used to prevent hypothermia and

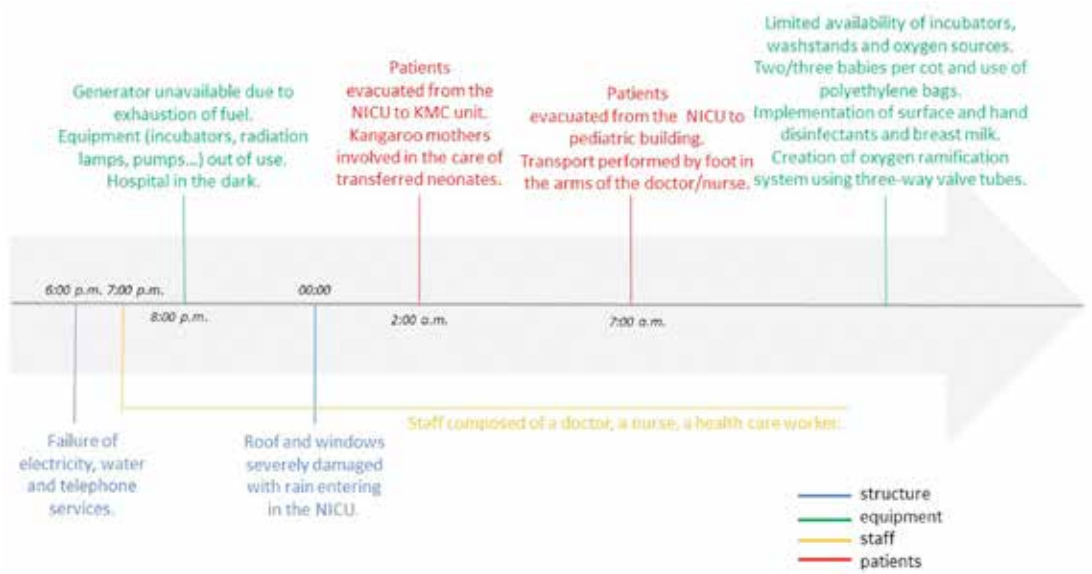

FIGURE 1 | Time line of events and interventions.

FIGURE 2 | Layout of the original and "new" NICU at the CHB hospital.

polyethylene bags were used for preterm infants. There was no washstand, but surface and hand disinfectants were used when possible. For milk preparation, water was boiled and additional water filters were used. The use of breast milk in the NICU and kangaroo care were further supported. Locally, flooding resulted in a significant increase in the incidence of malaria and a cholera outbreak (6), and one infant with cholera was isolated and treated. For a long time after the cyclone Idai, medical and

FIGURE 3 | The neonatal intensive care unit the day after the cyclone.

nurse staff suffered human and material losses. Nevertheless, demonstrating resilience and resourcefulness, the local NICU staff never stopped to offer their service to the patients and their mothers.

The humanitarian response in Beira was coordinated by the Government and was supported by United Nations Agencies, international NGOs and Red Coss. In particular, an advanced medical post of the Italian Civil Protection was built within the CHB. In the emergency phase, the NICU was supported by an integrated collaboration between CUAMM doctors, Italian Red Cross staff and the portuguese NGO HealthforMoz with international staff, drugs and equipment supply and emergency strategies.

Current Situation

The NICU is going to be rebuilt. This is the opportunity to adapt the NICU infrastructure and equipment to emergency situations, considering the high risk of extreme weather events in Mozambique. A preparedness evacuation plan is going to be created at the CHB.

DISCUSSION AND LESSONS LEARNED

This is the first report describing a NICU evacuation after a natural disaster in Africa. Many of the challenges faced by the staff in Beira have not been reported because of the unique features of a low resource setting. Following debriefing with the staff, we have identified lessons learned from our experience that can be generalized to NICUs in other resource limited settings (**Table 1**).

Preparation

Preparation has been identified as the key component for limiting damages during disasters (7). Although the population was alerted, the cyclone's impact was underestimated and there was no pre-existing disaster preparedness plan. In low-resource settings, the lack of effective risk management systems, technology and infrastructure make adequate preparation challenging. Our experienced emphasized the importance of local NICU staff developing disaster preparedness plans that include triage priorities, contingency planning and evacuation plans. However, a written plan does not ensure preparedness. The effort, courage and improvisation exhibited by the staff in Beira was commendable and inspiring; however, training on the response to emergency situations must become a part of the basic education for all healthcare staff and disaster preparedness must become a part of the hospital culture. It is critically important for the hospital leadership and staff to train and regularly practice with disaster drills so existing plans can be rapidly implemented. Moreover, we believe that NICU staff must develop a sense of ownership in the plans and regularly update them to ensure they remain useful.

Resource Allocation

The disaster response has to consider available resources and must be tailored to the country's health service. In settings where emergency response facilities and technology may not be available, the most effective resource is the community. During a crisis, the greatest impact may be achieved by employing local resources and simple remedies rather than relying on the rapid deployment of international aid (5). In our experience, the dedication of the local staff and the involvement of mothers providing kangaroo care addressed key challenges during the acute emergency and post-emergency phases. After the disaster, the risk of contaminated water and subsequent diarrheal disease is high. For this reason, the use of formula milk should be reduced to a minimum and breastfeeding should be encouraged. Kangaroo mother care can help with thermoregulation, provision of safe nutrition, infection prevention and reducing overcrowding by allowing early discharge. We believe that early and expanded implementation of kangaroo care is one of the key strategies for managing disasters in NICUs with limited resources. In addition, adequate supplies to support hand hygiene, provide safe drinking water and food for staff and lactating mothers, culturally appropriate sanitation, and medications to treat malaria, cholera and continue HIV prophylaxis must be considered. Other simple strategies, such as portable oxygen with an oxygen distribution system, use of independent battery operated communication devices, and the use of polyethylene bags for neonatal thermoregulation should be considered.

International Aid

Finally, the governmental response to Idai was supported by international aid. The coordination of local and international aid is challenging, but fundamental to managing complex problems such as infectious disease outbreaks and rebuilding the health infrastructure. In Mozambique, international organizations ensured adequate staffing, provided medications and allowed the possibility of constructing a new NICU. Successful cooperation between local and international institutions is mandatory

TABLE 1 | Problems and possible solutions.

Issue	Problem	Solution
Prevention	Although the population was pre-alerted, the cyclone's impact was underestimated	Implementation of a local emergency plan
Triage	Patients were evacuated without a specific order of priority	Staff education on the triage to adopt in local emergency situations
Oxygen supply	Lack of oxygen sources	System with multiple "Y" -connectors and tubing to provide oxygen to more babies from an oxygen source
Thermal control	Loss of incubators and infant warmers (one preterm infant had severe hypothermia. This likely contributed to his death)	Use of polyethylene bags Implementation of kangaroo mother care Education on thermoregulation of preterm infants Preparation of a new medical chart with more emphasis on temperature
Hygiene	No washstand	Implementation of disinfectant use kangaroo mother care
Nutrition	Milk preparation	Water filters Use of fresh breast milk in the NICU Kangaroo mother care, breastfeeding
Electricity	Due to electrical blackout, communication in and outside hospital were interrupted; staff worked in the dark, unaware of their relatives' conditions at home; medical devices stopped to work	Mobile phones were used to have light and for communication in and outside hospital, but an independent hospital generator should be implemented
Patient records	NICU archive was destroyed and patient records were definitively lost	Opportunity to create an electronic hospital archive that can be saved in an external electronic store
Local and international aids	Local and international coordination of health issues during post Idai phase has been challenging	A strict cooperation between local and international institutions, including a defined leadership, is mandatory to avoid waste of human and economic resources

to avoid duplication of aid in some areas while leaving others uncovered.

CONCLUSIONS

This report is a descriptive analysis of NICU evacuation during a natural disaster in Africa. Consistently with high-resource setting experiences, we reported that preparation, situation awareness, communication, clear coordination structure, flexibility, and adaptability in utilizing the available resources and staff dedication are of pivotal importance to ensure continuous care for critically ill neonates during a natural disaster in a low-resource setting.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

AUTHOR CONTRIBUTIONS

SC and MB performed the literature review, collected the data, contributed to data interpretation, drafted the initial manuscript, and critically reviewed the manuscript. AS, MT, AG, and BC contributed to the collection and analysis of data, contributed to data interpretation and reviewed, and critically reviewed the manuscript. GP and DT conceptualized the study, contributed to data interpretation, writing of the manuscript, and critically reviewed the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Reliability of ultrasound findings acquired with handheld apparatuses to inform urgent obstetric diagnosis in a high-volume resource-limited setting

PAPER

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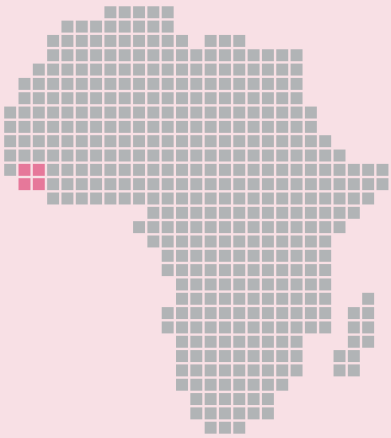

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Non linear association between admission temperature and neonatal mortality in a low resource setting

PAPER

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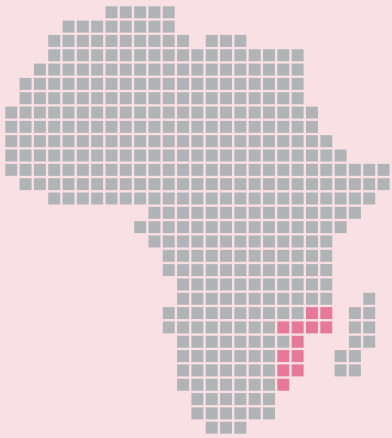

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Non-linear association between admission temperature and neonatal mortality in a low-resource setting

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Both neonatal hypothermia and hyperthermia represent important risk factors for neonatal mortality, but information on mortality risk across a full range of neonatal temperatures is lacking in low-resource settings. We evaluated the association between neonatal mortality and a full range of admission temperatures in a low-resource setting. This retrospective observational study was conducted at Beira Central Hospital, Mozambique. The relationship between admission temperature and mortality was evaluated using multivariable analyses with temperature modeled as non-linear term. Among 2098 neonates admitted to the Special Care Unit between January–December 2017, admission temperature was available in 1344 neonates (64%) who were included in the analysis. A non-linear association between mortality rate and temperature was identified. Mortality rate decreased from 84% at 32 °C to 64% at 34.6 °C (– 8% per °C), to 41% at 36 °C (– 16% per °C), to 26% to 36.6 °C (– 25% per °C) and to 22% at 38.3 °C (– 2% per °C), then increased to 40% at 41 °C (+ 7% per °C). Mortality rate was estimated to be at minimum at admission temperature of 37.5 °C. In conclusions, the non-linear relationship highlighted different mortality risks across a full range of neonatal temperatures in a low-resource setting. Admission temperature was not recorded in one third of neonates.

Maintaining normothermia at birth is a major challenge for newbosrn survival[1]. Both hypothermia and hyperthermia represent important risk factors for neonatal morbidity and mortality[2]. Neonatal hypothermia is common in both high- and low-resource settings, but is rarely indicated as direct cause of death, while it is associated with a considerable portion of neonatal mortality, mostly as comorbidity of preterm birth, asphyxia and sepsis[3]. Neonatal hyperthermia is associated with brain injury and hemodynamic changes[4]. A recent systematic review including 20,911 participants from 12 studies indicated a 57.2% prevalence of neonatal hypothermia in Eastern Africa[5]. Of note, hypothermia in low-resource settings involves both term and preterm infants[5,6]. In low-middle resource settings, neonatal hypothermia was associated with elevated mortality risk in both hospital and community studies[7–12].

The World Health Organization (WHO) recommends maintaining neonatal temperature between 36.5 and 37.5 °C, with lower temperatures (< 36.5 °C) defining hypothermia ranges and higher temperatures (> 37.5 °C) defining hyperthermia ranges[13]. Literature offers heterogeneous definitions of neonatal thermal ranges[3], in search for an optimal classification that mirrors clinical outcomes.

Although offering the advantages of easy interpretation and application in clinical practice, the classification of a continuous variable has the strong disadvantage of underestimating the variation of the outcome[14]. In 2015, the Canadian Neonatal Network attempted to overcome such disadvantages by evaluating a large cohort of very preterm infants where neonatal temperature at admission to neonatal intensive care unit (NICU) was categorized in nine groups with 0.5 °C increments from < 34.5 to ≥ 38.0 °C[15]. The authors suggested a U-shaped relationship between admission temperature and adverse neonatal outcomes, with lowest rate of adverse outcomes between

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36.5 and 37.2 °C[15]. The U-shape relationship highlights that both low and high temperatures impair neonatal outcomes, in agreement with international recommendations[2,15,16].

Maintaining normothermia at birth is an even more crucial challenge in low-resource settings, where appropriate thermal care of the newborn is often neglected due to poor provider training, limited awareness of the problem and limited availability of equipment[3,17]. Furthermore, thermal stability (including warm delivery room, immediate drying, skin-to-skin contact, early breastfeeding, delayed bathing, adequate clothing, warm transport, keeping baby close to the mother) is not a central objective in management protocols in low-resource settings[6,13]. To our knowledge, information on mortality risk across a full range of admission temperatures is lacking in these settings. This study aimed to evaluate the relationship between mortality and a full range of admission temperatures in a low-resource setting.

Methods

Study design and setting. This is a retrospective study on the relationship between admission temperature and in-hospital neonatal mortality at the Special Care Unit (SCU) of the Beira Central Hospital (BCH) in Beira (Mozambique). The study was approved by the Clinical Board of BCH (January 30, 2018), which waived the need for written informed consent given the retrospective nature of the study and the use of anonymized data from hospital records. Research was performed in accordance with relevant guidelines and regulations.

BCH is located in the province of Sofala, Mozambique and is the referral hospital for a geographical area that covers about 1.7 million people. In the province, average temperature ranges from 21 °C in July to 28.5 °C in January; the hot (and rainy) season runs approximately from November to March, and the cold season from June to August. About 5000 deliveries and 2100 admissions to the SCU occur every year at BCH. Medical transport system was not available in the province and outborn infants were brought to the hospital by their families.

Patients. All neonates admitted to the SCU between January 1 and December 31, 2017 were evaluated for inclusion in the study. All neonates were included in (1) the assessment of availability of temperature at admission, and (2) the comparison of patient characteristics according to availability of temperature at admission. Then, only neonates with available temperature at admission were included in the analysis of mortality.

Data collection. All data were retrieved from hospital records by hospital staff and were collected in an anonymized dataset. Maternal data included maternal age, HIV infection, twin pregnancy and number of previous gestations. Neonatal data included mode of delivery, birthplace, gestational age, sex, birth weight, 5-min Apgar score (for inborns), time to transfer and admission to SCU, diagnosis at admission, temperature at admission, and mortality through facility discharge.

Diagnosis at admission was based on clinical examination because availability of laboratory and instrumental exams was limited[18].

At admission to SCU, neonatal axillary temperature was measured by the attending nurse using a digital thermometer (C202; Terumo, Tokyo, Japan). The nurse repeated the measurement of temperature in case of extreme hypothermia (< 35 °C) or extreme hyperthermia (> 39 °C). Severe/moderate hypothermia was defined as temperature < 36 °C, mild hypothermia as 36–36.4 °C, normal temperature as 36.5–37.5 °C and hyperthermia as > 37.5 °C[13].

Statistical analysis. Continuous data were reported as median and interquartile range (IQR), while categorical data as number and percentage.

The comparison of included (available temperature at admission) and excluded (unavailable temperature at admission) neonates was performed using Mann–Whitney test (continuous data) and Chi-square test (categorical data).

The relationship between mortality rate and neonatal temperature at admission was investigated with logistic regression models where temperature was modeled with first order polynomial or restricted cubic splines. The number of knots for the temperature was chosen in order to maximize the model likelihood ratio.

In all neonates (inborn, outborn, homebirth), a logistic regression model was estimated to assess the effect of admission temperature (modeled with restricted cubic splines) on mortality, adjusting for a set of pre-defined clinically relevant factors (diagnosis, place and mode of delivery, seasonality, sex, birthweight, twin birth, maternal age, HIV, and number of previous gestations). Model selection was performed by AIC reduction.

In the subgroup of inborn/outborn neonates, the 5-min Apgar score was added among the factors of the logistic regression model. In fact, the 5-min Apgar score is known to be a clinically relevant predictor of mortality, but it is not available in neonates born at home. Model selection was performed by AIC reduction.

Model performance was evaluated with internal validation (c-index) and calibration (calibration-in-the-large and calibration slope) using bootstrap methods (re-sampling with replacement to create 1000 samples of the same size as the original)[19].

The results from the two regression models were summarized in two nomograms (one for all admitted neonates and one for inborn/outborn neonates).

All tests were 2-sided and a p value less than 0.05 was considered statistically significant. Statistical analysis was performed using R 3.5 (R Foundation for Statistical Computing, Vienna, Austria)[20].

Results

From 1st January to 31st December 2017, 2098 neonates were admitted to SCU for prematurity (648, 30.9%), asphyxia/HIE (559, 26.6%), wet lung (216, 10.3%), trauma (15, 0.7%), congenital malformations (96, 4.6%), fever (67, 3.2%), sepsis (55, 2.6%), seizures (17, 0.8%), jaundice/hyperbilirubinemia (34, 1.6%), or with other

	Included neonates (available temperature at admission)	Excluded neonates (unavailable temperature at admission)	*p* value
No. of subjects	1344	754	–
Neonates			
Gestational age (weeks)[a,b]	37 (34–39)	37 (33–39)	0.20
Sex male:female[c]	752:591	430:313	0.43
Birth weight (g)[a,d]	2450 (1700–3050)	2600 (1850–3100)	0.004
Twin[e]	263 (19.6)	73 (19.9)	0.94
5-min Apgar score[a,f]	8 (6–9)	8 (6–8)	0.006
Mode of delivery[g]			0.91
Vaginal	995 (75.4)	264 (75.0)	
Caesarean	340 (24.6)	88 (25.0)	
Birthplace[h]			0.02
Inborn	746 (55.5)	460 (61.8)	
Outborn	499 (37.1)	234 (31.5)	
Homebirth	99 (7.4)	50 (6.7)	
Total time from birth to admission (min)[a,i]	61 (39–194)	66 (40–134)	0.82
Diagnosis at admission			0.003
Asphyxia/HIE	356 (26.5)	203 (26.9)	
Prematurity/LBW	441 (32.8)	207 (27.5)	
Sepsis	42 (3.1)	13 (1.7)	
Fever	53 (3.9)	15 (2.0)	
Congenital malformations	54 (4.0)	42 (5.6)	
Wet lung	123 (9.1)	93 (12.3)	
Trauma	10 (0.7)	5 (0.7)	
Seizures	12 (0.9)	5 (0.7)	
Jaundice/ hyperbilirubinemia	25 (1.9)	9 (1.2)	
Other diagnoses	229 (17.0)	162 (21.5)	
Mothers			
Maternal age (years)[a,j]	23 (19–28)	23 (20–28)	0.98
Number of previous gestations (n)[a,k]	2 (1–4)	2 (1–3)	0.55
HIV positive mothers[l]	327 (25.5)	98 (20.2)	0.19
Mortality[m]	488 (36.5)	215 (30.5)	0.007

Table 1. Comparison of included (available temperature at admission) and excluded (unavailable temperature at admission) neonates. *HIE* Hypoxic ischemic encephalopathy, *LBW* low birth weight. Data expressed as No. (%) or [a]median (IQR). Data not available in [b]504, [c]12, [d]14, [e]387, [f]233, [g]411, [h]10, [i]1021, [j]472, [k]438, [l]478, and [m]56 subjects.

diagnoses (381, 18.2%). Neonatal temperature at admission was available in 1344 neonates (64%), who were included in the analysis. The comparison of 1344 included neonates (available temperature at admission) and 754 excluded neonates (unavailable temperature at admission) neonates is reported in Table 1. Birth weight ($p = 0.004$), 5-min Apgar score ($p = 0.006$), birthplace ($p = 0.02$) and diagnosis at admission ($p = 0.003$) were different between included and excluded neonates (Table 1). Mortality rate was 36.5% in included neonates and 30.5% in excluded neonates ($p = 0.007$). Among inborns, resuscitation in delivery room was needed in 334 out of 746 included subjects (44.8%) and in 91 out of 193 excluded subjects (57.2%; information not available in 267 outborns) ($p = 0.61$). Time from birth to admission was not different between included and excluded neonates ($p = 0.82$, Table 1). Maternal age, number of gestation and HIV infection were not different between included and excluded neonates (Table 1).

Among 1344 included neonates, median temperature at admission was 36.3 °C (IQR 35.8–36.9 °C; min 32 °C, max 41.1 °C). Severe/moderate hypothermia was reported in 395 neonates (29.4%), mild hypothermia in 376 (28.0%), normal temperature in 436 (32.4%) and hyperthermia in 137 (10.2%) (Fig. 1A,B). Birthplace was associated with neonatal temperature at admission ($p < 0.0001$): the highest proportion of homebirths was found in severely/moderately hypothermic neonates, while the highest proportion of outborn was found in neonates with hyperthermia (Fig. 1C).

After a median length of stay of 4 days (IQR 2–8), 848 neonates were discharged alive and 488 died, while the information was not available in eight neonates. Observed mortality rate was 58% (231 out of 395) in severe/moderate hypothermia, 33% (123 out of 372) in mild hypothermia, 24% (103 out of 432) in normal temperature range and 23% (31 out of 137) in hyperthermia (Fig. 2A). The relationship between mortality rate and neonatal temperature at admission was investigated with logistic regression models where temperature was modeled with

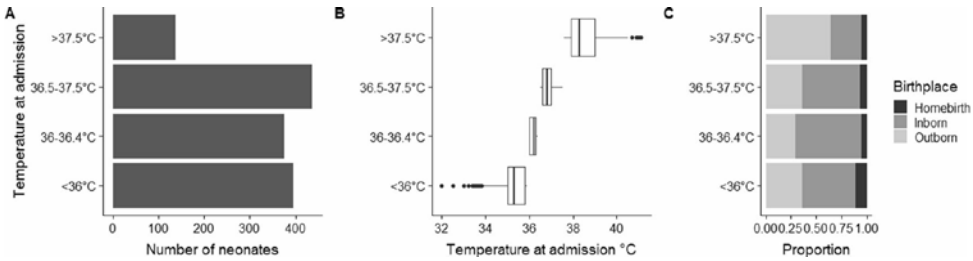

Figure 1. Number of neonates (**A**), boxplot of neonatal temperature (**B**) and birthplace (**C**) according to ranges of neonatal temperature at admission.

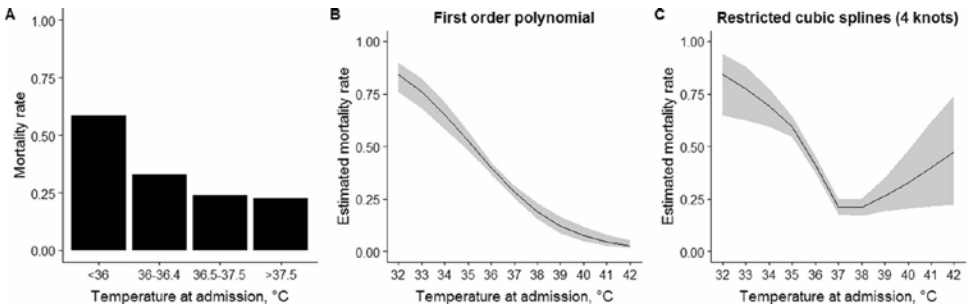

Figure 2. Observed mortality rate according to ranges of neonatal temperature at admission (**A**); estimated mortality rate according to neonatal temperature at admission as modeled with first order polynomial (**B**) or restricted cubic splines (**C**). Shaded areas represent bootstrap 95% confidence intervals.

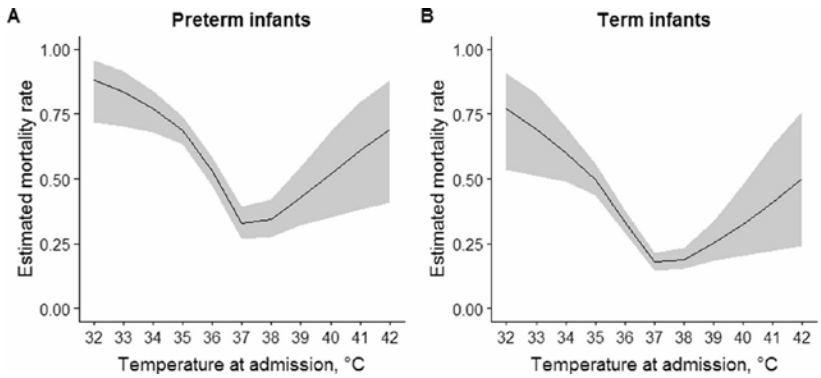

Figure 3. Non-linear association between mortality rate and temperature in preterm (**A**) and term (**B**) infants. Shaded areas represent bootstrap 95% confidence intervals.

first order polynomial and with restricted cubic splines (Fig. 2B,C). A non-linear association between mortality rate and temperature was identified (non-linear term: $p < 0.0001$), thus the model with cubic splines was preferred over the model with first order polynomial. Four knots were identified in 34.6 °C, 36 °C, 36.6 °C and 38.3 °C. Estimated mortality rate decreased from 84% at 32 °C to 64% at 34.6 °C (mean − 8% per °C), to 41% at 36 °C (mean − 16% per °C), to 26% to 36.6 °C (mean − 25% per °C) and to 22% at 38.3 °C (mean − 2% per °C), then increased to 40% at 41 °C (mean + 7% per °C). Mortality rate was estimated to be at a minimum at admission temperature of 37.5 °C (Fig. 2C). The curve of estimated mortality rate according to admission temperature had similar shape in term and preterm infants ($p = 0.78$), but the latter had higher mortality rate ($p < 0.0001$) (Fig. 3).

Since information on gestational age was largely missing, multivariable analysis included the diagnosis of prematurity as proxy of the role of gestational age, although prematurity underlines a wide range of gestational ages.

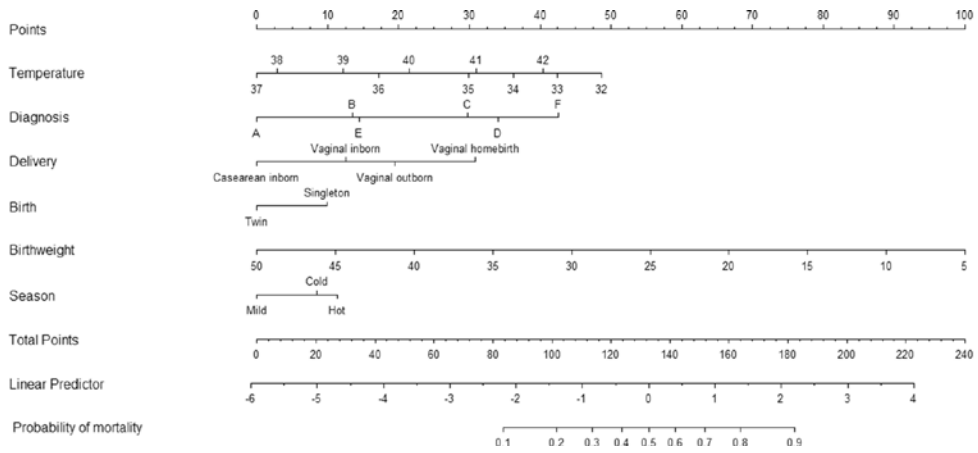

Figure 4. Nomograms for all patients. Diagnosis legend: fever, trauma, jaundice/hyperbilirubinemia, other (**A**); wet lung (**B**); asphyxia/HIE (**C**); sepsis/seizures (**D**); prematurity (**E**); congenital malformations (**F**). Neonatal temperature at admission is expressed in °C. Birthweight is expressed as 100 g.

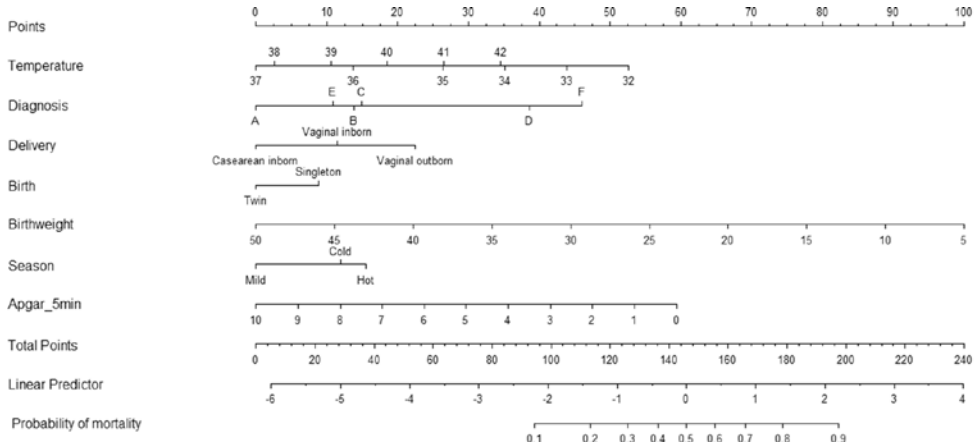

Figure 5. Nomograms for inborn and outborn patients. Diagnosis legend: fever, trauma, jaundice/hyperbilirubinemia, other (**A**); wet lung (**B**); asphyxia/HIE (**C**); sepsis/seizures (**D**); prematurity (**E**); congenital malformations (**F**). Neonatal temperature at admission is expressed in °C. Birthweight is expressed as 100 g.

Since all neonates born from caesarean sections were inborns, birthplace and mode of delivery were collapsed in one variable with four categories (caesarean inborn, vaginal inborn, vaginal outborn and vaginal homebirth).

In all infants (inborns, outborns, homebirths), admission temperature (linear term $p < 0.0001$, non-linear term $p < 0.0001$), diagnosis ($p < 0.0001$), delivery ($p < 0.0001$), birthweight ($p < 0.0001$), twin birth ($p = 0.01$) and seasonality ($p < 0.0001$) were included in the final model. Internal validation and calibration via bootstrapping showed good validation (c-index 0.78) and calibration (calibration-in-the-large − 0.0264 and calibration slope 0.9530). The model was graphically represented by the nomogram in Fig. 4.

In inborn/outborn infants, admission temperature (linear term $p < 0.0001$, non-linear term $p = 0.0002$), diagnosis ($p < 0.0001$), delivery ($p < 0.0001$), 5-min Apgar score ($p < 0.0001$) birthweight ($p < 0.0001$), twin birth ($p = 0.01$) and seasonality ($p < 0.0001$) were included in the final model. Internal validation and calibration via bootstrapping showed good validation (c-index 0.79) and calibration (calibration-in-the-large − 0.0286 and calibration slope 0.9407). The model was graphically represented by the nomogram in Fig. 5.

Information on both models is reported in Supplementary Table 1.

Discussion

Our findings highlighted a substantial underreporting of neonatal temperature at admission, but also showed that the majority of neonates were admitted with hypothermia. Neonatal temperature at admission had a non-linear relationship with mortality, which was the lowest rate at 37.5 °C and increased with different slopes when departing from the interval 36.6–38.3 °C.

To our knowledge, this is the first study to investigate the differences in mortality risk across a full range of admission temperatures and to describe a non-linear relationship between neonatal temperature at admission and mortality in a low-resource setting. Our findings confirm that both hypothermia and hyperthermia at admission are associated with mortality, but add a differentiation of mortality risk according to the specific temperature.

The study has some limitations. First, it is a retrospective study, thus quality of data was limited. For example, information on gestational age was largely missing (a common problem in low-resource settings), thus the model included the diagnosis of prematurity as proxy of the role of gestational age, although prematurity underlines a wide range of gestational weeks. Second, temperature at admission was not available in about one third of neonates. Third, diagnosis at admission was based on clinical examination because availability of laboratory and instrumental exams was limited.

Both hypothermia and hyperthermia represent important predictors of neonatal morbidity and mortality[1,2]. However, neonatal temperature is often missing in clinical records although being an important and easy-to-measure indicator[3]. Our findings showed that admission temperature was not available in around one out of three neonates, thus highlighting the substantial underreporting of such indicator. Since neonatal temperature at admission can be used as quick feedback of neonatal care during the immediate postnatal phase, the lack of such data hampers the implementation of quality improvement processes[2].

In low resource settings, the incidence of postnatal hypothermia is very high, ranging from 32 to 85%[3], while hyperthermia at admission has received less attention[1,3,6]. Our data indicated that around 57% of neonates were admitted with hypothermia, thus confirming that prevention of postnatal thermal losses is still an underappreciated major challenge in low resource settings[3].

Available literature approached the investigation on neonatal temperature based on the few categories indicated by the WHO classification[3,6,13]. This approach offers the advantages of easy interpretation and application in clinical practice, but constrains the variability of the phenomenon into pre-specified classes[14]. A recent study attempted to overcome such disadvantage by splitting admission temperature in a larger number of categories and suggested a U-shaped relationship between admission temperature and adverse neonatal outcomes[15]. The U-shape relationship implicated that both low and high temperatures impaired neonatal outcomes, but the generalizability of these findings was limited by the inclusion of very preterm infants, the high-resource setting and the categorization of the temperature[15]. Our study adds the information on the differences in mortality risk across a full range of admission temperatures, in both preterm and term infants born in a low-resource setting. In addition, our findings displays the relationship between mortality and temperature as asymmetric inverted omega-shaped curve rather than U-shaped curve. Such non-linear relationship confirmed that both low and high temperatures increased the mortality risk, but highlighted the different slopes when departing from normothermia (Fig. 2C).

These findings reinforce the need for temperature assessment in all admitted neonates and confirm the worse impact on mortality of low temperatures compared to high temperatures in a low-resource setting. Moreover, this approach allows the definition of a personalized risk assessment that goes beyond the categorical approach. Our results are summarized in two nomograms (one for all admitted neonates and one for inborn/outborn neonates) that can be considered among the proposals for the development of a quick mortality-risk calculator to be used in clinical practice. The nomograms require external validation in order to assess their generalizability to other low-resource settings. If confirmed, the nomograms can be transformed in on-line tools or apps for an easy and quick assessment of personalized mortality risk in clinical practice. Available literature offers other neonatal mortality risk scoring systems, such as CRIB-II, SNAP, NMS, NMR-2000[21–24]. Unfortunately, we could not use such scores because they include some parameters that were not available in the care (hence in the hospital records) of our study setting (i.e. blood gas analysis, oxygen saturation, mechanical ventilation). In addition, some of them were developed for specific categories of neonates (i.e. birthweight < 1500 g or gestational age < 31 weeks; birthweight < 2000 g).

Neonatal temperature at admission should be recorded as prognostic factor as well as quality indicator[2]. In the present study, the underreporting of such indicator highlights the need for enhancing the awareness of the importance of including temperature measurement among routine care. Appropriate actions may include audits (to identify local reasons for the underreporting), education to health care givers who are involved in neonatal care at admission (to enhance awareness of the importance of neonatal temperature), and continuous feedback on this quality improvement (to monitor the implementation).

Furthermore, the high rate of hypothermia and hyperthermia at admission calls for implementation of adequate strategies to ensure normothermia immediately after birth in low-resource settings[3,17]. Quality improvement activities should focus on enlisting thermal stability (i.e. warm delivery room, immediate drying, skin-to-skin contact, early breastfeeding, delayed bathing, adequate clothing, warm transport, keeping baby close to the mother) among the central objectives in management protocols in low-resource settings[6,13]. Provider training, enhancing awareness and revision of management routines seem to be the key elements for achieving such goal[3,6,13,17].

Conclusions

In a low-resource setting, neonatal temperature at admission showed a non-linear relationship with mortality rate, with different impacts of low and high temperatures. Only 32% of the infants were normothermic at admission, indicating the need for implementation of adequate strategies to enhance thermal stability. Temperature at admission was not reported in 36% of the infants, suggesting the need for more closely monitoring the admission temperature.

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Author contributions

F.C. was responsible for the statistical design and analysis, drafted the manuscript, contributed to interpret the results, and approved the final manuscript as submitted. S.C. contributed to design the study, coordinated and supervised data collection, and critically reviewed the manuscript. V.B. contributed to design the study, collected the data collection, and critically reviewed the manuscript. O.M.W. contributed to design the study, supervised data collection, and critically reviewed the manuscript. A.R.M. contributed to design the study, contributed to data collection, and critically reviewed the manuscript. L.D.D. contributed to design the trial and to interpret the results, and critically reviewed the manuscript. D.P. contributed to design the study, coordinated and supervised data collection, and critically reviewed the manuscript. G.P. contributed to design the study, developed the idea into a formal grant application contributed to interpret the results, and critically reviewed the manuscript. D.T. contributed to the study concept, study design, data interpretation, and writing of the manuscript and critically reviewed the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Competing interests
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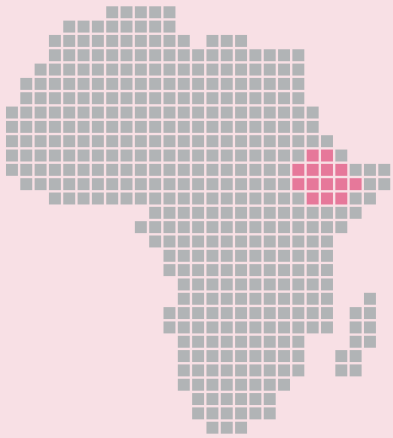

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Risk factors for mortality among neonates admitted to a special care unit in a low-resource setting

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Abstract

Background: Although under-5 mortality has decreased in the last two decades, neonatal mortality remains a global health challenge. Despite achieving notable progress, Ethiopia has still one of the highest neonatal mortality rates worldwide. We aimed to assess the risk factors for mortality among neonates admitted to a special care unit in a referral hospital in rural Ethiopia.

Methods: This was a retrospective observational study including all 4182 neonates admitted to the special care unit of the St. Luke Wolisso Hospital (Ethiopia) from January 2014 to December 2017. Data were retrieved from hospital charts and entered in an anonymized dataset. A logistic regression model was applied to identify predictors of mortality and effect sizes were expressed as odds ratios with 95% confidence intervals.

Results: Proportion of deaths was 17% (709/4182 neonates). Neonates referred from other health facilities or home (odds ratio 1.52, 95% confidence interval 1.21 to 1.91), moderate hypothermia at admission (odds ratio 1.53, 95% confidence interval 1.09 to 2.15) and diagnosis of late-onset sepsis (odds ratio 1.63, 95% confidence interval 1.12 to 2.36), low birthweight (odds ratio 2.48, 95% confidence interval 2.00 to 3.09), very low birthweight (odds ratio 11.71, 95% confidence interval 8.63 to 15.94), extremely low birthweight (odds ratio 76.04, 95% confidence interval 28.54 to 263.82), intrapartum-related complications (odds ratio 4.69, 95% confidence interval 3.55 to 6.20), meconium aspiration syndrome (odds ratio 2.34, 95% confidence interval 1.15 to 4.43), respiratory distress (odds ratio 2.25, 95% confidence interval 1.72 to 2.95), other infections (odds ratio 1.92, 95% confidence interval 1.31 to 2.81) or malformations (odds ratio 2.32, 95% confidence interval 1.49 to 3.57) were associated with increased mortality. Being admitted in 2017 vs. 2014 (odds ratio 0.71, 95% confidence interval 0.52 to 0.97), and older age at admission (odds ratio 0.95, 95% confidence interval 0.93 to 0.97) were associated with decreased likelihood of mortality.

Conclusions: The majority of neonatal deaths was associated with preventable and treatable conditions. Education on neonatal resuscitation and postnatal management, and the introduction of an on-call doctor for high-risk deliveries might have contributed to the reduction in neonatal mortality over time.

Keywords: Low-resource setting, Mortality, Neonates, Risk factors

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Background

Although under-5 mortality has decreased in the last two decades, neonatal mortality remains a global health challenge [1]. Worldwide, 2.4 million neonates die every year, a third of them within the first day of life [1, 2]. The vast majority of neonatal deaths occur in sub-Saharan Africa and Southern Asia [3, 4]. The main causes of neonatal mortality are prematurity (35%), intrapartum-related events (24%) and infections (15%) [5].

Despite achieving notable progress in neonatal mortality during 1999–2018 (from 49.5 deaths to 28.1 deaths per 1000 live births), Ethiopia has still one of the highest neonatal mortality rates worldwide [6]. Infant mortality is considered a standard indicator for the assessment of a country health status [7] and warrants for continuous research on interventions to achieve the United Nations Sustainable Development Goals (SDGs) [8]. Many neonatal deaths can be prevented with feasible and low-cost interventions [9]. Knowledge of risk factors for mortality can be useful in identifying areas of intervention and planning appropriate strategies to improve neonatal prognosis [10].

Previous studies showed varying figures (neonatal mortality 5.7–16.5%) and heterogeneous risk factors for neonatal mortality (i.e. lack of antenatal care, outborn infants, home delivery, cesarean section, multiple birth, low birth weight, inability at cry at birth, perinatal asphyxia, need for resuscitation at birth, and respiratory distress syndrome) across different areas of Ethiopia [11–13], thus requiring further investigation to expand the knowledge and support the identification of appropriate interventions to reduce neonatal mortality [14]. This study aimed to assess the risk factors for mortality among neonates admitted to a special care unit in a referral hospital in rural Ethiopia.

Methods

Study design

This was a retrospective observational study on risk factors for mortality among neonates admitted to the special care unit of the St. Luke Wolisso Hospital (Ethiopia) from January 2014 to December 2017. The study was conducted according to Helsinki Declaration principles, and was approved by the Ethical Review Committee of St Luke Catholic Hospital and College of Nursing and Midwifery (ref. 245/2020), which waived the need for patient written consents, given the retrospective nature of the study and the use of anonymized data.

Setting

The study was conducted at the special care unit of the St. Luke Wolisso Hospital (Ethiopia), where around 3500 deliveries occur every year. This is a referral, private, non-profit hospital located in Wolisso town, which is the capital of the Southwest Shoa Zone in the Oromiya region. The area has a population of about 1.1 million inhabitants and is served by 81 health facilities (including only one hospital). At St. Luke Wolisso Hospital, midwives were responsible for maternal and neonatal management at delivery. Medical transport system was not available in the area and outborn infants were brought to the hospital by their families. The special care unit consisted in one room with 10 beds and was cared for by two daytime nurses and one nighttime nurse. Phototherapy, intravenous therapies and oxygen supplementation (but not equipment for respiratory support) were offered. Availability of pulse oxymeter was limited. During the study period, education on neonatal resuscitation (Helping Babies Breathe program) and courses on postnatal management were offered to midwives and nurses, and the presence of an on-call doctor for high-risk deliveries was introduced.

Patients

All neonates admitted to the special care unit at the St. Luke Wolisso Hospital between 2014 and 2017 were included in the study. There were no exclusion criteria.

Data collection

All data were retrospectively retrieved from hospital charts and entered in an anonymized dataset. Data included neonatal characteristics (i.e. age, sex, weight), admission information (neonatal temperature, outborn/inborn, mode of delivery, main diagnoses), length of stay and outcome. Clinical definitions are summarized in Table 1 [15–21].

Statistical analysis

Continuous variables were expressed as median and interquartile range (IQR), and categorical variables as number and percentage. Association between categorical variables was evaluated with Chi Square test. A logistic regression model was applied to identify predictors of mortality among clinically relevant factors (year of admission, mode of delivery, birthplace, age and temperature at admission, sex, birth weight, early-onset sepsis, late-onset sepsis, intrapartum-related complications, meconium aspiration syndrome, respiratory distress, transient tachypnea of the newborn, other infections, malformations). Multicollinearity was assessed using variance inflation factor (VIF), with values > 4 suggesting further investigation and values > 10 indicating need for correction for multicollinearity. Estimated effects from the model were expressed as odds ratios (OR) with 95% confidence intervals (CI). Trends over time of the prevalence of prognostic factors were investigated with linear and logistic regression models where time was modeled with linear and quadratic terms. All tests were 2-sided and a p-value less than 0.05 was considered statistically significant. Statistical analysis was performed

Table 1 Clinical definitions

Diagnosis at admission	Definition
Sepsis	Maternal history of fever or prolonged rupture of membranes > 18 h, and/or neurologic findings (apnea, convulsions, unconsciousness), and/or moderate hypothermia (< 36 °C) or hyperthermia (> 37.5 °C), and/or breastfeeding difficulties [15–18] within 72 h (early onset) or later (late onset).
Other infections	Skin infections, abscesses, genital-urinary infections, pneumonia.
Low birthweight	Birthweight below 2500 g [16]. Sub-groups in the manuscript were: -LBW (low birthweight, 1500–2499 g), -VLBW (very low birth weight, 1000–1499 g), -ELBW (extremely low birth weight, < 1000 g).
Intrapartum-related complications	Failure to initiate spontaneous regular respirations after birth and/or 5-min Apgar score less than 7 and/or Sarnat & Sarnat stage 2 or more at admission [10, 15, 19].
Meconium aspiration syndrome (MAS)	Presence of respiratory distress in infants born through meconium-stained amniotic fluid [20].
Respiratory distress	Signs of respiratory insufficiency (tachypnea, dyspnea, and grunting) and need for oxygen supplementation for more than 2 days [21].
Transient tachypnea of the newborn	Presence of tachypnea and need for oxygen supplementation within 2 days of life [21].
Malformations	Diagnosis was based on clinical examination and/or radiological investigation (i.e. X-rays and Doppler ultrasound). Magnetic resonance imaging (MRI), computer tomography (CT), chromosome analysis and chromosome microarray were not available in the hospital.
Neonatal hypothermia at admission	Mild hypothermia: 36–36.4 °C [16]. Moderate hypothermia: neonatal temperature 32–35.9 °C [16]. Severe hypothermia: neonatal temperature < 32 °C [16].
Neonatal hyperthermia at admission	Neonatal temperature > 37.5 °C [16].

using R 3.5 software (R Foundation for Statistical Computing, Vienna, Austria) [22].

Results

Patients

Overall, 4182 neonates (2424 males and 1758 females) were admitted to the special care unit of the St. Luke Wolisso Hospital (Ethiopia) from January 2014 to December 2017. Neonatal characteristics are reported in Table 2. Median age at admission was 1 day (IQR 1–4). Almost half of neonates were outborn (1577/3521, 44.8%), while the information was not available in 661 neonates. Among 1179 inborn neonates who were admitted at day of birth, 379 (32%) had moderate hypothermia (32–36 °C) and none severe hypothermia (< 32 °C). Moderate hypothermia was not different (p = 0.75) in neonates born through vaginal delivery (439/1794, 26.9%) and in those born through caesarean section (109/480, 28.6%). Moderate hypothermia was 24.8% (323/1300) in outborn and 28.3% (442/1560) in inborn neonates (p = 0.04).

Diagnosis at admission

The most common diagnoses at admission were birthweight< 2500 g (1,426, 34.1%), early-onset sepsis (787, 18.8%), respiratory distress (644, 15.4%), intrapartum-related complications (595, 14.2%) and late-onset sepsis (540, 12.9%) (Table 3). Median length of stay was 5 days (IQR 4–8). Eight neonates with spina bifida were transferred to another center for surgical treatment.

Neonatal mortality

Proportion of deaths was 17% (709/4182) and was highest in ELBW and VLBW neonates (27/31, 87.1%, and 137/270, 50.7%, respectively), and in those with intrapartum-related complications (173/595, 29.1%), malformation (36/129, 27.9%) or respiratory distress (146/644, 22.7%) (Table 3). The majority of deaths (84%) occurred during the first week of admission.

Predictors of neonatal mortality

At multivariable analysis (Table 4), increased likelihood of mortality was associated with outborn neonates (OR 1.64, 95% CI 1.31 to 2.06) and with diagnosis of late-onset sepsis (OR 1.63, 95% CI 1.12 to 2.36), LBW (OR 2.48, 95% CI 2.00 to 3.09), VLBW (OR 11.71, 95% CI 8.63 to 15.94), ELBW (OR 76.04, 95% CI 28.54 to 263.82), intrapartum-related complications (OR 4.69, 95% CI 3.55 to 6.20), MAS (2.34, 95% CI 1.15 to 4.43), respiratory distress (OR 2.25, 95% CI 1.72 to 2.95), other infections (OR 1.92, 95% CI 1.31 to 2.81) or malformations (OR 2.32 95% CI 1.49 to 3.57). On the other hand, being admitted in 2017 vs. 2014 (OR 0.71, 95% CI 0.52 to 0.97) and older age at admission (OR 0.95, 95% CI 0.93 to 0.97) were associated with decreased likelihood of mortality. Multicollinearity was not present (VIF < 2 for all factors).

In the subsample of 1994 neonates with complete data on temperature at admission and mode of delivery, moderate hypothermia (32–35.9 °C) at admission was a predictor of mortality (OR 1.53, 95% CI 1.09 to 2.15; p =

Table 2 Neonatal characteristics at admission

	All neonates	Neonates who survived	Neonates who died
No. of neonates	4182	3473	709
Year of admission:			
2014	692 (16.5)	563 (16.2)	129 (18.2)
2015	1113 (26.6)	916 (26.4)	197 (27.8)
2016	1278 (30.6)	1059 (30.5)	219 (30.9)
2017	1099 (26.3)	935 (26.9)	164 (23.1)
Age at admission, days [a]	1 (1–4)	1 (1–5)	1- (1, 2)
Sex:			
Male	2424 (58.0)	2006 (57.8)	418 (59.0)
Female	1758 (42.0)	1467 (42.2)	291 (41.0)
Birth weight:			
Normal weight (≥2500 g)	2756 (65.9)	2440 (70.3)	316 (44.6)
Low birth weight (1500–2499 g)	1125 (26.9)	896 (25.8)	229 (32.3)
Very low birth weight (1000–1499 g)	270 (6.5)	133 (3.8)	137 (19.3)
Extremely low birth weight (< 1000 g)	31 (0.7)	4 (0.1)	27 (3.8)
Temperature at admission: [b]			
< 32 °C	0 (0.0)	(0.0)	0 (0.0)
32–35.9 °C	779 (26.7)	583 (24.0)	196 (40.5)
36–36.4 °C	759 (26.1)	634 (26.1)	125 (25.8)
36.5–37.5 °C	948 (32.5)	822 (33.8)	126 (26.0)
> 37.5 °C	428 (14.7)	391 (16.1)	37 (7.7)
Outborn [c]	1577 (44.8)	1291 (44.3)	286 (47.0)
Mode of delivery: [d]			
Vaginal	1794 (73.1)	1422 (71.1)	372 (82.1)
Instrumental	179 (7.3)	158 (7.9)	21 (4.7)
Caesarean section	480 (19.6)	420 (21.0)	60 (13.2)

Data expressed as No. (%) or [a] median (IQR). Data not available in [b]1268, [c]661 and [d]1729 neonates

0.01), while mild hypothermia (36–36.4 °C), hyperthermia (> 37.5 °C) and mode of delivery were not associated with mortality ($p = 0.71$, $p = 0.98$ and $p = 0.67$, respectively).

Change over time in predictors of neonatal mortality

During the study period, there was an increase of outborn neonates ($p = 0.02$) and those with late-onset sepsis ($p < 0.0001$), and a decrease of neonates with moderate hypothermia ($p = 0.003$) or other infections ($p = 0.0003$) (Table 5). The proportion of admissions for LBW ($p = 0.0001$) or malformations ($p = 0.01$) displayed a U-shaped trend, while the proportion of admissions for intrapartum-related complications ($p = 0.04$) or respiratory distress ($p < 0.0001$) displayed an inverted U-shaped trend (Table 5).

Discussion

Our findings indicated some neonatal characteristics (outborn, lower weight and age at admission) and a subset of diagnoses (hypothermia at admission, late-onset sepsis, low birth weight, intrapartum-related complications, MAS, respiratory distress, malformations and other infections) as risk factors for mortality after admission to the special care unit of a low-resource setting.

While neonatal mortality in high-resource countries is usually due to unpreventable causes, the majority of neonatal deaths in low-resource areas occur from preventable and treatable diseases, including intrapartum-related complications, prematurity and infections [9, 23].

In the last two decades, Ethiopia has succeeded in reducing neonatal mortality rate from 49.5 deaths to 28.1 deaths per 1000 live births thanks to many efforts from the government and other stakeholders [24]. Despite the implementation of the National Child Survival Strategy (2005–2015) [25], Ethiopia has still one of the highest neonatal mortality rates worldwide [6]. Investigation of mortality among neonates admitted to the special care unit in a low-resource setting is an important step for planning appropriate interventions [9, 23].

The magnitude of neonatal mortality was 17% among admissions to the special care unit of the St. Luke

Table 3 Main diagnoses at admission and mortality rate according to diagnosis at admission

	No. of neonates	Deaths
Early-onset sepsis	787 (18.8)	107/787 (13.6)
Late-onset sepsis	540 (12.9)	75/540 (13.9)
Low birth weight (1500–2499 g)	1125 (26.9)	229/1125 (20.4)
Very low birth weight (1000–1499 g)	270 (6.5)	137/270 (50.7)
Extremely low birth weight (< 1000 g)	31 (0.7)	27/31 (87.1)
Intrapartum-related complications	595 (14.2)	173/595 (29.1)
Meconium aspiration syndrome	67 (1.6)	12/67 (17.9)
Respiratory distress	644 (15.4)	146/644 (22.7)
Transient tachypnea of the newborn	129 (3.1)	8/129 (6.2)
Other infections	490 (11.7)	62/490 (12.7)
Malformations	129 (3.1)	36/129 (27.9)
Hypothermia/hyperthermia: [a]		
Severe hypothermia (< 32 °C)	0 (0.0)	Nil
Moderate hypothermia (32–36 °C)	779 (26.7)	125/759 (16.5)
Mild hypothermia (36–36.4 °C)	759 (26.1)	196/779 (25.2)
Hyperthermia (> 37.5 °C)	428 (14.7)	37/428 (8.6)

Data expressed as No. (%). [a] Temperature at admission was not available in 1268 neonates

Wolisso Hospital during 2014–2017, which laid in the mortality range of previous studies in Ethiopia [11–13, 26]. The majority of deaths (84%) occurred during the first week of admission - in agreement with previous studies [12, 26] - with low birth weight, intrapartum-related complications, malformation and respiratory distress representing a heavy burden on neonatal mortality. These findings suggest the need for further efforts in improving labour, intrapartum and immediate postnatal newborn care practices [11].

Our analysis of risk factors of mortality confirmed the role of low birth weight [9], which is known to contribute to the largest number of both admissions and deaths in low-resource settings. Thermal care and appropriate feeding play an important role in these neonates, thus prevention and treatment of hypothermia (i.e. kangaroo mother care) and the promotion of early and exclusive breastfeeding are warranted [27]. Despite the very high mortality among ELBW and VLBW infants, their limited occurrence along with constrains for their treatment in low-resource settings suggested that efforts should target neonates with birth weight 1500–2500 g. In addition, other comorbidities (intrapartum-related complications, late-onset sepsis, MAS, respiratory distress) and malformations were also associated with increased risk of neonatal mortality. All these factors can be both preventable (through appropriate antenatal and perinatal care) and cared for (with available skills and equipment) in the special care unit [9]. Quality improvement initiatives to reduce neonatal mortality should focus on strengthening the continuum of care including fetal, intrapartum and postnatal phases [9].

Outborn neonates and those with moderate hypothermia at admission were also identified as subjects at high risk of mortality. This is noteworthy since half of admissions were outborn, which mirrors the geographical distribution of population in Ethiopia, where over 80% of people resides in the rural part of the country [24]. Of note, our data suggested that the increased mortality risk in outborn neonates was not due to their temperature at admission.

About half of neonates were hypothermic at admission, thus underlying the importance of thermal control during the postnatal period [28]. Neonatal hypothermia is common in both health facilities and homes, even in tropical environments. While hypothermia is not often considered a direct cause of death, it contributes to a substantial proportion of neonatal mortality, mostly as a comorbidity of severe neonatal infections, preterm birth, and intrapartum-related complications [28, 29]. Of note, the surprising high proportion of hypothermia among inborn neonates calls for urgent actions for preventing thermal losses immediately after delivery. In low-resource settings, such condition is likely to persist in the days following birth, with negative impact on prognosis [30].

During the study period, the implementation of quality improvement interventions (education on neonatal resuscitation, courses on postnatal management, and the introduction of an on-call doctor for high-risk deliveries)

Table 4 Multivariable analysis of predictors of mortality

	p-value	Odds ratio (95% confidence interval)
Year of admission:	0.03	
2014		Reference
2015		1.00 (0.73 to 1.36)
2016		0.86 (0.63 to 1.16)
2017		0.71 (0.52 to 0.97)
Age at admission, days	0.0003	0.95 (0.93 to 0.97)
Sex:	0.62	
Female		Reference
Male		1.05 (0.86 to 1.28)
Birth weight:	< 0.0001	
Normal weight (≥2500 g)		Reference
Low birth weight (1500–2499 g)		2.48 (2.00 to 3.09)
Very low birth weight (1000–1499 g)		11.71 (8.63 to 15.94)
Extremely low birth weight (< 1000 g)		76.04 (28.54 to 263.82)
Birthplace:	< 0.0001	
Inborn		Reference
Outborn		1.64 (1.31 to 2.06)
Early-onset sepsis:	0.96	
No		Reference
Yes		0.99 (0.75 to 1.31)
Late-onset sepsis:	0.01	
No		Reference
Yes		1.63 (1.12 to 2.36)
Intrapartum-related complications:	< 0.0001	
No		Reference
Yes		4.69 (3.55 to 6.20)
Meconium aspiration syndrome:	0.01	
No		Reference
Yes		2.34 (1.15 to 4.43)
Respiratory distress:	< 0.0001	
No		Reference
Yes		2.25 (1.72 to 2.95)
Transient tachypnea of the newborn:	0.26	
No		Reference
Yes		0.62 (0.25 to 1.33)
Other infections:	0.0007	
No		Reference
Yes		1.93 (1.31 to 2.81)
Malformations:	0.0002	
No		Reference
Yes		2.32 (1.49 to 3.57)

In the subsample of 1994 neonates with complete data on temperature at admission and mode of delivery, moderate hypothermia (32–35.9 °C) at admission was a predictor of mortality (OR 1.53, 95% CI 1.09 to 2.15; p = 0.01), while mild hypothermia (36–36.4 °C), hyperthermia (> 37.5 °C) and mode of delivery were not associated with mortality (p = 0.71, p = 0.98 and p = 0.67, respectively)

Table 5 Summary of predictors of mortality during the study period

	2014	2015	2016	2017	*p*-value
No. of neonates	692	1113	1278	1099	–
Age at admission, days [a]	1 (1–4)	1 (1–4)	1 (1–5)	1 (1–4)	0.77
Low birth weight (1500–2499 g)	202 (29.1)	258 (23.2)	323 (25.3)	342 (31.1)	0.0001 [b]
Very low birth weight (1000–1499 g)	46 (6.6)	56 (5.0)	82 (6.4)	86 (7.8)	0.09
Extremely low birth weight (< 1000 g)	3 (0.4)	9 (0.8)	11 (0.9)	8 (0.7)	0.56
Outborn	202 (39.1)	401 (45.6)	514 (46.6)	460 (45.1)	0.02 [b]
Moderate hypothermia (32–35.9 °C)	171 (38.4)	156 (21.6)	218 (28.2)	234 (24.0)	0.003 [b]
Late-onset sepsis	56 (8.1)	127 (11.4)	168 (13.1)	189 (17.2)	< 0.0001
Intrapartum-related complications	84 (12.1)	163 (14.6)	199 (15.6)	149 (13.6)	0.04 [b]
Meconium aspiration syndrome	5 (0.7)	18 (1.6)	24 (1.9)	20 (1.8)	0.09
Respiratory distress	67 (9.7)	177 (15.9)	302 (23.6)	98 (8.9)	< 0.0001 [b]
Other infections	87 (12.6)	172 (15.4)	127 (9.9)	104 (9.5)	0.0003
Malformations	32 (4.6)	23 (2.1)	37 (2.9)	37 (3.4)	0.01 [b]

Data expressed as n (%) or [a] median (IQR). [b] Quadratic curve over time

could contribute to explain the mortality reduction in 2014–2017 [31]. In addition, we observed different trends over time of factors associated with neonatal mortality. While these data provide useful information about the changing characteristics of admitted neonates, the interpretation goes beyond the scope of the present study and should rely on a longer time span.

During the study, problems in documentation emerged when retrieving data from hospital charts. In fact, information on important prognostic indicators (such as temperature at admission and place/mode of delivery) was missing in 15–30% of the records. The underreporting of such indicators highlights the need for enhancing the awareness of the importance of including those measurements among routine care [32].

This study has some limitations. First, it is a single-center study thus generalizability is limited to similar settings. Second, the retrospective data collection limited the quality and completeness of available information. Third, the diagnosis was mostly based on clinical examination due to the limited availability of laboratory and instrumental equipment.

Our study adds information about risk for mortality among neonates admitted to a special care unit in Ethiopia, where available literature on risk factors for neonatal mortality is limited [11–13, 27]. Our findings confirm that the majority of neonatal deaths seemed to be associated with preventable and treatable conditions [14]. Thus, improvements of referral system, ante- and perinatal care, and postnatal management are warranted to reduce neonatal mortality [11, 15]. Of note, education to health care givers, audits and continuous feedback should be implemented to improve quality and completeness of documentation.

Our findings also contribute to feed up an on-going systematic review which aims at filling the gap in understanding burden and risk factors of neonatal mortality in Ethiopia [14]. The summary of the available evidence will inform health policy makers and stakeholders about which factors should be targeted to reduce neonatal mortality in Ethiopia [14].

Conclusions

Our findings showed that neonatal mortality was associated with admission at early age, low birthweight, being outborn, late-onset sepsis, intrapartum-related complications, meconium aspiration syndrome, respiratory distress, infections, malformations and hypothermia. Education on neonatal resuscitation and postnatal management, and the introduction of an on-call doctor for high-risk deliveries might have contributed to the reduction in neonatal mortality over time.

Abbreviations

CI: Confidence interval; ELBW: Extremely low birthweight; LBW: Low birthweight; MAS: Meconium aspiration syndrome; OR: Odds ratio; VLBW: Very low birthweight

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Authors' contributions

FC participated in the conception and design of the study, performed the data analysis, wrote the initial draft of the manuscript and gave a substantial contribution to the design and interpretation of the data. TB and DAY contributed to data collection, strictly coordinated all the local phases of the study and made a substantial contribution to the interpretation of the data. FM and GP participated in the conception and design of the study and made a substantial contribution to the analysis and interpretation of the data. DT conceived and designed the study; made substantial contribution to the analysis and interpretation of the data; redrafted the manuscript and revised it for important intellectual content. All authors contributed to the

final version of the manuscript and provided critical interpretation of the contents and approved the manuscript for publication.

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Availability of data and materials
The material of the current study is be available from the corresponding author on reasonable request.

Ethics approval and consent to participate
The study was approved by the Ethical Review Committee of St Luke Catholic Hospital and College of Nursing and Midwifery (ref. 245/2020), which waived the need for patient written consents, given the retrospective nature of the study and the use of anonymized data.

Consent for publication
Not applicable.

Competing interests
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Publisher's Note

Pediatric emergency care in a low-income country: Characteristics and outcomes of presentations to a tertiary-care emergency department in Mozambique

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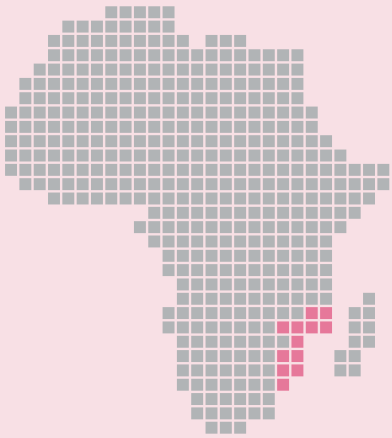

PLOS ONE

RESEARCH ARTICLE

Pediatric emergency care in a low-income country: Characteristics and outcomes of presentations to a tertiary-care emergency department in Mozambique

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Abstract

Background

An effective pediatric emergency care (PEC) system is key to reduce pediatric mortality in low-income countries. While data on pediatric emergencies from these countries can drive the development and adjustment of such a system, they are very scant, especially from Africa. We aimed to describe the characteristics and outcomes of presentations to a tertiary-care Pediatric Emergency Department (PED) in Mozambique.

Methods

We retrospectively reviewed PED presentations to the "Hospital Central da Beira" between April 2017 and March 2018. Multivariable logistic regression was used to identify predictors of hospitalization and death.

Results

We retrieved 24,844 presentations. The median age was 3 years (IQR 1-7 years), and 92% lived in the urban area. Complaints were injury-related in 33% of cases and medical in 67%. Data on presenting complaints (retrieved from hospital paper-based registries) were available for 14,204 (57.2%) records. Of these, respiratory diseases (29.3%), fever (26.7%), and gastrointestinal disorders (14.2%) were the most common. Overall, 4,997 (20.1%) encounters resulted in hospitalization. Mortality in the PED was 1.6% (62% ≤4 hours from arrival) and was the highest in neonates (16%; 89% ≤4 hours from arrival). A younger age, especially younger than 28 days, living in the extra-urban area and being referred to the PED by a health care provider were all significantly associated with both hospitalization and death in the PED at the multivariable analysis.

DANS public repository as "dataset 'Access to Beira PED from April 2017 to March 2018'": https://doi.org/10.17026/dans-zf9-xwzp.

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Conclusions

Injuries were a common presentation to a referral PED in Mozambique. Hospitalization rate and mortality in the PED were high, with neonates being the most vulnerable. Optimization of data registration will be key to obtain more accurate data to learn from and guide the development of PEC in Mozambique. Our data can help build an effective PEC system tailored to the local needs.

Introduction

Over the last two decades, child mortality significantly decreased worldwide thanks to the development of the Millennium Development Goals (MDGs) and the Sustainable Development Goals (SDGs), elaborated by the United Nations to reduce healthcare disparities [1–5]. However, child mortality remains high in low-income countries (LICs) and, in particular, in Sub-Saharan Africa [6, 7].

The development of efficacious pediatric emergency care services has been identified as one of the crucial steps to reduce child mortality [8–10]. However, pediatric care services still represent the weakest links in the healthcare systems chain [11–13], with pediatric emergency medicine still being an understudied field [14, 15].

The study of the burden and profile of pediatric emergencies is important to understand how to optimize resource allocation and healthcare facilities to develop a structured emergency care system that could further reduce child mortality.

In Mozambique, as in other sub-Saharan countries, the health care system is extremely diverse. Mozambique has approximately 1,600 healthcare facilities (including health posts, health centers, district hospitals, provincial hospitals, and four referral/central hospitals) distributed in 11 provinces, 30 municipalities, and 157 provinces. Overall, 96% of these facilities only deliver primary care (i.e. essential preventive and curative health). Only two of the four tertiary-care referral hospitals have a Pediatric Emergency Department (PED), one of which is in Beira, the capital of the Province of Sofala. In 2017, the under-5 and neonatal mortality rates in Sofala were 75.6 per 1,000 and 25 per 1,000 live births, respectively [16–19].

As for other LICs, data on the epidemiology of pediatric presentations to the PED is important to develop tailored strategies to improve the management of acutely and critically ill children, in order to further reduce child mortality.

The present study aims to describe the profile and outcomes of pediatric presentations to a referral care PED in Mozambique over one year. We also aimed to identify predictors of hospitalization and death, eventually suggesting strategies to improve pediatric emergency care services.

Materials and methods

Study design and population

We retrospectively collected data on presentations of all children accessing the PED at Hospital Central da Beira (HCB, Beira, Mozambique), over a 12-month period, between April 2017 and March 2018. The upper age limit for patients' inclusion was 15 years. The study was approved by the ethical review committee of Hospital Central da Beira.

Study setting: Healthcare in Beira and the Sofala province

Beira is the second largest city of Mozambique (with approximately 530.000 inhabitants over an area of 633 km^2) and the capital of the Sofala province (with approximately 2.3 million inhabitants, over an area of 68.018 km^2), which includes 159 health centers and posts (13 in the urban area of Beira), four rural/district hospitals, and one referral Hospital (HCB). By merely averaging the overall distribution of healthcare facilities in the Sofala province, we obtain a health facility every 450 km^2 in the extra-urban area and one every 45km^2 in the urban area. At the time of the study an ambulance service was not available, and patients could reach health care facilities on foot, with private transport or with public transport, where available.

The HCB hosts a Pediatric Department with approximately 200 beds, and one of the two PEDs of the country. The wards are mostly staffed with generalists and pediatric residents, while only seven Pediatricians run the whole Pediatric Department. In the PED some beds are available for short-stay observation and a room is dedicated to Pediatric Intensive Care, where critical children are admitted once stabilized. The Pediatric Department also provides neonatal care to approximately 6000 newborns/year. The Neonatal Intensive Care Unit (NICU) counts about 30 beds and 2000 hospitalizations/year. Based on the most recent available data from 2017, in-hospital overall pediatric mortality was 13%, while in the NICU mortality was 33%.

Sources of data and data collection procedures

Demographic, clinical, and outcome data of all presentations to the PED were abstracted from three hospital paper registries: i) the "presentations registry"; ii) the "hospitalizations registry"; and iii) the "deaths registry". Death and hospitalization registries were filled by PED medical personnel, while the presentation registry was filled by hospital administrative personnel. Details on data systematically recorded in each of the registries are reported in Fig 1. We were unable to collect data on interventions, treatments, or resuscitations in the PED because this information was reported on paper charts, which were not filed systematically and were therefore unavailable to either clinical or research staff. Also, reliable information on comorbidities was not available from the registries.

All the registries were reviewed by two of the Authors (VB and LNF) and patient identity was crossed-matched between registries. Data were entered into an electronic standard data collection system. Abstractors were trained locally based on the initial review of 200 registry records each. A two-month data abstraction overlap between the abstractors helped in ensuring consistency in data abstraction and coding, by training of the second data abstractor. No formal double entry of data by the two abstractors occurred during this time.

The following data were collected from the registries: sex, age, area of residence, modality of presentation, presenting complaint, outcome (discharge, hospitalization, or death, and time

Type of Registry	Presentations registry 5 paper registries	Hospitalizations registry * 3 paper registries	Deaths registry 1 paper registry
Type of data systematically recorded in the registries	Name of patient Date of visit Age Sex Area of residence Modality of presentation Presenting complaint Date of discharge	Name of patient Date of hospitalization Diagnosis of hospitalization Ward of hospitalization	Name of patient Time of death (<4h or >4 h from arrival) Date of death
Number of total records	24.884	4.997	396

Fig 1. Characteristics of hospital registries from which study data were collected.

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of death). Children's age ranged from 0 to 15 years, and the age variable was categorized in four age groups for analysis: from 0 to 28 days (neonates), from 29 days to 1 year (infants), from 1 to 5 years (preschoolers), and from 5 to 15 years (school-aged). The modality of presentation included self-presentations or referrals from other health care providers (i.e. health care centers, rural hospitals, private clinics, etc.). The area of residence variable was categorized in urban, when the child lived in the Beira urban area, and in extra-urban, which was sub-categorized into within the Sofala province and outside the Sofala province. Information on presenting complaints was categorized in the registries as medical or injury related. Medical complaints included the following locally predefined categories of non-traumatic complaints: fever of any origin, respiratory, gastrointestinal, cardiovascular, neurological, musculoskeletal, constitutional, sense organs (which included medical complaints to the eyes, ears, nose, throat and to the skin), and others (which included psychiatric disorders, genitourinary disorders, etc.). Injury-related presentations were locally classified into road accidents, falls, wounds, violence, inhalation/ingestion, burn, and drowning. This categorization system was maintained for data analyses in the current study. Time from presentation to death was categorized in early death (death on arrival or within four hours from arrival), and later death in the PED (after four hours from arrival). Unfortunately, the HBC did not have the facilities and resources (i.e., trained staff, information technology infrastructure) to code diagnoses according to the ICD 9/10 codes. Data on diagnosis were reported as per local documentation practices.

Statistical analysis

Descriptive statistics were reported as median and interquartile range (IQR) for continuous variables. Categorical variables were reported as proportions and percentages. The Wilcoxon test was used for comparison of continuous variables, while Chi-square and Fisher's exact tests, as appropriate, were used for categorical variables.

We then fit univariable logistic regression models specifying hospitalization, death, and death within four hours as the dependent variable, and clinical and demographic variables as independent variables. Subsequently, we fit multivariable logistic regression models to identify independent predictors of hospitalization, mortality, and mortality within four hours, with the variables that were found to be significant from the univariable models ($p<0,05$). Results of dependent variables analysis were tested again in a multivariable model for interaction with age, sex, area of residence, the modality of presentation (self vs referred presentation), the reason for presentation, and outcomes [20].

Given the high rate of missing data for the independent variable "presenting complaint" a sensitivity analysis was carried out to assess how missing values would affect the association of the independent variables with the dependent variable. With this respect we performed the following analyses:

1. A complete case analysis estimating the model on the valid case data (excluding records with missing data for the variable presenting complaint)
2. A missing data imputation analysis based on the model estimation on an imputed dataset. A Multiple Imputation by Chained Equations (MICE) procedure was used to handle the missing data for the variable presenting complaint.
3. An estimation of the multivariable model for the outcomes, but excluding the variable presenting complaint from the model.

When the p-value was $<.05$, the difference was regarded as statistically significant. All statistical tests were 2-tailed. All statistical analyses were performed using Stata Version 13.0

(StataCorp, College Station, TX) and R 3.6.2 together with caret, rms, and MICE packages [21–24].

Results

Patients characteristics

During the 12-month study period, 24,844 presentations were recorded. Of these, 14,448 (58.8%) were male, with a male to female ratio of 1.43 to 1. The median age at presentation was 36.5 months (IQR 12–85.2 months). The majority of patients (92%) came from the urban area, with 42% already been assessed by a health care provider in a health care center or at a countryside hospital. A summary of demographics and general characteristics of study presentations by age-group is presented in Table 1.

Data on presenting complaints specifications were available for 14,204 (57.2%) presentations. A medical issue was the reason for presentation in 67% of cases, while 33% were consequent to an injury. The most common medical presentations were respiratory diseases (29.3%), followed by fever (26.7%), and gastrointestinal disorders (14.2%). Among injury presentations, falls (63%) were the most common, followed by foreign body ingestion/inhalation (10.2%) and road accidents (9.8%). Data on presenting complaints by age group are reported in Table 2.

Outcomes

Overall, 4,997 (20.1%) of encounters resulted in hospitalizations and 396 (1.6%) in death in the PED. Data on outcomes by age group are described in Table 3. Data on length of stay in the PED for patients who were discharged were available for only 5,639 out of 19,451 visits (29.0%). Of these, 5,505 (97.6%) were discharged within 24 hours of arrival.

Hospitalization analysis

Of the 4,997 hospitalizations, 37 (0.7%) were direct admission from the PED to the PICU. Of these, 17 (45.9%) were for burns. Overall, the length of stay in the PED for visits that resulted in hospitalization was < 24 hours in 37%, between 24 and 48 hours in 56%, between 48 and 72 hours in 5% and > 72 hours in 2% of cases. Data on presenting complaints were available for 4,057 (81.2%) of visits resulting in hospitalization. Of these, 88.1% presented with a medical

Table 1. Demographic characteristics of Pediatric Emergency Department presentations by age group.

Number of visits to the PED	Total	< 28 d	29 d–1 y	1–5 y	5–15 y
	(n= 24,844)	2.7% (n = 677)	22.7% (n = 5,634)	43.7% (n =10,845)	30.9% (n = 7,688)
Sex *					
Male	**58.8%**	50.6% (260)	59.3% (3,315)	58.3% (6,293)	59.9% (4,580)
Residency *					
Urban (Beira)	**92.5%**	87.0% (585)	92.0% (5,189)	94.0% (10,171)	91% (7,003)
Sofala Province	**6.2%**	12.0% (82)	6.0% (338)	5.0% (569)	7% (567)
Extra Sofala	**1.3%**	1.0% (9)	2.0% (105)	1.0% (102)	1.0% (115)
Modality of Access to the PED					
Self-presentations	**58.0%**	54.0% (367)	62.0% (3,466)	59.0% (6,439)	45.0% (4,205)
Heath Care Center	**36.0%**	37.0% (249)	32.0% (1,827)	36.0% (3,885)	39.0% (2,976)
Peripheral Hospital	**6.0%**	9.0% (61)	6.0% (341)	5.0% (521)	7.0% (507)

*Data on sex available for 24,562/24,844 (98.9%); data on residency available for 24,835/24,844 (99.9%).

Data are reported in terms of percentages and absolute frequencies.

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Table 2. Presenting complaints by age group.

PRESENTING COMPLAINT	Total	< 28 d	29 d–1 y	1–5 y	5–15 y
	n = 14,204	n= 297	n = 3,067	n = 6,232	n = 4,608
Injury	**33.0% (4,682)**	**14.5% (43)**	**16.3% (500)**	**31.1% (1,941)**	**47.7% (2,198)**
Fall	63.0% (2,949)	39.5% (17)	61.4% (306)	60.6% (1,178)	66.0% (1,448)
Ingestion/Inhalation	10.2% (480)	14.0% (6)	10.1% (52)	16.2% (314)	5.0% (108)
Road Accident	9.8% (457)	27.9% (12)	6.9% (34)	7.4% (144)	12.0% (267)
Wound	8.6% (401)	14.0% (6)	7.4% (37)	7.0% (135)	10.1% (223)
Burns	5.1% (237)	4.6% (2)	10.1% (52)	6.3% (123)	2.7% (60)
Violence	3.0% (143)	0.0% (0)	3.0% (15)	2.1% (41)	4.0% (87)
Drowning	0.3% (15)	0.0% (0)	0.8% (4)	0.3% (6)	0.2% (5)
Medical	**67.0% (9,522)**	**85.5% (254)**	**83.7% (2,569)**	**68.9% (4,289)**	**52.3% (2,410)**
Respiratory	29.3% (2,789)	27.2% (69)	35.6% (914)	26.3% (1,124)	28.3% (682)
Fever	26.7% (2,540)	22.0% (56)	20.9% (537)	31.0% (1,328)	25.7% (619)
Gastrointestinal	14.2% (1,355)	8.3% (21)	17.1% (440)	13.8% (593)	12.5% (301)
Sense Organs*	9.8% (936)	13.8% (35)	9.0% (231)	9.5% (410)	10.8% (260)
Constitutional**	8.4% (794)	20.1% (51)	8.3% (213)	8.5% (367)	6.8% (163)
Neurological	7.9% (752)	2.7% (7)	6.7% (171)	8.3% (355)	9.1% (219)
Musculoskeletal	2.4% (225)	3.9% (10)	1.5% (39)	1.7% (72)	4.3% (104)
Cardiovascular	0.8% (77)	1.6% (4)	0.6% (15)	0.4% (16)	1.7% (42)
Other***	0.6% (54)	0.0% (1)	0.4% (9)	.6% (24)	0.8% (20)

* sense organs are defined as the body organs by which humans are able to see, smell, hear, taste and touch or feel. This category includes medical complaints to the eyes, ears, nose, throat and to the skin.

**lethargy, weakness, loss of appetite, fatigue etc.

Data are reported in terms of percentages and absolute frequencies.

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complaint, and 11.9% with an injury. A significantly higher proportion of medical presentations were hospitalized compared to injuries (37.9% vs. 9.6%, p-value < 0.001). Results of the univariable analysis assessing the association of available clinical variables with hospitalization is reported in S1 Table.

The multivariable analysis carried out on the subgroup of encounters with data on presenting complaint available and the multivariable analysis with missing data imputation showed similar high odds of being hospitalized if presentations to the PED were due to a medical problem rather than an injury (OR 12.19, 95% CI: 10.78 – 13.38 and 11.79, 95% CI: 10.62-13.1, respectively). (Table 4). A younger age, especially younger than 28 days, living in the extra-urban area and being referred to the PED by a health care provider were all predictors of hospitalization, with similar ORs at all the multivariable analyses performed.

Table 3. Outcomes of pediatric emergency department presentations by age group.

OUTCOMES	Total	< 28 d	29 d- 1 y	1–5 y	5–15 y
	n = 24,844	n = 677	n = 5,634	n = 10,845	n = 7,688
Mortality	**1.6% (396)**	**16.1% (109)**	**1.7% (96)**	**1.1% (118)**	**1% (73)**
≤ 4 h	1.0% (247)	14.3% (97)	1% (57)	0.5% (57)	0.5% (36)
> 4 h	0.6% (149)	1.8% (12)	0.7% (39)	0.6% (61)	0.5% (37)
Hospitalization	20.1% (4,997)	29.7% (201)	25.2% (1,422)	19,7% (2,132)	16.1% (1,242)
Discharge	78.3% (19,451)	54.2% (367)	73.1% (4,116)	79,2% (8,595)	82.9% (6,373)

Data are reported in terms of percentages and absolute frequencies.

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Table 4. Determinants of hospitalization.

		Total of Data Available	Hospitalization	Multivariable analysis on valid cases only*	p-value	Multivariable analysis imputing missing data for the variable presenting complaint	p-value	Multivariable analysis excluding the variable presenting complaint	p – value
		N	n: 4997	OR (95% CI)		OR (95% CI)		OR (95% CI)	
SEX	Male	14,448	2,893	0.97 (0.89 – 1.05)	0.43	0.99 (0.92 – 1.06)	0.75	0.92 (0.92 – 1.06)	0.02
	Female	10,114	2,054	Reference		Reference		Reference	
AGE		24,844	4,997						
	0 – 28 days	677	201	1.81 (1.34-2.43)	**<0.001**	1.68 (1.36-2.07)	**<0.001**	2.8 (2.28-3.43)	**<0.001**
	29 d – 1 year	5,634	1,422	1.53 (1.36-1.72)	**<0.001**	1.19 (1.08-1.31)	**<0.001**	2.07 (1.89-2.27)	**<0.001**
	1 – 5 years	10,845	2,132	1.12 (1.01-1.24)	**0.03**	1.05 (0.96-1.15)	0.27	1.42 (1.31-1.54)	**<0.001**
	5 – 15 years	7,688	1,242	Reference		Reference		Reference	
RESIDENCY	Extra-urban	1,887	818	2.97 (2.55-3.45)	**< 0.001**	2.61 (2.31-2.95)	**< 0.001**	2.617 (2.31-2.95)	**< 0.001**
	Urban	22,948	4,177	Reference		Reference		Reference	
MODALITY OF PRESENTATION	Health Care Provider referral	10,360	3,380	5.57 (5.08-6.11)	**< 0.001**	7.16 (6.63-7.73)	**< 0.001**	3.65 (3.4-3.91)	**< 0.001**
	Self-Presentations	14,477	1,617	Reference		Reference		Reference	
PRESENTING COMPLAINT	Medical	9,522	3,607	12.19 (10.78-13.78)	**< 0.001**	11.79 (10.62-13.1)	**< 0.001**		
	Injury	4,682	450	Reference		Reference			

* Missing values for the variable presenting complaint were excluded from the analysis

The valid cases (total of data available) have been reported with the number of hospitalized patients. A sensitivity analysis has been performed reporting the results (OR, 95% Confidence Intervals (CI), and p-values) for 1) Multivariable Analysis on valid cases; 2) Multivariable Analysis on imputed data for variable presenting complaint; 3) Multivariable analysis excluding the variable presenting complaint.

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S2 Table describes the univariable association between type of presenting complaint and hospitalization. The multivariable analysis (Table 5) showed that children presenting for a medical complaint had higher odds of being hospitalized if they presented for cardiovascular, constitutional, and neurological complaints compared to fever. Within the injury-related presentations children presenting for burns, road accidents, wounds or ingestion/inhalations had higher odds of being hospitalized compared to children presenting for falls.

The diagnosis distribution for hospitalized patients is described, stratified by age, in Fig 2.

Mortality analysis. Overall, mortality in the PED was 1.6%. The majority of deaths (81%) occurred in patients younger than five years, with the highest mortality found in the 0 – 28 days group (16.1%).

Results of the univariable analysis is reported in S1 Table, while those of the multivariable analyses are reported in Table 6. A younger age, especially younger than 28 days, living in the extra-urban area and being referred to the PED by a health care provider were predictors of mortality in the PED at all the multivariable analyses performed, although some variability in ORs for age, modality of presentation and presenting complaint was noticed between the models.

Of the 396 deaths, 247 (62%) occurred within four hours from arrival (early deaths). Due to the low number of patients and the high rate of missing values for the independent variable "presenting complaint" we only performed a multivariable analysis excluding this variable from the model (Table 7).

Table 5. Association between presenting complaints and hospitalization.

		N^	Hospitalization (n)^^	Multivariable Analysis OR (95% CI)	p – value
PRESENTING REASON					
	Medical	9,522	3,607		
	Fever ‡	2,540	754 (21%)		
	Respiratory	2,789	873 (24%)	1.17 (1.03-1.33)	**0.019**
	Neurological	752	465 (13%)	3.28 (2.72–3.96)	**<0.001**
	Gastrointestinal	1,355	461 (13%)	1.32 (1.13-1.65)	**0.005**
	Cardiovascular	77	64 (2%)	7.86 (4.08-15.13)	**<0.001**
	Musculoskeletal	225	81 (2%)	0.54 (0.39-0.73)	**0.001**
	Constitutional*	794	638 (18%)	6.98 (5.65 -8.62)	**<0.001**
	Sense Organs**	936	242 (7%)	0.72 (0.60-0.87)	**<0.001**
	Others***	54	29 (1%)	1.99 (1.08-3.69)	**0.028**
	Injury	4,682	450		
	Drowning	15	1 (0%)	1.98 (0.25-15.70)	0.520
	Road Accident	457	84 (19%)	4.37 (3.26-5.87)	**<0.001**
	Fall ‡	2,949	175 (39%)		
	Burn	237	109 (24%)	25.01(17.99-34.78)	**<0.001**
	Wound	401	36 (8%)	2.35 (1.60-3.47)	**<0.001**
	Violence	143	3 (1%)	0.42 (0.13-1.35)	0.150
	Ingestion/Inhalation	480	42 (9%)	2.24 (1.56-3.23)	**<0.001**

*lethargy, weakness, loss of appetite, fatigue, etc.

** sense organs are defined as the body organs by which humans can see, smell, hear, taste and touch or feel. This category includes medical complaints to the eyes, ears, nose, throat, and the skin.

***Psychiatric and genitourinary diseases.

‡ Reference Category.

Absolute number and percentages of hospitalized patients have been reported. Multivariable and Logistic Regression Model results (OR, 95% Confidence Intervals (CI), and p-values, adjusted for gender, age, residency and modality of presentation) are represented in the table.

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A younger age, especially younger than 28 days, was a predictor of early mortality in the PED, while visits that were referred to the PED by a health care provider had lower odds of dying in the first four hours from arrival. Of patients who died after 4 hours, 34% died in the first 24 hours, 43% between 24 and 48 hours, 13% between 48 and 72 hours and 10% beyond 72 hours since arrival.

Limitations

The results of our study should be interpreted in light of its limitations, which are mostly related to its retrospective design and the available sources of data collection. First, approximately 40% of data on presenting complaints were missing in the "presentation registry". This registry was filled by hospital administrative staff who were less aware of the importance of accurate data completion with respect to reporting and analysis purposes. The rate of missing information on presenting complaints was higher for patients who died in the PED (presenting complaint was not reported in 81.3% of deaths), followed by visits resulting in discharge to home (48.2% of missing information) and those resulting in hospitalization (missing information for 18.8%). While this lack of information affects the accuracy of our findings with respect to the description of presenting complaints, this was the best available data we could get access to at the time of the study. In addition, we performed a sensitivity analysis to report how missing values could have affected our results based on different scenarios. Missing information on

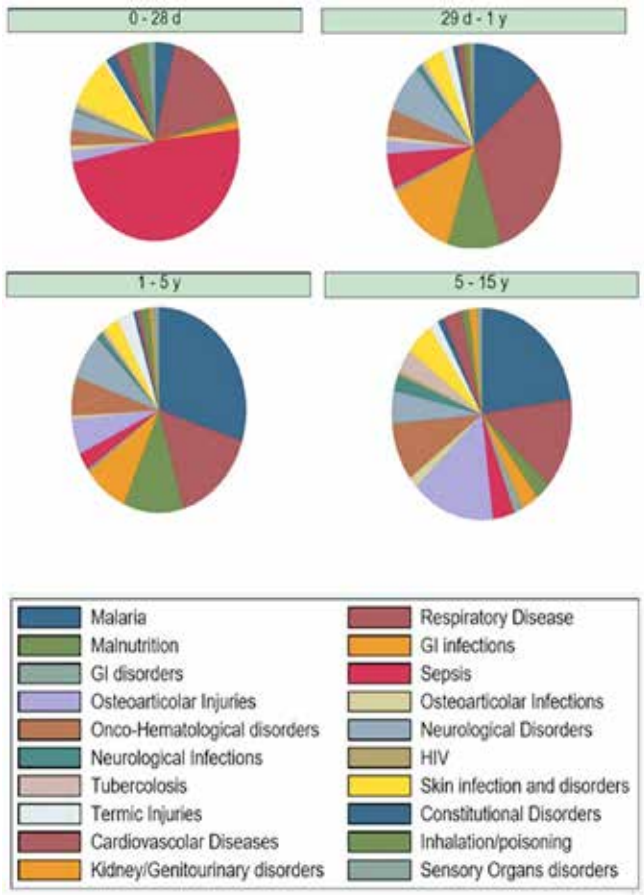

Fig 2. Hospitalization diagnosis, by age and frequency.

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ED visits records is a common challenge for many LICs and is inherently related to the limitations of the local data registration and repository system. Lack of human and information technology resources represent the major obstacles to the establishment of an accurate and long-lasting data recording and monitoring system in these Countries. Learning from local data is a valuable opportunity for a growing health system to improve the quality of care while optimizing resource use. Efforts towards establishing a robust data management and monitoring system should be made at an institutional and governmental level to best support the development of a pediatric emergency care system in Mozambique.

Second, data on comorbidities were reported inconsistently and only in the hospitalization registry and could not be analyzed. This would be extremely valuable information to include in the multivariable analysis, as underlying conditions such as malnutrition, HIV, and tuberculosis have shown to be associated with the need for hospitalization and mortality [11, 25–27]. Systematic collection of the main comorbidities should be pursued in order to be able to appropriately interpret data to improve care and optimize resource organization and use.

Table 6. Determinants of mortality in the Pediatric Emergency Department.

		Total of Data available	Mortality in the PED	Multivariable Analysis on valid cases only*	p-value	Multivariable Analysis imputing missing data for variable presenting complaint	p-value	Multivariable analysis excluding variable presenting complaint	p – value
		N	(n 396)	OR (95% CI)		OR (95% CI)		OR (95% CI)	
SEX	Male	14,448	182	1.02 (0.63–1.65)	0.94	0.96 (0.78 – 1.18)	0.72	0.99 (0.79 – 1.25)	0.92
	Female	10,114	125	Reference		Reference		Reference	
AGE		24,844	396						
	0 – 28 days	677	109	5.34 (1.09–15.01)	<**0.001**	16.12 (11.69-22.22)	<**0.001**	5.91 (3.06–9.68)	<**0.001**
	29 d – 1 year	5,634	96	2.33 (1.25–4.34)	**0.01**	1.34 (0.99-1.83)	0.06	2.25 (1.65 -3.07)	<**0.001**
	1 – 5 years	10,845	118	0.98 (0.54–1.79)	0.95	0.95 (0.71 – 1.28)	0.74	1.31 (0.97 – 1.75)	0.08
	5 – 15 years	7,688	73	Reference		Reference		Reference	
RESIDENCY	Extra-urban	1,887	43	2.40 (1.28-4.50)	**0.01**	2.14 (1.5–3.05)	<**0.001**	2.11 (1.49–2.98)	<**0.001**
	Urban	22,948	353	Reference		Reference		Reference	
MODALITY of PRESENTATION	Health Care Provider referral	10,360	165	7.18 (3.97-12.98)	<**0.001**	2.36 (1.89 –2.95)	<**0.001**	1.95 (1.53 –2.47)	<**0.001**
	Self-presentation	14,477	231	Reference		Reference		Reference	
PRESENTING COMPLAINT	Medical	9,522	48	2.68 (1.57-4.59)	<**0.001**	10.36 (6.94-10.45)	<**0.001**		
	Injury	4,682	26	Reference		Reference			

*Missing values for the variable presenting complaint were excluded from the analysis.

The valid cases (total of data available) have been reported with the number of deceased patients. A sensitivity analysis has been performed reporting the results (OR, 95% Confidence Intervals (CI), and p-values) for 1) Multivariable Analysis on valid case; 2) Multivariable Analysis on imputed data for variable presenting complaint; 3) Multivariable analysis excluding the variable presenting complaint.

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Table 7. Determinants for early mortality in the PED (≤ 4h vs mortality> 4h).

		Total of Data available N 28,844	Early death (≤ 4 h) n: 247	Multivariable Analysis	p – value
				OR† (95% CI)	
SEX	**Male** Vs	14,448	90	0.91 (0.66 – 1.26)	0.58
	Female	10,114	71		
AGE		28,844	247		
	0 – 28 days	677	97	2.71 (1.4 – 5.25)	< **0.001**
	29 d – 1 year	5,634	57	1.36 (0.88 – 2.09)	0.160
	1 – 5 years	10,845	57	0.93 (0.61 – 1.43)	0.753
	5 – 15 years ‡	7,688	36		
RESIDENCY	Urban Vs	22,948	230		
	Extra sofala	1,887	17	0.85 (0.50 – 1.44)	0.727
MODALITY of PRESENTATION	Self-presentations Vs	14,477	178		
	Health Care Provider referral	10,360	69	0.35 (0.25 – 0.49)	< **0.001**

‡Reference category.

The number of valid cases (total of available data) and early death patients has been reported. Logistic Regression Model results (OR, 95% Confidence Intervals (CI), and p-values) are represented in the table.

https://doi.org/10.1371/journal.pone.0241209.t007

Third, we could not get access to data prior to April 2017 to identify possible biases in our results from random yearly variations. Based on the local clinical registry filing system, completed paper registries were temporarily filed and available for some months and then periodically burnt.

Fourth, this is a single center study and may not represent the rest of Mozambique or other LICs with different disease prevalence. However, there are only four tertiary care level hospitals in Mozambique, two of which (in Beira and Maputo) have a PED, and it is reasonable to believe our data may provide some useful insights into pediatric emergency care at a local and national level to help optimize distribution and use of resources, as well as plan the most appropriate feasible and effective interventions to improve pediatric emergency care within an integrated system of care.

Discussion

In this study we were able to provide the first, albeit limited, data on pediatric emergency visits to a tertiary care PED in the LIC of Mozambique. Our data represent a first important step to help the establishment of a pediatric emergency care monitoring system in Mozambique in order to guide the formulation of appropriate strategies to improve the management of the acutely and critically ill children and develop a structured and sustainable emergency care system. The first important finding of our study is that the current PED data registration system has many flaws and challenges, which hamper the provision of accurate and valid data to learn from and guide the development of pediatric emergency care tailored to local needs. Optimization of data registration is an important area on which to focus resources in order to obtain more accurate data for this purpose.

Our study found an overall high mortality rate in the PED setting of 1.6%. Although higher than reported in high-income countries (1.5/100 000 visits) [28], our result is in line or even lower compared to other sub-Saharan countries [29]. The majority of deaths occurred in patients younger than five years (81%), with the highest mortality found in the neonatal group (16%). Based on a recent systematic review [30], about a third of all neonatal deaths tend to occur on the day of birth, and approximately 75% die in the first week of life. These findings suggest that focusing on perinatal care, maternal education and improved access to healthcare is essential for saving newborn lives.

Our analysis also showed that living in extra-urban areas is a predictor of death. This may reflect the many challenges in transportation to the hospital that these children have to face even when severely ill. Fernandes and colleagues [18], highlighted the importance of health service availability, showing an overall improvement in child survival in Mozambique, associated with increased health workforce density, institutional birth coverage, and government health financing, despite the substantial disparity between provinces.

Physicians working at HCB's PED noticed that death occurred more frequently in children presenting late in their course of illness. As evidenced by Punchak and coworkers [31] there are many potential contributing factors to late presentations, including delays related to triage organization, bad tiered health care system, late care-seeking by families due to a lack of health education, and socioeconomic factors related to the geographic distribution of health centers and inadequate transportation infrastructures. Improving access to care, and further promoting health education, would likely result in an earlier presentation to the PED, eventually translating in better disease recognition and treatment.

The majority of deaths in our study occurred in the first four hours from arrival (62%). This group mostly included neonates and children living in the urban area who were brought in by parents. Our study also found that children who had already been evaluated by a health

care provider (in a health care center or a peripheral hospital) had lower odds of dying early (within 4 hours) in the PED. In fact, these children died more often after four hours from arrival to the PED. Our findings may reflect the ability of health care centers or peripheral hospitals to stabilize severely ill patients for transport. However, late presentation to a health care facility and inability to provide effective care during transport may contribute to the unfavorable outcome of these children. Although WHO and UNICEF [6, 7] report that infectious diseases remain a leading cause of death for children under the age of 5 in sub-Saharan Africa, accurate local data would be paramount to better understand which interventions could be most effective to further reduce child mortality both in the PED and at a community level, within an integrated system of care.

We also found a high hospitalization rate of 20.1%, with neonates and infants showing higher odds of being hospitalized compared to older children, as previously described for other sub-Saharan regions [29]. Also, children who lived in the extra-urban area were at higher risk of being hospitalized compared to children who lived in the urban area, especially if already evaluated by health care center physicians or in a peripheral hospital. These results reflect a good organization of the health care referral system in treating pediatric critically ill presentations [11]. However, peripheral health centers have limited resources or lack of training for the management of the most severe presentations, and transfer conditions to the referral center remain challenging.

Our study showed that children presenting for a medical reason were more likely hospitalized, especially if admitted with cardiovascular, constitutional, and neurological diseases. Among injury presentations, burns, road accidents, wounds, and ingestion/inhalations were significantly associated with hospitalization, compared to fall. Based on our field experience, only severe burns with an intrinsic high risk of complications were referred to HBC, which justified the need for hospitalization [31–33]. The causes and risk factors behind the substantial number of severe burns should be further explored in order to implement effective preventive measures.

The analysis of hospitalization diagnosis by age group showed that sepsis, followed by lower respiratory infections (i.e pneumonia and bronchiolitis) and skin infections (i.e cellulitis, impetigo, piodermitis, etc.) were the most common in the neonatal age group. This highlights the need for interventions to improve perinatal care and parents' education. At HBC neonates and their mothers are usually discharged on the first day after delivery, without provision of any further assistance from health personnel in the out of hospital setting. Indeed, the implementation of specific protocols to educate mothers before discharge, such as providing informative graphic pamphlets and clear verbal instructions on when is necessary to present to a health care facility, could be an effective way to prevent clinical deterioration and delayed care, as demonstrated by Berhea and colleagues in Ethiopia [34]. We also found that severe malnutrition became a more frequent cause of hospitalization with increasing age, being the third cause of admission in preschoolers. This is an important finding, considering that it is estimated that malnutrition is the underlying cause of 45% of global deaths in children below 5 years of age [35, 36]. In the school-aged group, malaria was the leading cause of hospitalization followed by osteoarticular injuries, mainly due to falls and road accidents. This is consistent with previous studies in LMICs, reporting an increased frequency of injury in this age group [37–39]. Lastly, we also found an increased prevalence of haemato-oncological disorders in this age group compared to the others, mainly due to severe anemia.

Although data on presenting complaints were limited by the number of missing data, we found a similar distribution compared with previously published data from other low and middle-income countries (LMICs) [12, 40]. As expected, infection-related presenting complaints were the most frequent, with respiratory, fever, and gastrointestinal conditions being

the most common [41, 42]. After analyzing presentations complaints by age groups, it becomes evident how injury-related presentations increased with age, reaching almost half of the visits (48%) in school-age children. This is consistent with a previous Mozambican report [43]. However, within the neonatal and infant age groups, we found a high rate of injury-related presentations (16% and 14%, respectively), in particular, due to falls. These rates are in contrast with reports from high-income countries and other LMICs [39, 40]. Our rates are concerning, considering the fragility of children in this young age group and the overall high mortality and morbidity associated with injury [39]. Although further investigations are necessary to identify the reasons behind the abnormally high prevalence of injury in non-ambulant children found in this study, our results suggest that there is an urgent need to develop injury-prevention programs and campaigns to reduce injury rates in young Mozambican children, supporting the needs evidenced by De Sousa Petersburgo and coworkers [43].

Other useful interventions to improve the quality of care provided to the acutely and critically ill children include the implementation of a triage system, training of healthcare personnel and the establishment of an efficient emergency call and transport system. Several studies have shown how the introduction of Emergency Triage and Treatment (ETAT) guidelines could be an easy and cost-effective strategy to improve emergency and overall care [44–46]. In Malawi, the implementation of ETAT halved the pediatric inpatient mortality rate [47]. Training of health care personnel to the early identification of critical diseases is another important step in the improvement of PEC, as shown by several studies [10, 18, 48, 49]. Training on the early recognition and management of conditions that most often result in death in the local setting should be prioritized. Although challenging and expensive, the establishment of an efficient emergency call and transport by ambulance service would be critical to ensure that severely ill children from both the extra-urban and urban areas have access to the PED in a timely manner [31].

Conclusions

Optimization of data registration is an important area on which to focus resources in order to obtain more accurate data to learn from and guide the development of pediatric emergency care in Mozambique, tailored to local needs. Our data provide insight into opportunities to reduce the high mortality in the pediatric emergency department and the high hospitalization rate, identifying the neonatal age group as the most vulnerable. Interventions such as maternal education, injury prevention, implementation of a triage system, training of health care personnel, and implementation of an emergency care transport system would be critical to improve the outcomes of acutely and critically ill children in Mozambique.

Supporting information

S1 Table. Determinants of hospitalization, mortality in the PED, and early death. The valid cases (total of data available) have been reported with the number of hospitalized patients. Univariable analysis results are reported in the table.
(DOCX)

S2 Table. Association between presenting complaints and hospitalization. Absolute numbers and percentages of hospitalized patients have been reported. Univariable Analysis (OR, 95% Confidence Intervals (CI), and p-values, adjusted for gender, age, residency, and modality of presentation) are represented in the table.
(DOCX)

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Designing, Implementing and Managing a National Emergency Medical Service in Sierra Leone

PAPER

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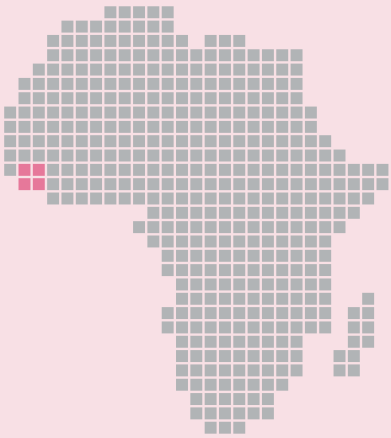

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Increased child abuse in Uganda amidst COVID-19 pandemic

PAPER

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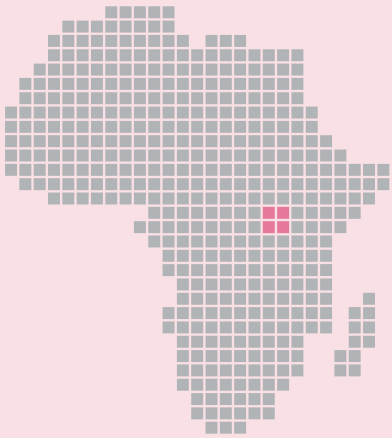

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VIEWPOINT

Increased child abuse in Uganda amidst COVID-19 pandemic

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Globally, COVID-19 lockdown measures have exposed children to more sexual, physical and emotional abuse and neglect. Although the COVID-19 pandemic is likely to have long-lasting adverse psychological effects on children, there have been comparatively few studies on children's health as compared with adults, particularly in low-income countries. Uganda implemented one of the most stringent lockdowns with bans on transportation and gatherings as well as the closure of schools, stores and places of worship. In order to address the dearth of information in less developed regions, the article aims to provide an insight into the increased cases of child abuse in Uganda during the COVID-19 pandemic. The data and information were primarily compiled from government and child welfare organisation open-source databases. The psychosocial impacts of COVID-19 have greatly disrupted the living conditions of children, limiting their access to basic needs such as food and health care. In addition, there is a lack of social support, thus putting children at an increased risk of different forms of child abuse. Since the implementation of the COVID-19 lockdown in Uganda, there has been a rise in the incidence of child abuse. Increased cases of physical and sexual abuse against children have been reported in different parts of the country as well as increased cases of child labour. To strengthen child protection during the COVID-19 pandemic, this article highlights a need for multi-level stakeholder cooperation to ensure increased funding, increased community awareness and sensitisation, early detection and effective management and referral of child abuse cases.

COVID-19 was declared a global pandemic by the World Health Organisation (WHO) on 11 March 2020, having spread to over 110 countries and territories.[1,2] As of 28 October 2020, 1 303 000 cases (3.0% of global cases) and 29 380 deaths (2.5% of global mortality) were reported in Africa.[3,4] Uganda reported the first case of COVID-19 on 21 March 2020. Within days, the government implemented the following measures: international border closures (including airport arrivals), closure of schools and places of worship, suspension of mass gatherings, suspension of public and private transportation, with a nationwide lockdown that was declared on 24 March 2020.[5,6] On 30 March 2020, a national 7:30 pm curfew was instigated.[7] As of 28 October 2020, 11 767 cases and 106 deaths had been reported in Uganda.[5]

Despite the widespread reach of the COVID-19's pandemic, children are an often-overlooked population due to their lower mortality rates.[8–10] For instance, one study has reported a mortality rate of 0.03 per 100 000 deaths among children aged 0–9 years,[11] with some countries having rates as low as 0.18%,[12] as compared with mortality rates exceeding 10% among adults.[12–14] However, child welfare organisations have warned that the various lockdown measures will lead to more cases of child sexual, physical and emotional abuse and neglect.[15] Of the one billion children that are exposed to various forms of violence globally, almost one-quarter are in Africa.[16,17] A recent Ugandan national violence against children survey showed that one in three girls and one in six boys, suffer sexual violence during their childhood, and 70% of boys suffer physical violence.[18] Over 8 million children in Uganda believed to be vulnerable[19]; previous studies conducted in Uganda have noted that child abuse victims are at higher risk of a multitude of adverse health outcomes (depression, suicidal behaviour, risky sexual behaviours, death) as well as poorer educational/employment outcomes later in life.[20]

During lockdowns, children are compelled to spend much more time at home with relatives who may be the main perpetrators of abuse and the additional economic stressors on parents may further increase the risk of child abuse. In Uganda, the Ministry of Gender, Labour and Social Development is the nodal institution for child protection in the country. However, the mandate is shared with the Ministry of Internal Affairs, Ministry of Justice and Constitutional Affairs, Ministry of Education and Sports and Ministry of Health.[21,22] At the district level, the mandate for child protection is with the Community-Based Services Department.[22] The Judiciary also plays a major role in the protection of the rights of children by being responsible for the overall administration of justice for children as well as the protection of their rights through judicial processes.[21] However, this child protection framework lacks proper coordination among the various stakeholders making it less effective compared with developed countries. This poorly coordinated child protection framework in Uganda combined with the stressors of COVID-19 pandemic makes children highly susceptible to abuse.[23]

Since children are extremely vulnerable to the 'secondary' impacts of the pandemic, with a possibility of life-time effects,[24] it is crucial to look into the impact of COVID-19 on child abuse in a society with high baseline rates of child abuse. This article aims to provide an insight into the increased cases of child abuse in Uganda during the COVID-19 pandemic, primarily examining data from the Uganda Ministry of Health and international child

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welfare organisations (Save the Children, World Vision). We believe the highlights of this paper could be vital in informing the stakeholders of the actual scope of the problem. In addition, the article also highlights practical interventions to address this public health issue in Uganda during the COVID-19 pandemic.

The Changing Child Abuse Situation in Uganda During the COVID-19 Pandemic

Amidst the COVID-19 lockdown, there has been a rise in the incidence of child abuse of various forms throughout Uganda:

Increased violence against children

The Uganda Child Helpline (UCHL) run by the Ministry of Gender, Labour and Social Development was established as a child protection mechanism 6 years ago.[18] Before the COVID-19 pandemic, the helpline averagely received 100 calls per day, reporting different forms of violence against children.[18] Shortly after the lockdown measures were put into place, between 10 and 26 April 2020, 21 904 calls were received with an average of 1369 calls a day, a 13-fold increase.[18] With the psychosocial impacts of the pandemic, many parents became stressed and aggressive due to the lack of social support, making children prone to experiencing violence at home.[18,25] The reported cases mainly included child neglect, physical and sexual abuse, with two reports of murder.[18] The lockdown has led to increased cases of child neglect in several parts of the country, where many children have been neglected by their parents and denied basic necessities such as food, medical care and shelter. According to the UCHL March 2020 report, 52.6% of all the violence cases reported were concerning child neglect, with girls being the most affected.[23] In addition, there has been a significant increase in the cases of physical abuse of children at home during the COVID-19 lockdown. In a recently concluded May 2020 child protection rapid survey comprising of 24 districts, 80% of the parents in Uganda were reported to have used violence, including spanking and slapping, to stop children from wandering away from home.[23]

Increased sexual abuse

There has been a noticeable increase in the number of reported cases of child abuse since the lockdown in Uganda.[26] The UCHL March 2020 report revealed that sexual abuse was the third most reported form of child abuse contributing 20.1% of all the cases (98% of the victims being girls and 17% of the perpetrators being family members, including fathers, cousins and uncles).[23] In addition, Save the Children's recent report, indicated 60% of the respondents observed an increase in sexual violence against children since the lockdown started.[24] In June 2020, a few months after the lockdown, 59 and 58 cases of defilement (sexual abuse of a child) were reported in Mayuge and Jinja districts, respectively, located in Eastern Uganda.[27]

Limited access to basic needs

The COVID-19 pandemic has limited children's access to basic needs such as food, health care, among others. Due to the lockdown, a large proportion of parents lost their source of income, resulting in many families unable to regularly feed their households.[24,27] In a recently concluded May 2020 child protection rapid survey that covered 24 districts, all the districts reported inability by most parents to provide their children with the basic needs citing the lack of gainful economic activities due to lockdown measures.[23] In such cash-strapped families, access to basic needs is hardly possible; further propelling children to indulge in risk behaviours for survival such as commercial sexual exploitation and, in some parts of the country, adolescent boys were reported resorting to food theft for survival.[24] Many girls are reported to have entered cross-generational relationships, to access basic supplies such as sanitary pads and soap, yet they have limited access to sexual and reproductive health services which have contributed to early pregnancies and sexually transmitted infections.[23,27]

Increased child labour

Prior to the pandemic, children as young as 10 years are often sent to work or are married off as part of a family's survival strategy.[19] As many parents lost income, unable to feed their families and their households being pushed into extreme poverty and hunger, children are thus increasingly forced into hazardous and exploitative work to support their families. According to the Save the Children's survey, 56% of respondents reported an increase in children working since lockdown began.[24] In many parts of the country, children have been seen selling food items, alcohol, firewood, working in gold mines and grazing animals, among others, since the lockdown started.[18,24]

Delayed detection of abuse

Since a high number of child abuse cases are usually detected early and reported by educational personnel, the closure of schools increases the risks of late detection, increase in cases and under-reporting of child maltreatment cases.[15,28] The closure of schools and places of worship, which act as safe havens for many children meant limited access to reach trusted adult figures who often can detect early signs of abuse and help families to cope with the added stress. Given the fact that the reporting channels and referral pathways are severely affected by the lockdown, the pandemic has worsened the living conditions of children, putting children at an increased risk of different forms of child abuse.[18]

Recommendations to Mitigate Harms to Ugandan Children During the Pandemic Lockdown

Adopting early detection measures with strengthened case management and referral

During the COVID-19 lockdown, common channels of reporting child abuse such as schools, friends, places of worship have been disrupted throughout the country. Hence, in addition to augmenting normative services (i.e. secure hotlines, opening outreach centres), strategic collaborations with the media houses/platforms is required to ensure increased awareness of UCHL services and case management referral pathways at the community

level.[25] Social media platforms whose utilisation in Uganda has increased, especially in urban areas, can be employed to facilitate immediate response.[29] District, parish, village and neighbourhood-level social media groups for stakeholders can also be initiated for more efficient communication. To ensure effective use of social media platforms, the government needs to stop the social media tax and also reduce taxes on telecommunication companies to ensure affordable internet rates.

Secondly, government frontline social workers who have the mandate to monitor cases of violence were classified as non-essential workers during the lockdown period in Uganda. Given the country-wide surge in child abuse cases during the pandemic lockdown, it is critical for these social workers to be reclassified as essential workers in order to provide early detection and management of cases. Once schools resume with proper standard operating procedures (SOPs), social workers can further strengthen the identification of child maltreatment cases by working with schools to ensure increased awareness of children and staff.

Thirdly, a multi-level stakeholder approach should be applied during this period by engaging different offices which are usually involved in the early detection of child abuse cases such as the District Probation and Social Welfare offices, police and health centres. Additionally, engaging local authority structures such as local council members in charge of children affairs may also strengthen the monitoring and reporting of cases. These interlinkages to the district task force teams and social workers may continue even after lockdown measures are relaxed in the country.

Child-friendly health services

In Uganda, health centres are usually the first, and often, the only point of contact for child survivors of violence and a frequented entry point into the system of care.[29] With the COVID-19 lockdown measures in the country, access to health services has been negatively affected due to the expensive transport means, curfew hours and reduced ability to afford private health services. Uganda initiated the Village Health Team (VHT) programme about two decades ago with the aim of reducing the gap created by the shortage of health workers and improving access to health services by bringing services closer to the community.[30] The VHT members undergo basic training after which they are signed households within their own communities, and they help provide a variety of health education and primary health services.[30] The capacity of existing VHTs can nonetheless be strengthened in numbers and provided with SOPs and proper personal protective equipment during the pandemic to ensure safe and effective treatment of the common childhood illnesses. Whenever feasible, paediatric units in public health facilities should also have psychologists/social workers to ensure free, timely identification and handling of child abuse cases. Given the normal public health facilities' structure in Uganda, where social workers/psychologists are not recruited in these facilities, this might have an impact on the limited available resources. However, collaboration with different child welfare organisations can minimise government's running costs and ensure these cadres are available in public health facilities. Through the engagement of stakeholders, child-friendly spaces can be set up in the communities with well-defined COVID-19 SOPs to provide counselling and management of child abuse cases. The use of child-friendly information can enable children to be fully aware of child abuse and hence contribute to more effective children-centred mitigation measures.

Ensuring improved access to water, sanitation and hygiene services

Given that girls are at increased risk of physical and sexual violence when accessing unsafe water, sanitation and hygiene facilities such as water points,[23] these facilities can be made safe for children during the pandemic by ensuring that they are well lit, free of bushes and easily accessible by children with disabilities.[29] Children should be involved in the safety mapping discussion of these water points. These discussions should include menstrual hygiene management, possibility of subsidies of sanitary pad costs and financial incentives to manufacturers of reusable sanitary pads to ensure increased availability of affordable sanitary pads.

Financial/Social support for families at risk

During the initial lockdown that was sustained for several months and the subsequent lockdowns, many families sustained economic hardship. There is a need to provide financial support for such families in order to prevent child labour and reduce at-home child abuse. Financial support in the form of tax holidays for companies, government enhancement of savings schemes for unemployed workers, bank loan forbearance and increased welfare payments for highly vulnerable families should be examined as possible social harms mitigation strategies.[25] Parents should also be encouraged to join peer support groups for emotional support and stress release and also to generate ideas for improving their household livelihood.

Conclusion

This paper has provided insight into the current situation regarding child abuse in Uganda, where it has shown a significant increase in the cases of child abuse during the COVID-19 pandemic. In this regard, the study has noted an increase in child sexual and physical abuse, child labour, limited access to basic needs and lack of social support, especially since the national lockdown. In order to ensure the safety of children, the study highlights a need for the adoption of alternative child abuse detection measures, increased parental support and financial support for families at risk and improvement in case-detection/referral services. These measures underscore the necessity of multi-sectoral participation in reducing child abuse during the COVID-19 pandemic.

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Infectious and tropical diseases

HIV continuity of care after Cyclone Idai in Mozambique

PAPER

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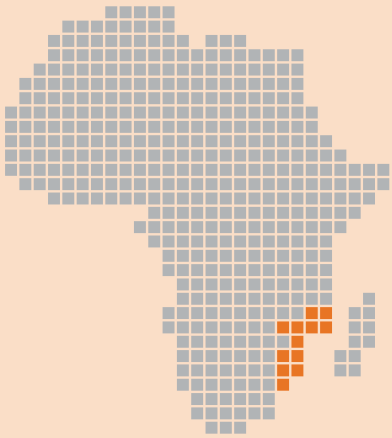

were reported because longitudinal changes in these markers in people living with HIV have been reported previously, providing context and assisting data interpretation.[5–7] To date, similar data providing context have not been produced for the markers of inflammation and atherogenesis, an emerging area of considerable interest in the field of HIV research. Longitudinal studies of these biomarkers have not been routinely done in randomised controlled studies evaluating treatment switches for people living with HIV.[8] We concluded that without the context of a randomised control group beyond week 48, interpretation of statistical testing on these biomarkers is limited.

Nevertheless, in the interest of transparency, the figure described by Serrano-Villar and Moreno, and presented in poster format at the HIV & Hepatitis Nordic Conference in 2018, is included as an appendix to this Correspondence. Further to the aforementioned discussion of data presented by us in table S3, on review of this figure it should be noted that the significant increase in sCD163 from baseline to week 48 in participants on the two-drug regimen was not significantly different to the increase in participants in the three-drug CAR group. In addition, the significant increase in sCD14 from baseline to week 48 observed in the two-drug group was found to be significantly lower in magnitude than that in the three-drug CAR group.[1] Further, both the figure in the appendix and table S3 in our paper show an absence of concordance in the change from baseline compared with the change from the late-switch baseline in the two treatment groups, at 48 weeks following the switch to the dolutegravir plus rilpivirine regimen. These observations, together with the described data of atherogenesis biomarkers, support the conclusion that there is no consistent, reproducible pattern of change over time following the switch to the two-drug dolutegravir plus rilpivirine regimen. Together, these observations highlight the need for caution in the interpretation of longitudinal changes over time in biomarkers of inflammation and atherogenesis in the absence of a control group.

To improve clarity and assist interpretation of these data of biomarkers of inflammation and atherogenesis from our SWORD studies, we are preparing a new manuscript that will describe changes in these biomarkers from baseline (day 1) through to week 148.

Finally, as the results from the SWORD studies do not show a consistent, reproducible pattern of increased biomarkers of inflammation following the switch to dolutegravir plus rilpivirine, the speculation regarding penetration into lymphoid tissue and effect on inflammation is not supported by these studies.

LPK is an employee of ViiV Healthcare and owns stock in GlaxoSmithKline.

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HIV continuity of care after Cyclone Idai in Mozambique

No person from Mozambique will forget March 14, 2019, the day Cyclone Idai devastated Beira, the capital of Sofala Province and the second largest city in Mozambique.[1] Approximately 850 000 people were affected, with around 146 000 internally displaced, more than 500 killed, and thousands injured.[1] Destruction occurred in and around Beira, and more than 100 health facilities were partially or completely damaged, with loss of equipment, furniture, essential medicines, and products.[2] An added, less visible vulnerability resulted from this damage: Cyclone Idai represented the first time a major natural disaster had hit a country with a high prevalence of HIV in Africa. Globally, Mozambique has the eighth highest prevalence of HIV, and in Beira, one in six adults have HIV.[3]

A rapidly occurring natural disaster, such as Cyclone Idai, can disrupt the continuity of care for people living with HIV and result in negative health consequences, in terms of both worsening the clinical condition of patients and thus halting progress, and causing resistance to antiretroviral drugs. These issues are not immediately visible but are difficult to manage in the complex setting of natural disaster in low-income regions.

Even if an accurate and comprehensive picture of the effect of Idai on HIV care in Beira is not available, and

Correspondence

possibly never will be, our experience shows how the HIV population in Beira were not abandoned. Since 2016, Doctors with Africa CUAMM have been working in Beira to provide support to the Geração Biz programme of the Government of Mozambique, which addresses adolescent health related to HIV.[4] The strategy has three main pillars: service delivery in health-care centres of the Beira District with specific services for adolescents (or Serviço Amigo do Adolescente e Jovem [SAAJ]); reproductive health promotion and education at the school and community levels; and follow-up of HIV-positive patients on antiretroviral therapy, with health-care activists taking a door-to-door approach to identify people living with HIV who default treatment.

Immediately after the cyclone, following an international appeal by the Government of Mozambique, the specific response of Doctors with Africa CUAMM was to reactivate SAAJ, which was disrupted during the cyclone, and provide community-based services for people living with HIV. The week after Idai, the number of health-care activists on the programme was tripled from 70 to 237, and these individuals were trained on delivering an emergency response in natural disasters.

Additionally, a new electronic data collection tool was introduced immediately after Idai to overcome the loss of data and improve monitoring. Activists were equipped with an Android-based smartphone to collect field-based data and monitor people living with HIV by confidential GPS tracing. Almost 4500 patients with HIV were reached from the time of Idai to December 2019.

Now, almost a year since the cyclone, the Mozambican population and health-care services together with international partners remain resilient. In many places where HIV services are community based and community led, the impact of natural disasters can be mitigated by preparedness training, rapid mobilisation of local and international services, and immediate strengthening of existing structures. Such actions were seen in Beira, which not only directly prevented disruptions in HIV care for patients, but also helped to mitigate the effects of the disaster on the general health and wellbeing of patients' families and the community.

We declare no competing interests.

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Seroprevalence of hepatitis B and hepatitis C among blood donors in Sierra Leone: A multi-year retrospective study

PAPER

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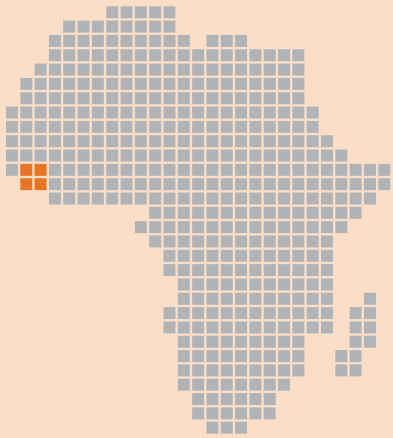

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Seroprevalence of hepatitis B and hepatitis C among blood donors in Sierra Leone: A multi-year retrospective study

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ABSTRACT

Objectives: In Sierra Leone, very little data are available on hepatitis B virus (HBV) and hepatitis C virus (HCV) prevalence. Blood donor screening permits estimation of the prevalence of transfusion transmissible infections in a general open population. We analyzed blood donor data in Sierra Leone to estimate national viral hepatitis prevalence and identify risk factors for hepatitis infection among the donor population.
Methods: We conducted a retrospective data analysis in five government hospitals. We collected HBV and HCV screening results, donor demographics, and donation type (family replacement or voluntary donor; first-time or repeat). Univariate and multivariate analyses were performed to determine associations between infections and socio-demographic factors.
Results: The number of donors screened was 29,713. The overall prevalence was: 10.8% (3200) for HBV and 1.2% (357) for HCV. HBV infection was most strongly associated with male sex (p: <0.0001) and younger age (p: <0.0004 for the 22–27 age group). Both HBV and HCV infection were higher in certain locations.
Conclusion: Our findings stress the presence of viral hepatitis infection throughout the country and the need to invest in safe blood services, vaccination and treatment of viral hepatitis at the national level.

1. Introduction

Hepatitis B (HBV) and Hepatitis C (HCV) virus infections are major health burdens. Globally, 257 million people are infected with HBV and 71 million are infected with HCV (World Health Organization, 2017). Viral hepatitis caused an estimated 1.3 million deaths in 2015 and both HBV and HCV can lead to chronic infection with complications including liver fibrosis, cirrhosis, hepatocellular carcinoma (HCC) and ultimately liver failure (World Health Organization, 2017). In the African region, HBV is highly endemic with a 6.1% prevalence estimate, and HCC is currently the leading cause of cancer among men (Stanaway et al., 2016; Ott et al., 2017; World Health Organization, 2017). Information about HCV in West Africa is scarce.

Sierra Leone is a small country in West Africa where under-resourced health systems and poor social and economic determinants of health have been attributed to a series of viral outbreaks in recent years including cholera, yellow fever, Lassa fever and Ebola virus disease (EVD) (World Health Organization, 2015). In particular, the 2013–2016 Ebola epidemic put the country's health system under considerable strain as many clinical staff lost their lives (Evans et al., 2015). Disruption of clinical services, fear of nosocomial transmission of the disease,

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misinformation and mistrust among authorities contributed to reduced access to health care services (Parpia et al., 2016; Ribacke et al., 2016).

There are no national estimates for the prevalence of viral hepatitis for Sierra Leone, but several small studies on HBV reported concerning rates. In these studies, the prevalence of HBV surface antigen (HBsAg) was found to be 18.2% in primary school children (Hodges et al., 1998), 6.2% in antenatal women (Wurie et al., 2005), 13.7% in a group of febrile patients in a small, private hospital (Ansumana et al., 2018), 39.5% in adults presenting to a private clinic (Adesida et al., 2010), 8.7% among health care workers (Massaquoi et al., 2018), and 14% in a group of 326 blood donors (García-Tardón et al., 2017). Recently, Yambasu et al found an overall HBV prevalence of 9.7% among blood donors in 2016 (Yambasu et al., 2018). HCV infection was reported in two of these studies and varied widely. In the studies by Garcia-Tardon and Yambasu, HCV antibodies were detected in 7.5% and 1% of blood donors (García-Tardón et al., 2017; Yambasu et al., 2018).

In the absence of country-prevalence reports, blood donor screening data can provide important information regarding risk associated with blood transfusion and some insight into the magnitude of the problem of transfusion transmissible infections (Buseri et al., 2009; Tessema et al., 2010; Hope et al., 2014; Agyeman et al., 2016; Ofori-Asenso and Agyeman, 2016).

Blood donors in Sierra Leone are screened for HBV, HCV, HIV and syphilis. In this study, we conducted a retrospective analysis of HBV and HCV rapid test screening results in the district National Safe Blood Services (NSBS) registers of five blood banks between 2013 and 2017, to determine HBV and HCV seroprevalence as well as to examine if the Ebola outbreak affected blood supply.

2. Methods

2.1. Study setting

The study includes blood bank data from public hospitals across the East, North, Southern regions and the Western area of the country, located in five out of the fourteen national districts (Fig. 1). These blood banks provide blood transfusions for the entire population in the districts; from 300,000 in Pujehun to 1,000,000 in Freetown. With the exception of Connaught in Freetown, these blood banks mainly serve rural populations (Fig. 1). The data collection period spanned the 2013–2016 Ebola outbreak, which affected all districts. Most EVD cases occurred in Bombali and Western Urban districts (Fig. 1).

2.2. Blood donor screening

Per national guidelines, blood was obtained from relatives of the transfusion recipient (family replacement) or from voluntary blood donors. Transfusion recipients in Sierra Leone are obliged to replace blood supply, except when their life is in danger. Family replacement donors donated at the blood bank on the hospital grounds, whereas voluntary donors either visited the hospital or were screened elsewhere during community blood drives. Prior to blood collection, donors received a hemoglobin and blood grouping test, and subsequently were screened with rapid test strips to detect HBsAg (this test does not discriminate between acute or chronic infection), HCV antibody, HIV 1/2 antibody and syphilis (anti-*treponema pallidum*). In case of a positive test or hemoglobin level <12 g/dl, the person was excluded from donating.

2.3. Data collection

Trained staff extracted data from written NSBS registers to develop an electronic database with de-identified information (name, residential address). Data on blood donor's sex, age and occupation were collected. We categorized age into four groups according to the median and interquartile range in the total dataset. To develop the following occupational categories we considered existing literature (Bower et al., 2016; Richardson et al., 2016; Jofre-Bonet and Kamara, 2018) and classifications from the International Labour Organization, adjusting to the Sierra Leone context as needed: 'Farming, fishing, mining'; 'Formal occupation', which included terms like government, office, business, often requiring secondary or higher education; 'Informal occupation', jobs generally associated with short contracts, not requiring education, such as petty trading, driving, or any type of laborer, non-paid persons; and 'students'. We separately developed a category for all health care workers, because of the occupational hazard associated with HBV and HCV infection. Because of the small number of health care workers in our dataset, we included them in the 'Formal occupation' group in the regression analyses. In addition, information about the type of donation (family replacement or voluntary donor) and the frequency (first-time or repeat donor) were registered.

2.4. Statistical analysis

Data were analyzed using SAS (Version 9.4. SAS Institute Inc., Cary, NC, USA) and Graphpad Prism (Version 7 Graphpad software Inc., La Jolla, CA, USA). We conducted univariate and multivariate

A

B

Blood bank	District	Region	Population (n) [a]	Population living in urban area (%) [a]	Estimated EVD cases (n) [b]
Bo Govt hospital	Bo	Southern	575,478	18.9	101-500
Connaught Govt hospital (Freetown)	Western-Urban	Western	1,055,964	100	501-4000
Koidu Govt hospital	Kono	Eastern	506,100	24.6	101-500
Makeni Govt hospital	Bombali	Northern	606,544	28.5	501-4000
Pujehun Govt hospital	Pujehun	Southern	346,461	8.1	21-100
Sierra Leone			7,092,113	41	14,124

EVD = Ebola virus disease
[a] 2015 Population and Housing Census (Statistics Sierra Leone 2016)
[b] Centers for Disease Control and Prevention (Centers for Disease Control and Prevention (CDC) 2017)

Fig. 1. (A) Map of Sierra Leone, indicating the locations of the five blood banks included in our study: Freetown (Connaught), Makeni, Bo, Koidu and Pujehun. (B) Characteristics of the study setting.

regression to estimate odds ratios (OR) with 95% confidence intervals (CI) for potential predictors for HBV and HCV infection. We included demographic variables, location, sex, age, and occupation as well as donation type. The multivariate model adjusted for all variables. We performed both complete case and missing indicator analyses with missing data indicators for the variables with >2% missing entries. We calculated p-values but did not define findings as "statistically significant" based on a p-value threshold (Amrhein et al., 2019).

3. Results

3.1. Demographic characteristics of blood donors

We included 29,713 of 30,467 donor entries for which hepatitis screening results were registered. The timeframe for data collection in the various districts did not completely overlap due to limited availability of registers and/or staff to extract the data (Table 1). The median age of donors was 27 years old and 76.5% of donors were male. The majority of screened donors were family replacement donors (80.2%); in Makeni and Kono these proportions were highest (Table 1). A total of 15.2% of donors were excluded from donating (deferred) following the rapid test screening process (95% of excluded donors had a single positive screening test; 5% had multiple positive tests) and this occurred most often in Bo (19.2%) and Makeni (22.6%).

3.2. Donor screening during the Ebola outbreak

Donor screening volumes generally fluctuated over time. Whilst blood banks remained open to provide blood throughout 2013–2016; during the peak of the EVD outbreak (June 2014–Jan 2015) we recorded the lowest number of screenings across the districts (Fig. 2). The reduction was most pronounced in Bombali (Makeni Govt Hospital) and Kono (Koidu Govt Hospital), where a high number of Ebola cases was registered (Fig. 1).

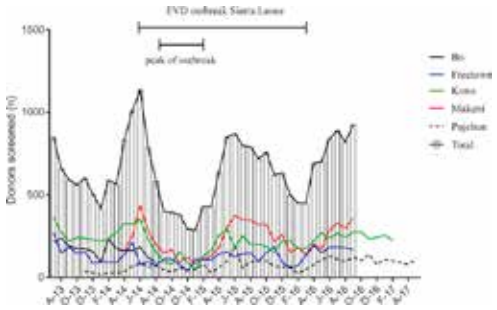

Fig. 2. Absolute number of blood donors screened per district blood bank between July 2013 and May 2017. Bars indicate the total number of screenings performed per month across the five blood banks. Black lines above the graph show the time of the Ebola outbreak.

3.3. Seroprevalence of HBV and HCV

Based on all screening data, seroprevalence of HBV and HCV was 10.8% (3200/29 713), and 1.2% (357/29 713) respectively (Table 2). The percentage of HBV positive tests ranged from 6.9% in Connaught to 15% in Makeni, whereas HCV prevalence was much lower, ranging from 0.3% in Pujehun to 1.9% in Makeni. A small percentage (0.2%) of donors screened positive for both viruses. Overall HBV and HCV seroprevalence was 11.3% and 1.3% respectively after limiting the dataset to first-time donors (Table 2). To obtain more insight into HBV and HCV prevalence, we plotted the HBV and HCV seroprevalence rates of all screened donors by month for all districts (Fig. 3). Despite some month-to-month

Table 1
Study period and demographic characteristics of blood donors.

		Bo Govt Hospital	Connaught Govt Hospital	Koidu Govt Hospital	Makeni Govt Hospital	Pujehun Govt Hospital	Total
Timeframe collected donor data	Start date	06/01/2012	07/03/2013	6/13/2013	3/16/2014	10/17/2013	06/01/2012
	End date	8/26/2014	10/17/2016	3/13/2017	9/30/2016	5/31/2017	5/31/2017
Screening data (*n*)		4189	5205	10 015	7122	3182	29 713
Sex	Male	3772 (90.0)	4525 (86.9)	7224 (72.1)	4904 (68.9)	2311 (72.6)	22 736 (76.5)
	Female	393 (9.4)	613 (11.8)	2781 (27.8)	2213 (31.1)	851 (26.8)	6851 (23.1)
	Missing	24 (0.6)	67 (1.3)	10 (0.1)	5 (0.1)	20 (0.6)	126 (0.4)
Age	<22	832 (19.9)	778 (14.9)	2551 (25.5)	1171 (16.4)	686 (21.6)	6018 (20.3)
	22–26	1327 (31.7)	1375 (26.4)	2330 (23.3)	2056 (28.9)	809 (25.4)	7897 (26.6)
	27–34	1126 (26.9)	1580 (30.4)	2565 (25.6)	1937 (27.2)	818 (25.7)	8026 (27.0)
	>34	842 (20.1)	1100 (21.1)	2569 (25.6)	1715 (24.1)	869 (27.3)	7095 (23.9)
	Missing	62 (1.5)	372 (7.1)	0	243 (3.4)	0	677 (2.3)
	Median	26	27	27	27	28	27
	[min;max]	15;70	14;89	15;82	14;93	17;65	14;93
Occupation	Farming, fishing, mining	202 (4.8)	58 (1.1)	2449 (24.4)	1372 (19.3)	1229 (38.6)	5310 (17.9)
	Informal	842 (20.1)	1769 (34.0)	2365 (23.6)	2932 (41.2)	849 (26.7)	8757 (29.5)
	Formal – medical	27 (0.6)	61 (1.2)	161 (1.6)	72 (1.0)	77 (2.4)	398 (1.3)
	Formal – other	251 (6.0)	765 (14.7)	1798 (18.0)	564 (7.9)	247 (7.8)	3625 (12.2)
	Student	819 (19.6)	1249 (24.0)	2823 (28.2)	1493 (21.0)	698 (21.9)	7082 (23.8)
	Missing	2048 (48.9)	1303 (25.0)	419 (4.2)	689 (9.7)	82 (2.6)	4541 (15.3)
Type of donation	Family replacement	2197 (52.4)	4174 (80.2)	8889 (88.8)	6464 (90.8)	2120 (66.6)	23 844 (80.2)
	Voluntary	78 (1.9)	555 (10.7)	1085 (10.8)	119 (1.7)	1025 (32.2)	2862 (9.6)
	Missing	1914 (45.7)	476 (9.1)	41 (0.4)	539 (7.6)	37 (1.2)	3007 (10.1)
Number of donations	>1 (repeat)	122 (2.9)	138 (2.7)	2349 (23.5)	60 (0.8)	301 (9.5)	2970 (10.0)
	1 (first-time)	2158 (51.5)	4609 (88.5)	7600 (75.9)	6531 (91.7)	2589 (81.4)	23 487 (79.0)
	Missing	1909 (45.6)	458 (8.8)	66 (0.7)	531 (7.5)	292 (9.2)	3256 (11.0)
Donors deferred		805 (19.2)	432 (8.3)	1353 (13.5)	1610 (22.6)	302 (9.5)	4502 (15.2)

Table 2
HBV and HCV seroprevalence among blood donors.

	Variable (*N*)	HBV*n* (%)	HCV*n* (%)	HBV + HCV *n* (%)
Site	Bo (4189)	597 (14.3)	39 (0.9)	4 (0.1)
	Connaught (Freetown; 5205)	359 (6.9)	19 (0.4)	6 (0.1)
	Kono (10 015)	947 (9.5)	153 (1.5)	18 (0.2)
	Makeni (7122)	1070 (15.0)	137 (1.9)	15 (0.2)
	Pujehun (3182)	227 (7.1)	9 (0.3)	4 (0.1)
Sex	Male (22 736)	2544 (11.2)	272 (1.2)	36 (0.2)
	Female (6851)	649 (9.5)	85 (1.2)	11 (0.2)
Age	<22 (6018)	684 (11.4)	64 (1.1)	10 (0.2)
	22–26 (7897)	926 (11.7)	83 (1.1)	9 (0.1)
	27–34 (8026)	857 (10.7)	106 (1.3)	13 (0.2)
	>34 (7095)	672 (9.5)	96 (1.4)	14 (0.2)
Occupation	Farming, fishing mining (5310)	564 (10.6)	93 (1.8)	14 (0.3)
	Informal (8757)	963 (11.0)	106 (1.2)	12 (0.1)
	Formal (4023)	358 (8.9)	45 (1.1)	5 (0.1)
	Student (7082)	758 (10.7)	61 (0.9)	10 (0.1)
Type of donation	Family Replacement (23 844)	2487 (10.4)	287 (1.2)	39 (0.2)
	Voluntary (2862)	185 (6.5)	21 (0.7)	3 (0.1)
Number of donations	First-time (23 487)	2665 (11.3)	301 (1.3)	41 (0.2)
	Repeat (>1) (2970)	12 (0.004)	4 (0.001)	0 (0)
Total		*3200 (10.8)*	*357 (1.2)*	*47 (0.2)*

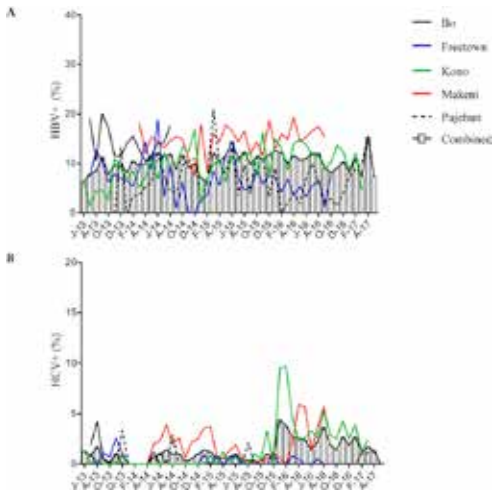

Fig. 3. HBV (A) and HCV (B) seroprevalence over time across the five district blood banks. The gray bars indicate the overall percentage of all screened donors per month.

variation, HBV seroprevalence remained relatively stable (Fig. 3A), which is in line with an endemic distribution pattern. In contrast, HCV seroprevalence (Fig. 3B) was low with a noticeable peak in detection in Kono and Makeni in early 2016 (cause unknown).

3.4. Factors associated with HBV and HCV infection

We next investigated whether demographic or donation-associated factors were predictors for HBV or HCV infection. In univariate analyses, being a first-time (OR:31.5 (95%CI: 17.9–55.7); $p < 0.0001$ and OR:9.6 (95%CI: 3.6–25.8); $p < 0.0001$ for HBV and HCV respectively) and family replacement (OR:1.7 (95%CI: 1.4–2.0); $p < 0.0001$; OR:1.6 (95%CI: 1.0–2.7); $p = 0.028$) donor were strongest associated with HBV and HCV infection (Table 3). The location of the blood bank was associated with HBV and HCV infection as well (Table 3). For occupation, being a farmer, fisherman or miner was associated with HBV and HCV infection (OR:1.2 (95%CI: 1.0–1.4); p = 0.0058; OR:1.6 (95%CI: 1.1–2.2); $p = 0.013$ for HBV and HCV, respectively; Table 3). For HBV, other occupations, men and individuals below 34 years of age had higher odds for HBV infection (Table 3). HCV infection was not associated with age or sex.

The HBV seroprevalence among health care workers was 7.8% (31/398), which is lower than the overall prevalence (10.8%) we found. Similarly, HCV among health care staff (4/398; 1.0%) was lower than the overall prevalence (1.2%).

In the adjusted models, being a first-time donor was strongly associated with HBV and HCV infection HCV (OR: 38.4 [95%CI: 20.5–71.8], $p < 0.0001$; OR: 13.3 [95%CI: 4.9–36.3], $p < 0.0001$ respectively). Younger people (<34 years) had a higher odds of HBV infection. Blood bank location was also important: donors in Bo, Kono and Makeni had higher odds of HBV and HCV infection. Family replacement donations were weakly negatively associated with HBV infection (OR 0.8 [95%CI: 0.7–1.0], $p = 0.063$). Occupation was not a predictor for a positive HBV or HCV test. Results remained similar in a missing indicator analysis (Supplementary Table 1).

4. Discussion

In our study, we observed a seroprevalence of 10.8% for HBV and 1.2% for HCV among blood donors across five Sierra Leonean districts. While we acknowledge that blood donors do not exactly reflect the general population, donor seroprevalence data are a useful first tool to estimate a country-level prevalence and the volume and duration of our data collection contribute to the generalizability of our results. To the best of our knowledge, this is the largest HBV and HCV prevalence study in Sierra Leone.

Our hepatitis seroprevalence estimates are comparable with outcomes of similar studies conducted in Sierra Leone (Yambasu et al., 2018) and other Sub-Saharan West-African countries (Allain et al., 2010; Nagalo et al., 2012; Xie et al., 2015). HBV infection was the main reason potential blood donors were ineligible to donate and was associated with male sex and younger age. None of the occupational groups were at higher risk for viral hepatitis, including health care workers, among whom we observed a lower HBV prevalence of 7.8%. This is slightly lower but comparable to the

Table 3
Univariate and multivariate (adjusting for all variables) regression for positive HBV and HCV tests. Estimates are reported as odds ratios with 95% confidence intervals (OR, 95% CI).

		HBV (univariate)		HBV (multivariate)		HCV (univariate)		HCV (multivariate)	
		OR (95%CI)	*p*-value	OR (95%CI)	*p*-value	OR (95%CI)	*p*-value	OR (95%CI)	*p*-value
Site	Bo	2.2 (1.8–2.5)	<.0001	1.9 (1.6–2.3)	<.0001	3.6 (1.7–7.4)	0.0005	3.1 (1.3–7.4)	0.01
	Connaught (Freetown)	1.0 (0.8–1.1)	0.68	0.7 (0.6–0.9)	0.0014	1.3 (0.6–2.9)	0.52	1.2 (0.5–3.1)	0.69
	Kono	1.3 (1.2–1.6)	<.0001	1.6 (1.4–1.9)	<.0001	5.5 (2.8–10.7)	<.0001	7.2 (3.5–14.8)	<.0001
	Makeni	2.3 (2.0–2.7)	<.0001	2.0 (1.7–2.3)	<.0001	6.9 (3.5–13.6)	<.0001	5.9 (2.8–12.2)	<.0001
	Pujehun	Ref		Ref		Ref		Ref	
Sex	Male	1.2 (1.1–1.3)	<.0001	1.4 (1.2–1.5)	<.0001	1.0 (0.8–1.2)	0.8	1.3 (1.0–1.7)	0.1
	Female	Ref		Ref		Ref		Ref	
Age-groups	<22	1.2 (1.1–1.4)	0.0004	1.3 (1.1–1.5)	0.0023	0.8 (0.5–1.0)	0.10	1.0 (0.6–1.5)	0.84
	22-27	1.3 (1.1–1.4)	<.0001	1.3 (1.1–1.4)	0.0004	0.8 (0.6–1.0)	0.079	0.8 (0.6–1.2)	0.29
	27-34	1.1 (1.0–1.3)	0.015	1.2 (1.0–1.3)	0.012	0.9 (0.7–1.3)	0.75	1.0 (0.7–1.4)	0.87
	>34	Ref		Ref		Ref		Ref	
Occupation	Farming, fishing mining	1.2 (1.0–1.4)	0.0058	1.0 (0.8–1.1)	0.65	1.6 (1.1–2.2)	0.013	1.2 (0.9–1.8)	0.24
	Informal	1.3 (1.1–1.4)	0.0003	1.0 (0.9–1.2)	0.92	1.1 (0.8–1.5)	0.65	1.0 (0.7–1.5)	0.95
	Formal	Ref		Ref		Ref		Ref	
	Student	1.2 (1.1–1.4)	0.0024	1.0 (0.8–1.1)	0.57	0.8 (0.5–1.1)	0.18	0.7 (0.5–1.1)	0.18
Type of donation	Family Replacement	1.7 (1.4–2.0)	<.0001	0.8 (0.7–1.0)	0.063	1.6 (1.0–2.7)	0.028	0.7 (0.4–1.1)	0.12
	Voluntary	Ref		Ref		Ref		Ref	
Number of donations	First-time	31.5 (17.9–55.7)	<.0001	38.4 (20.5–71.8)	<.0001	9.6 (3.6–25.8)	<.0001	13.3 (4.9–36.3)	<.0001
	>1 (repeat)	Ref				Ref		Ref	

reported HBV prevalence of 8.7% and 10% among healthcare workers in Freetown (Massaquoi et al., 2018; Qin et al., 2018).

HCV infection was only associated with location of the blood bank and was highest among donors in Kono and Makeni. The blood banks in these two districts are located on busy trade routes – and HCV transmission here is potentially linked to sex work (UNAIDS, 2017).

Being a first-time donor was strongly associated with HBV and HCV infection. This is likely because following a positive test result, donors are advised that they cannot donate again. Similar findings were reported in Ghana and Burkina Faso, countries with comparable donation systems that showed equally high HBV prevalence among first time volunteer and replacements donors (Allain et al., 2010; Nagalo et al., 2012). In a country where viral hepatitis is endemic with a blood donation system that largely relies on first-time donors, this finding stresses a high transmission risk and thus a need for safe transfusions. Blood services in Sierra Leone largely depend on family replacement donations, which made up 52%–91% of donations in the districts. To increase safe donations, WHO recommends phasing out the 'family replacement' system and working with voluntary blood donations (World Health Organization, 2012). It will require policy changes and support throughout the public health system to build a sustainable pool of voluntary donors. Voluntary blood donations in Sierra Leone now often rely on ad hoc community mobile drives and students donating blood in exchange for a meal and transport fee, and our study shows that these first-time voluntary donors do not have lower risk for HBV infection.

Due to the high HBV prevalence in a setting of a weak health system, transfusion itself is a risk for viral hepatitis (Nagalo et al., 2012; World Health Organization, 2017). An accurate and robust screening process is therefore crucial to ensure safe blood services. HBV and HCV screening is currently performed with rapid tests (RDTs) per minimum WHO standards (World Health Organization, 2012). HCV antibody RDTs generally have high sensitivity and specificity (Khuroo et al., 2015; Tang et al., 2017), but the sensitivity of HBsAg RDT varies strongly among brands. A systematic review estimated a pooled 90% sensitivity and 99.5% specificity (Amini et al., 2017). Therefore, introduction of HBV tests with higher sensitivity, such as enzyme immune assays or molecular tests, would contribute to reliable HBV diagnosis and safer transfusions.

Blood donations continued uninterrupted throughout the Ebola outbreak-for which the blood bank technicians should be commended. However, particularly in Makeni and Kono, we observed a reduction in screenings during the peak of the outbreak, suggesting reduced access to blood donations. Other districts were not deeply affected by the outbreak. In Pujehun with the lowest number of confirmed Ebola cases, a referral system at the hospital was reinforced at the time, which caused an increase in admissions (Quaglio et al., 2019), and consequently an increasing trend in blood donor screening. An accurate analysis of the impact on blood services, however, would require pre and post epidemic numbers over a longer time period, which were not available. Moreover, decline in maternal (Brolin Ribacke et al., 2016) and child health services (Sun et al., 2017) caused by Ebola may also have impacted blood donations, of which women and children are the main recipients.

Our study has several limitations. First of all, all data were derived from handwritten registers in which certain information, including the number of times a person donated, may not be accurate or complete. Additionally, we only included entries with registered hepatitis test results; it is unclear if missing test results were due to data entry omissions or an interrupted supply of test kits. Secondly, blood banks used HBsAg and HCV tests from different manufacturers with variation in sensitivity and specificity, possibly resulting in heterogenous underestimation of infections. HBsAg and HCV tests were supplied by NSBS on the central level or provided by non-governmental organizations. None of the blood banks documented test manufacturer information.

Overall, our findings indicate the presence of viral hepatitis infection throughout the country and provide some insight in predictors for infection. Our study stresses the need to develop policies to invest in safe blood services, as well as expanding access to vaccination, including HBV birth-dose vaccines (Spearman et al., 2017), and antiviral treatment.

Ethical approval

All aspects of the study were approved by the Sierra Leone Ethics and Scientific Review Committee and Partners in Health Sierra Leone Research Committee.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ijid.2020.07.030.

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PAPER

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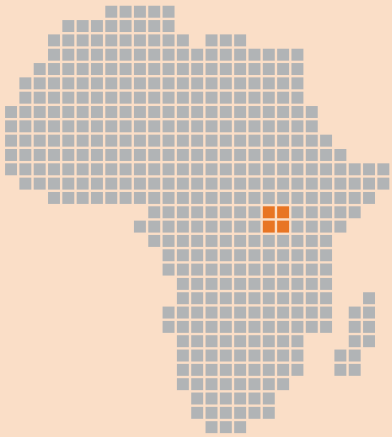

Capacity assessment for provision of quality sexual reproductive health and HIV-integrated services in Karamoja, Uganda

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Abstract

Introduction: Sexual and reproductive health (SRH) and Human Immunodeficiency Virus (HIV) are crucial global health issues. Uganda continues to sustain a huge burden of HIV and AIDS.

Methods: A cross-sectional health facility-based assessment was performed in November and December 2016 in Karamoja Region, northern Uganda. All the 126 health facilities (HFs) in Karamoja, including 5 hospitals and 121 Health Centers (HCs), covering 51 sub-counties of the 7 districts were assessed. We assessed the capacity of a) leadership and governance, b) human resource, c) service delivery, d) SRH and HIV service integration and e) users satisfaction and perceptions.

Results: 64% of the established health staffing positions were filled leaving an absolute gap of 704 units in terms of human resources. As for service delivery capacity, on 5 domains assessed, the best performing was basic hygiene and safety measures in which 33% HCs scored "excellent", followed by the presence of basic equipment. The level of integration of SRH/HIV services was 55.56%.

Conclusion: HFs in Karamoja have capacity gaps in a number of health system building blocks. Many of these gaps can be addressed through improved planning. To invest in improvements for these services would have a great gain for Uganda.

Keywords: Quality Sexual Reproductive Health, HIV-Integrated Services, Karamoja, Uganda.
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Introduction

Sexual and reproductive health (SRH) and Human Immunodeficiency Virus (HIV) are significant and related global health issues 1-4. Their impact is particularly significant in Sub-Saharan Africa, where about 85% of adolescents were estimated to live with HIV in 2012 5-8. SRH refers to a state of complete physical, mental and social well-being in all matters relating to the reproductive system and sexuality 9. It includes a wide range of areas such as family planning, control of unintended pregnancies and sexually transmitted infections, as well as serious public health and human rights issues like sexual violence and female genital mutilation 10. SRH care plays a crucial role also in the sexually transmitted diseases, primarily HIV. In fact, it is globally recognized that, in order to decrease HIV transmission, other than ensuring HIV testing, an early treatment and follow up, it is necessary to educate young people, especially in order to prevent new infections 11-13 and co-infections 14-17. Moreover, in countries where HIV prevalence has declined, a change in sexual behavior among young people is considered an important contributing factor[18].

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In this scenario, Uganda continues to sustain a huge burden of HIV and AIDS with an estimated 1.3 million people living with HIV, among them 95,000 children[19]. The number of new HIV infections has been rising from about 124,000 in 2009 to 140,000 in 2012, being over 380 Ugandans daily infected[20]. However, this number has been significantly reduced to 52,000 by 2016[21]. Interestingly, several groups are increasingly vulnerable to get infected by HIV, such as sex workers and their clients, fishing communities, long-distance truck drivers and armed forces[20-22]. The Ugandan Ministry of Health (MoH), in line with the global agenda, has prioritized SRH and HIV interventions, including community mobilization and capacity building, especially at district and lower levels, together with proper information on education and communication strategies[23-24]. However, there was still an underutilization of SRH and HIV/AIDS services[25-26]. Moreover, during 2015 and 2016, although about 90% of pregnant mothers attended the first antenatal care (ANC) visit, only 38% attended all the four recommended visits 27. Furthermore, only 58% of deliveries underwent to skilled care and only 68.3% of HIV+ pregnant women, that were not on highly active antiretroviral therapy (HAART), received antiretroviral therapy (ARVs) to avoid mother-to-child transmission (MTCT) during pregnancy, labor, delivery and postpartum[27].

Karamoja, northern Uganda sub-region, continues to sustain a great burden of SRH and HIV challenges where only 7.3% of the currently married women are using any contraceptive method, far below the national average 28. Moreover, according to the Uganda Demographic and Health Survey (UDHS), in 2016 Karamoja had 10.8% of women in the age group 15-49 experienced physical violence, far above the national average of 12.7%[26].

Although globally growing attention is paid to SRH and HIV, few studies are available on this topic, in particular in Uganda, and in Karamoja no data is available. Therefore, the aim of this study was to perform a comprehensive capacity assessment for the provision of quality integrated SRH and HIV services in Karamoja region.

Methods

Study design and setting

A cross-sectional health facility-based assessment was performed in November and December 2016 in Karamoja. Karamoja region is predominantly inhabited by pastoral and agro-pastoral groups that share common languages, culture, history and livelihood systems across northeastern Uganda, NorthWestern Kenya, southeastern South Sudan and SouthWestern Ethiopia. Karamoja is a semi-arid region characterized by low level, erratic rainfall patterns and is considered marginal. The region presents a unique socio-economic and cultural background that requires a unique interventional approach, necessary for meeting the livestock development needs. The dominating livelihood activities are pastoralism and agro-pastoralism with a focus on livestock production. In Karamoja there are 126 HFs including 5 hospitals and 121 Health Centers (HCs) (4 HC IVs, 41 HC IIIs and 76 HC IIs), covering 51 sub-counties of the 7 districts (Abim, Amudat, Kaabong, Kotido, Moroto, Nakapiripirit, Napak) were assessed[31]. The population covered by all of the health facilities was estimated at 1,023,248 individuals in 2015, with 206,696 women in child-bearing age and 51,162 expected pregnancies (pregnant women) and 49,628 expected deliveries (pregnant women achieving birth).

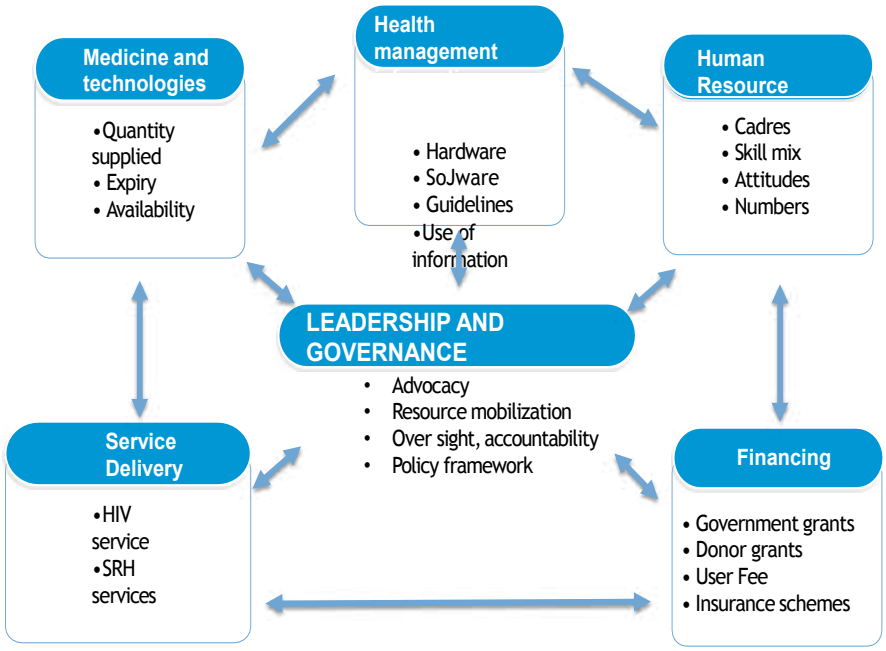
Data collection

Semi-structured questionnaires were elaborated and administered to respondents at three different levels:

- District level: the questionnaire was administered to the district health officers (DHO) or any other person of the district health team (DHT) acting for and on behalf of the DHO;
- Health Facility level: the questionnaire was administered to the person in charge of the health unit or any other person acting for and on behalf of the in charge;
- Exit level: questionnaires were administered to clients, accessing the facility to utilize health services, on the day of the assessment. At least 20 clients were consecutively interviewed from each hospital, 15 from each HC IV, 10 from each HC III and 5 from each HC II.

For each level a specific questionnaire was developed in agreement with the MoH. The questionnaires elaborated were pretested in a sample of 10 health units from the Lango sub-region and all the inconsistencies noted were corrected. In order to ensure accuracy, verification of reported information was made from the existing health unit record or records at the district health offices, when applicable. At the end of each day of data collection, the filled questionnaires were checked for completeness and correctness by trained investigators.

In order to perform a comprehensive capacity assessment, the building blocks conceptual framework for the health system, as defined by WHO 20, has been adapted to the SRH and HIV services[21] (Figure 1) and used to develop the data collection tools.



We assessed the capacity of a) leadership and governance, b) human resource, c) service delivery, d) SRH and HIV service integration and e) users satisfaction and perceptions.

Governance and leadership capacity

Governance and leadership capacity was investigated in terms of presence of a governing body–health unit management committee (HUMC) or board and their functionality (meetings, issues discussed and actions taken). In particular, the attention of the governing structures to the discussion on issues dealing with sexual and reproductive health and HIV/AIDS was investigated. In addition, the presence of a functional supervision (visits, issued followed) from higher levels of the Ugandan health system, presence of oversight committees for particular services particularly Reproductive, Maternal, Newborn and Child Health (RMNCH) Committee and Maternal and Perinatal Death Review (MPDR) committee and joint planning meetings at the health units were explored.

Human resource capacity

We collected information on the available staff compared to the standards recommended by MoH and analyzed gaps for selected cadres of health staff, excluding support staff. The existing staff at the district health office included 11officers, 7 of these directly involved in health-related work: a district health officer, an assistant district health officer for maternal child health, an assistant district health officer for environmental health, a senior environmental health officer, a senior health educator, a biostatistician and a cold chain technician. The recommended health facility staffing in Karamoja is 1,934 positions overall.

Service Delivery capacity

The presence of service delivery guidelines, infrastructure, equipment, medicines and diagnostic services, together with trained staff, is considered a prerequisite to guarantee the quality of SRH and HIV services. We assessed the presence of basic amenities (electricity power, improved water source, room with privacy, adequate sanitation facilities, communication equipment,

access to computer, staff accommodation and transport equipment), basic equipment (blood pressure machine, stethoscope, fetoscope, adult weighing scale, examination couch, infant weighing scale, thermometer, refrigerator), hygiene and safety measures (sterilization equipment, disinfectant, hand washing facilities, gloves, safe disposal of waste), laboratory services (general microscopy, HIV test, Syphilis diagnosis, urine dipstick, pregnancy test, hemoglobin, CD4 cell count), essential medicines (Cotrimoxazole, Nevirapine, first-line antiretrovirals (ARVs), HIV test kit, injectable and oral contraceptives, Moon Beads, Amoxycillin/Ampicillin, Oxytocin/Misoprostol, Ferrous Sulphate, Fansidar (Sulphadoxine – Pyrimethamne), Artemisinin Combination Therapy (ACT), Tetracycline eye ointment, Vitamin A, Metronidazole, Doxycycline, Lignocaine, suture materials, intravenous (IV fluids) and Magnesium Sulphate) in the health units.

All these requirements were further categorized by the percentage of the items available graded as: 0-20% = poor, 30-50% = fair, 60-70% = good and 80-100% = excellent.

The delivery capacity for selected HIV and SRH services was further evaluated through the availability guidelines, the presence of at least one trained worker, the availability of tracer medicine, supplies and equipment for three specific sectors: family planning services, ANC and labor and delivery services.

SRH and HIV service integration

For each facility level, we evaluated both the model of integration between the SRH and HIV services implemented and the specific integration service in place. Four models of integration were evaluated; the "kiosk" model where SRH and HIV services are offered in the same site on the same day by the same provider, the "supermarket" model where services are offered in the same site on the same day by different providers, the "mall model" where services are offered by different providers, at different service sites within the same facility and the "referral model" where services are offered in different facilities.

Users satisfaction and perception

We assessed the perception and satisfaction pattern of the users through exit interview to randomly selected health unit service users. The areas evaluated included the waiting time at health units, communication with the health service provider, privacy, cleanliness of the unit, availability of medical drugs, kindness of medical workers, the overall impression of the services received and the willingness to return for additional services.

Data analysis

All the collected quantitative data were coded and double entered, cleaned, and edited in the statistical software Epidata version 3.1 and thereafter exported to STATA version 13.0 for analysis.

Descriptive and comparative analyses were performed. Categorical variables were summarized into frequencies and proportions. The continuous variables were summarized as means, median, standard deviation and range.

Ethical approval was obtained from the Mbale Regional Referral Hospital Institutional Review Board and the Uganda National Council of Science and Technology (UNCST) and participants provided written infrmed consent.

Results

Overall, 7 questionnaires were collected from District, 126 from Health Facilities (HFs) and 897 were Exit questionnaires from the 5 hospitals and the 4 HCs IV, 41 HCs III and 76 HCs II sampled. Results are described following the five dimensions explained above.

Governance and leadership capacity

Health unit management committees were present in 124 (98.4%) HCs and all the 5 (100.0%) hospitals had boards of governors. The functionalities of these governance bodies were variable: 44 facilities (34.9%) reported to have the recommended 4 or more meetings in the 2016 calendar year. Among districts, Amudat registered the least proportion (0.0%) of HCs with the recommended 4 or more HUMC meetings per years, while Nakapiripirit had the highest (58.8%). A number of facilities either had no meetings or couldn't demonstrate they have them, 10 (7.9%) clearly stated to perform no meetings and 10 (7.9%) were not able to show or state the presence of any meeting see Additional file 1.

Additional File. Functionality of Health Unit Management Committee (HUMC) / Boards of Governors (BOG) in Karamoja, 2016.

District	Number of Facilities n	Functional HUMC n (%)	Number of facilities with the recommended 4 or more meetings per years n (%)	Total meetings n	Average HUMC/BOG Meetings in 2016
Moroto	18	18 (100.0)	6 (33.3)	50	2.8
Amudat	8	8 (100.0)	0 (0.0)	22	2.8
Napak	14	14 (100.0)	8 (57.1)	47	3.4
Nakapiripirit	17	16 (94.1)	10 (58.8)	53	3.1
Kaabong	30	29 (96.7)	5 (16.7)	45	1.5
Abim	20	20 (100.0)	6 (30.0)	57	2.9
Kotido	19	19 (100.0)	9 (47.4)	58	3.1
Total	**126**	**124 (98.4)**	**44 (34.9)**	**332**	**2.6**

Infrastructure, human resource for health, medicines and equipment, finance and transport were the main issues discussed during the meeting (in 60% or more of the health facilities), while SRH and HIV/AIDS were the less discussed topics, only 38% and 29%, respectively.

Human resource capacity

The 64% (1,230/1,934) of the established health staff positions (excluding support staff) were filled leaving an absolute gap of 704 positions (Table 1).

Table 1. Total health staff, midwives and nurses positions filled and absolute gap for by level of facility, in Karamoja 2016.

	Total Health Staff	Midwives	Nurses			
	In post/ establishment n (%)	Absolute Gap n	In post/ establishment n (%)	Absolute Gap N	In post/ establishment n (%)	Absolute Gap n
HC II	313/395 (79)	82	66/79 (84)	13	122/79 (154)	-43
HC III	462/532 (87)	70	100/76 (132)	-24	114/152 (75%)	38
HC IV	107/136 (79)	29	22/16 (138)	-6	26/32 (81)	6
General Hospital	262/652 (40)	390	40/112 (36)	72	106/332 (32)	226
Regional Hospital	86/219 (40)	133	12/43 (28)	31	27/84 (32)	57
Total	**1230/1934 (64)**	**704**	**240/326 (74)**	**86**	**395/679 (58)**	**284**

Differentiating the staff gaps by district and level of facility for selected staff cadres, Amudat stood out as the most understaffed district with only 25% (216) of the staff in place, leaving an absolute gap of 163 staffing position, while from the perspective of the level of facility the biggest gaps were in the general and regional referral hospital that had only 40% of the staff positions filled, with an absolute gap of 390 and 132, respectively (Table 2). Staffing was fairly stable during 2016, staff that left were 144 while 280 joined giving an annual retentiorate of 88% and a turnover rate of 12%.

Table 2. Total health staff and selected staff cadres positions filled and absolute gap by districts, Karamoja 2016.

	Tot Health Staff		Midwives		Nurses		Doctors		Anesthetists	
	In post/establishment n (%)	Absolute Gap n	In post/establishment n (%)	Absolute Gap n	In post/establishment n (%)	Absolute Gap N	In post/establishment n (%)	Absolute Gap n	In post establishment n (%)	Absolute Gap n
Abim	189/294 (64)	105	29/51 (57)	22	67/114 (59)	47	4/6 (67)	2	0/3 (0)	3
Amudat	53/216 (25)	163	12/37 (32)	25	11/96 (11)	85	2/6 (33)	4	0/3 (0)	3
Kaabong	251/382 (66)	131	60/65 (92)	5	83/134 (62)	51	3/8 (37)	5	2/4 (50)	2
Kotido	151/196 (77)	45	28/30 (93)	2	44/50 (88)	6	1/2 (50)	1	0/1 (0)	1
Moroto	237/367 (65)	130	37/67 (55)	30	86/122 (70)	36	7/4 (175)	-3	3/7 (43)	
Nakapiripirit	153/206 (74)	53	31/30 (103)	-1	39/52 (75)	13	4/4 (100)	0	0/2 (0)	2
Napak	196/273 (72)	77	43/46 (93)	3	65/111 (59)	46	4/6 (67)	2	0/3 (0)	4
Total	**1230/1934 (64)**	**704**	**240/326 (74)**	**86**	**395/679 (58)**	**284**	**25/36 (69)**	**11**	**5/23 (22)**	**18**

Delivery capacity for selected HIV and SRH services

Service delivery capacity was assessed on 5 domains, looking at the presence of the required basic amenities (i.e. store or room for drugs storage), basic equipment (i.e. stethoscope), basic hygiene and safety measures, laboratory capacity and availability of medicines. The best performing domain was basic hygiene and safety measures in which 33% scored "excellent". Presence of basic equipment came second with 29.4% of the facilities achieving the excellent score; this was followed by the availability of medicines at 27.8% and basic amenities at 26.2%. The least capacity was seen in laboratory services with only 6.3% of the facilities scoring excellent and, 59.2% scoring poor or fair (Table 3).

Table 3. Overall rating of each domain of service delivery capacity for selected HIV and SRH services Karamoja 2016.

	None/Poor n (%)	Fair n (%)	Good n (%)	Very good n (%)	Excellent n (%)
Basic amenities	1 (0.79)	14 (11.1)	78 (61.9)	-	32 (26.2)
Basic equipment	0 (0.0)	6 (4.8)	22 (17.5)	61 (48.4)	37 (29.4)
Basic hygiene and safety measures	0 (0.0)	12 (9.5)	28 (22.2)	44 (34.9)	42 (33.3)
Laboratory capacity	26 (20.6)	36 (28.6)	35 (27.8)	21 (16.7)	8 (6.3)
Medicines available	1 (0.79)	3 (2.4)	21 (16.7)	66 (52.4)	35 (27.8)

Regarding specific SRH services, the service capacity was looked at against presence of guidelines, training of health workers on the specific service area, availability of tracer medicines and supplies and availability of tracer equipment for those services. We did a deeper analysis of the main services: antenatal care, family planning, and labor and delivery services (Table 4).

Table 4. Service delivery capacity assessed as guideline available, workers trained, tracer medicine and equipment and supplies available for a) ANC services, b) Family planning services and c) Labour and Delivery services, Karamoja 2016.

	Guidelines available	At least one worker trained	Tracer medicine and supplies available	Tracer equipment available
	n (%)	n (%)	n (%)	n (%)
ANC services				
HC II	74 (94)	21 (27)	59 (75)	23 (29)
HC III	38 (100)	12 (31.6)	33 (87)	25 (66)
HC IV	4 (100)	2 (50.0)	2 (50)	3 (75)
General Hospital	4 (100)	1 (25.0)	2 (50)	2 (50)
Regional Hospital	1 (100)	1 (100)	1 (100)	1 (100)
All facilities	121	37	97	54
Percentage	96%	29%	77%	43%
Family planning services				
HC II	74 (94)	52 (66)	68 (86)	55 (70)
HC III	38 (100)	31 (81.6)	31 (82)	38 (100)
HC IV	4 (100)	3 (75)	4 (100)	4 (100)
General Hospital	4 (100)	1 (25)	4 (100)	4 (100)
Regional Hospital	1 (100)	1 (100)	1 (100)	1 (100)
All facilities	121 (96)	88 (70)	108 (86)	102 (81)
Labour and Delivery services				
HC II	74 (94)	51(65)	18 (23)	10 (13)
HC III	38 (100)	37 (97)	19 (50)	17 (45)
HC IV	4 (100)	4 (100)	0 (0)	1 (25)
General Hospital	4 (100)	4 (100)	2 (50)	3 (75)
Regional Hospital	1 (100)	1 (100)	1 (100)	1 (100)
All facilities	121 (96)	97 (77)	40 (32)	32 (25)

Overall, facilities performed well in regard to the presence of guidelines scoring 96% for each of the 3 main services of interest. Recent staff training of at least 1 health worker was best for labor and delivery services at 77% followed by family planning at 70% and least for antenatal at 29%. Tracer medicines for the three services were substantially (77-86%) available with the exception of tracer medicines for labor and delivery services at 32%. Availability of tracer equipment attained the much lower average scores compared to the other domains, for labor and delivery services, only 25% of the facilities had tracer equipment available and for antenatal services, and only 43% did so. Family planning tracer equipment had better availability though with 82% of the facilities having the equipment.

SRH and HIV service integration

The level of integration of SRH/HIV services was 55.56% of health units providing SRH/HIV services in the same service site and the same provider offered on the same day (the "kiosk" model of integration). Furthermore, 14.29% health units provided services in the same site, with different providers and in the same day (the "supermarket" model of integration). Only 19.84% of the health units reported no integration of SRH/HIV services (Table 5).

Table 5. Model of integration between the SRH and HIV services and the specific integration service in place by level of care, Karamoja 2016.

		HC II n (%)	HC III n (%)	HC IV n (%)	General Hosp n (%)	Regional Hosp n (%)	Karamoja n (%)
Models of SRH and HIV integration	1. Services located in the same service site, with the same provider, offered on the same day (the "kiosk" model of integration)	35 (44)	28 (74)	4 (100)	4 (75)	0 (0)	70 (55)
	2. Services located in the same service site, with different providers, offered on the same day (the "supermarket" model of integration)	11 (14)	6 (16)	0 (0)	0 (0)	1 (100)	18 (14)
	3. Services offered with different providers at different service site within the same facility on the same day (the "shopping mall" model of integration)	0 (0)	1 (3)	0 (0)	1 (25)	0 (0)	2 (1)
	4. Referred to another facility	9 (11)	2 (5)	0 (0)	0 (0)	0 (0)	11 (9)
	5. No integration	24 (30)	1 (3)	0 (0)	0 (0)	0 (0)	25 (20)
Specific SRH and HIV integration	Family planning + HIV services	39 (49)	33 (87)	4 (100	4 (100	1(100)	81 (64)
	STI + HIV services	38 (48)	35 (92)	4 (100	4 (100	1(100)	82 (65)
	Maternal and Newborn care + HIV services	44 (56)	32 (84)	4(100)	4(100)	1(100)	83 (65)
	Sexual Gender Based Violence (SGBV) + HIV services	18 (23)	21 (55)	3 (75)	4(100)	1(100)	47 (37)
	Post abortal care + HIV services	19 (24)	30 (79)	4 (100	2 (50)	1(100)	56 (44)
	Cervical cancer screening + HIV services	0 (0)	0 (0)	0 (0)	2 (50)	1(100)	3 (2)
	Adolescent SRH + HIV services	29 (37)	30 (79)	4(100)	2 (50)	1(100)	66 (52)

Users satisfaction and perception

Of the 897 respondents to the exit interviews, 657 (73.2%) were definitely satisfied with the services they received, while 18 (2%) were not satisfied and 211 (23.5%) were partially satisfied. A variation of satisfaction across districts was observed, with Moroto having the highest reported satisfaction at 93.2% and Abim the least at 47.3%. While stratifying by level of facility, Hospitals resulted to be the most appreciated structures with 100% of respondents satisfied, while HC IV resulted the less appreciated with 70.7% of user satisfied. (Table 6).

Table 6. Users satisfaction level classified by districts and level of facilities, Karamoja 2016.

	Definitely Satisfied n (%)	Not satisfied n (%)	To some extent satisfied n (%)
District			
Abim	138 (93.2)	0 (0.0)	10 (6.8)
Amudat	105 (75.0)	4 (2.9)	28 (20.0)
Kaabong	33 (50.8)	3 (4.6)	29 (44.6)
Kotido	101 (69.2)	1 (0.7)	44 (30.1)
Moroto	61 (47.3)	5 (3.9)	57 (44.2)
Nakapiripirit	76 (72.4)	0 (0.0)	28 (26.7)
Napak	143 (87.2)	5 (3.1)	15 (9.2)
Level of facility			
HC II	246 (70.9)	3 (0.9)	98 (28.2)
HC III	295 (76.4)	11 (2.9)	80 (20.7)
HC IV	41 (70.7)	1 (1.7)	16 (27.6)
General Hospital	55 (73.3)	3 (4.0)	17 (22.7)
Regional Hospital	20 (100.0)	0 (0.0)	0 (0.0)
Total	**657 (74.2)**	**18 (2.0)**	**211 (23.8)**

Discussion

Sexual reproductive and maternal and neonatal health conditions account for over 60% of the life years lost in Uganda[29-30]. The Karamoja sub-region of Northern Uganda has a fair share of this burden. We performed a comprehensive capacity and quality assessment of integrated SRH and HIV services in order to identify the major gaps for action and, thus, to improve services availability and use to address the population burden. To the best of our knowledge, this is the first study that assesses this topic in Uganda. The district health systems covering this region are meant to serve 1.02 million people, a fifth of which are women of child-bearing age, therefore documenting its preparedness and capacity in addressing SRH and HIV/AIDS services could be considered an important starting point for strategies to be employed. For these reasons, 5 capacity dimensions were explored: governance and leadership, human health resources, service delivery, SRH and HIV service integration and users satisfaction and perception.

Governance and leadership in improvement of health service delivery is the most critical building block of Uganda health system. The key functions include policy guidance, oversight, collaboration and coordination and ensuring accountability[31]. While these actions may be more pronounced at higher levels of government, they are similarly important at the level of health facilities, management organs should be in place and should be able to discuss management specific and also service specific agenda. Although the relevant structures for governance of HFs was documented to be in place by the existence of management committees and good frequency of meetings, the very rare presence of SRH and HIV/AIDS in their agenda meant that they are bound not to contribute significantly to addressing these service delivery challenges.

With only 64% of the staff positions filled compared to the national average of 73%[32], the ability to provide required SRH and HIV/AIDS integrated services was significantly affected. Poorer staffing at referral facilities (hospitals and HC IVs) meant that these more skill intensive levels are not likely to provide the level of output and quality of care expected of them. For the lower level facilities though, better staffing at their level is ad-

vantageous given their proximity to households and a much larger number of users served[33]. Staffing disparities across districts were huge: Amudat, for instance, had only one-fourth of the health staff positions filled with an absolute requirement of 163 staff. Midwives and nurses are the cornerstones of SRH and HIV/AIDS services, the large gap for these cadres needs to be filled incrementally particularly in hospitals. A major setback for comprehensive emergency obstetric care is as the result of severe shortage of anesthetic officers. The shortage in the region was critical with 5 of the 7 districts having no anesthetic officers and, even the two districts with the officers, had only 43 – 50% of the positions filled. It, therefore, means that the majority of the districts can only do major operations with apprentice assistants or, often, are not able to conduct these operations. This shortage of anesthetic officers is a country-wide phenomenon that calls for higher level policy interventions to promote training and motivation of the anesthetic cadre.

The presence of basic equipment for routine examination was very good in almost all the facilities, however, simple but very important equipment like blood pressure machine, stethoscopes and thermometers were sometimes lacking even in larger facilities, suggesting also negligence other than lack of capacity to acquire the equipment. In fact, usually, the Uganda Health System, also thanks to the International cooperation, is able to provide the basic equipment in each health centre. However, may be due to the work overload, the procurement chain sometimes can fail and, thus, it can happen that some centers remain without equipment. In order to overcome this situation, a standardized and regular "equipment check" could be introduced in each centre, identifying a responsible focal point. Patient safety was likely to be compromised in more than half of the facilities, due to gaps in hygiene and safety measures with reference to sterilization equipment, presence of disinfectants, hand washing facilities, gloves and waste safe disposal. The aspects of hygiene and safety measures are even more important for maternal and neonatal care. Infection control at health units is necessary to minimize possible nosocomial infections, such as puerperal and neonatal sepsis, that are major causes of maternal and infant mortality. Poor infection control also carries possible risk of cross transmission of HIV[34-36].

The gaps regarding laboratory services in health centers were very glaring with simple tests like hemoglobin (Hb) estimation missing even in health centre IVs[37-39]. While effort could be made to get the necessary inputs to improve laboratory services, the functionality of laboratory supervision and the quality assurance has to be stressed as well[40-41]. This finding is in line with other experience from low-income countries reporting that, quality assurance practices and provision of laboratory services reported by laboratory ae poor and need consistent efforts for improving[42]. As laboratory service is an essential component of a health care system, laboratory capacity building and quality management system implementation will enable to provide quality and reliable services for disease treatment and prevention including sexual and reproductive conditions. Therefore, government and stakeholders should address the factors affecting the provision of laboratory service and they should work together for strengthening laboratory quality assurance and accreditation program[43]. Availability of essential medicines for SRH and HIV/AIDS services was variable: of the 20 indicator items, none of them was universally present in the facilities. This dimension is a sensitive element if quality recognition by the population.

The SRH/HIV integration agenda is of high priority both globally and nationally[44]. HIV is predominantly sexually transmitted or is associated with pregnancy, childbirth and breastfeeding, and moreover sexually transmitted infections affect HIV transmission. On the other hand, HIV has a devastating impact on maternal, infant and child survival[45]. Interestingly, a recent meta-analysis underlined the role of integrating HIV and reproductive health services with regard to the pregnancy-related mortality associated with HIV in areas of high HIV prevalence and pregnancy-related mortality[45-47]. This integrative approach is supposed to lead to an increased coverage and to a reduction in HIV stigma and discrimination during service delivering 48. Moreover, it will also increase clients' satisfaction by having their needs addressed in a one-stop setting[46-48]. To reduce fragmentation and achieve better efficiency, a coordinated effort is necessary both at policy and operative levels, implementing partner levels at the same time.

This study represents an attempt to look at the extent of integration of SRH/HIV services in the Karamoja sub-region. Among the four models investigated, the

most desirable one was the fully integrated or "kiosk" model, where services are offered on the same site, on the same day, by the same provider. It was followed by partially integrated or "supermarket" model, where services are offered on the same site, on the same day, but by different providers. Other less desirable models were the "mall model" where services are offered by different providers, at different sites, but within the same facility, and the "referral model" where services are offered in different facilities. Our survey highlighted a substantial integration of SRH/HIV services in Karamoja with almost half of the facilities providing the "kiosk" model, followed by the "Supermarket" one. The most common SRH services integrated with HIV were, family planning, sexually transmitted infections and maternal-neonatal health and to a lesser extent adolescent sexual and reproductive health[49-51]. It is known from other experiences, that these approaches can benefit both patients and health workers[52-53]. While this could seem impressive, at the time of the study, no national guidelines were available in Uganda on this issue, and so it appears not driven by deliberate systemic effort, rather by convenience. Therefore, there is a need to roll out the national SRH/HIV integration strategy in this sub-region and indeed in the region.

Last but not least, we explored the overall satisfaction of users by facility level and district. The level of satisfaction reported was high for the majority of users, varying across districts, with Abim and Amudat showing lowest levels. Whereas all districts should address satisfaction gaps, a lot more focus to be placed on Abim and Amudat. Satisfaction across different levels of facilities was similar but the regional referral hospital stood out with 100% definite satisfaction an attestation that the recent efforts to improve the infrastructure and staffing within the regonal referral hospital seem to have paid off.

This study presents also some limitations: first of all this capacity assessment involved only one region of Uganda and, thus, our finding may not be representative for the whole country. Again, although research assistants underwent a 5 days training in order to minimize the interviewer variability, we can't ensure the same data quality for each district.

Although a lot can be done to improve the capacity for SRH/HIV services through staff training, equipment, infrastructure, medicines and supplies, unless these services meet the expectation of the users and user experience at facilities leading to better satisfaction, health systems will still struggle to achieve high coverage of SRH/HIV services. Integration of services into a one-stop point improves user satisfaction and thus augments demand for services. While health facilities in Karamoja have capacity gaps in a number of health system building blocks, many of these gaps can be addressed through improved planning and management in a supportive environment of good governance without the needed for additional resources. While evidence-based interventions exist, they are not able to reach the people who need them most, because of the various capacity criticism documented in the health system and in the population. Given the high burden of disease caused by the sexual reproductive and maternal conditions, to invest in improvements for these services would have a great gain for Uganda and in general for low and middle income countries.

List of abbreviations

SRH: Sexual and reproductive health
HIV: Human Immunodeficiency Virus
MoH: Ministry of Health
HC: Health Centers
DHO: District Health Officers
DHT: District Health Team
UDHS: Uganda Demographic and Health Survey
HUMC: Health Unit Management Committee
RMNCH: Reproductive, Maternal, Newborn and Child Health
MPDR: Maternal and Perinatal Death Review
AIDS: Acquired Immuno-Deficiency Sindrome

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Conflict of interest

None declared.

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Households experiencing catastrophic costs due to tuberculosis in Uganda: magnitude and cost drivers

PAPER

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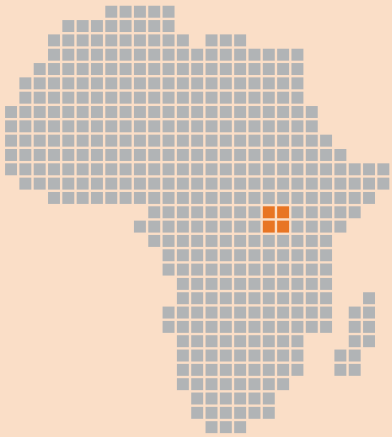

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Households experiencing catastrophic costs due to tuberculosis in Uganda: magnitude and cost drivers

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Abstract

Background: Tuberculosis (TB) patients in Uganda incur large costs related to the illness, and while seeking and receiving health care. Such costs create access and adherence barriers which affect health outcomes and increase transmission of disease. The study ascertained the proportion of Ugandan TB affected households incurring catastrophic costs and the main cost drivers.

Methods: A cross-sectional survey with retrospective data collection and projections was conducted in 2017. A total of 1178 drug resistant (DR) TB (44) and drug sensitive (DS) TB patients (1134), 2 weeks into intensive or continuation phase of treatment were consecutively enrolled across 67 randomly selected TB treatment facilities.

Results: Of the 1178 respondents, 62.7% were male, 44.7% were aged 15–34 years and 55.5% were HIV positive. For each TB episode, patients on average incurred costs of USD 396 for a DS-TB episode and USD 3722 for a Multi drug resistant tuberculosis (MDR TB) episode. Up to 48.5% of households borrowed, used savings or sold assets to defray these costs. More than half (53.1%) of TB affected households experienced TB-related costs above 20% of their annual household expenditure, with the main cost drivers being non-medical expenditure such as travel, nutritional supplements and food.

Conclusion: Despite free health care in public health facilities, over half of Ugandan TB affected households experience catastrophic costs. Roll out of social protection interventions like TB assistance programs, insurance schemes, and enforcement of legislation related to social protection through multi-sectoral action plans with central NTP involvement would palliate these costs.

Keywords: Catastrophic costs, Dissaving, Direct medical costs, Indirect non-medical costs

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Background

Uganda is a high Tuberculosis/Human Immunodeficiency Virus (TB/HIV) burden country, and the Tuberculosis prevalence survey conducted in 2014 put the prevalence at 253 per 100,000 population [1] while data available for 2018 puts the incidence at 200 per 100,000 population [2]. The TB incidence among HIV positive individuals is 80 per 100,000 population while the mortality among the HIV co-infected is 32/100,000 population [3]. The proportion of multi drug resistant TB (MDR TB) among the new TB cases and previously treated TB cases is 1.6 and 12% respectively [3]. In 2018, Uganda notified 52,458 TB patients and 65% of these were male [4].

TB patients often navigate complex healthcare systems before and after a TB diagnosis has been made. This often results in them incurring large costs related to illness and disability, as well as seeking and receiving health care. Low income countries like Uganda have TB patients that face costs that could amount to half their annual income [5] despite TB services being provided free of charge in public health facilities [6]. In the private health facilities, patients incur costs of screening and diagnosis. For the private health facilities designated as diagnostic and treatment units (DTU), the TB drugs are provided free of charge. TB affects the poorest segment of society disproportionately and the poverty-aggravating effects of TB are therefore gravest for those who are already vulnerable [7].

To cushion TB patients against the costs, the Global TB Programme suggests several cross-sectoral measures including increasing insurance coverage, reimbursements, regulating and eliminating user fees, inclusion of TB patients in social protection schemes among others [7]. The end TB strategy has as one of the targets that no TB-affected household should face catastrophic costs due to tuberculosis care [8]. Catastrophic costs in most surveys have been set at 20% of the household's annual income as this threshold is mostly associated with adverse TB outcomes [9].

While some countries may attempt to provide free services for TB related care, often only diagnostics and anti TB drugs are free and patients may face other TB-related expenses. Such include direct payments on transport, symptom relieving medications, food and indirect expenses due to lost income [9]. In Uganda, social protection services (cash transfers, food support, social insurance, housing, social assistance) are limited, with the MDR TB patients being prioritized. An unpublished report from one of the USAID funded projects (Strengthening Uganda's Systems for Treating AIDS Nationally- SUSTAIN) indicates that MDR TB patients at the hospitals they support receive a refund of United States Dollars (USD) 1.4 every time they come to the health facility or a monthly lump sum of USD 32.0. The median monthly wage for people in paid employment is equivalent to USD 20.0 in rural areas and USD 57.0 in urban areas [10].

This survey was designed to ascertain the proportion of TB affected households experiencing catastrophic costs and to identify cost drivers in order to guide policies on cost mitigation and delivery model improvements. It measures the proportion of TB patients (and their households) that experienced catastrophic total cost in 2017.

Methods

This survey followed World Health Organization (WHO) methodology and protocol design [7]. It was designed as a cross-sectional survey design with retrospective data collection and projections. The survey was conducted across TB diagnostic and treatment units (DTU) which report to the national TB program and were sampled through a cluster sampling strategy. A sample size of 1174 patients was selected from 67 of the 1680 DTUs. Patients were consecutively enrolled as they visited the health facility. Consecutive enrollment was continued till the number of patients allocated to the DTU was reached. In cases of children, the guardian accompanying them was interviewed and guardian costs calculated. The guardian costs (direct non-medical and direct medical) were included in the calculation of costs if the guardian was part of the same household of the patient. Clusters were allocated to 13 regions proportionately according to the TB notification rates.

All consecutive Drug Sensitive TB (DS-TB) and multi drug resistant TB (MDR-TB) patients registered for treatment who were attending a sampled facility for a follow-up visit (after a minimum of 2 weeks into the present intensive or continuation treatment phase) were interviewed using a questionnaire developed by WHO [11], and reported on expenditures, time loss, measures ability to pay (including assets ownership, household expenditures and income) and coping mechanisms (taking loans, selling assets, taking children out of school) retrospectively. Patients in each of the two treatment phases were interviewed at different time points during their treatment phase. Data collection for patients in different treatment phases allowed for the imputation of data and model projections of future and past costs during the entire illness episode.

Costs of TB and MDR episodes

For each TB-affected household, total costs were calculated as the sum of direct medical costs, direct non-medical costs (transportation, accommodation, food, nutritional supplements) and indirect costs after the onset of TB symptoms and while in care as per WHO definitions [7]. Costs for food and nutritional supplements included food required

during hospitalization or food and nutritional supplements recommended and additional to the regular food basket. Patients were asked if they have had to buy any additional food e.g. meat, fruits, energy drinks, or nutritional supplements e.g. multivitamins outside their regular diet because of TB as recommended by the health care staff.

Indirect costs were calculated using reported time used while seeking and receiving care during the TB episode (in hours) multiplied by an individual hourly rate derived from self-reported hourly income which was calculated based on the reported individual income in conjunction with the reported hours worked (so-called the human capital approach) [7], assuming that hours lost would have been used for a productive activity. Annual household expenditures were calculated as the sum of weekly, monthly and annual reported expenditures. The household expenditure questions excluded consumption that is not based on market transactions and included validated questions from a household consumption survey questionnaire.

Catastrophic cost calculation

To ascertain the proportion experiencing catastrophic costs, our main analysis used the human capital approach paired with household expenditures as a measure of ability to pay for health. Household expenditures were the money payments or the incurrence of liability to obtain goods and services. While we collected assets and reported income, household expenditures appeared more robust as this could easily be collected at the facility. Catastrophic costs were calculated as total costs (indirect and direct combined) exceeding 20% of the household's annual expenditure.

In addition to catastrophic cost calculations, data collected allowed for assessment of dissaving strategies, evaluation of risk factors for incurring catastrophic costs and calculation of the proportion of TB-affected households below the poverty line (i.e. living on less than USD 1.9 per day) before and after contracting the disease (impoverishment).

Impoverishment was calculated as the proportion of households with daily expenditure below 6760 Uganda Shillings (2017) which is equivalent to 1.90 US$ (2011 international poverty line). The proportion below poverty (before TB) was calculated as the number with monthly individual income (pre-TB) below the monthly poverty threshold.

To obtain those pushed below poverty due to TB, we added total costs (from output approach) to individual income pre-TB, and checked the number falling below the threshold.

Similarly, for those pushed below poverty level due to direct medical and non-medical costs we added these costs in and recalculated the proportion below threshold.

Data collection process and analysis

This facility-based survey collected data at 67 health facilities across the country. Data were collected electronically by trained research assistants using a mobile and web -based system (ONA, https://ona.io/home/) downloaded onto tablets, collected off-line and uploaded when online. Part of the data collected was from TB cards and registers while the rest were collected by interviewing eligible patients at the facility for around 1 hour.

Data cleaning and analysis was done in Stata® Version 13 (StataCorp. 2013) in line with WHO minimum reporting formats [7].

Results were adjusted for survey design and presented by household expenditure quintiles where appropriate (e.g. dissaving strategy).

Results

Table 1 shows the socio-demographic and clinical characteristics of the respondents. The DS-TB respondents were 1134 (96.2%) while the MDR-TB respondents were 44 (3.7%). Males, 739 (62.7%) were more than women, 439 (37.3%). Up to 362 (30.8%) respondents were in the age group of 25–34 years and this accounted for the highest number of respondents. The HIV positive respondents in this survey were 654 (55.5%) while the respondents that had previously been treated for TB were 103 (8.7%), with the proportion higher among the MDR-TB patients; 28 (64%) than DS-TB patients; 75 (6.6%). Up to 618 (52.5%) patients were interviewed while they were in the continuation phase of TB treatment. Under a half (48.3%) of the respondents had attained primary school education.

Table 2 below highlights the model of care patients were receiving at the time of interview i.e. whether they were ambulatory or hospitalized. More MDR-TB patients than DS-TB patients were hospitalized i.e. 18 (41.9%) vs 74 (6.5%). The MDR-TB patients were hospitalized more times than the DS-TB patients (2 vs 1) and on average, the MDR-TB patients were hospitalized for 91 days while the DS-TB patients were hospitalized for 13 days.

For ambulatory care and per TB episode, MDR-TB patients had more visits to the facilities than the DS-TB patients (1093 vs 51). The number of directly observed therapy (DOT) visits was 614.5 for the MDR-TB patients compared to 167.6 for the DR-TB patients, with more follow-up visits for the MDR-TB patients than the DR-TB patients (10.9 vs 3.7).

Among the MDR-TB patients, treatment was delayed by 9.5 weeks compared to 9.9 weeks among the DS-TB patients with 3 (50.0%%) of the MDR-TB patients and 223 (45.9%) of DS-TB patients delaying treatment by 28 days.

Table 3 summarizes the costs the patients and their guardians incurred both pre-diagnosis and post-diagnosis.

Table 1 Socio-demographic and clinical characteristics of the respondents (unweighted)

	MDR-TB		DS-TB		Overall	
	Sample (weighted)	National	Sample (weighted)	National	Sample (weighted)	National
N	**44**	**1100**	**1134**	**43,413**	**1178**	**45,284**
Socio-demographic characteristics of survey sample						
Sex, N (%)						
Male	30 (67.9%)		709 (62.5%)		739 (62.7%)	73%
Female	14 (32.1%)		425 (37.5%)		439 (37.3%)	28%
Age (%)						
0–14	2 (5.1%)		54 (4.8%)		57 (4.8%)	10%
15–24	5 (11.3%)		159 (14%)		164 (13.9%)	90%
25–34	14 (31.3%)		349 (30.7%)		362 (30.8%)	
35–44	11 (24.4%)		294 (25.9%)		304 (25.8%)	
45–54	9 (21.5%)		159 (14.1%)		169 (14.3%)	
55–64	0 (0%)		74 (6.5%)		74 (6.3%)	
65+	3 (6.6%)		45 (4%)		48 (4.1%)	
Patient's (guardian's) education status %						
Not yet started school	8 (18.8%)		151 (13.3%)		159 (13.5%)	
Primary school	23 (53%)		546 (48.2%)		570 (48.3%)	
Secondary school	12 (26.5%)		315 (27.8%)		327 (27.7%)	
Tech/Tertiary School	0 (0%)		75 (6.6%)		75 (6.4%)	
University and higher	1 (1.7%)		46 (4.1%)		47 (4%)	
Occupation pre-disease						
Professionals	2 (5.3%)		70 (6.2%)		72 (6.1%)	
Technicians and associate professionals	0 (0%)		33 (2.9%)		33 (2.8%)	
Clerical support workers	1 (2.8%)		7 (0.6%)		8 (0.7%)	
Service and sales workers	15 (34.2%)		272 (24%)		287 (24.4%)	
Skilled agricultural, forestry and fishery workers	0 (0%)		21 (1.8%)		21 (1.8%)	
Craft and related trades workers	2 (4.3%)		56 (4.9%)		58 (4.9%)	
Plant and machine operators, and assemblers	0 (0%)		6 (0.6%)		6 (0.5%)	
Elementary occupations	4 (10.3%)		225 (19.8%)		229 (19.4%)	
Armed forces	2 (3.6%)		14 (1.2%)		15 (1.3%)	
Other	2 (3.9%)		76 (6.7%)		78 (6.6%)	
Clinical Characteristics						
Phase, N (%)						
Intensive	18 (41.9%)		541 (47.7%)		560 (47.5%)	
Continuation	25 (58.1%)		593 (52.3%)		618 (52.5%)	
Recorded HIV Status, N (%)						
Positive	25 (57.3%)		487 (42.9%)		654 (55.5%)	40%
Negative	19 (42.7%)		636 (56%)		512 (43.4%)	53%
Unknown	0 (0%)		12 (1.1%)		12 (1%)	7%
Retreatment status, N (%)						
New	16 (36%)		1060 (93.4%)		1075 (91.3%)	
Retreatment/Relapse	28 (64%)		75 (6.6%)		103 (8.7%)	

Table 2 Model of care

	MDR-TB	DS-TB
	44	1134
	Mean (95% CI)	Mean (95% CI)
Hospitalisation		
Hospitalized at time of interview, N (%)	18 (41.9%)	74 (6.53%)
Previously hospitalized during current phase, N (%)	7 (16.7%)	125 (11.0%)
Times hospitalized during current phase, Mean (95% CI)	1.64 (0.83–2.45)	1.14 (1.04–1.23)
Mean duration (days) hospitalized during current phase (95% CI)	91.4 (0–199.2)	12.9 (10.1–15.8)
Median duration (days) hospitalized during current phase (IQR)	30 (26–102)	7 (5–14)
Ambulatory care		
Number of visits per episode: total (95% CI)	1093.4 (917–1269.8)	51.2 (42.1–60.3)
Number of visits: DOT (95% CI)	614.5 (555.6–673.5)	167.6 (157.7–177.5)
Number of visits: follow-up (95% CI)	10.9 (0–22.5)	3.7 (3.1–4.3)
Number of visits: drug pick-up (95% CI)	569.1 (529.9–608.3)	9.1 (7.7–10.5)
Number of visits pre-diagnosis (95% CI)	1.6 (0.9–2.2)	1.1 (1.1–1.2)
Proportion of first visits to primary health facilities	5 (84.2%)	189 (39%)
Proportion of first visits from private facilities	2 (28.8%)	159 (32.8%)
Proportion of TB diagnoses made at private or NGO facility	2 (5%)	300 (26.5%)
Treatment duration		
Treatment duration: intensive phase, weeks Mean (95% CI)	7 (6.1–7.9)	2 (2–2.1)
Treatment duration: continuation phase, weeks Mean (95% CI)	14.8 (12.8–16.8)	4.1 (4.1–4.1)
Treatment delay (among new patients in intensive phase)	**6**	**486**
Weeks of treatment delay Mean (95% CI)	9.5 (3.4–15.7)	9.9 (8.1–11.8)
Proportion of patients with delay > 28 days (%)	3 (50.0%)	223 (45.9%)

Pre-diagnosis, the biggest drivers of costs were medical and travel for both MDR-TB and DS-TB. The biggest drivers of costs after a TB diagnosis was made were nutritional supplements (MDR-TB = US$ 1262, DS-TB = US$ 189) followed by travel (MDR-TB = US$ 1019, DS-TB = US$ 44) and food (MDR-TB = US$ 498, DS-TB = US$ 31). The non-medical costs were the biggest contributor of the costs for both types of TB. On average, it costs an MDR-TB patient US$ 3722 for an entire episode of TB while for DS-TB patients it costs US$ 396 for an entire TB episode. Figure 1 highlights that the biggest costs for both types of TB are direct non-medical followed by the indirect costs and direct medical costs.

Table 4 shows the coping mechanisms (dissaving) that the TB patients adopt to defray the TB costs, and also shows the social consequences they encounter because of TB. In the survey, up to 571(48.5%) patients used at least one of the 3 dissaving strategies (took a loan, sold assets or used savings) ranging from 536 (47.2%) for DS-TB patients to 35 (81.2%) for MDR-TB. Regarding social consequences, 585 (49.7%) experienced food insecurity, 477 (40.5%) lost a job, 140 (11.8%) had a child interrupt schooling and 633 (53.7%) were socially excluded due to TB and 94 (8%) had divorce or separation from a spouse. The social consequences were worse for the patients in the poorest income quintile and MDR-TB patients. Up to 43.9% of survey households had received a form of social protection after a TB diagnosis was made, with the proportion bigger for MDR-TB patients (56.4%) than for the DS-TB patients (1.8%).

Table 5 presents the proportion of households experiencing catastrophic costs for different households. At a 20% threshold, 614 (53.1%) participants experienced catastrophic costs. The proportion experiencing catastrophic costs increased with lower thresholds at 15 and 10% i.e., 62.4 and 75.2% respectively. The proportion of respondents experiencing catastrophic costs decreased with increased thresholds; 25 and 30% i.e. 45.2 and 38.9% respectively. Regarding direct costs (direct medical and direct non-medical), 33.1% (383) of the respondents spent up to 20% of their annual household income and the same trend as for catastrophic costs was followed with changing thresholds.

In terms of direct medical costs, 3% (35) of the households used up to 20% of their annual income for these costs. A similar trend of proportions was followed with adjusted thresholds as for catastrophic costs (i.e., proportions increasing/decreasing) with decreasing/increasing thresholds.

Table 3 Estimated total costs borne by patients' households affected by TB, MDR-TB or all, median breakdown (USD† 2017 (95% CI)

	Costs	MDR-TB Mean,95%CI	DS-TB Mean,95%CI	Overall Mean,95%CI
Pre-diagnosis	Medical	4.11(0.27–7.94)	8.55(2.80–14.31)	8.50(2.79–14.20)
	Travel	6.48(3.84–9.13)	2.10(1.39–2.81)	2.15(1.45–2.86)
	Accommodation	0(0–0)	0.34(0.10–0.58)	0.34(0.10–0.57)
	Food	0.69(0.41–0.97)	1.10(0.33–1.87)	1.09(0.33–1.85)
	Nutritional supplements	0.44(0.15–0.73)	1.08(0.32–1.84)	0.80(0.20–1.41)
	Hours lost by patient and guardian multiplied by hourly wage	1.52(0.97–2.08)	1.7(0.67–2.72)	1.69(0.67–2.71)
Post-diagnosis	Medical	78.7(12.5–145.0)	16.2(9.2–23.2)	18.5(11.2–25.9)
	Travel	1019(896–1143)	43.9(34.0–53.7)	79.9(51.0–108.8)
	Accommodation	0.4(0–1.1)	1.4(0–3.4)	1.4(0–3.3)
	Food	498(353–642)	30.6(15.8–45.5)	47.9(25.8–70.1)
	Nutritional supplements	1263.(928–1597)	189(151–227)	225(173–277)
	Caregiver (guardian) costs	115(0–248)	25.2(14.7–35.7)	27.9 (17.3–38.5)
	Hours lost by patient and guardian x Hourly wage	1219(537–1899)	115(96–135)	156(116–196)
Medical costs		79.3(12.7–146)	20.0(11.7–28.2)	22.2(15.0–30.4)
Non-medical costs		2239(1742–2737)	198(162–234)	273(199–347)
Indirect costs	Human Capital Approach	1219(538–1901)	116.5(97–136)	157(117–197)
Dissaving/Coping Costs		183(19.0–348)	62.1(48.8–75.5)	66.6(50.3–83.0)
Total		3722(3071–4374)	396(337–456)	519(407–632)

Table 6 illustrates the risk factors for experiencing catastrophic costs. At both bivariate and multivariate analysis, participants belonging to the poorest expenditure quintile had higher odds of experiencing catastrophic costs i.e. bivariate analysis: OR (IQR): 23.5 (12.9–42.7) and multivariate analysis: 24 (13.2–43.8). HIV, age and gender were not associated with higher odds of experiencing catastrophic costs.

Figure 2 shows the impoverishment due to TB care. Even before TB, 51.8% of the respondents were already below the poverty level. Direct costs pushed an additional 9.9% of the TB patients below the poverty level

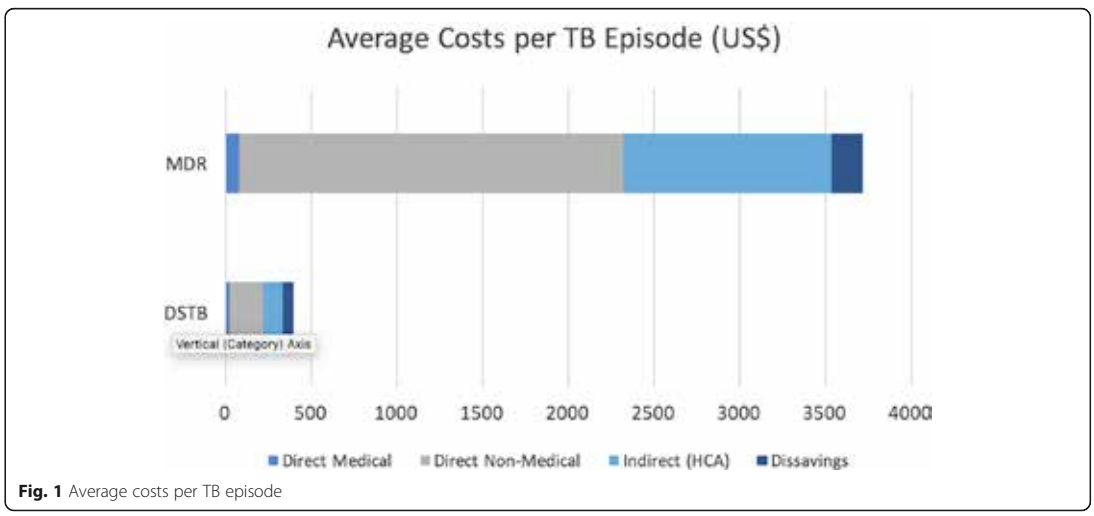

Fig. 1 Average costs per TB episode

Table 4 Dissaving mechanisms and social consequences for sample participants

	Expenditure Quintiles[a]						Treatment Group	
	Poorest (*N* = 219)	Less Poor (*N* = 229)	Average (*N* = 218)	Less Wealthy (*N* = 274)	Wealthiest (*N* = 215)	Overall (*N* = 1178)	DS (*N* = 1134)	MDR (*N* = 44)
Dissaving Strategies								
Loan	22.8%	29.1%	27.6%	27%	25.6%	26.3%	25.9%	35.5%
Use of savings	6%	8.6%	12%	14.1%	14.9%	11.2%	10%	39.9%
Sale of assets	29.4%	27.6%	30.1%	25.1%	22%	26.5%	25.4%	54.4%
Any of the three above	**45.5%**	**48.6%**	**54.3%**	**48.2%**	**47.6%**	**48.5%**	**47.2%**	**81.2%**
Food insecurity	60.9%	48.6%	49.7%	50%	43.2%	49.7%	49.3%	59.7%
Divorce/separated from spouse/partner	8.7%	6.6%	10.5%	5.3%	9.2%	8%	7.8%	10.6%
Loss of Job	45.1%	44.3%	40.2%	34%	40.9%	40.5%	39.9%	56%
Child interrupted schooling	8.7%	10.7%	11%	11.6%	15.4%	11.8%	11.9%	11.5%
Social exclusion	60%	55.3%	51.4%	53.3%	50.8%	53.7%	54%	46.1%
Any days of work lost	16%	9.2%	4%	2.4%	5.7%	7.2%	4.4%	2.6%
Household received social protection after TB diagnosis	3.2%	2.9%	5.1%	4.2%	3.5%	3.9%	1.8%	56.4%

[a]12 people excluded due to zero consumption data

while the indirect costs pushed an additional 2.6% below the poverty level.

Discussion

This national TB cost survey established that up to 53% of Ugandan TB affected households incur TB-related costs that are higher than 20% of their annual household expenditures, despite the free TB care policy. The survey also identified the main cost drivers as non-medical expenditure such as travel, nutritional supplements and food.

The proportion of 53% of TB affected households experiencing catastrophic costs is lower than was found in

Table 5 Households facing catastrophic costs

	Expenditure quintiles [a]					
	Poorest (*N* = 219)	Less Poor (*N* = 229)	Average (*N* = 218)	Less Wealthy (*N* = 274)	Wealthiest (*N* = 215)	Overall (*N* = 1155)
Households experiencing total (direct and indirect) costs above (%) - Human capital Approach						
10%	178 (81.4%)	162 (70.8%)	168 (77.2%)	214 (78.2%)	145 (67.5%)	868 (75.2%)
15%	157 (71.7%)	133 (58.4%)	141 (64.8%)	171 (62.4%)	118 (54.9%)	721 (62.4%)
20%	143 (65.4%)	106 (46.6%)	112 (51.3%)	152 (55.5%)	100 (46.4%)	613 (53.1%)
25%	119 (54.2%)	90 (39.4%)	98 (44.8%)	130 (47.4%)	86 (39.8%)	522 (45.2%)
30%	103 (47%)	76 (33.2%)	84 (38.7%)	117 (42.8%)	68 (31.7%)	449 (38.9%)
Number of households experiencing direct medical and non-medical costs above (%) annual household expenditure						
10%	123 (56.1%)	106 (46.2%)	115 (52.9%)	140 (51.2%)	83 (38.6%)	567 (49.1%)
15%	107 (48.9%)	86 (37.5%)	95 (43.4%)	117 (42.6%)	61 (28.5%)	465 (40.3%)
20%	89 (40.7%)	69 (30.4%)	81 (37.2%)	95 (34.8%)	48 (22.2%)	383 (33.1%)
25%	82 (37.3%)	53 (23%)	72 (32.8%)	79 (28.9%)	40 (18.6%)	325 (28.1%)
30%	74 (33.9%)	46 (20.2%)	64 (29.4%)	67 (24.4%)	29 (13.3%)	280 (24.2%)
Number of households experiencing direct medical costs above (%) annual household expenditure						
10%	18 (8%)	22 (9.6%)	14 (6.4%)	11 (4%)	7 (3.1%)	71 (6.1%)
15%	11 (5%)	12 (5.4%)	10 (4.3%)	9 (3.3%)	3 (1.4%)	45 (3.9%)
20%	9 (3.8%)	12 (5.4%)	6 (2.5%)	7 (2.6%)	1 (0.5%)	35 (3%)
25%	8 (3.4%)	11 (4.8%)	5 (2.3%)	6 (2.2%)	1 (0.5%)	30 (2.7%)
30%	8 (3.4%)	11 (4.8%)	5 (2.3%)	5 (1.7%)	1 (0.5%)	29 (2.5%)

[a]12 people excluded due to zero consumption data

Table 6 Odds ratios of experiencing catastrophic costs

	Univariate OR (95%CI)	Multivariate OR (95%CI)
Age		
0–14	Reference	Reference
15–24	0.6 (0.3–1.3)	0.4 (0.2–0.9)
25–34	0.7 (0.3–1.4)	0.5 (0.2–1)
35–44	0.7 (0.3–1.4)	0.5 (0.2–1)
45–54	0.6 (0.3–1.3)	0.4 (0.2–1)
55–64	0.9 (0.4–1.9)	0.5 (0.2–1.1)
65+	1.2 (0.5–2.8)	0.7 (0.3–1.8)
Sex		
Male	1 (0.8–1.4)	1 (0.7–1.3)
Female	Reference	Reference
Long delay (> 4 weeks before diagnosis)	1.3 (0.9–2)	1.1 (0.7–1.8)
HIV Status		
Positive	1 (0.7–1.4)	1 (0.7–1.3)
Negative	Reference	Reference
Expenditure Quintile		
Poorest	23.5 (12.9–42.7)	24 (13.2–43.8)
Less Poor	6.1 (3.9–9.6)	6.2 (4–9.8)
Average	3.9 (2.7–5.8)	4 (2.7–5.9)
Less Wealthy	2.3 (1.6–3.5)	2.3 (1.5–3.4)
Wealthiest (Reference)	Reference	Reference

similar studies done in Vietnam, Ghana and Myanmar [7, 12, 13] but higher than was found in Kenya and Indonesia [14, 15]. This difference could be explained by the differences in the geographic, health system and economic profiles of the countries.

TB patients incur direct medical, direct non-medical and indirect costs while they seek care. The study found direct non-medical costs to be the biggest drivers of catastrophic costs, with most of the costs incurred on nutritional supplements, travel and food. This is consistent with findings from similar surveys conducted elsewhere [7, 14, 16]. Data from previous studies have highlighted the contribution of food and transportation to the nearest TB care service on indirect costs; putting the figures at 50 and 37% respectively [17]. A study done in Philippines found out that paying attention to the nutrition costs could reduce the catastrophic costs by 5% [18]. In Uganda, MDR-TB patients receive enablers in form of food and transport vouchers [19]. This survey however shows that despite this, these patients still incur high costs on nutrition and food. Potential solutions could include increasing nutritional and transport support for MDR-TB patients and possibly introducing similar support in the DS-TB patients.

The study found out DS-TB patients spent US$396 for the entire TB episode while DR-TB patients spent up to US$ 3722. Previous work done in Uganda on costs of TB treatment analyzed from health services, patients and community volunteers' perspective showed the amount needed to successfully treat a new smear-positive TB patient was US$ 911.0 and US$ 391.0 using the hospital-based approach and community-based care approach respectively [20]. The costs incurred by MDR-TB patients

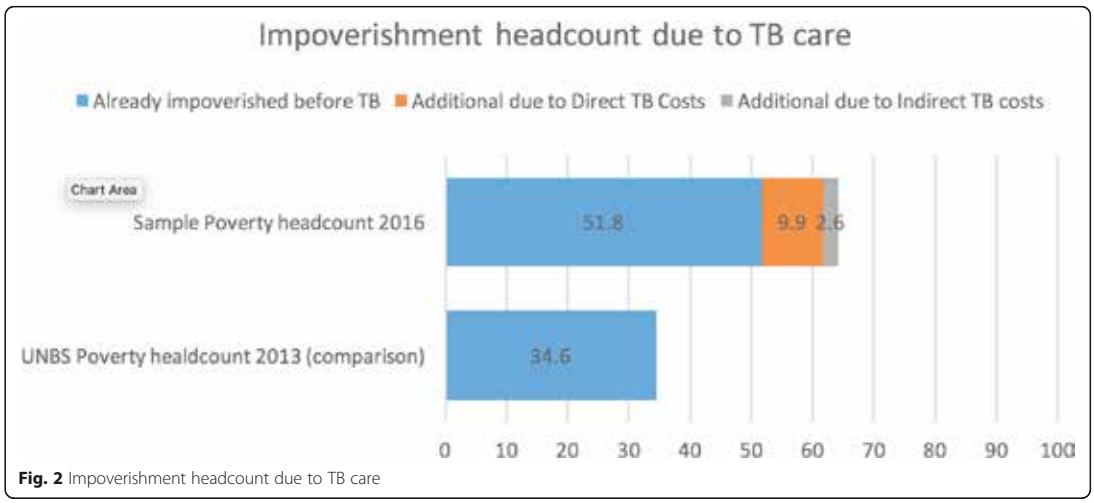

Fig. 2 Impoverishment headcount due to TB care

in previous surveys have been found to be higher than for DS-TB patients. In Ghana, costs per DS-TB episode were US$429.6 while it was US$659.0 for MDR-TB patients [12]. The amount spent on TB treatment is high in a setting like Uganda where the minimum monthly wage is US$ 36 [21], and 21.4% of the population are below the poverty level [22]. This survey established that even before a TB diagnosis is made, 52% of the TB patients were already below the poverty level, with an additional 12.5% pushed below the poverty level while in TB care. These costs represent a large economic burden to the Ugandan TB affected households, who are financially compromised in the first place.

TB patients adopt several coping measures in a bid to cushion against the TB-related costs. Close to half (48.5%) of the patients had adopted at least one coping mechanism. TB patient cost studies done elsewhere found borrowing money and taking loans were the widely used coping strategies for TB patients [5, 23]. The survey revealed respondents in the lowest income quintiles (poorest, less poor and average) were more likely to take up loans and sell assets as opposed to using up their own savings. This is hardly surprising as this group of patients do not normally have a stable income source compared to individuals in the high-income quintiles and thus hardly have any savings to draw upon.

TB patients encounter several social consequences while in care. In this survey patients experience encountered food insecurity (49.7%), job loss (40.5%), interruption in schooling for children (11.8%) and social exclusion (53.7%). The proportion experiencing these consequences was higher than was found in similar surveys [14, 16], and this could be due to differences in the health care systems, sample sizes and economic profiles of the countries.

In this survey, patients/households belonging in the poorest expenditure quintile had higher odds of experiencing catastrophic costs. TB has often been known as a disease of the poor since the burden follows a strong socio-economic gradient, and also poor communities have been known to have high incidences [23, 24]. TB catastrophic costs are thus disproportionately experienced by individuals who are already at a higher risk of TB. Despite the high proportion of HIV/TB co-infected patients in the survey, HIV didn't increase the odds of experiencing catastrophic costs. This possibly could be due to the implementation of the one stop shop model for TB/HIV services where TB and HIV services are offered to the clients at the same time and location.

The survey results provide a baseline upon which future catastrophic costs measurements could be compared and progress towards the high-level End TB Strategy target assessed. The survey results are disaggregated by TB resistance status (i.e., DR TB and MDR TB). However, the costs for the MDR TB patients need to be appreciated in context of the low number sampled. For example, the results showed costs incurred by the MDR TB patients for a TB episode are 10 times higher than for DS TB patients. It's possible there is an over estimation for the MDR TB costs owing to the small number of MDR TB patients included in the survey. Despite this, we believe the costs would still be higher even with bigger numbers as has been seen in other studies that have sampled more MDR TB patients [14, 16, 25].

Based on the survey findings, we recommend a policy shift in order to be able to protect the TB patients against catastrophic costs. This could include operationalization of the national health/social insurance, strengthening and enforcement of legislation related to social protection and intersectoral collaborations as the effects span several sectors.

Limitations

The survey included a few MDR-TB patients. Subsequent surveys should purposely involve more MDR-TB patients in the sample. Patients also were asked costs previously incurred which might have led to a recall bias. Recall bias mainly affects cost estimates for the pre-treatment period and the approach to only interview persons in intensive phase about diagnostics costs was intended to minimize this type of bias. Also, most of the costs were estimated as the study was cross-sectional in nature. The survey also did not include costs after treatment as some of the direct and indirect costs of TB for the patients and the household can extend beyond the treatment period.

Conclusion

In conclusion, this survey established that over a half of TB affected households in Uganda face catastrophic TB care expenditure, with the major cost drivers being nutritional supplements, travel, and food. This expenditure results in adverse coping behaviors such as selling assets, taking loans and using savings at high rates among the patients.

Abbreviations

TB: Tuberculosis; HIV: Human Immunodeficiency Virus; MDR: Multi drug resistant; DTU: Diagnostic and Treatment Unit; USD: United States Dollars; WHO: World Health Organization; DS-TB: Drug Sensitive Tuberculosis; UGX: Uganda Shillings; DOT: Directly Observed Therapy

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Authors' contributions

IGB, BK, AN, ST, FM, KM, AK, SD, EB, CM and PL designed the study, WM, RT, RS and BK participated in data acquisition. SK, CB, LM and IGB conducted data analysis. WM and BK wrote the original draft of the manuscript. RKM, PL, IGB, AN proof read the manuscript. All authors read and approved the manuscript.

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Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate
All patients gave written informed consent and were compensated for their time and inconvenience during the interview. Assent was obtained for participants under 18 years while their parents gave parental consent. Ethics approval was obtained from the Mulago Hospital Research and Ethics committee (MREC 1028) and the Uganda National Council for Science and Technology (ADM 194/212/01).

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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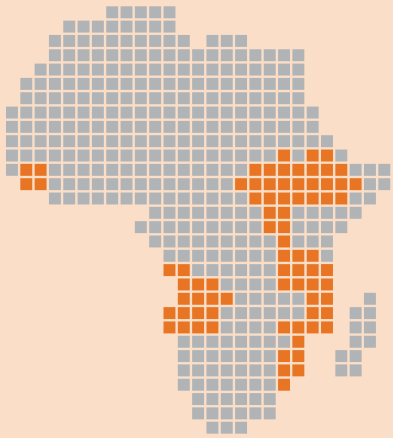

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RESEARCH ARTICLE Open Access

Households experiencing catastrophic costs due to tuberculosis in Uganda: magnitude and cost drivers

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Abstract

Background: Tuberculosis (TB) patients in Uganda incur large costs related to the illness, and while seeking and receiving health care. Such costs create access and adherence barriers which affect health outcomes and increase transmission of disease. The study ascertained the proportion of Ugandan TB affected households incurring catastrophic costs and the main cost drivers.

Methods: A cross-sectional survey with retrospective data collection and projections was conducted in 2017. A total of 1178 drug resistant (DR) TB (44) and drug sensitive (DS) TB patients (1134), 2 weeks into intensive or continuation phase of treatment were consecutively enrolled across 67 randomly selected TB treatment facilities.

Results: Of the 1178 respondents, 62.7% were male, 44.7% were aged 15–34 years and 55.5% were HIV positive. For each TB episode, patients on average incurred costs of USD 396 for a DS-TB episode and USD 3722 for a Multi drug resistant tuberculosis (MDR TB) episode. Up to 48.5% of households borrowed, used savings or sold assets to defray these costs. More than half (53.1%) of TB affected households experienced TB-related costs above 20% of their annual household expenditure, with the main cost drivers being non-medical expenditure such as travel, nutritional supplements and food.

Conclusion: Despite free health care in public health facilities, over half of Ugandan TB affected households experience catastrophic costs. Roll out of social protection interventions like TB assistance programs, insurance schemes, and enforcement of legislation related to social protection through multi-sectoral action plans with central NTP involvement would palliate these costs.

Keywords: Catastrophic costs, Dissaving, Direct medical costs, Indirect non-medical costs

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Background

Uganda is a high Tuberculosis/Human Immunodeficiency Virus (TB/HIV) burden country, and the Tuberculosis prevalence survey conducted in 2014 put the prevalence at 253 per 100,000 population [1] while data available for 2018 puts the incidence at 200 per 100,000 population [2]. The TB incidence among HIV positive individuals is 80 per 100,000 population while the mortality among the HIV co-infected is 32/100,000 population [3]. The proportion of multi drug resistant TB (MDR TB) among the new TB cases and previously treated TB cases is 1.6 and 12% respectively [3]. In 2018, Uganda notified 52,458 TB patients and 65% of these were male [4].

TB patients often navigate complex healthcare systems before and after a TB diagnosis has been made. This often results in them incurring large costs related to illness and disability, as well as seeking and receiving health care. Low income countries like Uganda have TB patients that face costs that could amount to half their annual income [5] despite TB services being provided free of charge in public health facilities [6]. In the private health facilities, patients incur costs of screening and diagnosis. For the private health facilities designated as diagnostic and treatment units (DTU), the TB drugs are provided free of charge. TB affects the poorest segment of society disproportionately and the poverty-aggravating effects of TB are therefore gravest for those who are already vulnerable [7].

To cushion TB patients against the costs, the Global TB Programme suggests several cross-sectoral measures including increasing insurance coverage, reimbursements, regulating and eliminating user fees, inclusion of TB patients in social protection schemes among others [7]. The end TB strategy has as one of the targets that no TB-affected household should face catastrophic costs due to tuberculosis care [8]. Catastrophic costs in most surveys have been set at 20% of the household's annual income as this threshold is mostly associated with adverse TB outcomes [9].

While some countries may attempt to provide free services for TB related care, often only diagnostics and anti TB drugs are free and patients may face other TB-related expenses. Such include direct payments on transport, symptom relieving medications, food and indirect expenses due to lost income [9]. In Uganda, social protection services (cash transfers, food support, social insurance, housing, social assistance) are limited, with the MDR TB patients being prioritized. An unpublished report from one of the USAID funded projects (Strengthening Uganda's Systems for Treating AIDS Nationally- SUSTAIN) indicates that MDR TB patients at the hospitals they support receive a refund of United States Dollars (USD) 1.4 every time they come to the health facility or a monthly lump sum of USD 32.0. The median monthly wage for people in paid employment is equivalent to USD 20.0 in rural areas and USD 57.0 in urban areas [10].

This survey was designed to ascertain the proportion of TB affected households experiencing catastrophic costs and to identify cost drivers in order to guide policies on cost mitigation and delivery model improvements. It measures the proportion of TB patients (and their households) that experienced catastrophic total cost in 2017.

Methods

This survey followed World Health Organization (WHO) methodology and protocol design [7]. It was designed as a cross-sectional survey design with retrospective data collection and projections. The survey was conducted across TB diagnostic and treatment units (DTU) which report to the national TB program and were sampled through a cluster sampling strategy. A sample size of 1174 patients was selected from 67 of the 1680 DTUs. Patients were consecutively enrolled as they visited the health facility. Consecutive enrollment was continued till the number of patients allocated to the DTU was reached. In cases of children, the guardian accompanying them was interviewed and guardian costs calculated. The guardian costs (direct non-medical and direct medical) were included in the calculation of costs if the guardian was part of the same household of the patient. Clusters were allocated to 13 regions proportionately according to the TB notification rates.

All consecutive Drug Sensitive TB (DS-TB) and multi drug resistant TB (MDR-TB) patients registered for treatment who were attending a sampled facility for a follow-up visit (after a minimum of 2 weeks into the present intensive or continuation treatment phase) were interviewed using a questionnaire developed by WHO [11], and reported on expenditures, time loss, measures ability to pay (including assets ownership, household expenditures and income) and coping mechanisms (taking loans, selling assets, taking children out of school) retrospectively. Patients in each of the two treatment phases were interviewed at different time points during their treatment phase. Data collection for patients in different treatment phases allowed for the imputation of data and model projections of future and past costs during the entire illness episode.

Costs of TB and MDR episodes

For each TB-affected household, total costs were calculated as the sum of direct medical costs, direct non-medical costs (transportation, accommodation, food, nutritional supplements) and indirect costs after the onset of TB symptoms and while in care as per WHO definitions [7]. Costs for food and nutritional supplements included food required

during hospitalization or food and nutritional supplements recommended and additional to the regular food basket. Patients were asked if they have had to buy any additional food e.g. meat, fruits, energy drinks, or nutritional supplements e.g. multivitamins outside their regular diet because of TB as recommended by the health care staff.

Indirect costs were calculated using reported time used while seeking and receiving care during the TB episode (in hours) multiplied by an individual hourly rate derived from self-reported hourly income which was calculated based on the reported individual income in conjunction with the reported hours worked (so-called the human capital approach) [7], assuming that hours lost would have been used for a productive activity. Annual household expenditures were calculated as the sum of weekly, monthly and annual reported expenditures. The household expenditure questions excluded consumption that is not based on market transactions and included validated questions from a household consumption survey questionnaire.

Catastrophic cost calculation

To ascertain the proportion experiencing catastrophic costs, our main analysis used the human capital approach paired with household expenditures as a measure of ability to pay for health. Household expenditures were the money payments or the incurrence of liability to obtain goods and services. While we collected assets and reported income, household expenditures appeared more robust as this could easily be collected at the facility. Catastrophic costs were calculated as total costs (indirect and direct combined) exceeding 20% of the household's annual expenditure.

In addition to catastrophic cost calculations, data collected allowed for assessment of dissaving strategies, evaluation of risk factors for incurring catastrophic costs and calculation of the proportion of TB-affected households below the poverty line (i.e. living on less than USD 1.9 per day) before and after contracting the disease (impoverishment).

Impoverishment was calculated as the proportion of households with daily expenditure below 6760 Uganda Shillings (2017) which is equivalent to 1.90 US$ (2011 international poverty line). The proportion below poverty (before TB) was calculated as the number with monthly individual income (pre-TB) below the monthly poverty threshold.

To obtain those pushed below poverty due to TB, we added total costs (from output approach) to individual income pre-TB, and checked the number falling below the threshold.

Similarly, for those pushed below poverty level due to direct medical and non-medical costs we added these costs in and recalculated the proportion below threshold.

Data collection process and analysis

This facility-based survey collected data at 67 health facilities across the country. Data were collected electronically by trained research assistants using a mobile and web -based system (ONA, https://ona.io/home/) downloaded onto tablets, collected off-line and uploaded when online. Part of the data collected was from TB cards and registers while the rest were collected by interviewing eligible patients at the facility for around 1 hour.

Data cleaning and analysis was done in Stata® Version 13 (StataCorp. 2013) in line with WHO minimum reporting formats [7].

Results were adjusted for survey design and presented by household expenditure quintiles where appropriate (e.g. dissaving strategy).

Results

Table 1 shows the socio-demographic and clinical characteristics of the respondents. The DS-TB respondents were 1134 (96.2%) while the MDR-TB respondents were 44 (3.7%). Males, 739 (62.7%) were more than women, 439 (37.3%). Up to 362 (30.8%) respondents were in the age group of 25–34 years and this accounted for the highest number of respondents. The HIV positive respondents in this survey were 654 (55.5%) while the respondents that had previously been treated for TB were 103 (8.7%), with the proportion higher among the MDR-TB patients; 28 (64%) than DS-TB patients; 75 (6.6%). Up to 618 (52.5%) patients were interviewed while they were in the continuation phase of TB treatment. Under a half (48.3%) of the respondents had attained primary school education.

Table 2 below highlights the model of care patients were receiving at the time of interview i.e. whether they were ambulatory or hospitalized. More MDR-TB patients than DS-TB patients were hospitalized i.e. 18 (41.9%) vs 74 (6.5%). The MDR-TB patients were hospitalized more times than the DS-TB patients (2 vs 1) and on average, the MDR-TB patients were hospitalized for 91 days while the DS-TB patients were hospitalized for 13 days.

For ambulatory care and per TB episode, MDR-TB patients had more visits to the facilities than the DS-TB patients (1093 vs 51). The number of directly observed therapy (DOT) visits was 614.5 for the MDR-TB patients compared to 167.6 for the DR-TB patients, with more follow-up visits for the MDR-TB patients than the DR-TB patients (10.9 vs 3.7).

Among the MDR-TB patients, treatment was delayed by 9.5 weeks compared to 9.9 weeks among the DS-TB patients with 3 (50.0%%) of the MDR-TB patients and 223 (45.9%) of DS-TB patients delaying treatment by 28 days.

Table 3 summarizes the costs the patients and their guardians incurred both pre-diagnosis and post-diagnosis.

Table 1 Socio-demographic and clinical characteristics of the respondents (unweighted)

	MDR-TB		DS-TB		Overall	
	Sample (weighted)	National	Sample (weighted)	National	Sample (weighted)	National
N	**44**	**1100**	**1134**	**43,413**	**1178**	**45,284**
Socio-demographic characteristics of survey sample						
Sex, N (%)						
Male	30 (67.9%)		709 (62.5%)		739 (62.7%)	73%
Female	14 (32.1%)		425 (37.5%)		439 (37.3%)	28%
Age (%)						
0–14	2 (5.1%)		54 (4.8%)		57 (4.8%)	10%
15–24	5 (11.3%)		159 (14%)		164 (13.9%)	90%
25–34	14 (31.3%)		349 (30.7%)		362 (30.8%)	
35–44	11 (24.4%)		294 (25.9%)		304 (25.8%)	
45–54	9 (21.5%)		159 (14.1%)		169 (14.3%)	
55–64	0 (0%)		74 (6.5%)		74 (6.3%)	
65+	3 (6.6%)		45 (4%)		48 (4.1%)	
Patient's (guardian's) education status %						
Not yet started school	8 (18.8%)		151 (13.3%)		159 (13.5%)	
Primary school	23 (53%)		546 (48.2%)		570 (48.3%)	
Secondary school	12 (26.5%)		315 (27.8%)		327 (27.7%)	
Tech/Tertiary School	0 (0%)		75 (6.6%)		75 (6.4%)	
University and higher	1 (1.7%)		46 (4.1%)		47 (4%)	
Occupation pre-disease						
Professionals	2 (5.3%)		70 (6.2%)		72 (6.1%)	
Technicians and associate professionals	0 (0%)		33 (2.9%)		33 (2.8%)	
Clerical support workers	1 (2.8%)		7 (0.6%)		8 (0.7%)	
Service and sales workers	15 (34.2%)		272 (24%)		287 (24.4%)	
Skilled agricultural, forestry and fishery workers	0 (0%)		21 (1.8%)		21 (1.8%)	
Craft and related trades workers	2 (4.3%)		56 (4.9%)		58 (4.9%)	
Plant and machine operators, and assemblers	0 (0%)		6 (0.6%)		6 (0.5%)	
Elementary occupations	4 (10.3%)		225 (19.8%)		229 (19.4%)	
Armed forces	2 (3.6%)		14 (1.2%)		15 (1.3%)	
Other	2 (3.9%)		76 (6.7%)		78 (6.6%)	
Clinical Characteristics						
Phase, N (%)						
Intensive	18 (41.9%)		541 (47.7%)		560 (47.5%)	
Continuation	25 (58.1%)		593 (52.3%)		618 (52.5%)	
Recorded HIV Status, N (%)						
Positive	25 (57.3%)		487 (42.9%)		654 (55.5%)	40%
Negative	19 (42.7%)		636 (56%)		512 (43.4%)	53%
Unknown	0 (0%)		12 (1.1%)		12 (1%)	7%
Retreatment status, N (%)						
New	16 (36%)		1060 (93.4%)		1075 (91.3%)	
Retreatment/Relapse	28 (64%)		75 (6.6%)		103 (8.7%)	

Table 2 Model of care

	MDR-TB	DS-TB
	44	1134
	Mean (95% CI)	Mean (95% CI)
Hospitalisation		
Hospitalized at time of interview, N (%)	18 (41.9%)	74 (6.53%)
Previously hospitalized during current phase, N (%)	7 (16.7%)	125 (11.0%)
Times hospitalized during current phase, Mean (95% CI)	1.64 (0.83–2.45)	1.14 (1.04–1.23)
Mean duration (days) hospitalized during current phase (95% CI)	91.4 (0–199.2)	12.9 (10.1–15.8)
Median duration (days) hospitalized during current phase (IQR)	30 (26–102)	7 (5–14)
Ambulatory care		
Number of visits per episode: total (95% CI)	1093.4 (917–1269.8)	51.2 (42.1–60.3)
Number of visits: DOT (95% CI)	614.5 (555.6–673.5)	167.6 (157.7–177.5)
Number of visits: follow-up (95% CI)	10.9 (0–22.5)	3.7 (3.1–4.3)
Number of visits: drug pick-up (95% CI)	569.1 (529.9–608.3)	9.1 (7.7–10.5)
Number of visits pre-diagnosis (95% CI)	1.6 (0.9–2.2)	1.1 (1.1–1.2)
Proportion of first visits to primary health facilities	5 (84.2%)	189 (39%)
Proportion of first visits from private facilities	2 (28.8%)	159 (32.8%)
Proportion of TB diagnoses made at private or NGO facility	2 (5%)	300 (26.5%)
Treatment duration		
Treatment duration: intensive phase, weeks Mean (95% CI)	7 (6.1–7.9)	2 (2–2.1)
Treatment duration: continuation phase, weeks Mean (95% CI)	14.8 (12.8–16.8)	4.1 (4.1–4.1)
Treatment delay (among new patients in intensive phase)	**6**	**486**
Weeks of treatment delay Mean (95% CI)	9.5 (3.4–15.7)	9.9 (8.1–11.8)
Proportion of patients with delay > 28 days (%)	3 (50.0%)	223 (45.9%)

Pre-diagnosis, the biggest drivers of costs were medical and travel for both MDR-TB and DS-TB. The biggest drivers of costs after a TB diagnosis was made were nutritional supplements (MDR-TB = US$ 1262, DS-TB = US$ 189) followed by travel (MDR-TB = US$ 1019, DS-TB = US$ 44) and food (MDR-TB = US$ 498, DS-TB = US$ 31). The non-medical costs were the biggest contributor of the costs for both types of TB. On average, it costs an MDR-TB patient US$ 3722 for an entire episode of TB while for DS-TB patients it costs US$ 396 for an entire TB episode. Figure 1 highlights that the biggest costs for both types of TB are direct non-medical followed by the indirect costs and direct medical costs.

Table 4 shows the coping mechanisms (dissaving) that the TB patients adopt to defray the TB costs, and also shows the social consequences they encounter because of TB. In the survey, up to 571(48.5%) patients used at least one of the 3 dissaving strategies (took a loan, sold assets or used savings) ranging from 536 (47.2%) for DS-TB patients to 35 (81.2%) for MDR-TB. Regarding social consequences, 585 (49.7%) experienced food insecurity, 477 (40.5%) lost a job, 140 (11.8%) had a child interrupt schooling and 633 (53.7%) were socially excluded due to TB and 94 (8%) had divorce or separation from a spouse. The social consequences were worse for the patients in the poorest income quintile and MDR-TB patients. Up to 43.9% of survey households had received a form of social protection after a TB diagnosis was made, with the proportion bigger for MDR-TB patients (56.4%) than for the DS-TB patients (1.8%).

Table 5 presents the proportion of households experiencing catastrophic costs for different households. At a 20% threshold, 614 (53.1%) participants experienced catastrophic costs. The proportion experiencing catastrophic costs increased with lower thresholds at 15 and 10% i.e., 62.4 and 75.2% respectively. The proportion of respondents experiencing catastrophic costs decreased with increased thresholds; 25 and 30% i.e. 45.2 and 38.9% respectively. Regarding direct costs (direct medical and direct non-medical), 33.1% (383) of the respondents spent up to 20% of their annual household income and the same trend as for catastrophic costs was followed with changing thresholds.

In terms of direct medical costs, 3% (35) of the households used up to 20% of their annual income for these costs. A similar trend of proportions was followed with adjusted thresholds as for catastrophic costs (i.e., proportions increasing/decreasing) with decreasing/increasing thresholds.

Table 3 Estimated total costs borne by patients' households affected by TB, MDR-TB or all, median breakdown (USD† 2017 (95% CI)

	Costs	MDR-TB Mean,95%CI	DS-TB Mean,95%CI	Overall Mean,95%CI
Pre-diagnosis	Medical	4.11(0.27–7.94)	8.55(2.80–14.31)	8.50(2.79–14.20)
	Travel	6.48(3.84–9.13)	2.10(1.39–2.81)	2.15(1.45–2.86)
	Accommodation	0(0–0)	0.34(0.10–0.58)	0.34(0.10–0.57)
	Food	0.69(0.41–0.97)	1.10(0.33–1.87)	1.09(0.33–1.85)
	Nutritional supplements	0.44(0.15–0.73)	1.08(0.32–1.84)	0.80(0.20–1.41)
	Hours lost by patient and guardian multiplied by hourly wage	1.52(0.97–2.08)	1.7(0.67–2.72)	1.69(0.67–2.71)
Post-diagnosis	Medical	78.7(12.5–145.0)	16.2(9.2–23.2)	18.5(11.2–25.9)
	Travel	1019(896–1143)	43.9(34.0–53.7)	79.9(51.0–108.8)
	Accommodation	0.4(0–1.1)	1.4(0–3.4)	1.4(0–3.3)
	Food	498(353–642)	30.6(15.8–45.5)	47.9(25.8–70.1)
	Nutritional supplements	1263.(928–1597)	189(151–227)	225(173–277)
	Caregiver (guardian) costs	115(0–248)	25.2(14.7–35.7)	27.9 (17.3–38.5)
	Hours lost by patient and guardian x Hourly wage	1219(537–1899)	115(96–135)	156(116–196)
Medical costs		79.3(12.7–146)	20.0(11.7–28.2)	22.2(15.0–30.4)
Non-medical costs		2239(1742–2737)	198(162–234)	273(199–347)
Indirect costs	Human Capital Approach	1219(538–1901)	116.5(97–136)	157(117–197)
Dissaving/Coping Costs		183(19.0–348)	62.1(48.8–75.5)	66.6(50.3–83.0)
Total		3722(3071–4374)	396(337–456)	519(407–632)

Table 6 illustrates the risk factors for experiencing catastrophic costs. At both bivariate and multivariate analysis, participants belonging to the poorest expenditure quintile had higher odds of experiencing catastrophic costs i.e. bivariate analysis: OR (IQR): 23.5 (12.9–42.7) and multivariate analysis: 24 (13.2–43.8). HIV, age and gender were not associated with higher odds of experiencing catastrophic costs.

Figure 2 shows the impoverishment due to TB care. Even before TB, 51.8% of the respondents were already below the poverty level. Direct costs pushed an additional 9.9% of the TB patients below the poverty level

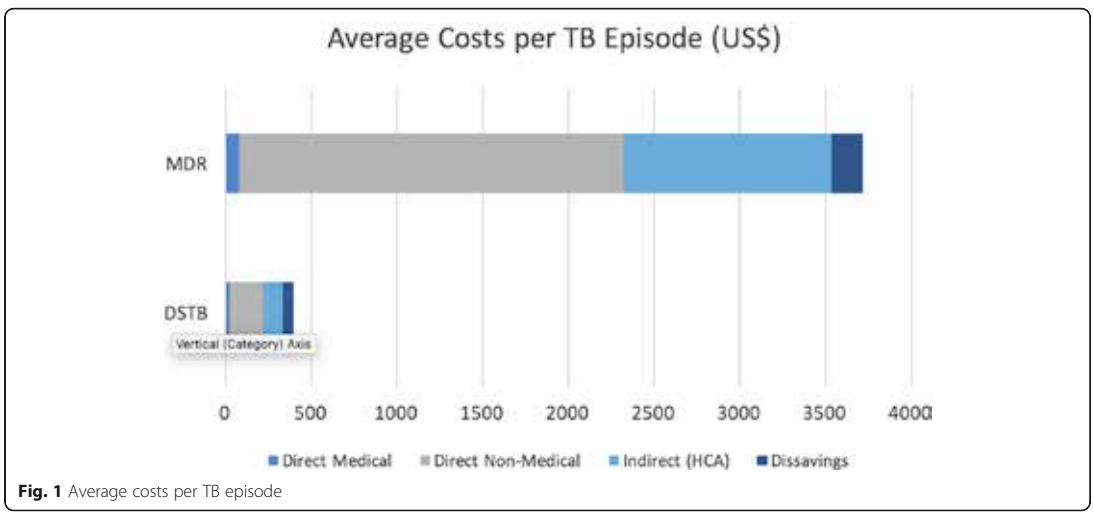

Fig. 1 Average costs per TB episode

Table 4 Dissaving mechanisms and social consequences for sample participants

	Expenditure Quintiles[a]						Treatment Group	
	Poorest (*N* = 219)	Less Poor (*N* = 229)	Average (*N* = 218)	Less Wealthy (*N* = 274)	Wealthiest (*N* = 215)	Overall (*N* = 1178)	DS (*N* = 1134)	MDR (*N* = 44)
Dissaving Strategies								
Loan	22.8%	29.1%	27.6%	27%	25.6%	26.3%	25.9%	35.5%
Use of savings	6%	8.6%	12%	14.1%	14.9%	11.2%	10%	39.9%
Sale of assets	29.4%	27.6%	30.1%	25.1%	22%	26.5%	25.4%	54.4%
Any of the three above	**45.5%**	**48.6%**	**54.3%**	**48.2%**	**47.6%**	**48.5%**	**47.2%**	**81.2%**
Food insecurity	60.9%	48.6%	49.7%	50%	43.2%	49.7%	49.3%	59.7%
Divorce/separated from spouse/partner	8.7%	6.6%	10.5%	5.3%	9.2%	8%	7.8%	10.6%
Loss of Job	45.1%	44.3%	40.2%	34%	40.9%	40.5%	39.9%	56%
Child interrupted schooling	8.7%	10.7%	11%	11.6%	15.4%	11.8%	11.9%	11.5%
Social exclusion	60%	55.3%	51.4%	53.3%	50.8%	53.7%	54%	46.1%
Any days of work lost	16%	9.2%	4%	2.4%	5.7%	7.2%	4.4%	2.6%
Household received social protection after TB diagnosis	3.2%	2.9%	5.1%	4.2%	3.5%	3.9%	1.8%	56.4%

[a]12 people excluded due to zero consumption data

while the indirect costs pushed an additional 2.6% below the poverty level.

Discussion

This national TB cost survey established that up to 53% of Ugandan TB affected households incur TB-related costs that are higher than 20% of their annual household expenditures, despite the free TB care policy. The survey also identified the main cost drivers as non-medical expenditure such as travel, nutritional supplements and food.

The proportion of 53% of TB affected households experiencing catastrophic costs is lower than was found in

Table 5 Households facing catastrophic costs

	Expenditure quintiles [a]					
	Poorest (*N* = 219)	Less Poor (*N* = 229)	Average (*N* = 218)	Less Wealthy (*N* = 274)	Wealthiest (*N* = 215)	Overall (*N* = 1155)
Households experiencing total (direct and indirect) costs above (%) - Human capital Approach						
10%	178 (81.4%)	162 (70.8%)	168 (77.2%)	214 (78.2%)	145 (67.5%)	868 (75.2%)
15%	157 (71.7%)	133 (58.4%)	141 (64.8%)	171 (62.4%)	118 (54.9%)	721 (62.4%)
20%	143 (65.4%)	106 (46.6%)	112 (51.3%)	152 (55.5%)	100 (46.4%)	613 (53.1%)
25%	119 (54.2%)	90 (39.4%)	98 (44.8%)	130 (47.4%)	86 (39.8%)	522 (45.2%)
30%	103 (47%)	76 (33.2%)	84 (38.7%)	117 (42.8%)	68 (31.7%)	449 (38.9%)
Number of households experiencing direct medical and non-medical costs above (%) annual household expenditure						
10%	123 (56.1%)	106 (46.2%)	115 (52.9%)	140 (51.2%)	83 (38.6%)	567 (49.1%)
15%	107 (48.9%)	86 (37.5%)	95 (43.4%)	117 (42.6%)	61 (28.5%)	465 (40.3%)
20%	89 (40.7%)	69 (30.4%)	81 (37.2%)	95 (34.8%)	48 (22.2%)	383 (33.1%)
25%	82 (37.3%)	53 (23%)	72 (32.8%)	79 (28.9%)	40 (18.6%)	325 (28.1%)
30%	74 (33.9%)	46 (20.2%)	64 (29.4%)	67 (24.4%)	29 (13.3%)	280 (24.2%)
Number of households experiencing direct medical costs above (%) annual household expenditure						
10%	18 (8%)	22 (9.6%)	14 (6.4%)	11 (4%)	7 (3.1%)	71 (6.1%)
15%	11 (5%)	12 (5.4%)	10 (4.3%)	9 (3.3%)	3 (1.4%)	45 (3.9%)
20%	9 (3.8%)	12 (5.4%)	6 (2.5%)	7 (2.6%)	1 (0.5%)	35 (3%)
25%	8 (3.4%)	11 (4.8%)	5 (2.3%)	6 (2.2%)	1 (0.5%)	30 (2.7%)
30%	8 (3.4%)	11 (4.8%)	5 (2.3%)	5 (1.7%)	1 (0.5%)	29 (2.5%)

[a]12 people excluded due to zero consumption data

Table 6 Odds ratios of experiencing catastrophic costs

	Univariate OR (95%CI)	Multivariate OR (95%CI)
Age		
0–14	Reference	Reference
15–24	0.6 (0.3–1.3)	0.4 (0.2–0.9)
25–34	0.7 (0.3–1.4)	0.5 (0.2–1)
35–44	0.7 (0.3–1.4)	0.5 (0.2–1)
45–54	0.6 (0.3–1.3)	0.4 (0.2–1)
55–64	0.9 (0.4–1.9)	0.5 (0.2–1.1)
65+	1.2 (0.5–2.8)	0.7 (0.3–1.8)
Sex		
Male	1 (0.8–1.4)	1 (0.7–1.3)
Female	Reference	Reference
Long delay (> 4 weeks before diagnosis)	1.3 (0.9–2)	1.1 (0.7–1.8)
HIV Status		
Positive	1 (0.7–1.4)	1 (0.7–1.3)
Negative	Reference	Reference
Expenditure Quintile		
Poorest	23.5 (12.9–42.7)	24 (13.2–43.8)
Less Poor	6.1 (3.9–9.6)	6.2 (4–9.8)
Average	3.9 (2.7–5.8)	4 (2.7–5.9)
Less Wealthy	2.3 (1.6–3.5)	2.3 (1.5–3.4)
Wealthiest (Reference)	Reference	Reference

similar studies done in Vietnam, Ghana and Myanmar [7, 12, 13] but higher than was found in Kenya and Indonesia [14, 15]. This difference could be explained by the differences in the geographic, health system and economic profiles of the countries.

TB patients incur direct medical, direct non-medical and indirect costs while they seek care. The study found direct non-medical costs to be the biggest drivers of catastrophic costs, with most of the costs incurred on nutritional supplements, travel and food. This is consistent with findings from similar surveys conducted elsewhere [7, 14, 16]. Data from previous studies have highlighted the contribution of food and transportation to the nearest TB care service on indirect costs; putting the figures at 50 and 37% respectively [17]. A study done in Philippines found out that paying attention to the nutrition costs could reduce the catastrophic costs by 5% [18]. In Uganda, MDR-TB patients receive enablers in form of food and transport vouchers [19]. This survey however shows that despite this, these patients still incur high costs on nutrition and food. Potential solutions could include increasing nutritional and transport support for MDR-TB patients and possibly introducing similar support in the DS-TB patients.

The study found out DS-TB patients spent US$396 for the entire TB episode while DR-TB patients spent up to US$ 3722. Previous work done in Uganda on costs of TB treatment analyzed from health services, patients and community volunteers' perspective showed the amount needed to successfully treat a new smear-positive TB patient was US$ 911.0 and US$ 391.0 using the hospital-based approach and community-based care approach respectively [20]. The costs incurred by MDR-TB patients

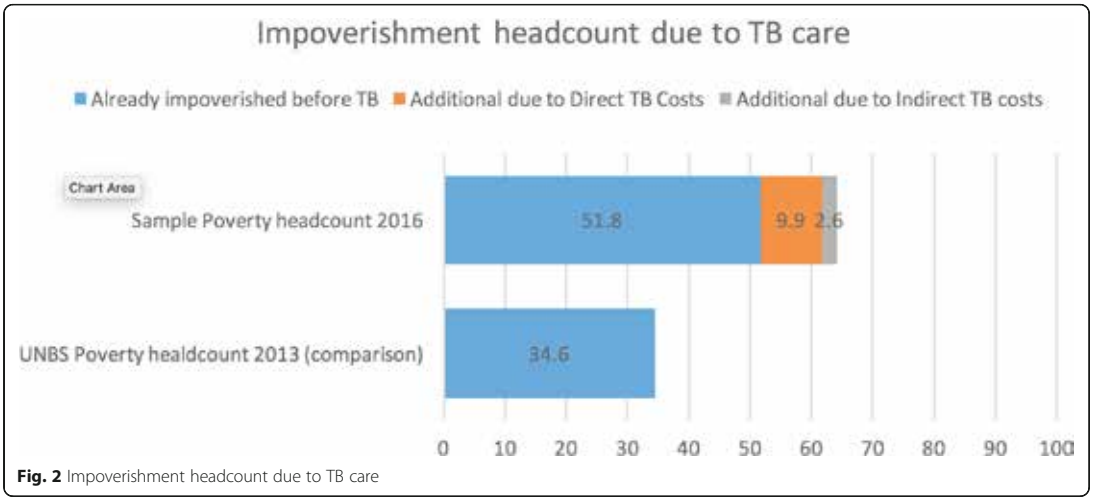

Fig. 2 Impoverishment headcount due to TB care

in previous surveys have been found to be higher than for DS-TB patients. In Ghana, costs per DS-TB episode were US$429.6 while it was US$659.0 for MDR-TB patients [12]. The amount spent on TB treatment is high in a setting like Uganda where the minimum monthly wage is US$ 36 [21], and 21.4% of the population are below the poverty level [22]. This survey established that even before a TB diagnosis is made, 52% of the TB patients were already below the poverty level, with an additional 12.5% pushed below the poverty level while in TB care. These costs represent a large economic burden to the Ugandan TB affected households, who are financially compromised in the first place.

TB patients adopt several coping measures in a bid to cushion against the TB-related costs. Close to half (48.5%) of the patients had adopted at least one coping mechanism. TB patient cost studies done elsewhere found borrowing money and taking loans were the widely used coping strategies for TB patients [5, 23]. The survey revealed respondents in the lowest income quintiles (poorest, less poor and average) were more likely to take up loans and sell assets as opposed to using up their own savings. This is hardly surprising as this group of patients do not normally have a stable income source compared to individuals in the high-income quintiles and thus hardly have any savings to draw upon.

TB patients encounter several social consequences while in care. In this survey patients experience encountered food insecurity (49.7%), job loss (40.5%), interruption in schooling for children (11.8%) and social exclusion (53.7%). The proportion experiencing these consequences was higher than was found in similar surveys [14, 16], and this could be due to differences in the health care systems, sample sizes and economic profiles of the countries.

In this survey, patients/households belonging in the poorest expenditure quintile had higher odds of experiencing catastrophic costs. TB has often been known as a disease of the poor since the burden follows a strong socio-economic gradient, and also poor communities have been known to have high incidences [23, 24]. TB catastrophic costs are thus disproportionately experienced by individuals who are already at a higher risk of TB. Despite the high proportion of HIV/TB co-infected patients in the survey, HIV didn't increase the odds of experiencing catastrophic costs. This possibly could be due to the implementation of the one stop shop model for TB/HIV services where TB and HIV services are offered to the clients at the same time and location.

The survey results provide a baseline upon which future catastrophic costs measurements could be compared and progress towards the high-level End TB Strategy target assessed. The survey results are disaggregated by TB resistance status (i.e., DR TB and MDR TB). However, the costs for the MDR TB patients need to be appreciated in context of the low number sampled. For example, the results showed costs incurred by the MDR TB patients for a TB episode are 10 times higher than for DS TB patients. It's possible there is an over estimation for the MDR TB costs owing to the small number of MDR TB patients included in the survey. Despite this, we believe the costs would still be higher even with bigger numbers as has been seen in other studies that have sampled more MDR TB patients [14, 16, 25].

Based on the survey findings, we recommend a policy shift in order to be able to protect the TB patients against catastrophic costs. This could include operationalization of the national health/social insurance, strengthening and enforcement of legislation related to social protection and intersectoral collaborations as the effects span several sectors.

Limitations

The survey included a few MDR-TB patients. Subsequent surveys should purposely involve more MDR-TB patients in the sample. Patients also were asked costs previously incurred which might have led to a recall bias. Recall bias mainly affects cost estimates for the pre-treatment period and the approach to only interview persons in intensive phase about diagnostics costs was intended to minimize this type of bias. Also, most of the costs were estimated as the study was cross-sectional in nature. The survey also did not include costs after treatment as some of the direct and indirect costs of TB for the patients and the household can extend beyond the treatment period.

Conclusion

In conclusion, this survey established that over a half of TB affected households in Uganda face catastrophic TB care expenditure, with the major cost drivers being nutritional supplements, travel, and food. This expenditure results in adverse coping behaviors such as selling assets, taking loans and using savings at high rates among the patients.

Abbreviations

TB: Tuberculosis; HIV: Human Immunodeficiency Virus; MDR: Multi drug resistant; DTU: Diagnostic and Treatment Unit; USD: United States Dollars; WHO: World Health Organization; DS-TB: Drug Sensitive Tuberculosis; UGX: Uganda Shillings; DOT: Directly Observed Therapy

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Authors' contributions

IGB, BK, AN, ST, FM, KM, AK, SD, EB, CM and PL designed the study, WM, RT, RS and BK participated in data acquisition. SK, CB, LM and IGB conducted data analysis. WM and BK wrote the original draft of the manuscript. RKM, PL, IGB, AN proof read the manuscript. All authors read and approved the manuscript.

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Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate
All patients gave written informed consent and were compensated for their time and inconvenience during the interview. Assent was obtained for participants under 18 years while their parents gave parental consent. Ethics approval was obtained from the Mulago Hospital Research and Ethics committee (MREC 1028) and the Uganda National Council for Science and Technology (ADM 194/212/01).

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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Protocol and Operational Procedures for the implementation of a Differentiated HIV Service Delivery Model in North-Western Tanzania

PAPER

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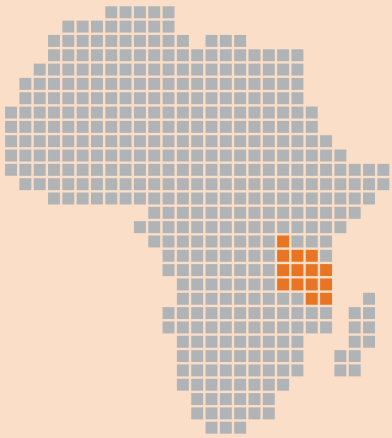

Protocol

Protocol and Operational Procedures for the Implementation of a Differentiated HIV Service Delivery Model in North-Western Tanzania: A Multicentre Implementation Research

Running Title: A Multicentre Implementation Research

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Abstract

World Health Organization's recommendation to "treat all diagnosed with HIV" challenges the capacity of health systems, especially in low- and middle- resource countries. Current Tanzanian National Guidelines for the Management of HIV and AIDS views differentiated service delivery (DSD) models as promising approaches to improve HIV services. Nonetheless, social, economic and health system factors greatly influence their efficacy and sustainability, and call for context-specific evidence. *Objectives*: This implementation research protocol outline plans to assesses the feasibility and effectiveness of a DSD intervention for stable anti-retroviral therapy (ART) clients in Tanzania. *Methodology*: Quantitative and qualitative methods will be employed to assess implementation which started in July 2018 and will run until July 2021 at four HIV clinics (CTC) located in Shinyanga (2), and Simiyu (2) regions. Stable clients (age >5 years, receiving ART first-line regimen ≥ six months, viral load (VL) ≤50 copies/ml, and no current illnesses) are offered the opportunity to join a club — community-based groups of 25-30 clients living in the same area, who receive drug refills, and health monitoring every three months (annual VL at the CTC) led by lay-workers. *Findings*: Primary outcome will be the proportion of ART clients maintaining virologic suppression within the club model over the intervention period (measured at 12, 24, and 36 months). Secondary outcomes will include retention in care, client and provider costs, and client perspectives, stratified by geographical location. *Conclusion/Recommendations:* Research finding will be published in peer-reviewed journals; and is potentially useful for informing policy and the HIV program in Tanzania.

Keywords: Differentiated Care, Decentralized Care, HIV Service Delivery Model, Club Model, Tanzania, HIV/AIDS

Introduction

The 2016 guidelines of the World Health Organization (WHO) recommend HIV service delivery based on a 'Differentiated Care framework' in order to achieve Universal Test and Treat (UTT) [1]. The goal of differentiated service delivery (DSD) is — firstly to provide different groups of people living with HIV (PLHIV) with client-centred services [2]. Secondly, to cushion the impact of increased demand for HIV services on over-burdened health systems especially in low- and medium- income countries (LMICs). As DSD gains popularity, evidence about its acceptability, adaptability, and effectiveness in different settings, is required. Four types of DSD models have been described, all addressed to stable clients: client-managed groups, healthcare worker-managed groups, facility-based individual models, and out-of-facility individual models [2].

Client-managed group models, for example anti-retroviral therapy (ART) groups such as Community ART group (CAG) and Community ART support groups (CASGs) have been piloted in Mozambique and Lesotho. Compared with standard clinical care, they show better outcomes that is — reduced costs, increased time savings, improved retention, and reduced loss to follow up (LTFU) [3-6]. Healthcare worker-managed group , for example — ART adherence clubs (ACs) and fast track refills (FTRs) are implemented in South Africa, Malawi, and Guinea [7-11]. Evidence suggests that AC leads to higher rates of retention and viral suppression compared to standard clinical care, both at individual sites and at scale [12]. Out-of-facility individual models (such as community-based ART distribution, mobile outreach ART delivery, and home delivery) have been implemented in Uganda and Swaziland. All of these models show promising results in terms of retention, mortality, reduced virologic failure and costs [13, 14]. Lastly, facility-based individual models, such as within-facility AC, are one of the most widely implemented DSD models. Evidence of effectiveness of ACs has been reported from different studies suggesting increased cost effectiveness [15], reduction in client time spent accessing health care [16], improved adherence to ART [17], in addition to better retention and viral suppression, than standard clinical care [18].

In 2017, the Tanzanian Ministry of Health, Community Development, Gender, Elderly and Children [MOHCDGEC], released the current National Guidelines for the Management of HIV and AIDS, based on the 2016 WHO guidelines recommending DSD [19]. Despite a wealth of evidence from elsewhere, there is a substantial lack of evidence about the efficacy and sustainability of DSD models in Tanzania. To address this gap, a DSD club model is currently being implemented in two socio-cultural and geographical settings in North-western Tanzania. The clubs are led by Community Health Workers (CHWs), supervised and coordinated by nurses. CHWs have been employed effectively for similar interventions in this setting, such as to improve retention in care, and adherence to ART among HIV positive mothers [20] and stable ART clients [21]. However, the potential role and contributions of this cadre of workers beyond health promotion is yet to be officially recognised in Tanzania as the latest guidelines still recommend that all DSD be conducted by any trained healthcare worker namely Doctor, Assistant Medical Officer, Clinical officer or Nurse [19].

This protocol outlines studies which aim to generate evidence on the implementation of this CHW-driven DSD club model. It provides details not just on the planned studies but also on the club model which is essential to guide the replicable implementation of the model. Findings will contribute evidence to inform the Tanzanian government's decision-making process about which type of DSD model to support and consider in the national strategy.

Methodology

Study Objectives

The overall aim of this implementation study is to assess the feasibility and effectiveness of a hybrid model of CHW-driven HIV DSD, 'Clubs and Hubs' in treating 'stable' ART in two Tanzanian regions, Shinyanga and Simiyu. There will be three specific research areas.

Clinical/epidemiological

Assesses the primary outcomes that is — effectiveness of the club model in terms of viral suppression, adherence, linkage to care and retention, and factors associated with these outcomes in routine care settings.

Social science studies

Gain insight into client and health care worker experiences in the clubs and hubs, implementation fidelity, and adaptations of the intervention protocol to clients' care needs in practice.

Costing studies

Investigate costs (client and provider), cost structure and drivers, and cost-effectiveness of delivering DSD in these settings. Additionally, estimate the quality of life among clients, and quality of care from clients' and providers' perspectives. Table 1 gives details of the study objectives and outcomes.

Setting

An estimated 1.4 million people are living with HIV in Tanzania with approximately 81,000 new cases of HIV annually among adults aged 15 to 64 years [22]. The overall adult HIV prevalence is estimated at 5%, but the regional prevalence varies widely across the country, from less than 1% to more than 11% [23]. Over 3,000 health facilities across Tanzania currently provide HIV care and treatment [23]. The recently published 2016-2017 Tanzania HIV Impact Survey estimates that 60.9% of PLHIV aged 15 to 64 years in the country know their serostatus. Among these, 93.6% are on ART while 87% are virally suppressed among those on ART [22].

In the regions of Shinyanga and Simiyu, the HIV prevalence is estimated at 5.9% and 3.9%, respectively [23]. Intervention sites include four Care and Treatment Centres (CTCs) also known as the hubs: Bugisi Health Centre (BHC) and Ngokolo Health Centre (NHC) in Shinyanga region; Songambele Health Centre (SHC) and Mwamapalala Dispensary (MD) in Simiyu region. The sites were purposively selected among health facilities owned by the Catholic diocese, to represent the wide variability of socio-cultural and economic realities existing within the Tanzanian context. Shinyanga region boasts of several truck routes and mines which attract a mobile and migrant population. BHC is located in a rural area, has a high client load and wide catchment area with clients traveling up to 3 hours to clinic. NHC is located within Shinyanga town, an urban area. In Simiyu region, the population is more widely dispersed. MD is located in a remote rural area about 15 kilometres from the regional centre. Similarly, SHC is located in a very remote area. As in 2018, the number of stable HIV+ clients in care at BHC was approximately 1300; both MD and NHC had an average of 200, while SHC had 100.

Study design

This implementation research will employ quantitative and qualitative methods to assess the effectiveness, and cost of CHW-driven club model for the management of stable ART clients within the study settings. The overall intervention period will last for 36 months. Appropriate cohort and evaluation designs will be employed to assess the primary study outcomes over the entire intervention period at 12, 24 and 36 months after enrolment in the club, depending on the duration of enrolment at the end of the study. Secondary outcomes will be assessed concurrently in nested costing, cross-sectional, mixed methods, and qualitative studies.

Participant recruitment, inclusion, and exclusion criteria

Only HIV+ clients who are enrolled in care at one of the intervention CTCs and are eligible for the studies, will be included. Stable ART clients will be defined as outlined in the Tanzanian HIV treatment guidelines (see Table 2). Accordingly, only clients with viral load (VL) of 50 copies/ml or less will be included in proposed studies as stable. However, all investigators agreed that if clients experience virologic blips that is — VL between 50–200 copies/ml [24], while remaining adherent, they continue to be managed as being stable. Participants for the clinical/epidemiology studies will be recruited during the CTC and club enrolment process. Participants for other nested studies will be recruited as appropriate from among eligible clients as they access care at the CTC clinics and the clubs.

Sampling strategy/ Sample size

Clients fulfilling the eligibility criteria (see Table 2) will be actively offered to join the club model at each visit to the clinic. On the basis of available data as of June 2018 from the CTC database, 60% and 70% of clients in Bugisi and Ngokolo, respectively, totalling 1500 clients were estimated eligible for enrolment. Clients who refuse to join the club or clients who do not meet the eligibility criteria remain in standard care.

Eligible clients will be determined per study and a representative sample will be sampled either randomly or purposively as appropriate at the hubs and in clubs. For the social science studies, four clubs per hub will be selected, two each in a remote and nearby location from the hub.

Sample size for each study planned will be determined separately depending on specific research question. All quantitative studies will however be designed to have power ≥80% and two-sided alpha of 0.05 to determine outcomes. Appropriate assumptions of differences and coefficients of variation to account for clustering where necessary will be based on evidence from literature and factored in calculations. Reaching saturation will guide the number client or groups interviewed for qualitative studies.

Consenting procedure

All clients who consent to participate in the club model will receive information about the implementation research before enrolment and during the first club meeting. Clients refusing to participate will be approached to be interviewed to gain their perspective. All participants in the nested studies will be taken through a separate consent procedure which will include access to their CTC files. This will allow for the triangulation of data collected.

Intervention

ARV clubs

Clubs are a group of 25-30 stable ART clients living in the same geographic area, who meet in their community at a venue of club members choice for example - homes, public spaces such as school classrooms or village executive offices, and if preferred, a designated space in the hub. The decision to establish a club triggers a sequence of activities (see Appendix 1). The club-nurse consults the Home-Based Carer [HBC] and potential club-members, on the best location and meeting-time of the Club. The time (working day *vs* weekend, timeframe during the day, etc.) and venue of the club meeting are agreed amongst the members of the club with the coordination of the club-responsible. After the initial agreement, a club meeting calendar will be established and communicated by the club-responsible to the members. The next appointment date will be written in the client's CTC 1 card. Clubs meeting duration are 90 minutes on average. Three distinct activities, taking approximately 30 minutes each, are conducted during club-meetings: 1. adherence counselling and health education session focusing on ART adherence, side effects, prevention of HIV transmission, and general health status; 2. brief symptoms screening, including TB screening and body weight monitoring; and 3. drug refilling and documentation.

The club schedule includes a club meeting (every 3 months), clinical consultation and review by a clinician at the hub plus laboratory monitoring – haematology and biochemistry (every 6 months) and VL monitoring (every 12 months).

Responsibilities in the Club model

Key staff involved in club activities include a CTC clinician, a trained nurse (club nurse), and a CHW (club-responsible). See Appendix 1 for details of their respective roles. In brief:

CTC Clinician

A clinician at each hub will be responsible for three main tasks: enrolling clients into clubs, collecting signed informed consent, and conducting scheduled bi-annual visits (and any unscheduled visits) during which stability is reviewed and request scheduled laboratory investigation such as VL.

Club nurse

S/he will be mainly based at the hub and will have overall responsibility for organizing the clubs. With oversight from the CTC pharmacist, s/he will pre-package anti-retrovirals (ARVs) and other medications for club use, provide training on the job to the club-responsible, and follow up clients referred back to the hub for any reason or who come for unscheduled clinical consultations. S/he communicates laboratory test results to the club-responsible to pass on to club members and document all interactions into appropriate registers.

Club-responsible

S/he will be a CHW who will be trained and supervised by the club nurse. Each CHW will oversee around 10-15 clubs to keep club operation manageable. S/he will liaise with the HBC to coordinate club meetings. S/he will receive the pre-packed medications for distribution and inform the club nurse within 24 hours of any clinical issue or concern raised during meetings. After each meeting, s/he will complete the club register, write a meeting summary, and conduct home visits together with the club-chair to clients who missed the meeting. Clients who miss the meeting for two consecutive times will be referred back to the hub.

Club chair

S/he will be an expert-client and club member residing in the community where the club is. Usually the HBC in that locality, s/he will be responsible for contacting each member before meetings and tracing club-members who fail to come to meetings. The club-chair will accompany the club-responsible on home-visits.

Data collection and management

Clinical data will consist mainly of routine HIV care and treatment data collected through the Tanzanian data management system of the National AIDS Control Program (NACP), under the MOHCDGEC. The data will be obtained from the CTC3 database which contains client-level data collected on standardized CTC cards at every clinic visit. Additional data required will be collected through specific data collection tools for example - HVL database for adherence determination, HIV testing registers for linkage efficiency determination, and club register.

Social science data will consist of focus-groups discussions with clients on experiences regarding receiving care through the clubs. Discussions will focus on adherence, family support, health system, socio-economic, socio-cultural, mental, and physical challenges, and mutual support. Perceptions of club-nurses and club-responsible about their responsibilities and information-provision will be collected similarly. Structured observations will provide information on information sharing among club members, and among club members and club staff, as well as care practices in the club meetings. Additional data about the club development and meeting processes in practice will be collected employing structured observations.

Costing for DSD services from a provider's perspective will be conducted through a micro-costing approach. We will estimate all the quantities and unit costs for all inputs

(capital, recurrent, personnel) needed to deliver this service. Observations of practice and interviews of healthcare providers will be used to allocate shared resources. As such, we will aim to estimate the real-world costs, reflecting current practice. Cost and utilisation data will be collected at different levels of service delivery that is - Community, Hub, DSD clubs using service delivery records such as - CTC2 and financial records. Start-up costs will not be included as we aim to reflect the cost of delivering the service only. We will be estimating economic costs, shadow prices will be applied for funded goods for example - ARVs or services such as ad-hoc staff employed to support intervention. In addition to the provider costs, we will also collect data on the financial burden to clients and their households (client-incurred costs like transportation, productivity losses).

Data for the nested cross-sectional study will be collected at the hubs and clubs using specific structured data-collection tools and questionnaires. For these and the social science data (not routinely collected for the NACP), data systems will be developed to capture data from registers, standardized forms, and questionnaires.

Data storage will consist of the safe retention of paper-based documents, digital data and devices connected with the electronic-based data systems. For documents and digital data that are part of the NACP, the National Guideline on HIV and AIDS data management will be followed [19]. For storage of data outside the scope of the National Program, project-specific standard operating procedures will be formulated to ensure data security. Implementation of these procedures will be facilitated by means of staff training.

Data Analysis

Quantitative

To assess the primary and secondary outcomes of the study, data will be described as proportions with 95% confidence intervals. Clients' characteristics will be described by means and standard deviations, median and interquartile ranges, or proportions and 95% confidence intervals, as applicable. Comparisons will be made using Chi-2 tests and student t-tests, as applicable. Appropriate uni- and multivariable regression models will be used to assess factors associated with study outcomes.

Qualitative

Qualitative data will be analysed using NVivo software. An inductive thematic approach will be applied. Data will be analysed for geographical location, gender, and age-group with a specific emphasis on diverging care needs or care strategies for gender and generation of stable clients. All qualitative client-level data will explicitly be triangulated with clinical outcome data.

Economic evaluation

Capital costs will be annuitized over their expected useful life. Economic costs will be depreciated using the local Tanzanian discount rate, with a 3% discount rate used in a sensitivity analysis. Financial costs will be depreciated using straight-line depreciation. Costs will be presented in the local currency and in US Dollars (USD). We will use the average exchange rate for the year of cost data collection to convert costs into USD. Any costs encountered in the past will be inflated using the local consumer price index (CPI) of Tanzania, before converting to USD.

Conclusion

While evidence suggests positive outcomes for all forms of DSD, the success recorded is not without challenges. Stigma, inadequate resources to manage increasing number of AC, gender dynamics in male-dominated societies, and data quality issues with paper-based health information systems, all remain issues in many African settings [25-29]. Emerging issues including not having conducive meeting places within the community, a growing erosion of social support as clubs become mere drug pick-up points, non-adherence to club protocols and widely varying preferences by geographical and socio-cultural contexts, all provide the impetus for more setting-based evidence of

DSD interventions such as we propose [30-33]. The diverse socio-cultural, geographic, and economic environment existing within our study setting presents a unique opportunity for auditioning a plethora of DSD interventions. Most importantly, data driven policies can be formulated to support on-going efforts and inform future strategic direction.

Ethical Approvals

Ethical approval from the National Institute for Medical Research (NIMR) has been obtained [NIMR/HQ/R.8a/Vol. IX/2711] along with an amendment approval capturing the additional nested studies [NIMR/HQ/R.8c/Vol. I/674]. The principal investigator is responsible for submission to and communication with NIMR. He will also ensure conduct of the study in accordance with the protocol. Several publications in peer-reviewed journals and presentations at national and international conferences are planned.

Conflict of interest

None of the authors has declared any conflict of interest.

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Author statement

PDN, JDK, EG and NO wrote the draft of this paper. JDK, NO, AB and SH provided input in writing of the study protocol and the development of the study materials (club register and informed consent form). SH, TRDW, AB, EvP, GG and GP contributed to reviewing and editing of the manuscript. GS, SM, AP, and BD reviewed the final version of the manuscript.

All authors read and approved the manuscript.

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Table 1: Objectives, outcome, and process indicators of the study

PRIMARY OBJECTIVES	OUTCOME INDICATORS	PROCESS INDICATORS
To evaluate the effectiveness of the club model in terms of treatment adherence, viral suppression, and loss to follow-up in urban and rural area in two geographical regions of Tanzania	Proportion of PLHIV maintaining virological suppression (VL <50cp/ml)* within the DSD. Proportion of clients lost to follow-up in clubs (defined as two consecutive meetings missed and no information available through CTC file consultation).	• Number and characteristics of clients referred back from Clubs to Project sites. • Number and characteristics of clients with suboptimal adherence (defined as missed ART doses on ≥2 days during the preceding 30 days). • Number and characteristics of clients with virological failure (VL >50cp/ml) measured at month 12, 24 and 36 post enrolment. • Number and characteristics of clients lost to follow-up in clubs. • Proportion of clients lost to follow up traced back through the Club staff
SECONDARY OBJECTIVES	**OUTCOME INDICATORS**	**PROCESS INDICATORS**
To examine how the DSD model (Clubs and Hubs) evolves from the original model through client and CHW/Club nurse practices.	1) Original structure of the Clubs and how these differ per hub/geographic location/type of leadership, etc. 2) Practices in Clubs (medication distribution, registration, how are decisions to send clients back made, small businesses, etc.) 3) Key factors that influence the development and changes of practices in Clubs. 4) Which types of Clubs (key determinants) provide the best retention in care services?	• Number of clients preferring to go back from the clubs to the CTCs. • Reasons for preferring to go back from the clubs to the CTCs. • Number of times club practices divert from protocol (pill-counting, weighing, referral).

To examine if the DSD model (Clubs and Hubs responds to the care needs of client	1. an overview of care needs of stable clients and how these are different by age and gender 2. Care practices provided by the different actors within the DSD-model (including self-care) 3. Gaps and inefficiencies in DSD care delivery in specific geographical and social settings (i.e. mobile populations) 4. A mapping of information-sharing on care needs different actors in the Club model	• Number and characteristics of club clients with sub-optimal adherence/self-care • Number and characteristics of club clients retained in care.
To assess total and unit costs, cost structure and drivers of service delivery	Costs per person-year on ART in the DSD model, by type of client.	• Cost per person diagnosed during community-based campaigns compared to facility-based testing Costs per person initiating ART at CTCs. • Costs per first year of ART by type of client. • Costs per person-year on ART after first year by type of client. • Costs per person-year on ART (excluding drugs) by type of client. • Total DSD model cost
To assess clients and provider perspectives comparing DSD with standard care	1. Costs to clients (financial and economic) 2. QALY 3. Health-related Quality of life (HRQoL) – Overall and dimension specific 4. Clients and providers perspective quality of care	• Medical costs per clinic or club visit e.g. lab tests and Non-medical costs per clinic visit e.g. transport, food • Productivity losses e.g. time loss, income loss • EQ-5D mean index score and VAS score • HRQoL across physical, emotional, functional, social, and cognitive functioning dimensions • Objective and subjective measures of structures, processes, and outcomes of care

PLHIV: people living with HIV; DSD: Differentiated Service Delivery; VL: viral load; CTC: Care and Treatment Centre (HIV Clinic); QALY: quality adjusted life years; EQ-5D: EuroQol 5 dimension; VAS: visual analogue score

Table 2: Inclusion and exclusion criteria

Inclusion Criteria (Stable Clients)	Exclusion Criteria (Unstable Clients)
Age above five years	Age below five years
Received ART for at least six months;	Current ART for less than 6 months
Have no adverse drug reactions that require regular monitoring	Presence of an active OI (including TB) in the past six months
No current illnesses (OIs and/or unstable co-morbidities)	Presence of comorbidity poorly controlled
Optimal adherence to clinic visit appointments for the past six months	Poor adherence to scheduled visits (defined as >1 missed scheduled visit or >1 drug refill through treatment supporter in the past six months)
Average adherence to ART >95% during last six months	Suboptimal adherence to ART (defined as missed ART doses on ≥2 days in a month during the preceding six months)
On first line ARVs, with undetectable VL (≤50 cp/ml)	Recent detectable VL >50 cp/ml
	People who Inject drugs
	Pregnant women and lactating women
	Clients on second line ART regimen

OI: opportunistic infection; VL: viral load

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Universal coverage and equity

Perception of basic package of health services' impact on health service delivery and mortality among residents of Wulu County, South Sudan

PAPER

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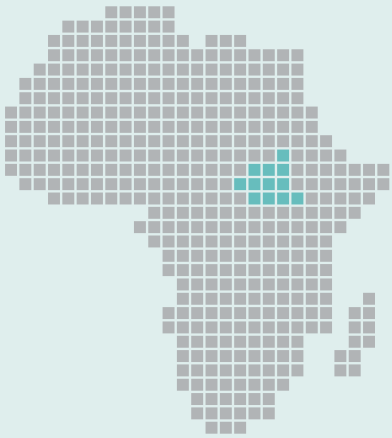

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COVID-19 in Italy: momentous decisions and many uncertainties

PAPER

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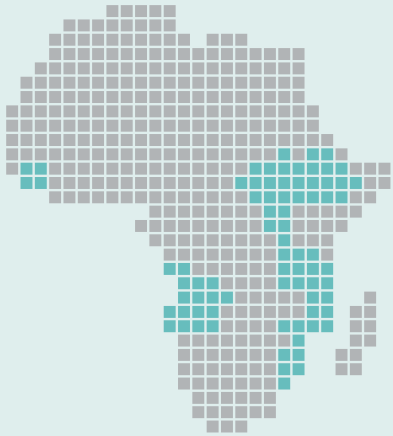

Correspondence

COVID-19 in Italy: momentous decisions and many uncertainties

On March 10, at 00:30 h, the official news was posted on the website of the Italian Ministry of Health: a new decree effective until at least April 3 limits the movement of individuals in the whole Italian national territory unless strictly motivated (in written form) by reasons of work or health. Schools, museums, cinemas, theatres, and any other social, recreational, or cultural centre must stay closed. Any gathering in public spaces is forbidden, including sporting events and funerals. Most shops must stay closed. Those selling essentials, such as supermarkets or pharmacies, need to ensure a distance of at least 1 m between customers.[1]

These measures are without precedent and aim to contain the coronavirus disease 2019 (COVID-19) epidemic in Italy after an increase in total deaths of nearly 100% in the 48 h before the decree. They follow a series of restrictions of increasing severity, starting on Feb 23, 2020, with the lockdown of the geographical area, Codogno, where the first COVID-19 cases occurred. The number of positive cases, according to the most recent estimates as of March 16, 18:00 h, is 27 980, which is about 2·8 times higher than 1 week before (10 149 cases recorded on March 10).[2,3] Among these, 2339 (8·4%) are health workers, a proportion that has been increasing over time.[2] With 2158 deaths, the estimated case fatality rate stands at 7·7%, which is about twice the rate reported in the first weeks of the epidemic.[2,3] Overall, 11 125 (39·8%) patients have been hospitalised and 1851 (6·6%) admitted to intensive care units (ICUs).[2,3]

The economic and psychological impact of the epidemic is enormous. Many sectors of the Italian economy, which is largely based on family-owned small businesses, are suffering. The tension is palpable. On March 9, riots broke out in prisons, leading to seven deaths and 18 hospitalisations in Modena and 50 escaped prisoners in Foggia.[4]

These difficult decisions on public health measures were taken without the support of official, real-time data being available for the public on key surveillance indicators. Before March 5, when total deaths were 105, there was no description available of the characteristics of the deceased cases in Italy. Later data, still not including all deaths, revealed only one death in a patient under the age of 50 years,[5] and 85·5% of patients presenting with at least two pre-existing pathologies.[6] While an open-access monitoring dashboard containing several essential indicators was created on March 8, no official Italian Government websites provide a full description of the characteristics (both age and comorbidities) of cases in the ICU, nor of those hospitalised, while unofficial and sometimes conflicting data are circulating in the media. Of the multitude of people tested for COVID-19 in Italy, as well as in other countries, it is not clear how many were asymptomatic versus symptomatic, and it is not clear whether a homogeneous criterion for testing has been applied. Data are lacking on the prevalence of the disease among asymptomatic populations, so the real prevalence of COVID-19, its spectrum of presentation, and the real mortality rate all remain unknown. Moreover, reported case fatality rates across countries are very heterogeneous, with Germany reporting very few fatalities compared with other European countries with similar populations and health systems that reported notably higher case fatality rates, thus suggesting a lack of uniform case definitions (table).

Clearly, better data are needed to support decision making and to build public awareness. As priority actions, we call for (1) a uniform system to count deaths and estimate case fatality rates across different countries, (2) surveillance of key characteristics (eg, age, pre-existing pathologies) of both deceased patients and those admitted to the ICU to identify populations at risk and to estimate health service needs, and (3) more research to identify the prevalence and characteristics of the infection in the overall population and to better estimate COVID-19 death rates. Strong collaboration is needed at different levels and across countries to optimise public availability of reliable real-time data.

	Confirmed cases	Deaths	Estimated case fatality rate
China	81 077	3218	4·0%
Italy	27 980	2158	7·7%
Iran	14 991	853	5·7%
South Korea	8236	75	0·9%
Spain	7753	288	5·7%
France	5380	127	2·4%
Germany	4838	12	0·2%
Switzerland	2200	13	0·6%
USA	1678	41	2·4%

Only countries with more than 1500 cases are included. Data are from WHO,[7] except for Italy, where Ministry of Health reports[3] were used. COVID-19=coronavirus disease 2019.

Table: **Reported deaths from COVID-19 on March 16, 2020**

We declare no competing interests.

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COVID-19 in Africa: what is at stake?

PAPER

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COVID-19 in Africa: what is at stake?

on May 22, 2020

SARS-CoV-2 has arrived in Africa and, progressively, almost all African countries have closed their borders and imposed various levels of "lockdowns" in the hope of limiting the spread of the pandemic, taking measures similar to those taken elsewhere in the world. The pandemic is producing shocking statistics and tragic consequences in developed regions of the world, such as in Europe and North America. What could be the impact in the more fragile context of the African continent? It is mostly in Sub-Saharan Africa that the pandemic gives greatest concern.

This article elaborates on the conditions in which Africa is facing the COVID-19 pandemic. It presents a series of "weaknesses" of the African health systems, but also at the social-economic level, which could facilitate the spread of the infection. Protecting factors specific to the African continent with respect to the spread of coronavirus are also explored.

The article concludes with a series of considerations, namely: the risk, in health emergencies, of the suspension of essential prevention and treatment health services; the difficulties of analysing current pandemic trajectories, since available data in a number of African countries are scarce and uncertain; and the need to prioritise triage based on clinical case definition and presumptive diagnosis as a consequence of the paucity of large-scale diagnostics. The analysis is aimed in particular at the Sub-Saharan region.

Weakness of the Health Systems

Africa, despite having the greatest infectious disease burden in the world, has a weak epidemiological surveillance system. Disease surveillance programmes in Africa often involve too much paperwork, too many dissimilar instructions and terminologies, conflicting priorities, etc. In its recently launched Investment Case for Vaccine-Preventable Disease Surveillance in the African Region 2020-2030, the World Health Organisation (WHO) highlights the drastic consequences that could be in store for the region if countries do not invest in disease surveillance efforts, including a US$22.4 billion economic burden over the next decade. This estimate was conducted before the advent of the SARS-CoV-2 pandemic.

Africa's health systems have been badly damaged by the emigration of their health professionals, with extremely low doctor-to-patient ratios in comparison to more developed countries. For example, in 2015 there were 0.22 physicians per 1,000 people in Sub-Saharan Africa, while in the EU there were 3.6.

The weakness of the infrastructure system results in a paucity of diagnostic and laboratory centres, which are present almost exclusively in urban areas and mostly cater to a private clientele. These labs have the ability to process a limited number of tests per day. Testing for COVID-19 is hugely important for the containment of the pandemic: it needs viral genome detection, which requires advanced facilities, expensive equipment and well-trained staff. Even some industrialised countries struggle. Despite the fact that Africa CDC drives to help countries in setting up COVID-19 diagnostic testing, and the WHO supports them through supply flights for essential equipment, the situation remains critical. Furthermore, the required kits and reagents are produced for a global market and so Africa is

competing with many far more affluent countries for scarce supplies; the severing of most aerial transport links aggravates the situation further.

Another infrastructure limit is the reduced intensive care unit beds capacity. For example, the three most populated Sub-Saharan African countries, Nigeria, Ethiopia and the Democratic Republic of the Congo, have respectively 0.2, <1.0, and <1.0 intensive care unit beds per 100 000 population (in France by comparison, there are 11.6 intensive care unit beds per 100 000 population).

It is important to note that the mere presence of an intensive care unit does not guarantee the ability to effectively care for critically ill patients. Indeed, the ability to comply with sepsis guidelines is minimal in most of Sub-Saharan Africa, despite the presence of an intensive care unit, because highly trained medical staff needed for intensive care units are also extremely scarce. The paucity of ventilators is much lamented, but also supplementary oxygen – a comparatively simple yet life-saving intervention – is often not available in many parts of Africa.

The shortage of personal protective equipment for health personnel is another problem, one which has also hit many European countries hard in the last few weeks. Should the pandemic expand in Africa, this raises concerns about potentially high morbidity and mortality rates among health care workers.

Pre-existing comorbidities, above all HIV/AIDS, tuberculosis and malaria, could increase the susceptibility to COVID-19 or increase the risk of severe disease. Additional factors are related to the lack of treatment. For example, 25.7 million HIV positive people live in Africa: 64% of them – 16.3 million – take antiretroviral treatment. However, the remnants – 9.4 million – are not taking medication. This means a large population with weakened immune systems, which is likely to increase the risk of severe COVID-19.

Socio-economic Factors That Could Further Worsen the Pandemic

A number of socio-economic factors, which influence health conditions, can further aggravate the general picture. 319 million people in Sub-Saharan Africa are without access to reliable drinking water sources, which raises concern of the risk of coronavirus transmission via the faecal-oral route. In addition, hand-washing and good hygiene, major measures for preventing COVID-19, are impossible when people lack access to clean water.

According to FAO, 20% of Africa's population is undernourished, a condition that makes it more vulnerable to infections. About 43% of the African population (587 million people in 2019) live in urban areas. There are cities with more than 10 million people (Cairo, Kinshasa and Lagos) and several others with a population between 5 and 10 million. About half of the urban population in Africa lives in overcrowded suburbs, with poor access to running water and decent latrines where confinement is unrealistic.

Other complications are related to the lack of a welfare system, which necessitates daily work in order to survive. In Sub-Saharan Africa, the labour market is characterized by widespread informal employment (which represent 89% of total employment), and a huge presence of small and medium-

sized enterprises (90% of business units), which are the drivers of growth in the region. Finally, conflicts and violence make the management of a pandemic even more complicated. At least twenty African countries suffer from armed conflict or strong social tensions. As a result, 6.3 million refugees and 17.7 million displaced people in Africa live in overcrowded camps with poor sanitation and hygiene conditions.

Potential Factors of Optimism

The list of negative factors could be – at least partially – counterbalanced by a series of other factors that are potentially useful in containing the epidemic.

Firstly, COVID-19 affects younger people less frequently and severely. The median age of the African population is 19.7 years, and 60% of the population is under 25 years of age.

Secondly, the warm climate promotes more time outdoors than indoors, which could limit the spread of the infection.

Thirdly, the SARS-CoV and MERS-CoV global outbreaks did not affect Africa on a large scale. The contribution of factors such as the effect of UV light on the survival of the viruses on surfaces, immunological differences of populations and pre-exposure to other coronaviruses is unclear.

Fourthly, the closing of national borders in most African countries, which took place early on, in some cases even prior to the reporting of any COVID-19 cases, may have reduced the spread of the virus significantly. In addition, in rural areas, the reduced mobility of populations might keep specific parts of countries from becoming infected.

Fifthly, previous epidemics – for example the Ebola outbreak – could provide valuable lessons in how to handle the current pandemic, at least in some countries.

Finally, the enormous improvement in antiretroviral treatment coverage including lab support over the past decade may also benefit the COVID-19 response. Platforms such as the Genexpert for tuberculosis testing can also be used for COVID-19 tests, provided affordable test devices become available in sufficient numbers.

Additional Reflections and Conclusions

The economic implications of the pandemic in Africa have only been briefly mentioned here. But the role of the state, international agencies and the international community in conditions such as the present one is beyond question. Africa will need indirect help in the form of debt cancellation, new international trade regulations, which will protect its production and export capacity, and the reorientation of international aid to health.

In health emergencies, especially in epidemic emergencies, one of the most frequent risks is that the new emergency absorbs resources destined for other disease conditions, which – unlike COVID-19 – are more easily preventable and have known therapeutic interventions: common infectious diseases in

are more easily preventable and have known therapeutic interventions: common infectious diseases in paediatrics, obstetric complications, vaccinations campaigns, etc. The burden of avoidable morbidity and mortality of common diseases could therefore inflict more damage and claim more victims than the epidemic itself. Indeed, such a burden was seen in the recent Ebola epidemic in Africa. Therefore, the aid and, more importantly, other forms of sustainable assistance that would change the socioeconomic trajectory of African countries – if and when it will be sent in the difficult times we are facing – will have to keep the health system in great consideration.

The data currently available on the pandemic trajectory in a number of African countries are scarce and uncertain due to the limited testing currently performed. They do not allow for an objective analysis to reflect the actual trend . In consideration of the factors discussed above, the trend of the pandemic in Africa should be interpreted by taking into account the following factors: the under-notification of cases, the slower development of the epidemic, a lower incidence compared to other continents.

European experience shows that even with tested information systems, official data are controversial due to poor standardization. Data governance in emergency contexts in Africa is historically difficult. Some evidence also shows that several African countries exert a tight control over public data and information. For example, recently the WHO rebuked the government of Tanzania for its refusal to pass on information on some alleged cases of Ebola, the country denying that it had any such cases. In addition, it is not uncommon for journalists to be subject to intimidation by public authorities for the disclosure of information regarding COVID-19.

Catastrophic predictions were made during previous epidemics (e.g. the AIDS epidemic in the 1980s-90s, the more recent Ebola epidemic, etc.) which, despite the dramatic situation, did not occur. They benefited from massive, albeit often delayed, investments into infection prevention and control, testing, and treatment. Therefore, caution should be applied on the extremely negative predictions of the present pandemic.

Finally, in Africa, particularly in the Sub-Saharan region, there is no nation-wide health system capable of coping with a wave of patients suffering from acute respiratory failure. Provision of intensive care for massive numbers of patients requiring assisted breathing and other organ-failure-support would be very challenging and likely impossible. As in Europe, and likely on a greater scale, any epidemic pressure will have to be addressed with home care under supervised self-medication. And because large-scale diagnostics will not be affordable, it will be necessary to prioritise triage based on clinical case definition or presumptive diagnosis.

COVID-19 in Africa – Letter to the editor

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The potential of mobile health clinics in chronic disease prevention and health promotion in universal healthcare systems. An on-field experiment

PAPER

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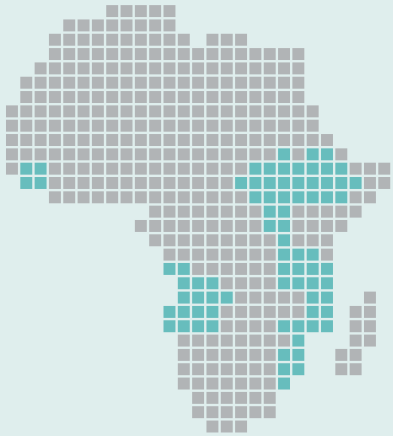

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The potential of mobile health clinics in chronic disease prevention and health promotion in universal healthcare systems. An on-field experiment

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Abstract

Background: Mobile health clinics (MHCs) are recognized to facilitate access to healthcare services, especially in disadvantaged populations. Notwithstanding that in Europe a wide-ranging background in mobile screening units for cancer is shared, evidences about MHCs targeting also at other non-communicable diseases (NCDs) in universal health coverage systems are scarce. The aim of this study was to describe the population attracted with a MHC initiative and to assess the potential of this tool in prevention and control of NCDs.

Methods: Our MHC was set up in a railway wagon. Standard body measurements, finger-stick glucose, total cholesterol and blood pressure were recorded. Participants were asked about smoking, physical activity, diet, compliance to national cancer screening programmes and ongoing pharmacological treatment. One-to-one counselling was then provided.

Results: Participants ($n = 839$) showed a higher prevalence of overweight/obesity, insufficient intake of vegetables, sedentary lifestyle, and a lower compliance to cancer screening compared with reference population. Our initiative attracted groups at higher risk, such as foreigners, men and people aged from 50 to 69. The proportion of newly diagnosed or uncontrolled disease exceeded 40% of participants for both hypertension and hypercholesterolemia (7% for diabetes). Adherence rate to counselling was 99.4%.

Conclusions: The MHC was effective in attracting hard-to-reach groups and individuals who may have otherwise gone undiagnosed. MHCs can play a complementary role also in universal coverage health systems, raising self-awareness of unreached population and making access to primary health care easier.

Keywords: Mobile health units, Noncommunicable diseases, Health promotion, Primary health care, Healthcare inequalities

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Key-points

- Mobile health clinics (MHCs) facilitate access to healthcare service.
- Scarce literature on MHCs for NCDs other than cancer in universal coverage systems.
- Our MHC detected undiagnosed conditions, bad lifestyles, lower compliance cancer screening.
- Effective in attracting foreigners, men, aged 50–69.
- MHCs can play a complementary role also in universal coverage systems.

Introduction

Noncommunicable diseases (NCDs) – including cardiovascular diseases, cancer, chronic respiratory diseases and diabetes – are by far the leading cause of death according to the latest estimates. In 2016, they were responsible for 71% of all deaths globally. In Italy, NCDs account for 91% of all deaths, [1]. The prevalence of NCDs is expected to rise over the next decades due to the ageing of population and an increase of risk factors [2]. Lifestyle counselling activities, screening initiatives, management of risk factors and treatment of disabilities are intended to become even more predominant in planning public health strategies [3].

The burden of NCDs does not affect population in an equal manner. As a whole, European National Healthcare Systems (NHSs) seem to be effective in narrowing the gap due to health inequalities originating from socioeconomic status (SES), nationality and gender [4, 5] in terms of mortality rates [6]. However, European NHSs seem not to be equally effective in reducing risk factors: prevalence of smoking, overweight/obesity, unhealthy diet and physical inactivity is higher in most disadvantaged sections of the population [7].

Socioeconomic inequalities heavily affect the participation in screening campaigns and contribute to worse outcomes [8] Thus, any effort made to extend the benefits of screening to individuals who may have otherwise gone undiagnosed – or diagnosed at a late-stage – appear reasonable.

In this respect, mobile health clinics (MHCs) could make a significant contribution, facilitating the access to healthcare services by reducing issues related with transportation and avoiding long waiting times and complicated administrative procedures [9, 10]. MHCs are used in a wide range of low and middle-income countries [11] and in the United States (US), where they are monitored by the national programme *Mobile Health Map* [9]. In the US, they are shown to facilitate access for minority groups, to attract people who usually exhibit poorer healthcare-seeking behaviours such as male patients [11–13] and to improve patient adherence to therapy [9].

The idea of screening for NCDs with MHCs dates back to 1960 [14, 15] and the employment of mobile units for cancer screening is a consolidated practice in Europe and Italy [16]. Nonetheless, literature about the efficacy of MHCs specifically addressed to prevent and control NCDs – except for early detection of cancer – is lacking.

Mobile screening units are very effective in increasing community access to cancer screening [2]. In Italy, the so-called *'mammography vans'* are commonly used within the national breast cancer screening program, both in association with fixed clinics and in exclusive use, particularly in regions with extended rural areas [17]. In addition to cancer screening, MHCs are often used in setting up information campaigns on the prevention and control of NCDs [18] or as research units with the aim of describing the prevalence of NCDs within the community and the level of chronicity management in the different parts of the country [19, 20]. The main difference between the mobile units for cancer screening and the MHC for NCDs lies not so much in in the way the services are delivered – in both cases through a mobile clinic – but rather in the strategy and purpose of use: while the former are used as a way of offering health services that are routinely implemented in a national screening program, services offered in MHCs for NCDs are to be considered as part of information and awareness-raising strategies. Services for the prevention and control of NCDs are provided in primary care services (such as general practitioners' surgeries and prevention services), but a nationally shared framework is missing, and the service is provided on a case-by-case basis.

Although primary health care services are 'offered to all' (free or co-payment) in our context, 'accessibility for all' in real life may still pose a challenge due to issues – such as disparities in the socio-economic status – that are not directly addressed by the NHS. The access to quality primary care for all is a major concern also in Europe. Insufficient access to primary care is a defeat for the individual and the society, as it ultimately leads to an increase in the disease burden at both levels. There is a need for new strategies that can overcome barriers and provide effective, accessible and affordable primary care for all [21].

MHC could be a useful strategy to reach this goal, but more evidences are needed. When testing the validity and the efficacy of MHC in preventing and controlling NCDs, it is important to consider the national health system context. In this work, we illustrate an initiative that could be studied and considered as a best practice. A MHC initiative with the main purpose of providing screening for NCDs and counselling for health promotion and prevention was set up in Veneto Region, Italy in 2017. The aim of the present study was to (i) describe the population attracted with a MHC initiative in a

Universal Health Coverage System; (ii) assess the potential contribution of this initiative in the prevention and the control of NCDs.

Methods

The MHC initiative was funded and organized by the Regional Health Authority and a local non-governmental organization between November and December 2017. The MHC was set up in a dedicated railway wagon and visited the main train stations in the Veneto Region (Italy), whose population is about 5 million inhabitants. Access to the MHC was completely free of charge for attendants; the MHC was open from 9 AM to 7 PM (Mon-Sat) and from 9 AM to 2 PM on Sundays for a total of 21 days of service. Local media were used to raise awareness about the initiative.

Biometric screening and counselling were provided into two adjacent wagons. Standard body measurements including height, weight and waist circumference were recorded. Finger-stick glucose, total cholesterol and blood pressure were recorded. Participants were asked about gender, age, nationality, education, employment, smoking habit, physical activity, diet and compliance to the national cancer screening programmes against cervical, breast and colorectal cancer. Individuals were also asked about the use of medications for high blood pressure, diabetes or high cholesterol. Based on medical findings and patient's medical history, participants were provided with counselling about smoking, physical activity, healthy diet and cancer screenings; when needed, they were referred to their general practitioner for further investigations. The staff consisted of medical doctors and nurses employed in the Italian National Health Service (or retired from it) and medical students. They agreed to participate on a voluntary basis and they did not receive any compensation for their time. All staff members had received a specific training on counselling prior to the start of the MHC initiative.

Sociodemographic, behavioural and health-related characteristics of participants were compared with the general population in the same Region. The following cardiovascular risk factors were considered: high blood pressure (≥ 140/90 mmHg); high blood total cholesterol (≥ 200 mg/dL); high fasting blood glucose (≥ 126 mg/dL); overweight and obesity (BMI ≥ 25 kg/m^2); smoking. According with the self-reported physical activity and latest WHO *Global Recommendations on Physical Activity* [22], participants were classified as *'active'* if they reported at least 150 min of moderate-intensity activity or 75 min of vigorous activity per week; *'sedentary'* when they reported no physical activity; *'partially active'* if in the between. The number of fruits and vegetables portions consumed per day was classified in no servings; one or two servings; three or more servings.

The potential of this initiative was assessed in terms of: (i) proportion of newly diagnosed or uncontrolled disease; and (ii) rate of adherence to counselling service following the biometric screening procedures.

Quantitative analyses were conducted with IBM SPSS® Statistics v23; χ^2 tests were performed to compare the study population with the reference population in terms of sociodemographic and health-related characteristics. *P* values were reported.

Results

Individuals who participated in the initiative were 839. The median age was 55 years (Q_1:38; Q_3: 65). Sociodemographic, behavioural and health-related characteristics are shown in Table 1: 54.1% of attendants were males; foreigners were 16.6% while they are the 9.9% of the general population in the region. The proportion of overweight and sedentary lifestyle was higher than the general population, while the daily fruit and vegetable intake was lower, as well as the compliance to routine cancer screenings. On the other hand, the proportion of smokers was lower. The percentage of individuals who had received already a pharmacological treatment for hypertension, diabetes or hypercholesterolemia was lower compared with the general population. The study population was characterized by a more sedentary lifestyle compared with the reference population (23.0% vs. 15.2%). While females were more sedentary than males (26.3% vs. 16.9%, $p < 0.01$), men were more overweight (65.0% vs. 44.1%, $p < 0.01$) and used to eat less fruit and vegetables (74.1% vs. 65.9%, $p = 0.03$), as shown in Table 2. Among foreigners, the proportion of smokers and diet poor in vegetables was significantly higher than Italians (21.2% vs. 13.0%, $p = 0.01$ and 83.3% vs. 67.9%, $p < 0.01$, respectively). The obesity rate was the highest among people with secondary education (63.9%), while it was the lowest among people holding a university degree (46.4%). The prevalence of obesity was the highest among retired people, even though the prevalence of sedentary lifestyle was the lowest (13.8%). The highest proportion of smokers was recorded among unemployed (28.8%).

In Table 3, the proportion of newly detected cases and uncontrolled cases of the chronic conditions investigated is shown. A *'new case'* is defined by an out of range value following biometric screening without a pharmacological treatment, while *'uncontrolled cases'* are characterized by a previous start of pharmacological therapy. Patients with a new diagnosis of high blood pressure were 27.8% of the study population, while new cases of diabetes and hypercholesterolemia were 5.0 and 37.5%, respectively. Cases of uncontrolled hypertension reached 12.8% of the sample, while uncontrolled diabetes and hypercholesterolemia accounted for 2.0 and 2.7%, respectively.

Table 1 Characteristics of participants of MHC initiative compared with general population living in the same region

		Study population		Reference Population		
Sociodemographic characteristics[a]		**n**	**%**	**n**	**%**	**χ2 test (p)**
Gender	Female	385	45,9%	2.512.962	51,2%	< 0.01
	Male	454	54,1%	2.394.567	48,8%	
Age	0–9 y	0	0,0%	435.947	8,88%	< 0.01
	10–19 y	22	2,6%	466.277	9,50%	
	20–29 y	117	14,0%	472.853	9,64%	
	30–39 y	78	9,4%	574.591	11,71%	
	40–49 y	101	12,1%	802.881	16,36%	
	50–59 y	195	23,4%	758.442	15,45%	
	60–69 y	192	23,0%	589.202	12,01%	
	70–79 y	96	11,5%	478.430	9,75%	
	80+ y	33	4,0%	328.906	6,70%	
Nationality	Italians	687	83,4%	4.422.052	90,1%	< 0.01
	Foreigners	137	16,6%	485.477	9,9%	
Education[b]	None or Primary School	75	9,4%	1.326.872	29,0%	< 0.01
	Lower Secondary School	159	19,9%	1.378.977	30,1%	
	High School	393	49,3%	1.450.833	31,7%	
	Degree	170	21,3%	421.682	9,2%	
Employment	Employed	394	50,3%	2.081.000	49,6%	< 0.01
	Unemployed	52	6,6%	151.000	3,6%	
	Inactive	337	43,0%	1.967.000	46,8%	
	Retired	221	28,2%	NA	NA	
	Student	97	12,4%	NA	NA	
	Housekeeper	19	2,4%	NA	NA	
Health-related conditions[c]		**n**	**%**	**n**	**%**	**χ2 test (p)**
Smoking habit	Smoker	114	16,4%	889	21,8%	< 0.01
	Ex-smoker	124	17,8%	841	20,6%	
	Non-smoker	457	65,8%	2.345	57,6%	
Hypertension drug treatment		104	14,9%	759	20,1%	< 0.01
Diabetes drug treatment		20	2,9%	146	3,6%	0.34
Hypercholesterolemia drug treatment		35	5,0%	792	24,8%	< 0.01
BMI	Underweight/Normal (< 25 kg/m2)	314	45,8%	2.402	59,2%	< 0.01
	Overweight (25–30 kg/m2)	242	35,3%	1.260	31,0%	
	Obese (> 30 kg/m2)	130	19,0%	393	9,8%	
Physical activity	Sedentary	135	23,0%	618	15,2%	< 0.01
	Partially active	99	16,8%	1.217	29,9%	
	Active	354	60,2%	2.231	54,9%	
Daily Fruit and Vegetable Intake	None	56	11,8%	70	1,7%	< 0.01
	1–2 servings	278	58,8%	1.794	44,0%	
	3+ servings	139	29,4%	2.211	54,3%	
Compliance to national Breast Cancer Screening[d]	Yes	152	80,9%	1.145	86,1%	0.15
Compliance to national Cervical Cancer Screening[e]	Yes	173	70,0%	1.453	90,9%	< 0.01
Compliance to national Colorectal Cancer Screening[f]	Yes	251	64,9%	1.277	77,2%	< 0.01

[a]ISTAT, Italian National Institute of Statistics; data warehouse updated on 1 January 2017
[b]ISTAT, Italian National Institute of Statistics; national census, 2011
[c]PASSI, national surveillance program, Veneto Region data warehouse, 2014–2017; only 18–69 years old included
[d]only target population included (females 50–69 y)
[e]only target population included (females 25–64 y)
[f]only target population included (both sexes 50–69 y)

Table 2 Distribution of modifiable risk factors by baseline characteristics

		Risk factors							
		Smokers		Overweight/obesity (BMI > 25)		Sedentary lifestyle		Less than 3 servings fruit/veg	
		%	χ2 test (p)	%	χ2 test (p)	%	χ2 test (p)	%	χ2 test (p)
Gender	Female	13.1%	0.18	44.1%	**< 0.01**	26.3%	**< 0.01**	65.9%	**0.03**
	Male	16.4%		65.0%		16.9%		74.1%	
Age	10–19 y	31.8%	**< 0.01**	14.3%	**< 0.01**	50.0%	**< 0.01**	75.0%	0.05
	20–29 y	15.4%		33.9%		23.5%		71.0%	
	30–39 y	23.1%		42.1%		19.0%		85.7%	
	40–49 y	15.0%		65.0%		27.9%		78.9%	
	50–59 y	19.7%		59.5%		25.3%		68.2%	
	60–69 y	10.5%		64.7%		18.0%		62.6%	
	70–79 y	6.3%		62.1%		9.5%		67.1%	
	80+ y	3.0%		60.6%		15.4%		79.2%	
Nationality	Italians	13.0%	**0.01**	55.5%	0.97	20.0%	0.14	67.9%	**< 0.01**
	Foreigners	21.2%		55.6%		26.5%		83.3%	
Education	None or Primary School	16.2%	0.31	58.1%	**0.02**	14.3%	0.57	70.6%	0.99
	Lower Seconday School	15.7%		63.9%		20.4%		70.1%	
	High School	15.9%		54.5%		22.5%		69.9%	
	Degree	10.1%		46.4%		21.1%		71.4%	
Employment	Employed	16.1%	**< 0.01**	58.0%	**< 0.01**	25.1%	**0.02**	71.8%	0.35
	Unemployed	28.8%		48.1%		21.1%		80.0%	
	Retired	7.3%		63.2%		13.8%		64.7%	
	Student	18.6%		34.0%		28.6%		71.4%	
	Housekeeper	5.3%		52.6%		22.2%		71.4%	

Out of 497 participants who were suggested to undergo at least one of the counselling services provided in the adjacent wagon, 494 agreed to receive the counselling (rate of adherence: 99.4%); 238 participants received counselling about smoking, 273 on cancer screenings, 352 about healthy diet and 294 about physical activity.

Overall, 319 participants (38%) were invited to contact their general practitioner; 6 (0,7%) were referred to the nearest emergency department because of a hypertensive or hyperglycaemic ongoing crisis.

Discussion

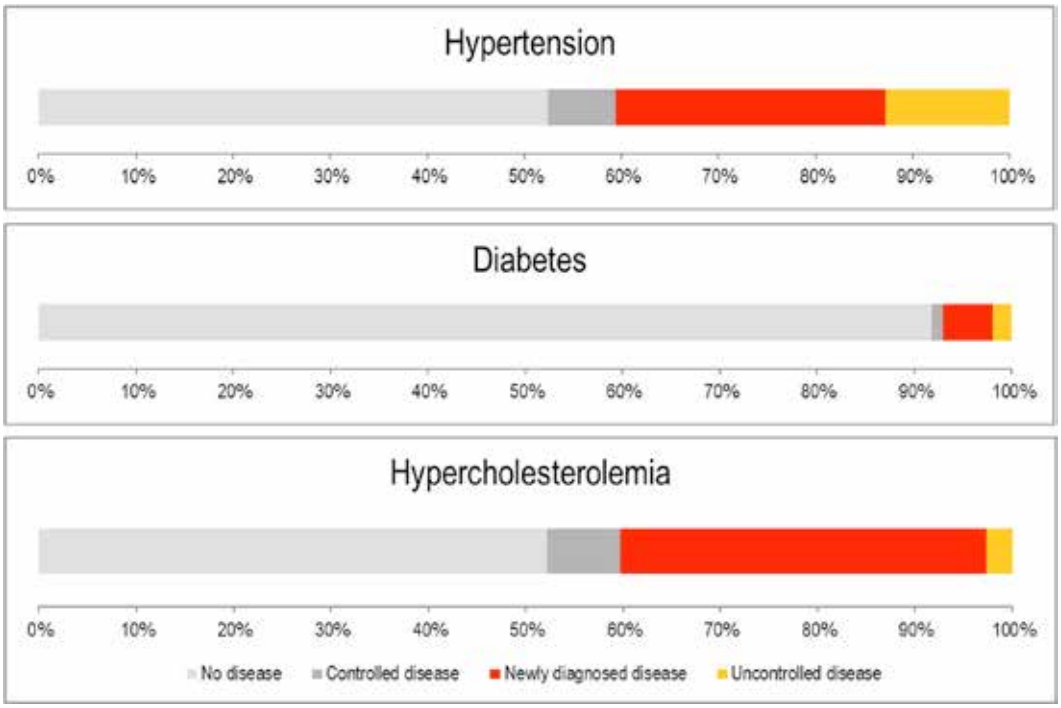
Participants in our initiative showed substantial differences in sociodemographic, behavioural and health-related characteristics compared with the general population. The MHC initiative was able to address to individuals who showed more risk factors compared with the general population, consistently with other studies [9, 11, 12].

The proportion of males, 50–69-year-old individuals, foreigners and people with higher education was significantly higher than the general population.

The ability of attracting the male population (54.1% of participants) is consistent with other experiences [12, 13]. Usually men show lower access to traditional health care facilities than women [13]. This may be due to peculiar features of the MHC: waiting times are limited, opening hours extended and people are not expected to book an appointment or to request a leave from work.

Foreigners may experience further barriers: navigating the healthcare system could be a complex task to achieve; primary health services might be ignored although offered free of charge; linguistic, cultural or psychological barriers and intimidation by healthcare settings may limit the access [11]. As a result, foreigners tend to overuse emergency departments where access appear easier and more immediate [23, 24]. This situation unavoidably leads to an increase in healthcare costs for the inappropriate use of emergency departments and to a widening of health inequalities due to a lack of prevention and management of chronic diseases, that are estimated to affect four foreigners out of ten in Italy [25, 26]. According to our results, foreigners show more behavioural risk factors for NCDs: smoking, sedentary lifestyle and lower intake of fruit and vegetables. Many studies confirm that immigrants participate less

Table 3 Distribution of newly diagnosed and uncontrolled conditions investigated



than natives in organised cancer screenings [22–24] and eat less portions of fruits and vegetables [27, 28]. The prevalence of NCDs and their risk factors should not be underestimated in foreigners as our data and other studies suggest [29, 30]. In the long-term this scenario may even worsen in relation to the process of getting acquainted to western unhealthy dietary and voluptuary habits [31–33].

Overall, participants showed a higher prevalence of unhealthy behaviours such as an insufficient daily intake of fruit and vegetable, sedentary lifestyle, overweight and a lower compliance to cancer screening (except for screening against breast cancer) compared with the general population. However, the proportion of participants who had started already a pharmacological treatment for hypertension, diabetes or hypercholesterolemia was lower than the general population. This finding may be interpreted as a warning light of insufficient access to primary care facilities – where these conditions are usually primarily diagnosed – rather than an evidence of a better health status, especially in the light of a higher rate of risk factors.

As a direct consequence, our MHC initiative was able to diagnose a remarkable number of new cases or cases of uncontrolled disease. The prevalence of previously undetected hypertension (27.8%), hypercholesterolemia (37.5%) and diabetes (5.0%) was analogue to other comparable international experiences [34, 35]. This offered to participants the chance to get acquainted with their own health condition and encouraged them to seek primary health care for an appropriate long-term follow up [36–38]. The counselling activity about the importance of getting below the recommended targets could play a key role in increasing patients' adherence to the therapy [9, 39].

MHCs were shown to be effective in improving health outcomes in the population, whether they are considered as 'alternatives' to more traditional healthcare models or not [21]. MHCs can reach cross-sections of the population that are at higher risk or stigmatized and help in identifying additional cases of NCDs: without these services, diagnoses and treatment would be delayed and subsequent management further complicated in more vulnerable groups [40, 41]. Findings from our MHC initiative definitely move in this direction: the proportion of newly diagnosed or uncontrolled disease, collectively, exceeded 40% of participants for both hypertension and hypercholesterolemia, although this percentage was significantly lower (7.1%) for diabetes. These results show how the MHCs bear an unexpressed potential.

Adherence to therapy and lifestyle changes have a pivotal role in the management of NCDs. Evidences show that MHCs are effective in sustaining patients to achieve these goals [21]: for example, screening and counselling services provided in the MHC described by Song et al. showed to be effective in lowering blood pressure in hypertensive patients [42]. Unfortunately, our MHC initiative was a *'première'* in our context and data on follow-up visits were not available; however, the considerable proportion of new diagnoses and uncontrolled disease in our study together suggest a high value of this tool and brief counselling activities are shown to be effective also when provided only on a single occasion [43].

In addition, results are overwhelmingly encouraging in the light of the fact that the rate of adherence to counselling interventions proposed was very close to 100% (99.4%).

In 38% of cases, participants were suggested to consult their general practitioner for a comprehensive and long-term management of chronicity. Unfortunately, we could not verify if participants actually consulted their general practitioner after the counselling service – data-linkage was not possible – but past studies showed the ability of MHCs in connecting community members with both medical and social services and the efficacy in reducing emergency department and hospital admissions for NCDs and their complications [21, 44].

In our study, adherence to counselling was very high. This may imply a positive impact given the fact that: (i) one-to-one counselling activities are strongly recommended to increase adherence to cancer screening [45]; (ii) counselling was shown to improve dietary and physical activity behaviors and reduce smoking habit, cholesterol levels, blood pressure, weight, glucose levels, and incidence of diabetes [46, 47].

The key of the success for a high adherence rate to counselling may be due to several factors: (i) by providing a more intimate, welcoming and less intimidating environment, the MHC put patients at the heart of the process, bringing healthcare into community spaces familiar to patients, allowing them to feel the sense of a more complete involvement and self-efficacy [11, 43]; (ii) all services provided were completely free; (iii) opening hours were broader than primary care 'traditional' facilities; (iv) the counselling was offered on the same occasion of biometric screening – the two services were provided in two adjacent wagons. Where practicable, it makes sense to integrate the provision of multiple services to enhance participation [48].

There is a strong evidence that reducing structural barriers and facilitating access to health care services – by reducing the distance between the service delivery settings and the target population, or changing service hours to meet patients' needs – are successful strategies that increase the adherence rate to screening for breast, cervical and colorectal cancer [45]. For this reason, MHCs for early detection of cancer are commonly used in Europe. In Italy, mobile vans for mammography have been used extensively in residential communities. Worldwide, cancer screening has been the most common service provided by MHC, but they are not the only ones: the services offered by MHCs are manifold, from primary to tertiary care [21]. The preventive services include screening for HIV and sexually transmitted diseases, ophthalmological diseases, cardiovascular conditions and diabetes, but also health promotion activities such as vaccinations or counselling or initiating preventative care, managing chronic diseases and enabling self-efficacy [9, 21].

Given the success of mobile units for cancer screening, it makes sense to extend the use of MHCs for other NCDs, implementing screening and counselling activities specifically addressed to prevention and management of chronicity. Khanna and colleagues showed how generally people do not consider MHC as substitute for primary healthcare facilities [21]; in this regard, our experience suggests that MHCs in our context can complement primary care by intercepting unexpressed needs. To achieve this goal, MHCs should be extended to reach even more remote rural areas and not only cities, resorting also to means of transportation other than train.

MHCs offer more opportunities for underserved populations to assess their health conditions and learn how to manage their health properly, by facilitating access to healthcare [42]. MHCs represent an extraordinary resource for those who would not otherwise ask for assistance to a health centre, delaying both diagnosis and treatment. The core of the management of chronic conditions is to support adherence to necessary medication and lifestyle changes: evidences suggest that MHCs are effective in helping patients meet these challenges [9].

Our MHC initiative occurred in the main train stations of the region. This may imply that individuals who do not live in urban areas or do not use trains were under-represented in the sample. Data were not available for all participants in every single required fields, leaving a slightly different denominator for each computation due to missing values. Some data were self-reported by the participants and we had no tools to validate them. Because of the *white coat effect*, having relied on a single measure of blood pressure may have led to an overestimation of the prevalence of hypertension among those screened. Unlike many other documented experiences, our MHC initiative was a one-time event, making follow up and monitoring of outcomes not possible. However, brief counselling activities are shown to be efficient and cost-effective in improving health status also when provided only on a single occasion [43].

Conclusions

Although MHCs could be considered redundant in a universal health coverage system as there is in Italy, our findings challenge this concept. Also in settings where primary care services are free of access and free of charge, MHCs can have a complementary role making a substantial contribution in reducing sociodemographic inequalities [9]. MHCs can intercept those cross-sections of the population which are usually difficult to reach, providing more easily accessible care and serving as a help in navigating traditional healthcare facilities. Currently in Italy, a national-based screening programme for NCDs other than cancer has not been implemented. The evaluation and the management of risk factors are carried out by general practitioners, each one individually. Our findings suggest that MHCs could be considered as a powerful and complementary tool in providing screening and counselling for NCDs (acceptance rate of receiving counselling was 99.4%) and further extending the proportion of people that can be reached.

Despite there being relatively few studies, the literature is able to provide a solid degree of evidence necessary for quantitative and qualitative assessments of the role of MHCs in reducing the impact of NCDs, not only through cancer screening.

Since the main difference between the MHC for cancer screening and the MHC for CDs lies not so much in in the way the services are delivered – in both cases through a mobile clinic – but rather in the strategy and purpose of use, an important impact in reducing morbidity and mortality of other NCDs can be expected through the adoption of this service delivery strategy, following the success of MHC-based strategies for cancer screening. This work is intended to be a valuable support in building evidence in this regard.

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Authors' contributions

CB: conceptualization; methodology; supervision. SC: validation; review and editing. MF: Formal analysis; methodology; writing original draft. SEB: Data curation. FR: project administration. GP: investigation and review. The authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

In accordance with the Italian legislation, data were treated with full confidentiality. Written informed consents were obtained and collected separately from body measurements and participants' characteristics in order to ensure the anonymous nature of the data. This study complies with the Declaration of Helsinki.

Consent for publication

Not applicable.

Competing interests

All the authors have no conflict of interest to declare.

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Publisher's Note

Situational brief: deportations and irregular migrants during the Covid-19 pandemic

PAPER

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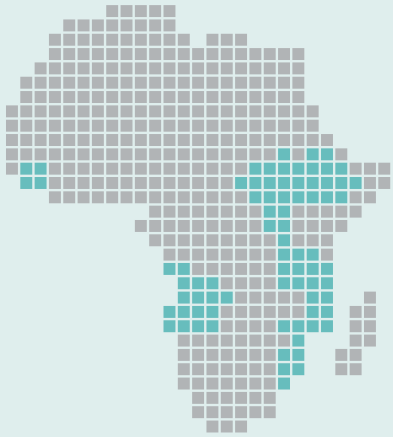

1 June 2020

SITUATIONAL BRIEF: DEPORTATIONS AND IRREGULAR MIGRANTS DURING THE COVID-19 PANDEMIC

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The World Health Organization (WHO)[6], the Civil Society Action Committee[7] and the Lancet Migration global collaboration[8] are amongst many organisations that have advised governments against returning irregular migrants during the Coronavirus disease 2019 (COVID-19) pandemic. The expulsion of irregular migrants to under-prepared countries puts migrants and communities at risk, and is against the principles of solidarity and public health that should inspire action during these challenging times. It also puts at risk the staff who implement these policies. Detention, overcrowded conditions and lack of hygiene all render irregular migrants more vulnerable to the impact of COVID-19. Irregular laborers, agricultural and food workers, cleaners and caregivers are all essential in the response to the pandemic, therefore the temporary or longer term regularisation of migrants to facilitate their access to health, social services and employment should be considered as a humane, practical and self-interested alternative to forcible return. It is paradoxical that some governments are allowing temporary migrant workers into the country for agricultural labour while attempting to deport the ones already there. Across the world, containment of the COVID-19 pandemic risks disproportionately harsh consequences for irregular migrants and their countries of origin.[9] This can be clearly seen already in the Horn of Africa, the Sahel, the Mediterranean Sea, Southern Italy and other regions. While thousands of people in all countries are affected by COVID-19 in the West and larger economies struggle to stay afloat, a call for attention to irregular migrants is crucial to prevent such marginalised groups being forgotten in the management of the pandemic. Rather, they need supporting through this crisis, for the benefits of the entirety of society.

KEY RISKS FOR IRREGULAR MIGRANTS DURING COVID-19 RESPONSE

(1) Poor treatment of migrants in host countries pre-deportation e.g. mass detention, lack of recourse to public funds for essential purchases, and the requirement to continue working in unsatisfactory conditions;
(2) Public health risk to staff and migrants during the process of return and then subsequently to the country of return;
(3) Economic strain on country of return due to cost of managing returnees and lost remittances.

DEPORTATIONS

While travel restrictions and social distancing have become interventions widely used to contain the pandemic, thousands of forcibly returned migrants are now kept in ill-prepared reception centers in Ethiopia[10], Niger, and many other contexts globally for the mandatory period of post-return quarantine[11]. The lockdown measures instituted in numerous countries

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[11] IOM Steps Up Response for Migrants Stranded in Niger Amidst COVID-19 Lockdown Posted: 04/01/2020. Available at https://www.iom.int/news/iom-steps-response-migrants-stranded-niger-amidst-COVID-19-lockdown

have caused loss of employment, especially for those working in low-wage jobs or in the gig economy; additionally for migrants this may mean the loss of a residence permit. Irregular migrants are often perceived as convenient manpower for agriculture, construction, domestic work and other low-wage jobs, yet they quickly become expendable in times of crisis. In some cases, they are being blamed for being the cause or continuing source of the pandemic or for using resources that should be reserved for nationals. Besides the economic loss in terms of remittances and failed family investments for the repayment of loans obtained to migrate, mass deportations put an avoidable strain on low-income countries of return, both for local governments and humanitarian organisations called to assist them. They also represent an added risk in terms of global spread of the virus and delaying its containment[12] if they are not included effectively in COVID-19 response. For example, Africa is the region of birth for 36 million migrants, out of an estimated 272 million migrants worldwide (2019)[13]. In 2018, migrants in the Sub-Saharan Africa region sent home remittances of a value of US$46 billion[14], representing close to 2.7% of African GDP[15]. Money sent back in remittances by migrants and refugees are spent by families on healthcare, education, livelihood, and small investments benefitting an estimated 100 million African people. Although remittances have already been seriously impacted by economic slowdown and job losses around the world, deportations exacerbate this problem by permanently ceasing remittance income. Households which relied on remittances will find it harder to meet basic needs during the pandemic, including spending on healthcare. It is imperative we avoid the COVID-19 pandemic undermining poverty reduction achievements in low income countries.

SELECTED CASE STUDIES: AFRICAN CONTEXT

ETHIOPIA

Before the COVID-19 pandemic, there were between 10,000 to 20,000 migrants deported from the Middle East to Ethiopia per month[16], which has continued during the epidemic. National governments and local communities often face great difficulty in assisting large numbers of returnees, especially with matters relating to housing, financial resources, employment, health and psycho-social support, but the need to quarantine them hugely complicates the situation. As of May 12, some 3000 Ethiopian migrants have already been returned from Saudi Arabia; another 3332 have been returned from Djibouti, 3827 from Sudan, 1336 from Somalia, 505 from Kenya, a total of approximately 11800 returnees.[17] Some of these returnees have been held in crowded detention centers before expulsion. The Ethiopian government is converting schools, meeting halls, and stadiums into temporary quarantine facilities, but given the unpredictability of future scenarios, the Ministry of Health (MoH) is working with partners such as IOM, Doctors with Africa CUAMM, MSF and others on a case-by-case approach trying to find new accommodation and urgent deliveries of essential supplies. This comes amid already staggering efforts and insufficient resources to implement a COVID-19 response for the whole population.

Additionally, returnees might not have been screened or quarantined before departure, and there is a high risk of importing infection. On March 22nd, a charter flight carrying deportees from Saudi Arabia to Bole International Airport in Addis Ababa was not allowed to land due to unavailability of quarantine sites. Seven of the passengers on that flight later

[12] U.S. Deported Thousands Amid COVID-19 Outbreak. Some Proved to Be Sick. The New York Times. By Caitlin Dickerson and Kirk Semple. April 18, 2020. Available at https://www.nytimes.com/2020/04/18/us/deportations-coronavirus-guatemala.html
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[17] IOM Ethiopia. COVID-19 Situation Report | 12 May 2020, https://ethiopia.iom.int/sites/default/files/IOM%20Ethiopia%20%E2%80%93%20COVID-19%20Response%20%E2%80%93%2012%20May%202020.pdf

tested positive for COVID-19 in Saudi Arabia, and were isolated to receive treatment by Saudi authorities.[18] Some of the returnees allowed into Ethiopia a few days later might have been on the same March 22nd flight, and may have come into contact with the seven confirmed cases. Some other Gulf countries such as the United Arab Emirates (UAE) are following the example of Saudi Arabia[19]. This has led the UN Resident Humanitarian Coordinator in Ethiopia, Catherine Sozi, to call for a suspension of deportations on behalf of the UN community[20].

NIGER

Niger has one of the highest numbers of COVID-19 cases in Africa after South Africa and Algeria. More than 8000 migrants have been deported from Algeria to Niger since January this year, but despite the current closure of borders across West Africa, deportations have not stopped. Returnees must be quarantined in makeshift tent camps in the middle of the desert, such as in Assamaka, some 15 km from the Algeria-Niger border, where the temperature can reach 50 degrees Celsius[21]. This has overwhelmed the government and humanitarian actors such as IOM, MSF, and others called upon to rescue, quarantine and assist thousands of new arrivals in strenuous environmental and operational conditions. Niger is one of the poorest countries in the world with more than 10 per cent of the population in need of humanitarian assistance and more than half a million refugees and internally displaced people living in crowded settlements amid ongoing activities by armed groups. Another half a million migrants are now stranded in the country by border closures, with resettlements and assisted voluntary returns at a stand-still.

A CALL FOR SUSPENSION OF DEPORTATIONS AND REGULARISATION OF MIGRANTS DURING THE COVID-19 PANDEMIC

The COVID-19 pandemic has highlighted an aspect of the health and migration discourse often untold: the achievement of 'health for all' requires not only that individuals practice social distancing and other protective measures, but also that states protect migrants regardless of their migration status or countries of origin. It has been said that 'No One is Saved Alone'[22], and actions to alleviate situation for the most marginalised groups, such as irregular migrants, is urgently needed during the COVID-19 pandemic[23]. We emphasise that this is essential not only for irregular migrants and their countries of origin but also for the current countries of residence. Without a degree of trust and mutual support irregular migrants will not be able to participate in the wider civic effort to control the pandemic, and risk being left behind.

BUILDING ON THE GLOBAL STATEMENT BY LANCET MIGRATION[24] WE CALL FOR THE FOLLOWING:

1. **Transfer of migrants & refugees held in overcrowded reception, transit and detention facilities to safer living conditions:** There should be prioritised evacuation of the most vulnerable, such as the elderly and those with underlying health conditions. Since such settings are generally overcrowded with poor sanitation and hygiene measures, the spread of COVID-19 has the potential to be rapid and devastating among affected populations and those working there.

[18] Financial Times April 12, 2020. D.Pilling, A. England. *Saudi Arabia repatriating thousands of migrants back to Ethiopia.* Available at https://www.ft.com/content/b4f3c258-7ec9-477c-92f7-5607203f77fc

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[21] 'Hundreds of Migrants Stuck in Niger amid Coronavirus Pandemic, G. Zandonini. 9 Apr 2020. Available at https://www.aljazeera.com/news/2020/04/hundreds-migrants-stuck-niger-coronavirus-pandemic-200409131745319.html

[22] Pope Francis on Pope pens editorial on joy in the time of coronavirus. By Junno Arocho Esteves • Catholic News Service • Posted April 17, 2020 Available at https://catholicphilly.com/2020/04/news/world-news/pope-pens-editorial-on-joy-in-the-time-of-coronavirus/

[23] Stop the exploitation of migrant agricultural workers in Italy. The BMJ OPINION, March 27, 2019. C. Marotta, F. Di Gennaro, P.Parente,G. Putoto, D.Mosca Available at https://blogs.bmj.com/bmj/2019/03/27/stop-the-exploitation-of-migrant-agricultural-workers-in-italy

[24] Lancet Migration. Leaving no one behind in the COVID-19 Pandemic: a call for urgent global action to include migrants in the COVID-19 response. Available at https://www.migrationandhealth.org/statements

2. **Deportations should be suspended**, while asylum procedures should continue according to the 1951 Refugee Convention, with no forced return (refoulement).
3. **Immediate suspension of laws that limit migrant & refugee access to healthcare services and economic support programmes**, through measures such as temporarily granting residency to migrants & refugees and suspending health care user fees for all conditions, especially those increasing susceptibility to infection, and not just for COVID-19 testing and treatment. There needs to be a special focus on migrants during lockdowns, in order to ensure that these measures do not disproportionately disadvantage these populations, and that their previous lack of access to basic shelter, water, sanitation and hygiene, or food is not compounded. There must be urgent measures to establish recourse to public funds.
4. **Rescue, dignified quarantine, and access to testing and treatment should be made available with no discrimination against irregular migrants**, as well as transparent communication and measures to relieve the social and economic consequences of the crisis.
5. **Governments should also actively counter racism and xenophobia that fuels discrimination and exclusion of migrant & refugee populations.** Xenophobia, prejudice and racism that might contribute to the exclusion of irregular migrants from measures to mitigate the impact of the pandemic should be strongly condemned. Irregular migrants must play their part, and be allowed to do so, in controlling this pandemic.
6. **Temporary citizenship for everyone within the land boundary of a country** with guarantees that once the pandemic has been controlled, there will be a just and lawful process for assessing claims for asylum and right of residence for irregular migrants, which will take into account contributions made by individuals during the pandemic period.

Organisations and acknowledgements

This situational brief was authored by Davide T. Mosca, MD[25], Claudia Marotta, MD[26]; Francesco Di Gennaro, MD[2]; Giovanni Putoto, MD, DTM&H, MAHMPP[27]; Michele D'Alessandro[28]; Raj Bhopal, DSc(Hon)[29]; and expert reviewed by Delan Devakumar MB ChB MRCPCH FFPH MSc DTM&H PhD [30]. Overall direction and review on behalf of the Lancet Migration global collaboration was provided by Miriam Orcutt and editorial review by Elspeth Carruthers. This brief represents the views of the authors.

This series of situational and policy briefs summarises key aspects of the COVID-19 response in relation to migrants and refugees at country or regional level. They include public health and policy recommendations and perspectives and build on the Lancet Migration Global Statement recommendations to ensure migrants and refugees: have access to healthcare; are included in prevention, preparedness and response; and are part of responsible and transparent public information strategies, during the COVID-19 pandemic. Policy and situational briefs have been authored by experts working in academia, operational, or clinical areas of migration and COVID-19, and are hosted on the Lancet Migration website (www.migrationandhealth.org). Lancet Migration is a global collaboration between The Lancet and researchers, implementers, and others in the field of migration and health that aims to address evidence gaps and drive policy change building on the recommendations of the UCL-Lancet Commission on Migration and Health published in December 2018.

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The National Emergency Medical Service Role During the COVID-19 Pandemic in Sierra Leone

PAPER

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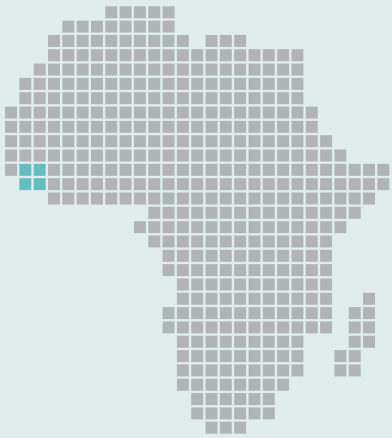

FIELD REPORT

The National Emergency Medical Service Role During the COVID-19 Pandemic in Sierra Leone

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Conflicts of interest: none

Keywords: COVID-19; Emergency Medical Services; prehospital care; Sierra Leone

Abbreviations:
CCC: community care center
CMP: case management pillar
COVID-19: novel coronavirus disease 2019
CRIMEDIM: Research Center in Emergency and Disaster Medicine
CTC: COVID-19 treatment center
EOC: emergency operations center
IPC: infection prevention and control
MoHS: Ministry of Health and Sanitation
NEMS: National Emergency Medical Service
OC: operation center
PPE: personal protective equipment
SOP: standard operating procedure

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Event Identifiers
a. Event Type: Pandemic
b. Event Onset Date: March 31, 2020
c. Location of Event: Sierra Leone
d. Dates of Observations Reported: March 31, 2020 - July 31, 2020
e. Response Type: Pandemic Management and Emergency Response

Abstract
This report describes the main adaptive and transformative changes adopted by the brand-new National Emergency Medical Service (NEMS) to face the novel coronavirus disease 2019 (COVID-19) in Sierra Leone, including ambulance re-distribution, improvements in communication flow, implementation of ad-hoc procedures and trainings, and budget re-allocation. In a time-span of four months, 1,170 COVID-19 cases have been handled by the NEMS through a parallel referral system, while efforts have been made to manage the routine emergencies of the country, causing a substantial intensification of daily activities.

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Introduction

Sierra Leone reported the first confirmed novel coronavirus disease 2019 (COVID-19) case on March 31, 2020.[1] By the end of July, the country had recorded a total number of 1,823 confirmed cases and 67 total deaths, thus rapidly changing the transmission pattern of the disease from sporadic cases to clusters and community transmission.[2,3]

Starting from October 2018, Sierra Leone has implemented the National Emergency Medical Service (NEMS), a coordinated prehospital referral system managed by Doctors with Africa (CUAMM; Padova, Italy) in collaboration with Veneto Region and Research Center in Emergency and Disaster Medicine (CRIMEDIM; Università del Piemonte Orientale; Novara, Italy), under the direct supervision of the Ministry of Health and Sanitation (MoHS; Freetown, Western Area, Sierra Leone). Since the beginning of the COVID-19 pandemic, the NEMS has been actively engaged in the national preparedness response plan to ensure a resilient referral system, able to effectively continue delivering routine services, and at the same time manage the sudden demands of referral of COVID-19-related cases. To fulfil this aim, NEMS' efforts have been directed towards the implementation of absorptive, adaptive, and transformative capacities representing the three levels of resilience of a health system when exposed to a shock, as based on the Dimensions of Resilience Governance framework.[4]

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Suspect	Acute respiratory infection associated with fever or history of fever >38°C, shortness of breath, cough or sore throat, who has had either close contact with a confirmed or probable case of COVID-19 or has visited/stayed in a country with community transmission of COVID-19 in the 14 days prior to onset of the symptoms.
Probable	A suspect case for whom laboratory testing for COVID-19 is inconclusive (inadequate samples or indeterminate results).
Confirmed	Laboratory confirmation COVID-19 infection, irrespective of clinical signs and symptoms.

Table 1. Case Definition for Novel Coronavirus Disease 2019 (COVID-19) Adopted in Sierra Leone During the National Response to the Pandemic

Data and Information Source

This field report is based upon NEMS monthly financial and management internal reports as well as on data collected though the NEMS operation center (OC) software, data shared by the MoHS, and by key stakeholders.

Observations

Learning form the Ebola experience (2014-2016) and thanks to funds received from the World Bank (Washington, DC USA) and the United Nations (New York USA), in April 2020, the Government had promptly implemented a national preparedness and response plan that featured different elements, including the set-up of COVID-19 treatment centers (CTCs) and community care centers (CCCs).[5] The response has been strengthened under the coordination of an emergency operations center (EOC) and was supported by several public health measures and recommendations such as the closing of public spaces, travel restrictions, physical distancing, and improved hygiene practices.[5,6]

The NEMS management team has been integrated in the case management pillar (CMP), a dedicated team of experts composed by members of the MoHS, the Republic of Sierra Leone Army Force, key partners, and stakeholders operating in the health care sector. The prime responsibility of the CMP was to devise and implement protocols and procedures for the management and referral of COVID-19 suspect, probable, and confirmed cases on a national scale. In line with the international guidelines, the CMP has agreed to comply to the case definition as showed in Table 1, according to clinical, epidemiological, and laboratory criteria.[3] The role of the NEMS in supporting the national response to COVID-19 in Sierra Leone was two-fold. First and foremost, NEMS ambulance teams were in charge of transporting suspect, probable, or confirmed cases to referral health care facilities following the standard operating procedures (SOPs) defined by the CMP. Secondly, a parallel referral system was set up for the transport of COVID-19 specimens to the different laboratories.

The NEMS internal and external communications underwent adaptive and transformative changes that altered the structure of information flow. The main goal of the CMP was to effectively coordinate all the actors involved in the response by creating direct bridges between them, while allowing NEMS to maintain the same control on its communication structure. The NEMS OC normally functions as main link between the caller requesting emergency medical assistance, represented by a health worker responsible for primary assessment of patients in a peripheral health unit, and the NEMS emergency care resources. To facilitate information flow in the COVID-19 response, the OC in-house software was upgraded to ease the triage process of COVID-19 emergency calls and to appropriately report the transportation of the COVID-19 patients. Specifically, in the event of a suspected or confirmed case notified by the EOC, the software allowed the OC operator access to a specific COVID-19 section and to mark signs, symptoms, and epidemiological data as appropriate, choosing between fever, cough, sore throat, difficulties in breathing, history of travel, and contact with confirmed cases. In a second step, the triage process was finalized with the communication of a patient's vitals by the NEMS paramedic on scene. A "red code" was identified when either body temperature was >38°C, respiratory rate >20, systolic blood pressure <100, peripheral capillary oxygen saturation (SpO2) <94%, or heart rate >100.

Moreover, the public was encouraged to call the 117 special emergency number, previously used by private citizens for any Ebola-related concerns, to report COVID-19 symptoms directly to the NEMS OC. The district EOC in charge of situation assessment and patient management provided instruction to the OC team leaders on both ambulance dispatch and final destination to the designated referral hospitals, represented either by CTCs for severe cases, CCCs, or district hospitals equipped with isolation units in cases of mild disease or asymptomatic patients. Bed availability in the abovementioned centers was communicated daily to the NEMS OC. Figure 1 shows the diagram of communication flow between the NEMS OC and the other actors involved in the management and referral of the COVID-19 cases.

Ambulance distribution criteria entailed some organizational adaptations to effectively respond to the changing environment caused by the pandemic, using the same level of resources and capacities available in the country. In a first planning phase characterized only by sporadic cases locally detected, eight out of 81 ambulances had been allocated specifically for the COVID-19 response. Four of these ambulances had been positioned in all the principal points-of-entry represented by land access and the Lungi International Airport; the other four had been distributed on a regional basis (Figure 2). As the transmission pattern of the disease changed to cluster of cases and community transmission, the number of dedicated ambulances was increased to one per district, reaching the total number of 15. Three of these ambulances had been located in the more densely populated Western Area (Figure 2). The abovementioned ambulances had been selected according to the geographical area covered so to guarantee an acceptable response time, utilization rate, and geographical distribution of the other 66 ambulances used for routine emergencies.

Several SOPs were implemented to safeguard both the NEMS ambulance teams, composed by a trained paramedic and an ambulance driver, and the patients. To this end, the provision of an adequate number of personal protective equipment (PPE) was guaranteed by the NEMS procurement office well in advance by diverting 25% of NEMS monthly budget to this purpose. Ambulance teams were provided with full PPE, including FPP3 masks, gowns, gloves, goggles, and were instructed to have patients always wearing a surgical mask. Relatives of the patients were not allowed in the ambulance during transport to the health care facility. At the end of every mission, the ambulance remained inoperative for the time needed to clean all the equipment and manage the waste following the proper infection prevention and control (IPC) procedures. The District Ambulance Supervisor (DAS) oversaw the work of ambulance teams and ensured that they complied with all the procedures abovementioned.

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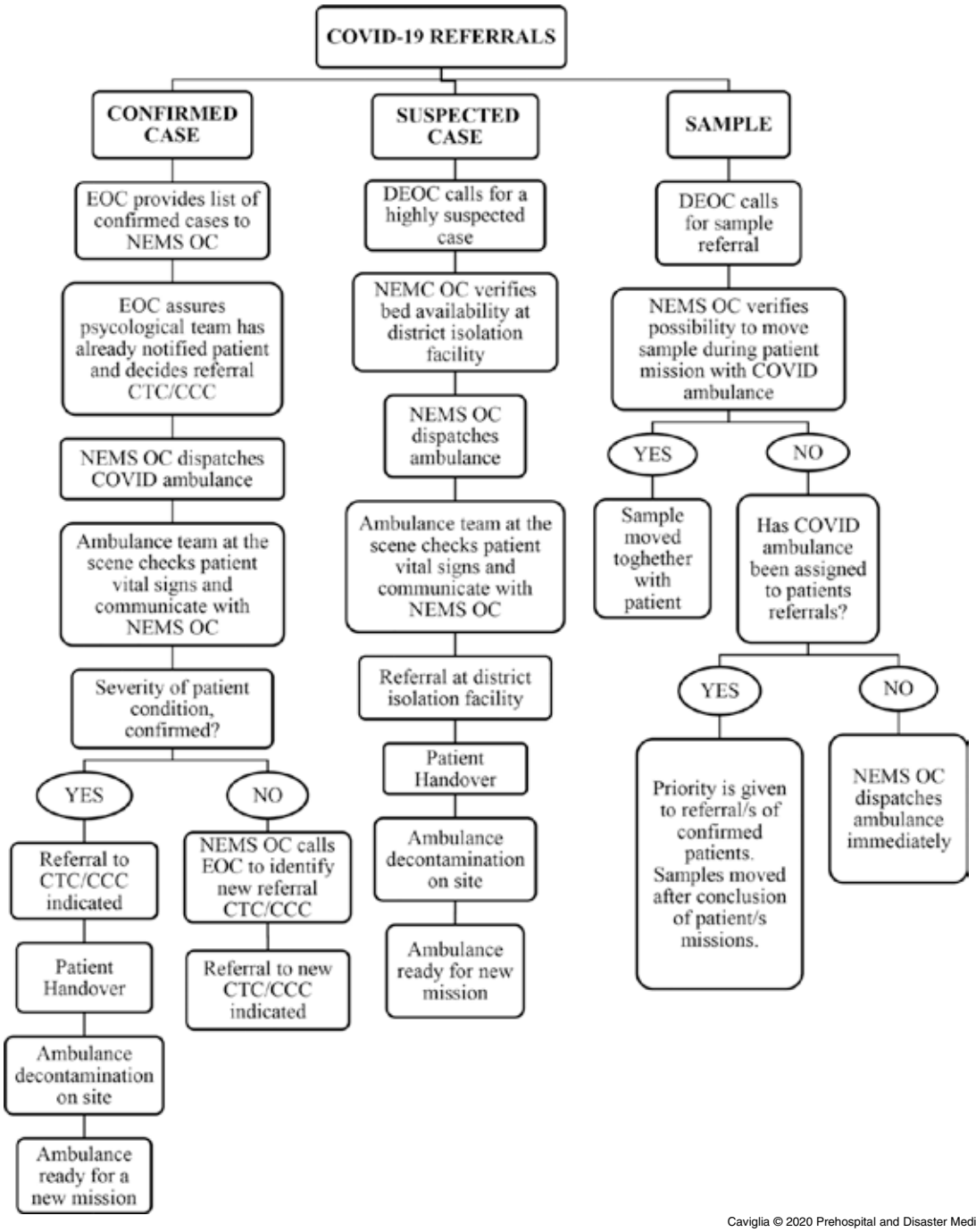

Figure 1. Communication Flow between the NEMS OC and Other Actors Involved in the Management and Referral of COVID-19 Cases.
Abbreviations: NEMS, National Emergency Medical Services; OC, operation center.

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Figure 2. Location of Ambulances Allocated Specifically for the COVID-19 Response.

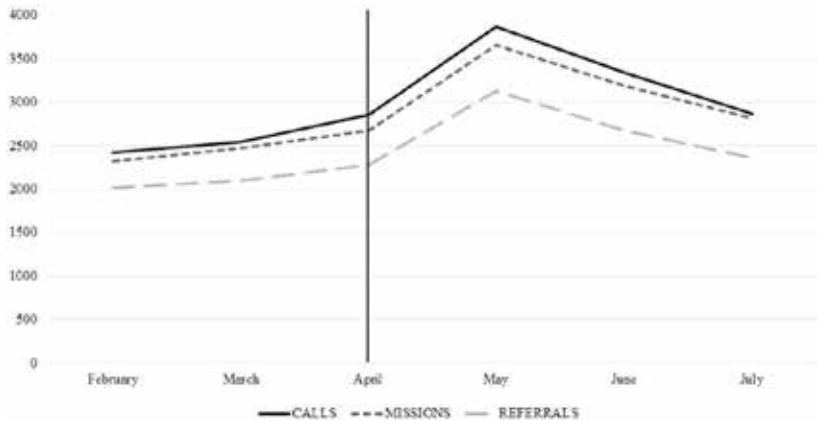

Figure 3. Upward Trend in NEMS Activities, Determined by the COVID-19 Outbreak.

As part of the national preparedness and response plan, different types of training sessions have been delivered to NEMS personnel, under the coordination and supervision of the CRIMEDIM. As Italy has been one of the most affected countries by the COVID-19 pandemic, researchers from CRIMEDIM have developed an ad-hoc training by integrating the Italian experience with the Sierra Leone national regulations and SOPs.[7] A COVID-19 Special Training has been provided initially to the 98 paramedics and ambulance drivers identified for the management of COVID-19 cases. Subsequently, the training has been delivered to all the remaining ambulance teams. It consisted of a one-day training that included both theoretical and practical sessions focused on the correct use of PPEs and IPC procedures. In parallel, the 30 OC operators have participated in a one-day training on COVID-19 case definition, triage, and dispatch procedures. Of note, a low absenteeism rate was reported amongst the NEMS workforce. This entails both a strong commitment of the NEMS personnel, even in time of difficulties and personal danger, and the existence of effective strategies to improve their engagement. On the contrary, health care facilities in the country are reporting high levels of absenteeism due to fear of contagion, similarly to what happened during the Ebola epidemic.[8]

Analysis

The COVID-19 outbreak determined an upward trend in NEMS activities (Figure 3). According to the NEMS OC database, from April 2020 through July 2020, a total of 1,033 confirmed cases and 137 probable or suspected cases have been referred by NEMS to the pre-identified treatment centers or isolation units. In the same period, a total of 257 missions were related to transportations of COVID-19 patients. The number of confirmed cases referred accounts for the 64% of the total confirmed cases in the country in the abovementioned timeframe. This figure acquires considerable

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importance when considering that NEMS referrals covered the entirety of long-distance transports, whereas the remaining 36% of confirmed cases in the country were identified in urban areas where hospital facilities are either at walking distance or easily accessible through short-distance transports.

From a financial point of view, the COVID-19 outbreak had a significant impact on NEMS. As expected, the need of PPEs, ambulance decontamination kits, and special equipment such as digital thermometers increased dramatically, demanding timely reallocation of the existing budget. Furthermore, the ambulance fleet reduced by 15 had to cover routine emergencies in a much larger area, thus increasing costs related to gasoline and wear costs of the vehicles. Lastly, the supplementary training sessions delivered to all the NEMS personnel required movement of additional funds. The NEMS involvement in the national response plan was not exempt from challenges. First of all, stigma and fear were still associated with ambulances years after the devastating Ebola epidemic, especially in the most rural areas of Sierra Leone.[9] This perception of fear and mistrust in the health care system recurred to some extent during the COVID-19 pandemic, with NEMS ambulance teams experiencing multiple cases of violence, including acts of vandalism against ambulances and refusal to be transported to treatment centers. To address the issue, the involvement of a psychological team in charge of adequately informing the patient and relatives about their condition and the need of isolation played a major role and showed some encouraging results.

The connection between the public emergency number 117 and NEMS OC established for the COVID-19 response has brought indirect consequences on the whole system. The route of emergency calls to NEMS OC through 117 has indeed not only been limited to coronavirus cases, but widened to all the typology of emergencies, resulting in an official opening of the NEMS service to the public. While the implementation of a public emergency number was part of the original design of NEMS, its abrupt activation during the current crisis has notably increased the number of incoming calls to the OC, testing the copying capacity of the whole system. Although the situation in Sierra Leone remains extremely challenging due to the vulnerability of its health sector, efforts to mitigate the impact of the pandemic and to implement rapid and effective response measures have received a considerable boost from the presence of a structured and fully equipped prehospital service.

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Chronic diseases

Successful management of a rare case of giant extra-abdominal fibromatosis

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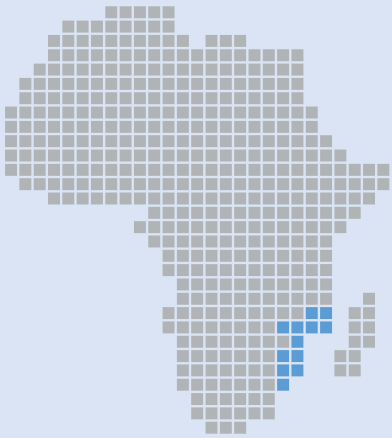

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Successful management of a rare case of giant extra-abdominal fibromatosis

Abstract

Fibromatosis or desmoid tumor is a rare a locally aggressive neoplasm with variable anatomic location and clinical course. Due to its rarity and diversity, to date, there is no a gold standard approach and the main and more update evidence regard mainly the high-income countries. We presented a rare case of giant extra-abdominal fibromatosis successfully treated in a low-income setting.

Keywords: fibromatosis, desmoid tumor, extra-abdominal fibromatosis, low-income countries

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Introduction

Aggressive fibromatosis, also known as desmoid tumor or desmoid-type fibromatosis are defined by the World Health Organization (WHO), as clonal fibroblastic proliferation that arises in the deep soft tissues and is characterized by infiltrative growth and a tendency toward local recurrence but an inability to metastasize.[1] Fibromatosis has variable and often unpredictable anatomic locations clinical course, and biologic behaviors.[2] Its incidence is five to six cases per 1 million of the population per annum and, due to the rarity of this disease, a very low level of evidence is present in the scientific literature.[2] Although it is a histologically benign neoplasm, in high income country, the sole surgery approach does not represent the gold standard as it is poorly encapsulated and locally invasive.[3] Indeed, growing evidence suggests a multidisciplinary and tailored approach including radiation therapy, hormonal therapy, or cytotoxic chemotherapy and considering that most patients can be managed with one treatment modality at a time.[2]

However, in low-resources settings, a multidisciplinary approach is unlikely both due to the lack of specialized health workers and the absence of adequate equipment and drugs for diagnosis, therapy and follow-up. We reported a case of a rare case of giant extra-abdominal fibromatosis successfully treated in a low-income setting.

Case report

A 25-year-old woman presented in our institution, with a back giant mass, evolved over about two years (Figure 1 A & B). The patient had no pain or other symptoms related to the mass. History of previous diseases was unremarkable, her general condition was good, and she had normal vital parameters. It was not possible to perform a magnetic resonance imaging and we decided to hospitalize the woman for surgery with a diagnosis of possible fibroma. She was HIV negative, and preoperative tests showed normal parameters.

The patient underwent surgical excision: we performed a diamond engraving in the middle on the mass. We tried to remove the entire tumor but it was poorly encapsulated with an extensive vascular supply. After hemostasis, in order to close the skin, we performed a slip flap. The excised mass was 25x17x12cm. Histologic examination showed sweeping fascicles of myofibroblasts with abundant collagenous stroma and the diagnosis was fibromatosis. The post surgical course was regular and the 3-month follow-up showed a clean scar (Figure 1C) and no sequela.

Figure 1 Giant fibromatosis at presentation (A and B) and three months after surgery (C).

Discussion

A recent consensus algorithm on fibromatosis suggests a multidisciplinary approach in order to obtain the best tailored management for patients affected by this disease.[2] Compared to this algorithm, the management of our case is very far in diagnostic, treatment and follow up procedures. Magnetic Resonance Imaging (MRI) is considered the gold standard of imaging in fibromatosis, not only for diagnosis, but also for staging and follow-up. Unfortunately, our hospital is not provided of MRI nor CT-scan and also ultrasound were not available. Moreover, other useful tests are biopsy, molecular biology and genetic. Among these, the only possible would have been the biopsy for an histological examination but we avoid the biopsy and used a sample of the excised lump for the histologic diagnosis.

With hindsight, although the surgery and the overall management was successful, to perform a biopsy should be recommended in order to help in assessing the risks and benefits of surgery or other therapies, including doing nothing. Thus, the decision to subject the patient to surgery was driven on one hand by the necessity to remove the giant lump and, on the other hand, by the lack of other choices. When possible, the consensus algorithm suggest a multidisciplinary and tailored management in agreement with the patient andconsidering alternative or adjuvant options as radiation therapy, hormonal therapy, or cytotoxic chemotherapy.[2]

Thees observations highlight the weakness of low-income countries health systems and suggest the development of algorithm consensus addressed to this poor settings. Especially for rare diseases, in fact, it is crucial, for the few and overload health professional to have clear, applicable and effectiveness guide line. In particular, although we have described just a case, we point out at least three recommendation: 1) to pay attention to alert signs (masses greater than 3-5cm, deep located, rapid growth), 2) to use radiologic adequate imaging, as ultrasound, both in order to make differential diagnosis (i.e. hematoma, abscess, infections) and to planning biopsy and surgery; 3) to perform the biopsy in order to help in assessing the risks and benefits of surgery or other therapies.

In this case, also looking at the three months follow-up, we can consider satisfactory the management of this case. However, we don't know the risk of relapse and, likely, in few months we will lose on follow-up the patient. To avoid this, not only in case of fibromatosis but in oncology in general, it is mandatory to strengthen the health system with particular attention to physical, psychologic and social aspects and to promote comprehensive programs including physical, psychologic and social support.

Ethic statement

Written informed consent was obtained from the patient for publication of this case report and any accompanying images.

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Diabetes and pre-diabetes among adults reaching health centers in Luanda, Angola: prevalence and associated factors

PAPER

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Diabetes and pre-diabetes among adults reaching health centers in Luanda, Angola: prevalence and associated factors

Claudia Robbiati[1*], Giovanni Putoto[2], Natália Da Conceição[3], António Armando[3], Giulia Segafredo[2], Andrea Atzori[2] & Francesco Cavallin[4]

With the lack of surveys, surveillance program and/or statistical data, epidemiologic studies can provide a better understanding of diabetes in Sub-Saharan Africa. This was a cross-sectional survey to determine prevalence of diabetes and impaired fasting glucose (IFG) among adults attending six health centres in six different districts of Luanda (Angola) during August-November 2018, followed by a case-control study to assess the risk factors for IFG and diabetes in a subgroup of subjects not receiving treatment for diabetes. Factors associated with diabetes/IFG were assessed using a generalized ordered logit model and the effects were expressed as odds ratios (OR_1 for IFG/diabetes vs. no IFG/diabetes; OR_2 for diabetes vs. no diabetes) with 95% CI (confidence interval). Some 1,803 participants were included in the survey. Prevalence of diabetes was 12.0% (95%CI 10.5% to 13.5%) and prevalence of IFG was 9.0% (95%CI 7.7% to 10.4%). Older age ($OR_1 = OR_2$ 1.03, 95%CI 1.02 to 1.04), higher weight ($OR_1 = OR_2$ 1.01, 95%CI 1.01 to 1.03), having measured glycaemia before (OR_2 2.07, 95%CI 1.29 to 3.31), feeling polyuria (OR_1 1.93, 95%CI 1.13 to 3.28; OR_2 2.18, 95%CI 1.32 to 3.59), feeling polydipsia (OR_1 1.92, 95%CI 1.16 to 3.18), feeling weakness ($OR_1 = OR_2$ 2.22, 95%CI 1.39 to 3.55), consumption of free-sugars food/beverages ($OR_1 = OR_2$ 2.34, 95%CI 1.44 to 3.81) and time spent seated (OR_1 1.80, 95%CI 1.17 to 2.76) were associated with increased likelihood of diabetes and/or IFG, while eating vegetables was associated with decreased likelihood of IFG or diabetes ($OR_1 = OR_2$ 0.69, 95%CI 0.47 to 0.99). In conclusion, the high prevalence of diabetes and IFG, with common unawareness of the disease, calls for appropriate interventions in Angolan urban settings. Further research may evaluate the impact of context-specific factors to enhance intervention strategies and feed the results into local health policies. In addition, such information may be useful for selecting high-risk subjects to test.

Diabetes is among the non-communicable diseases (NCDs) with an increasing prevalence in Sub-Saharan Africa (SSA)[1]. Some 15.5 million adults aged 20–79 years were estimated to be living with diabetes in the Africa Region in 2017[2], and this number is expected to rise to 23.9 million by 2030[3]. However, these figures have a high degree of uncertainty since 66.7% of people with diabetes in Africa are not diagnosed with the disease[4]. This is mostly due to inadequate NCDs screening programs and awareness in many African countries[5]. Epidemiological evidence about diabetes and other NCDs in SSA is scant, despite their increasing burden and the need for reliable data to develop policies, guidelines and interventions[6].

The World Health Organisation (WHO) estimates a diabetes prevalence of 5.6% in Angola[7], but this figure is derived by extrapolation due to the lack of epidemiological data. Angola, as other SSA countries, is experiencing an epidemiological transition and a double burden of communicable and non-communicable diseases especially in urban settings, due to changes in lifestyle, diet and physical activity[6]. The diabetes growing challenge undermines the already weak Angolan health system. The lack of national policies and guidelines on diabetes, on top of the absence of accurate estimates of disease prevalence[7], highlights the urgency to develop proper programs for the early detection of diabetes and impaired fasting glucose (IFG) (or pre-diabetes). IFG is a condition that precedes diabetes and increases the risk to develop it, therefore identifying people with IFG and associated risk factors is a preliminary step to define prevention programs to stop the progression of diabetes[8].

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With the lack of surveys, surveillance program and/or statistical data, epidemiologic studies (such as cross-sectional and longitudinal) can provide a better understanding of diabetes in Angola. This study aimed to investigate the prevalence of IFG and diabetes in people attending healthcare facilities in Luanda, the capital city of Angola. Factors associated with IFG and diabetes were also investigated among people not receiving treatment for diabetes.

Methods

Study design. This was a cross-sectional survey to determine prevalence of diabetes and IFG among people attending six health centres in six different districts of Luanda (Angola), followed by a case-control study to assess the factors associated with IFG and diabetes in a subgroup of subjects not receiving treatment for diabetes.

Setting. The study was conducted in the urban area of Luanda (Angola), with a population of approximately 7 million people. According to national authorities, the capital city of Angola has the highest diabetes mortality rate in the country (3.4%)[9]. One health center was randomly chosen in each of the six districts. People attending the six health centres between August 2018 and November 2018 were evaluated for inclusion in the study.

Participants. The study population included adult men and women older than 18 years attending the six health centres between August 2018 and November 2018. Pregnant women and people not fasting for at least 8 hours were excluded from the study.

Cross-sectional survey. All participants were included in the cross-sectional survey to determine the prevalence of IFG and diabetes. Fasting blood glucose (FBG) levels were measured by professional nurses using a glucometer (Infopia, South Korea). Diabetes measurements and definitions were based on WHO guidelines[10]. IFG was defined as FBG levels between 110–125 mg/dl. Diabetes was defined as FBG levels $\geq$126 mg/dl or a self-report of previous diagnosis of diabetes by a health care professional or currently receiving treatment for diabetes.

Case-control study. A subgroup of participants was selected for the investigation of factors associated with IFG and diabetes among those who were not receiving treatment for diabetes, as follows. All subjects with IFG were included. The chosen ratio of participants with IFG, diabetes and without IFG /diabetes was 1:1:1. For each participant with IFG, the next participant without IFG /diabetes was also included in the second step. Participants with diabetes were included in the second step and "linked" with the closest (past or next) participant with IFG, to warrant the achievement of the set 1:1:1 ratio. This approach was chosen to overcome the logistics issues of evaluating the factors in all participants of the cross-sectional survey.

A set of information of interest for IFG/diabetes (demographics, clinical parameters, clinical information, diet habits and physical activity) was collected by professional nurses using a case-report form. Demographics included age, sex, marital status, employment, education, number of children and number of people living at home. Clinical parameters included weight, body mass index (BMI), waist circumference, systolic blood pressure (SBP), diastolic blood pressure (DBP) and heart rate. Clinical information included having already heard about diabetes, having glycaemia measured before, losing weight, and feeling polyuria, polydipsia and weakness. Diet habits included eating vegetables, fruits, free-sugars food, adding refined salt in meals and drinking alcohol or free-sugars beverages daily. Tobacco use was self-reported. Information on physical activity included whether the subject usually performed physical activity for at least 30 minutes per day, and how long the subject remained seated daily (<2 hours, 2–5 hours,>5 hours). Demographics, clinical information, diet habits and physical activity were self-reported, while clinical parameters were measured by a professional nurse. All data were collected by a professional nurse before participants went into the doctor's consultation room. Data collection was coordinated and supervised by one research assistant.

Sample size. The sample size was calculated according to the primary aim of reporting the prevalence of diabetes and IFG in the cross sectional survey. Assuming a proportion of participants with IFG between 60 and 90 per 1,000 subjects, some 963 to 1,400 participants needed to be enrolled to estimate a 95% confidence interval (CI) not wider than 30 per 1,000 subjects. Assuming a proportion of participants with diabetes between 80 and 120 per 1,000 subjects, some 1,257 to 1,803 participants needed to be enrolled to estimate a 95% CI not wider than 30 per 1,000 subjects. The largest of the calculated sample sizes (1,803 participants) was chosen.

Statistical analysis. In the cross sectional survey, the proportions (with 95% confidence interval, CI) of participants with IFG, diabetes or without IFG/diabetes were estimated in all sample.

In the case-control study, factors associated with IFG and diabetes were investigated in the subgroup of participants, who were divided in three study groups (no IFG/diabetes; IFG; diabetes). Continuous data were reported as median and interquartile range (IQR), while categorical data as number and percentage. Continuous data were compared among study groups using Kruskal-Wallis test, and categorical data using Chi-square test or Fisher's exact test, as appropriate.

Multivariable regression was performed to identify independent predictors of study group (no IFG/diabetes; IFG; diabetes) among a set of clinically relevant variables. These included age, sex, marital status, employment, weight, BMI, waist circumference, SBP, DBP, having glycaemia measured before, polyuria, weight loss, polydipsia, weakness, eating vegetables, eating fruits, consuming free-sugars food and beverages, alcohol assumption, adding refined salt in meals, doing physical activities for at least 30 minutes and time spent seated. Some of them (DBP, BMI, waist circumference, marital status, employment) were not included in the initial model due to collinearity with SBP, weight or age. Eating free-sugars food and drinking free-sugars beverages conveyed the same meaning, thus were combined in a single variable (named "consuming free-sugars food/beverages"). As proxy for sedentary

	N of participants	Estimated prevalence	95% confidence interval
No IFG/diabetes	1,425	79.0%	77.1% to 80.9%
IFG	162	9.0%	7.7% to 10.4%
Diabetes	216	12.0%	10.5% to 13.5%

Table 1. Prevalence of IFG and diabetes among 1,803 participants who attended the six health centers in Luanda (Angola) during August-November 2018 and had their FBG levels tested (cross sectional survey).

habits, time spent seated was preferred to "doing physical activities for at least 30 minutes". Model selection was performed by AIC reduction. Owing to the ranked outcome, the ordered logistic regression model was initially chosen. The proportional odds assumption was checked graphically because statistical tests for this purpose have been criticized to be un-conservative[11]. The proportional odds assumption was not satisfied for some variables, thus a generalized ordered logit (partial proportional odds) model was estimated[12]. Effects sizes were reported as odds ratios (OR) with 95% confidence intervals (CI), where OR_1 indicated the odds ratio for IFG/diabetes vs. no IFG/diabetes, and OR_2 indicated the odds ratio for diabetes vs. no diabetes. The analysis estimated two different odds ratios (OR_1 and OR_2) for the explanatory variables violating the proportional odds assumption, while equal odd ratios ($OR_1 = OR_2$) were reported for all other explanatory variables not violating the assumption. Missing data were not imputed. All test were 2-sided and a p-value less than 0.05 was considered statistically significant. Statistical analysis was performed using R 3.5 (R Foundation for Statistical Computing, Vienna, Austria)[13].

Ethics. This study was approved by the National Public Health Directorate of the Ministry of Health of Angola and by the Ethics Committee of the Ministry of Health of Angola (number 21/2018). Each participant signed a full informed consent form. All methods were performed in accordance with the relevant guidelines and regulations. The study used anonymized data and no identifiable data were collected.

Results

Cross sectional survey. A total of 1,803 participants were included in the cross sectional survey and had their FBG levels tested between August 2018 and November 2018. Diabetes was diagnosed in 216 participants (prevalence 12.0%, 95% CI 10.5% to 13.5%) and IFG in 162 participants (prevalence 9.0%, 95% CI 7.7% to 10.4%), while 1,425 participants had no IFG/diabetes (prevalence 79.0%, 95% CI 77.1% to 80.9%) (Table 1).

Among the 216 participants with diabetes: 144 (66.7%) had FBG $\geq$ 126 mg/dl without previous diagnosis or treatment for diabetes; 27 (12.5%) were not receiving treatment for a previously diagnosed diabetes and had FBG $\geq$ 126 mg/dl; 27 (12.5%) had FBG $\geq$ 126 mg/dl despite receiving treatment for diabetes; 18 (8.3%) were receiving treatment for diabetes and had FBG $\leq$ 125 mg/dl.

Case-control study. Factors associated with IFG and diabetes were investigated in a subgroup of 486 participants (162 per study group) as described in Methods. Participant characteristics are reported in Table 1. Age ($p < 0.0001$), marital status ($p = 0.001$) and employment ($p < 0.0001$) were different among the study groups (Table 2).

Weight ($p < 0.0001$), BMI ($p = 0.01$), waist circumference ($p = 0.01$), systolic blood pressure ($p = 0.0002$), diastolic blood pressure ($p = 0.0003$) and heart rate ($p < 0.0001$) were different among the study groups, with the increasing values in participants with IFG and diabetes with respect to those with no IFG/diabetes (Table 3).

The proportion of participants who already heard about diabetes was not different in study groups ($p = 0.22$), but having glycaemia measured before ($p < 0.0001$) was more frequent in participants with diabetes (Fig. 1). The occurrence of symptoms (i.e. polyuria, weight loss, polydipsia and weakness) was different among study groups, with higher rates in subjects with IFG or diabetes (Fig. 1). Only 14 participants were smokers. All numeric data are reported in Supplementary Information.

Eating vegetables ($p = 0.03$), eating free-sugars food ($p = 0.04$), alcohol assumption ($p = 0.006$) and time spent seated ($p = 0.0007$) were different among study groups (Fig. 2). Eating vegetables was more frequent in participants without IFG/diabetes, who also reported shorter time spent seated and less frequent assumption of sweetened products and alcohol (Fig. 2). Eating fruit ($p = 0.07$) and doing physical activities for at least 30 minutes ($p = 0.07$) showed small (non-statistically significant) differences among study groups (Fig. 2). There were no statistically significant differences in drinking free-sugars beverages ($p = 0.34$) and adding refined salt in meals ($p = 0.24$) among study groups (Fig. 2). All numeric data are reported in Supplementary Information.

Multivariable analysis was performed to identify predictors of study group (no IFG/diabetes; IFG; diabetes) among a set of clinically relevant variables (as described in Methods). Sex, SBP, weight loss, eating fruits and adding refined salt in meals were excluded to the model due to AIC reduction. The final model is shown in Table 4. Older age ($OR_1 = OR_2$ 1.03, 95% CI 1.02 to 1.04) and higher weight ($OR_1 = OR_2$ 1.01, 95% CI 1.01 to 1.03) were associated with increased likelihood of IFG or diabetes. Having measured glycaemia before was associated with increased risk of diabetes (OR_2 2.07, 95% CI 1.29 to 3.31) but no significant difference was found for IFG/diabetes vs. no IFG/diabetes (OR_1 0.75, 95% CI 0.47 to 1.20). Feeling polyuria was associated with increased likelihood of IFG/diabetes (OR_1 1.93, 95% CI 1.13 to 3.28) and of diabetes (OR_2 2.18, 95% CI 1.32 to 3.59). Feeling polydipsia was associated with increased likelihood of IFG/diabetes (OR_1 1.92, 95% CI 1.16 to 3.18) but no significant difference was found for diabetes vs. no diabetes (OR_2 1.43, 95% CI 0.87 to 2.36). Feeling weakness was associated with increased likelihood of IFG or diabetes ($OR_1 = OR_2$ 2.22, 95% CI 1.39 to 3.55). Eating vegetables daily was associated with decreased likelihood of IFG or diabetes ($OR_1 = OR_2$ 0.69, 95% CI 0.47 to 0.99), while daily consumption

	No IFG/diabetes	IFG	Diabetes	p-value
N	162	162	162	—
Age, years[a,b]	33 (26–48)	42 (30–55)	46 (35–58)	<0.0001
Male:female	40:122	42:120	50:112	0.42
Marital status[c]				0.001
Single	136 (84)	121 (76)	100 (64)	
Married	20 (12)	29 (18)	39 (25)	
Widow/divorced	6 (4)	9 (6)	17 (11)	
Employment[d]				<0.0001
Student	26 (16)	14 (9)	11 (7)	
Worker	52 (33)	66 (43)	60 (39)	
Housewife/other	68 (43)	36 (23)	44 (29)	
Retired/unemployed	13 (8)	38 (25)	38 (25)	
Education[e]				0.10
None	6 (4)	24 (16)	17 (11)	
Primary	35 (24)	25 (16)	30 (20)	
Secondary 1st cicle	37 (26)	35 (24)	40 (27)	
Secondary 2nd cicle	46 (32)	49 (33)	44 (30)	
University	21 (14)	16 (11)	18 (12)	
Number of children[f]				0.06
0	28 (18)	20 (13)	15 (10)	
1	11 (7)	17 (11)	12 (8)	
2	24 (15)	14 (9)	12 (8)	
≥3	94 (60)	105 (67)	112 (74)	
Number of people living at home[g]				0.53
1–3	25 (16)	23 (16)	31 (20)	
4–6	76 (48)	65 (42)	65 (42)	
≥7	56 (36)	65 (42)	59 (38)	

Table 2. Characteristics of 486 participants not receiving treatment for diabetes who attended the six health centers in Luanda (Angola) during August-November 2018 (case-control study). Data expressed as n(%) or [a] median (IQR). Data not available in [b]5, [c]9, [d]20, [e]43, [f]22 and [g]21 participants. The comparisons were performed using Kruskal-Wallis test, Chi-square test or Fisher's exact test, as appropriate.

	No IFG/diabetes	IFG	Diabetes	p-value
N	162	162	162	—
Weight, kg[a]	60 (54–69)	68 (56–81)	68 (59–78)	<0.0001
BMI, kg/m^{2}[b]	22.4 (19.4–25.8)	24.1 (20.6–28.0)	23.8 (20.9–27.4)	0.01
Waist circumference, cm [c]	77 (63–89)	79 (60–95)	84 (69–98)	0.01
Systolic blood pressure, mmHg[a]	120 (110–136)	130 (113–147)	130 (114–150)	0.0002
Diastolic blood pressure, mmHg[d]	73 (63–80)	78 (70–90)	80 (70–90)	0.0003
Heart rate, bpm[e]	70 (62–79)	75 (65–82)	80 (67–92)	<0.0001

Table 3. Clinical parameters of 486 participants not receiving treatment for diabetes who attended the six health centers in Luanda (Angola) during August-November 2018 (case-control study). Data expressed as median (IQR). Data not available in [a]10, [b]42, [c]38, [d]12 and [e]26 participants. The comparisons were performed using Kruskal-Wallis test.

of free-sugars food/beverages was associated with increased likelihood of IFG or diabetes ($OR_1 = OR_2$ 2.34, 95% CI 1.44 to 3.81). Remaining seated for more than 2 hours per day was associated with increased likelihood IFG/diabetes (OR_1 1.80, 95% CI 1.17 to 2.76) but no significant difference was found for diabetes vs. no diabetes (OR_2 0.95, 95% CI 0.61 to 1.50).

Discussion

Our study revealed a high prevalence of diabetes and IFG among adults attending healthcare facilities in the capital city of Angola. Every 100 of them, diabetes was likely to be found in 12 and IFG in nine. Of note, two out of three adults with diabetes were unaware of their condition. Multivariable analysis indicated some factors associated with diabetes and/or IFG. Some were diet/lifestyle factors such as not eating vegetables daily, consumption of free-sugars food/beverages and time spent seated. Some were demographics/biometrics (i.e. older

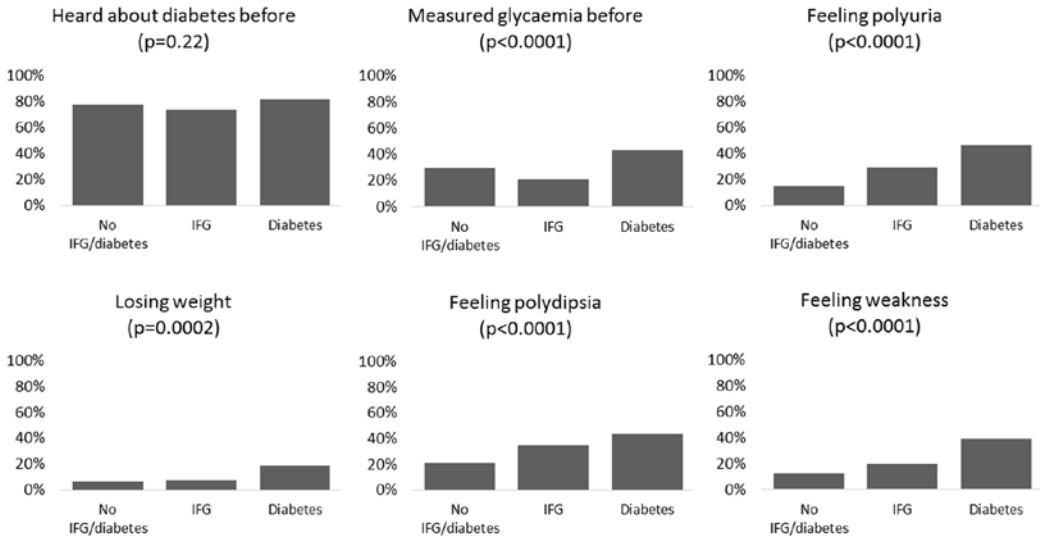

Figure 1. Clinical information of 486 participants not receiving treatment for diabetes who attended the six health centers in Luanda (Angola) during August-November 2018 (case-control study).

Figure 2. Diet habits and physical activity of 486 participants not receiving treatment for diabetes who attended the six health centers in Luanda (Angola) during August-November 2018 (case-control study).

age, higher weight) or symptoms (i.e. polyuria, polydipsia, weakness), that could be used to identify adults to test. Interestingly, a previous measurement of glycaemia was associated with increased likelihood of diabetes.

Our findings contributes to the investigation of diabetes in SSA, where available figures are based on extrapolation for 32 out of 49 countries[2]. In Angola, WHO reports no policies or action plans for diabetes, and the absence of registries, surveys or surveillance on the disease[7]. In this context, epidemiologic studies can shed some light on magnitude and features of the situation. So far, four cross-sectional studies have provided some data on diabetes in Angola. High prevalence (9.2%) and low awareness of diabetes were found in adults living in Dande municipality[14], while low prevalence (2.8%) but no awareness of diabetes were reported in a rural community[15]. Low but not-negligible prevalence of diabetes was found among healthy workers of a private tertiary health center (2.69%) and a university (5.7%)[16,17]. The present study adds on available information from rural areas or restricted to very specific subjects (i.e. workers of a health center and workers of a university) by presenting data from an urban setting. Our findings indicate a high prevalence of diabetes and IFG among adults attending health centers in the capital city of Angola, while confirming the common unawareness of the disease[4].

Our study focused the investigation on an urban setting because many SSA counties are experiencing an increase in NCDs due to changes in diet and lifestyle associated with urbanization[6]. In the African region, the prevalence of diabetes has been found higher in urban compared to rural settings[18], with urbanization boosting

	Risk factors for IFG/diabetes		Risk factors for diabetes	
	OR_1 (95% CI)	p-value	OR_2 (95% CI)	p-value
Age, years	1.03 (1.02 to 1.04)	<0.0001	1.03 (1.02 to 1.04)	<0.0001
Weight, kg	1.01 (1.01 to 1.03)	<0.0001	1.01 (1.01 to 1.03)	<0.0001
Measured glycaemia before:		0.23		0.003
No	Reference		Reference	
Yes	0.75 (0.47 to 1.20)		2.07 (1.29 to 3.31)	
Feeling polyuria:		0.01		0.002
No	Reference		Reference	
Yes	1.93 (1.13 to 3.28)		2.18 (1.32 to 3.59)	
Feeling polydipsia:		0.01		0.16
No	Reference		Reference	
Yes	1.92 (1.16 to 3.18)		1.43 (0.87 to 2.36)	
Feeling weakness:		0.0008		0.0008
No	Reference		Reference	
Yes	2.22 (1.39 to 3.55)		2.22 (1.39 to 3.55)	
Eating vegetables daily:		0.04		0.04
No	Reference		Reference	
Yes	0.69 (0.47 to 0.99)		0.69 (0.47 to 0.99)	
Consuming free-sugars		0.0006		0.0006
food/beverages daily:	Reference		Reference	
No	2.34 (1.44 to		2.34 (1.44 to	
Yes	3.81)		3.81)	
Drinking alcohol daily:		0.14		0.14
No	Reference		Reference	
Yes	1.43 (0.89 to 2.30)		1.43 (0.89 to 2.30)	
Seated >2 hours daily:		0.007		0.84
No	Reference		Reference	
Yes	1.80 (1.17 to 2.76)		0.95 (0.61 to 1.50)	

Table 4. Multivariable analysis of risk factors of IFG and diabetes among 486 participants not receiving treatment for diabetes who attended the six health centers in Luanda (Angola) during August-November 2018 (case-control study). Results from the generalized ordered logit (partial proportional odds) model. Effects sizes are reported as odds ratio (OR) with 95% confidence interval (CI). OR_1 indicated the odds ratio for IFG/diabetes vs. no IFG/diabetes, while OR_2 indicated the odds ratio for diabetes vs. no diabetes. The analysis estimated two different odds ratios (OR_1 and OR_2) for the explanatory variables violating the proportional odds assumption, while equal odd ratios ($OR_1 = OR_2$) were reported for all other explanatory variables not violating the assumption.

the increasing trend but also representing an opportunity to develop urban strategies conducive to healthy behaviours[6]. WHO underlines the role of regular physical activity, weight control and healthy diet in reducing the risk of diabetes[19], but context-tailored approaches are needed to reduce the prevalence of modifiable risk factors in SSA population[20]. Within its limitations, our findings provided suggestions for identification of subjects to test and for diabetes reduction strategies in Angolan urban settings. While there is little evidence of benefit of diabetes screening in low-resource settings[5], it is still plausible that early detection of diabetes in Luanda may improve patient's outcomes by avoiding serious complications before diagnosis. On the other hand, there is no evidence that counselling people with IFG changes their future risk of diabetes[10].

The present study has some limitations that should be considered. First, it is a cross-sectional study including adults attending health facilities in Luanda, thus the generalization of the findings may be limited to similar settings (i.e. adults attending health facilities in urban areas in sub-Saharan countries). The demographics of our sample might be compared with those of the population served by the health centers, in order to generalize the findings to the larger community and to identify gaps in terms of who was seeking care at the health facilities. Unfortunately, such information was not available at the time of the analysis, but further investigations may contribute to fill this gap. Second, information about the reason for attending the health facilities was not collected because the study aimed to evaluate the magnitude of IFG/diabetes burden among people attending the health facilities irrespective of the reason, in order to advise health care stakeholders. Future investigations may disclose the reasons for seeking care at the health centers in Luanda, as well as possible associations with IFG and diabetes. Third, we relied only on FBG to classify prediabetes and diabetes, while a 2-h oral glucose tolerance test (OGTT) was not conducted. Since estimated diabetes prevalence may be higher with 2-h OGTT thresholds compared with FBG thresholds[21], our results may be considered a conservative estimate of the diabetes prevalence among adults attending the health centers in Luanda. Forth, the cross-sectional nature precludes any causal association, and the reliance of self-reported information on diet and physical activity may bias some results in the analysis of risk factors.

Nevertheless, the high prevalence of diabetes and IFG - coupled with large unawareness - in the capital city of Angola calls for improvements in prevention and identification of the disease. While population-wide screening should be avoided in low-resource settings[5], the identification of factors associated with diabetes/IFG may help in selecting subjects to test in sub-Saharan urban settings. In addition, participants who reported a previous measurement of glycaemia resulted at increased risk of diabetes, thus confirming poor management of the disease and unmet need for diabetes care in low-resource settings[22]. With diabetes increasing in SSA, improving the understanding of the disease in the local context is essential for the implementation of proven interventions[6,19]. Moreover, risk-based interventions may be especially effective where diagnostic tools are lacking[23]. Detailed diet and lifestyle investigation with appropriate tools may provide useful information for context-tailored interventions[20,24]. SSA countries share some limitations to prevention and management options for diabetes, including poor understanding of the disease, poor control of glycaemia and other risk factors, and barriers to treatment or transport to treatment facilities[5]. Although there are examples of successful strategies in high-resource settings, further research should focus on assess whether these strategies are transferable to SSA[5,20,25,26].

Conclusions

The high prevalence of diabetes and IFG, with common unawareness of the disease, calls for appropriate interventions in Angolan urban settings. Further research may evaluate the impact of context-specific factors to enhance intervention strategies and feed the results into local health policies. In addition, such information may be useful for selecting high-risk subjects to test.

Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Author contributions
C.R. contributed to conception and study design, data acquisition, interpretation of results and drafting the manuscript. G.P. contributed to study conception and interpretation of results, and revised the manuscript critically for important intellectual content. N.d.C. contributed to data acquisition and revised the manuscript critically for important intellectual content. A.A. contributed to data acquisition and revised the manuscript critically for important intellectual content. G.S. contributed to study conception and revised the manuscript critically for important intellectual content. A.A. contributed to study conception and revised the manuscript critically for important intellectual content. F.C. contributed to study design, data analysis, interpretation of results and drafting the manuscript. All authors read and approved the final manuscript.

Competing interests
The authors declare no competing interests.

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Giant mesenteric cyst: Successful management in low-resource setting

PAPER

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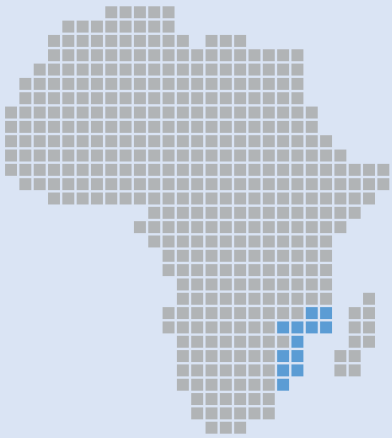

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Giant mesenteric cyst: Successful management in low-resource setting

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ABSTRACT

INTRODUCTION: Mesenteric cysts are rare, generally benign intra-abdominal lesions with a wide range of presentation in terms of size, clinical presentation, etiology, radiological features, and pathological characteristics.
PRESENTATION OF CASE: We reported a case of giant mesenteric cyst in a 16-month-old girl successfully managed in a low-resource setting.
DISCUSSION: This case is particularly important not only due to the rarity of the presented case, but also for the highlighted aspects from a public health point of view.

We faced of the problem of a late stage disease and the lack of preoperative diagnosis due to cultural and economic reasons and the weaknesses of healthcare systems, as in the majority of low- and middle-income countries.
CONCLUSION: Despite all these limitation, this case illustrates that complex, rare diseases can also be managed successfully in a low-resource setting. It is mandatory to strengthen and improve the health system both in terms of equipment both in terms of public health policies in order to offer a better and more effective quality of care to patients also in low-income countries.

1. Introduction

Mesenteric cysts are rare, generally benign intra-abdominal lesions with an incidence ranging from 1 in 105,000 to 1 in 250,000 among admitted surgical patients [1]. Mesenteric cysts have a wide range of presentation in terms of size, clinical presentation, etiology, radiological features, and pathological characteristics [2]. In fact, the average size ranges from 2 to 35 cm and, thus, patients present with nonspecific complaints of abdominal pain, distension, or an abdominal mass [2]. Although several classifications have been proposed, the most widely recognized includes 4 groups based on clinical and etiological features: 1) lymphatic, 2) mesothelial, 3) enteric, 4) urogenital, 5) mature cystic teratoma and 6) non pancreatic pseudocysts [3]. In general, simple lymphatic and mesothelial cysts are usually asymptomatic, while lymphangiomas and benign cystic mesotheliomas can be aggressive and invasive [3]. Finally, the only malignant is the malignant cystic mesothelioma [3]. Simple lymphatic and mesothelial cysts seems to have a congenital etiology, while lymphangiomas and benign cystic mesotheliomas have not a known origin [3]. The diagnosis is mainly based on clinical and radiological findings with histological confirmation [3]. Surgical removal is considered the gold standard procedure especially for giant cysts and minimally invasive surgery is the approach of choice [4].

We reported a case of giant mesenteric cyst successfully managed in a low-resource setting. The work has been reported in line with the SCARE criteria [5].

2. Ethic statement

Written informed consent was obtained from the parents of the girl for publication of this case report and any accompanying images.

3. Case report

A 16-month-old girl presented with diffuse abdominal distention, nausea, vomiting and severe pain after one month history of abdominal discomfort. The physical examination, made difficult by painful palpation, showed severe abdominal distention with a palpable, soft and fluid-filled mass (Fig. 1A). Plain abdominal

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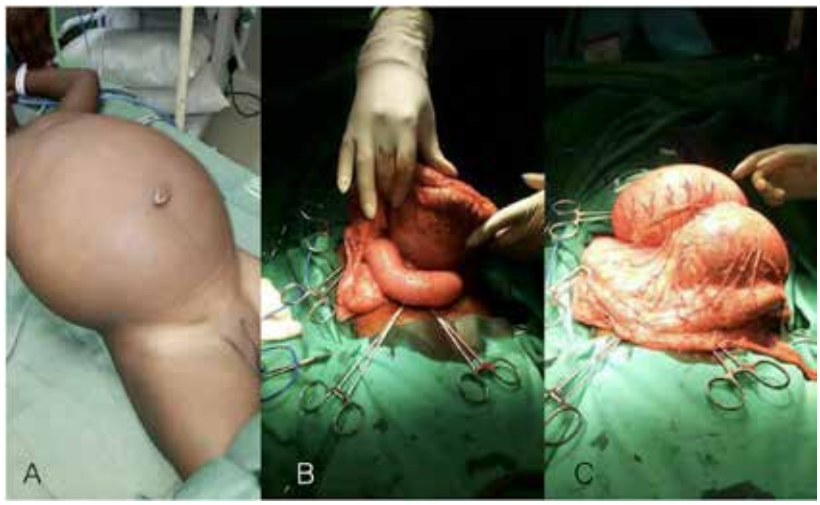

Fig. 1. Giant mesenteric cyst at presentation (A) and intra-operative images (B and C).

radiographs showed air–fluid levels and distended bowel loops, suggesting intestinal occlusion. Without the possibility to perform more adequate imaging tests, and worsening the conditions of the girl, we planned a surgical intervention. We performed a laparotomy and found a giant, soft, cystic, milky fluid–filled mass in the mesentery of the ileum (Fig. 1B and C). The intestinal resection of about 10 cm of the involved loops was necessary. Pathological examination confirmed a diagnosis of mesenteric cystic lymphangioma containing chylous milky fluid. We removed a mass containing about 400 ml fluid.The following postoperative course was regular. On the tenth postoperative day the girl was discharged.

4. Discussion

This is a very rare case considering that lymphangiomas incidence ranges from 1 in 105,000 to 1 in 250,000 among admitted surgical patients and are predominant in male [1]. Mesenteric cysts are frequently symptomatic and localized in the mesentery but can appear also in adults and middle aged women mainly in retroperitoneal space [6,7]. The clinical presentation is influenced by the size of the cyst and the age of patients [7]. During childhood, it can simulate an appendicitis, while in adults is often asymptomatic [7,8]. The symptoms are generally a-specific and include pain, nausea and vomiting, constipation or diarrhea. Moreover, an abdominal palpable mass is present in up to 61% of the patients [9].

Usually, the preoperative diagnosis is done by ultrasound in order to distinguish between plain and cystic masses and computerized tomography (CT) or magnetic resonance imaging (MRI) to determine extension and cystic content [10]. Needle aspiration or explorative laparoscopy can further help in differentiating between a pancreatic pseudocyst, a benign cyst mesothelioma or a lymphangioma before any operative procedure [10].

Unfortunately, in our case we had no adequate diagnostic imaging and we preferred to directly choose the surgery option considering the late stage situation with noticeable symptoms. The surgical treatment is mandatory for large mesenteric cysts in order to exclude malignant transformation and to prevent complications, such as rupture, hemorrhage, torsion or infections. In case of simple lymphatic and mesothelial cysts, it is easy and curative to enucleate the mass, but lymphangiomas and benign cystic mesotheliomas could be adherent to vital intra-abdominal structures and their complete excision could be very difficult or impossible. Although limphangiomas and benign cystic mesothelioma are considered benign tumors and, thus, should be avoided the resection of vital organs, in some cases is reported a resection of different organs due to adhesion [6,7]. In our case, we performed a 10 cm of intestinal resection without remove any part of terminal ileum. This is a crucial aspect for a good grow and development of the girl considering that she shouldn't have important consequences in terms of nutrients absorption and, thus, nutritional status.

Recurrence and metastasis are not frequent and occur especially if the resection is incomplete [11].

We were able to confirm the hypnotized diagnosis first of all by macroscopic characteristics that are useful for the distinction from simple lymphatic cysts (small and unilocular), to lymphangiomas (large and multi-loculated, with multiple cysts). Moreover, we confirmed the diagnosis by the histological examination characterizing endothelial and mesothelial cells.

This case is particularly important not only due to the rarity of the presented case, but also for the highlighted aspects from a public health point of view. In fact, as the result of the weaknesses of healthcare systems and also due to cultural and economic reasons, as in the majority of low- and middle-income countries we faced of the problem of a preoperative diagnosis lacking ultrasound, CT and MRI scanners. Moreover, although it is not the case, surgical and anesthesiology equipment is often poor being impossible to perform a complete preoperative or laparoscopic diagnostic procedure. In this case, an explorative laparotomy was necessary without a clear preoperative diagnosis, but this would probably not have changed outcome. In a high-resource country, a laparoscopic approach would have been used to perform the whole operation that we made by open surgery. Despite all these limitation, this case illustrates that complex, rare diseases can also be managed successfully in a low-resource setting. Unfortunately, we lost the patient in follow up due to difficult access to the hospital, living far from the hospital and due to the lack of an effective network and system for monitoring and ensuring follow-up visits.

Therefore, it is mandatory to strengthen and improve the health system both in terms of equipment both in terms of public health policies in order to offer a better and more effective quality of care to patients also in low-income countries.

Conflict of interest

All authors declare no conflict of interest

Funding

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Ethical approval

Written informed consent was obtained from the parents of the child for publication of this case report and any accompanying images.

Moreover the ethical approval has been exempted by our institution considering that the case was written using retrospective and anonymous data.

Consent

Written informed consent was obtained from the parents of the child for publication of this case report and any accompanying images.

Author contribution

MA: data collection and interpretation and final revision.
DP: writing paper and data interpretation.
MS: writing paper.
ACC: data analysis and final revision.

Registration of research studies

This is a case report and it is not registered.

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Type 2 Diabetes Mellitus in urban and rural districts in the area of Wolisso Hospital, Ethiopia

PAPER

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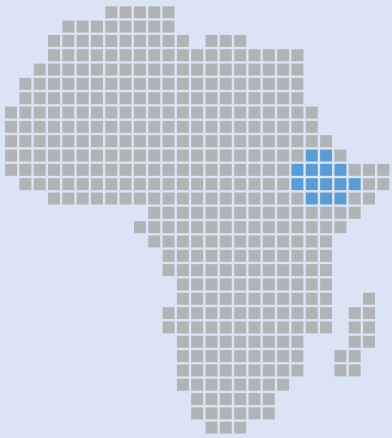

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Lung Ultrasound for Detection of Pulmonary Complications in Critically Ill Obstetric Patients in a Resource-Limited Setting

PAPER

Authors
Pisani L., De Nicolo A., Schiavone M., Adeniji A.O., De Palma A., Di Gennaro F., Emuveyan E.E., Grasso S., Henwood P.C., Koroma A.P., Leopold S., Marotta C., Marulli G., Putoto G., Pisani E., Russel J., Serpa Neto A., Dondorp A.M., Hanciles E., Koroma M.M., Schultz M.J.

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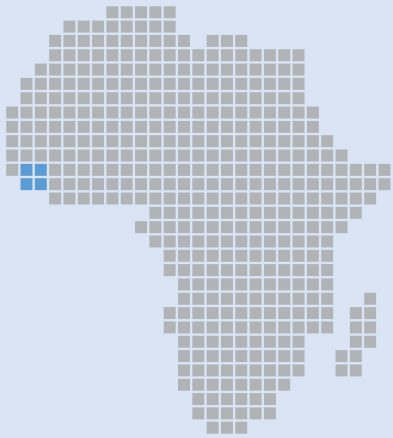

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Lung Ultrasound for Detection of Pulmonary Complications in Critically Ill Obstetric Patients in a Resource-Limited Setting

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Abstract. Critically ill parturients have an increased risk of developing pulmonary complications. Lung ultrasound (LUS) could be effective in addressing the cause of respiratory distress in resource-limited settings with high maternal mortality. We aimed to determine the frequency, timing of appearance, and type of pulmonary complications in critically ill parturients in an obstetric unit in Sierra Leone. In this prospective observational study, LUS examinations were performed on admission, after 24 and 48 hours, and in case of respiratory deterioration. Primary endpoint was the proportion of parturients with one or more pulmonary complications, stratified for the presence of respiratory distress. Secondary endpoints included timing and types of complications, and their association with "poor outcome," defined as a composite of transfer for escalation of care or death. Of 166 patients enrolled, 35 patients (21% [95% CI: 15–28]) had one or more pulmonary complications, the majority diagnosed on admission. Acute respiratory distress syndrome (period prevalence 4%) and hydrostatic pulmonary edema (4%) were only observed in patients with respiratory distress. Pneumonia (2%), atelectasis (10%), and pleural effusion (7%) were present, irrespective of respiratory distress. When ultrasound excluded pulmonary complications, respiratory distress was related to anemia or metabolic acidosis. Pulmonary complications were associated with an increased risk of poor outcome (odds ratio: 5.0; 95% CI: 1.7–14.6; $P = 0.003$). In critically ill parturients in a resource-limited obstetric unit, LUS contributed to address the cause of respiratory distress by identifying or excluding pulmonary complications. These were associated with a poor outcome.

INTRODUCTION

Maternal mortality in Sierra Leone is among the highest in the world, with 1,360 maternal deaths/100,000 babies born alive.[1] Major direct obstetric complications are an important cause of increased mortality.[2] The three leading causes of mortality and morbidity during pregnancy are peripartum hemorrhage, sepsis, and preeclampsia[3,4]—each of these directly or indirectly predispose for pulmonary complications.[3] Pulmonary complications requiring transitory or intense critical care treatment may arise before, during, and even after the primary obstetric disease is resolved. Among obstetric patients in Sierra Leone, additional risk factors for developing pulmonary complications include pregnancy-associated cardiopulmonary changes,[5] iatrogenic fluid overload, tocolytic therapy,[5] transfusion-related acute lung injury in patients who receive blood transfusions,[6] and sickle cell disease.[7]

Bedside imaging techniques are increasingly available to detect pulmonary pathologies, including point-of-care lung ultrasound (LUS).[8,9] Lung ultrasound is a low-cost, repeatable, and radiation-free imaging technique with a steep learning curve. It is an example of frugal innovation in critical care, thus sustainable also in resource-limited settings where conventional radiological tools are absent.[10] Besides, X-ray imaging is preferably restricted in parturients because of the ionizing risk on the fetus. Lung ultrasound patterns are usually normal in parturients during the last gestational weeks,[11] allowing the detection of acute pulmonary abnormalities. A recent hospital-wide study performed in Rwanda found that acute respiratory distress syndrome (ARDS) detected by LUS was a frequent and often lethal complication.[12] Up to one in every 10 patients with ARDS in that study was obstetric, of whom 20% died.

The frequency with which ARDS and other pulmonary complications develop and are associated with poor outcome in critically ill parturients is largely unknown in resource-limited settings with a high maternal mortality. The objectives of the current study were to determine frequency, timing with regard to admission, type of pulmonary abnormalities detectable by LUS, and their associations with poor outcome in parturients admitted to the high dependence unit (HDU) of a large urban maternity hospital in Freetown, Sierra Leone. The primary hypothesis tested is that a large proportion of patients develop pulmonary complications identifiable by LUS and that development of these complications is associated with poor outcome.

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METHODS

Design and ethical approval. This was a prospective observational study conducted between July 2018 and February 2019 in critically ill parturients admitted to the HDU of the Princess Christian Maternity Hospital (PCMH) in Freetown, Sierra Leone. The study was approved by the Sierra Leone Ethical Research Committee on June 5, 2018. A waiver of written consent was granted because of the observational purpose of the study. The study was registered at clinicaltrials.gov (study identifier NCT 03828630).

Patients. Patients were eligible for participation if 1) parturient and 2) admitted to the HDU of the PCMH. Patients were excluded if they had passed the time window of 6 hours after admission to the HDU. Anticipated logistical reasons for exclusion were the nonavailability of the physician sonographer, for example, during weekend days, or when the dedicated physician was on call in the operating room or another ward. Patients were stratified by the presence of respiratory distress at any point during HDU stay.

Data collected. Patient clinical and ultrasound granular data were collected at predefined timepoints: on admission, after 24 hours and 48 hours, and at any point in case of patient deterioration. Demographic data collected on admission included age, weight, height, reported reason for hospital and for HDU admission, and the women gravidity, parity, and gestational age; malaria status and preexistent comorbidities; and surgical and transfusion status during the current hospital admission.

Vital signs, including heart rate, respiratory rate, temperature, neurological status, and systolic and diastolic arterial blood pressure, were captured at the moment of each LUS examination and used to compute the modified obstetric early warning score (OEWS).[13] Obstetric early warning score is a composite score reflecting impairment of physiological parameters at admission. Also, peripheral pulse oximetry oxygen saturation (SpO_2), findings of chest auscultation, use of accessory muscles, and presence of nasal flaring were collected at each time point. Whenever performed for clinical reasons, point-of -care laboratory measures such as hemoglobin, glucose, and capillary lactate levels were recorded. However, no systematic laboratory examination was performed for the study purpose. Urinary output was recorded at each timepoint for catheterized patients together with the amounts of intravenous fluids administered at 24 and 48 hours. It was also recorded whether supplementary oxygen, vasopressors, and diuretics were administered. Follow-up ended at HDU discharge. Then, it was recorded whether the patients left the HDU alive or not, and status at discharge, that is, improved and discharged to ward, or transfer to tertiary hospital because of escalation of care.

Primary and secondary endpoints. The primary endpoint was the proportion of parturients with pulmonary complications detectable by LUS during stay in HDU. Secondary endpoints were the timing of appearance and types of pulmonary complications, the patients' global LUS aeration score, and occurrence of poor outcome.

The protocol for LUS. A comprehensive LUS examination was performed at each timepoint and in case of respiratory distress or clinical pulmonary edema during HDU stay (Figure 1). To minimize operator dependency and bias, LUS was performed using standardized operating procedures and structured region-based case report forms. All LUS examinations were performed by senior residents in intensive care medicine or thoracic surgery (A. d. N., M. S.), with a > 2-year experience in ultrasound procedures in critically ill patients. Dedicated bedside and remote training on at least 12 supervised examinations[14] was performed together with an experienced LUS sonographer (L. P.) to familiarize with the systematic LUS scoring and case report form completion. Lung ultrasound was performed using a MyLab™Five ultrasound machine (Esaote Spa, Genova, Italy) and a low frequency (2.5–5 MHz) convex probe. The ultrasound machine, the probe, and the probe holder were disinfected before and after each use as from hospital indications. The patient remained in supine or semi-recumbent position, and the probe was held perpendicular to the skin.

The 12-region technique was used, in which ultrasound was performed on six areas on each side of the chest, that is, two ventral regions, two lateral regions, and two posterolateral regions, with a transversal approach to maximize lung exposition and minimize rib-related artifacts.[15] The examiner scored the worst aeration pattern observed in each region using the LUS aeration score.[16] Each lung field was scored from 0 to 3 as follows: "0," A-pattern with ≤ 2 B-lines; "1," more than 2 separated B-lines; "2," multiple coalescent B-lines; or "3," lung consolidation, defined as anechoic or tissue-like images arising from the pleural line that is limited in depth by an irregular border. A global LUS score was calculated at each time point and ranged from 0 to 36. The presence of subpleural consolidations, effusion, air bronchograms, and abnormal pleural line was assessed in each field. Normal lung aeration observed using LUS was defined as all lung fields normally aerated, that is, with an A-pattern or aeration score of 0; bilateral interstitial syndrome was defined as the presence of two or more regions with a B-pattern (score 1 or 2) per hemithorax.[8,17] A subcostal view was also acquired with the maximal and minimal diameter of the inferior vena cava, measured in motion mode 2 cm distal to the origin of the right atrium.[18] Twelve ultrasound clips of 5 seconds each were stored after each examination on the ultrasound machine and exported as video files to a portable computer for offline analysis and quality control purposes.

Definitions. Respiratory distress was defined as the presence of one or more among the following criteria: respiratory rate ≥ 30 breaths/minute, SpO_2/fraction of inspired oxygen (FiO_2) ≤ 315, and signs of difficult breathing, including the use of accessory muscles or nasal flaring.

The following definitions were used to derive the pulmonary complications from the collected clinical and ultrasound data.

Acute respiratory distress syndrome—defined according to the Kigali modification of the Berlin definition for ARDS.[12] The oxygenation status was computed as the ratio between SpO_2 and FiO_2. Fraction of inspired oxygen was derived from the oxygen flow using the formula $FiO_2 = 0.21 + (O_2 \text{ flow} \times 0.03)$.[12] Bilateral opacities on LUS were defined as the presence of interstitial syndrome and/or two or more regions with lung consolidation bilaterally, not fully explained by effusions, lung collapse, or nodules. To fulfill the origin of edema criteria (i.e., respiratory failure not fully explained by cardiac failure or fluid overload) in a setting with absent echocardiography, all patients with a known history of

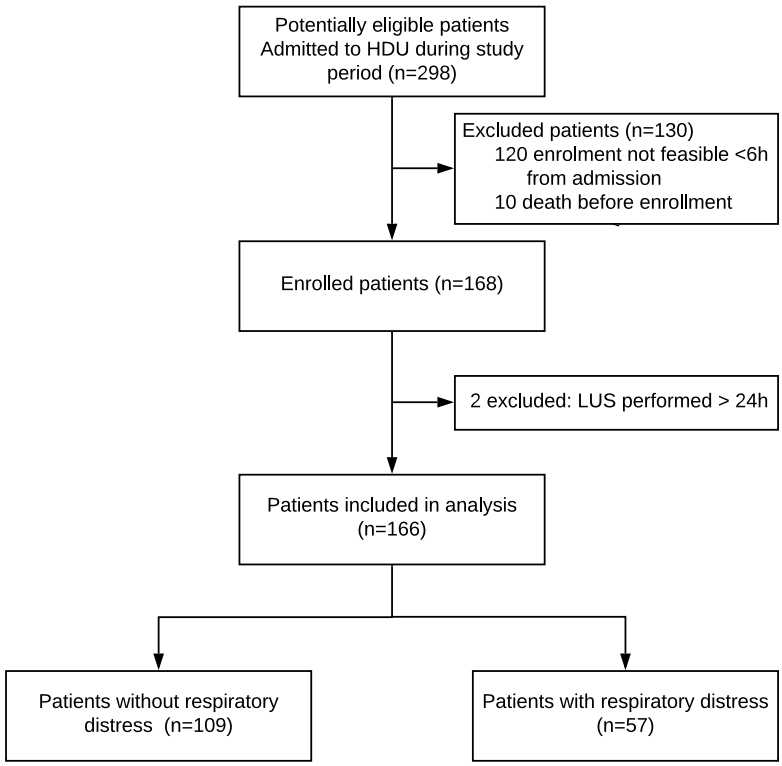

FIGURE 1. Patient flowchart. HDU = high dependency unit; LUS = lung ultrasound.

cardiac failure or diagnosed with fluid overload were excluded from this potential diagnosis.

Fluid overload or hydrostatic pulmonary edema—defined as the presence of a bilateral interstitial syndrome or pleural effusion on LUS, associated with a positive fluid balance (> 1,000 mL in the last 24 hours), and/or a maximal diameter of the inferior vena cava of > 23 mm.[19]

Pneumonia—defined as focal or multifocal interstitial syndrome and/or consolidation on LUS plus at least one of the following: temperature > 38.3°C or white blood cell count > 12,000/mm^3 (if available).

Atelectasis—defined as the presence of mono or bilateral focal consolidations, denoting a focal loss of aeration, which did not fall in the case definitions for ARDS, pneumonia, or fluid overload.

Pleural effusion—defined as hypoechoic or anechoic collection between the parietal and visceral pleura in at least one lung region.[17]

Poor outcome—a composite of transfer for escalation of care or death in the HDU.

Power calculation. All patients admitted over the time span the study ran were to be included. Considering previous semester admission rates and operator availability, it was expected that more than 150 patients would be eligible during the predefined 6 months recruitment period. Considering an estimated prevalence of 20%, this sample size allows to estimate the proportion of pulmonary complications with 5% precision and 95% CI in a finite population.[20]

Statistical analysis. Demographic, clinical, and outcome variables were presented as percentages for categorical variables and as medians with interquartile ranges for continuous variables.

Patients were stratified according to the presence or absence of respiratory distress. The proportion of patients with pulmonary complications during the HDU stay was calculated as the number of patients suffering from at least one pulmonary complication divided by the total number of patients enrolled in the study, and by the number of patients in the group with and without respiratory distress. Types of pulmonary complications and individual frequencies were reported separately for the group with and without respiratory symptoms. The chi-square statistics was used to seek significant differences across patient groups for categorical endpoints.

The Mann Whitney *U* test and the Kruskal–Wallis test were used to compare LUS scores and other numerical variables between patients with and without respiratory symptoms on admission. Interobserver variability for the LUS scoring between the study sonographers and the expert scorer was assessed on 320 LUS images and expressed as Fleiss' kappa statistics.

A logistic regression model was used to test potential associations between occurrence of pulmonary complications and a poor outcome, defined as death in the HDU or transfer for escalation of care. The model was corrected for severity of illness on admission as estimated by the OEWS.

All statistical analyses were performed in *R* (version 3.3.1, www.r-project.org, R Core Team, Vienna, Austria) and graphs built using GraphPad Prism (version 7.03, www.graphpad.com, GraphPad Software, San Diego, CA). A *P*-value below 0.05 was considered significant.

RESULTS

Patient cohort. Of 298 potentially eligible patients, 166 patients were enrolled in the study. Patient flow is detailed in Figure 2. Baseline characteristics are reported in Table 1. Of all patients, 34% presented with or developed respiratory distress during HDU stay. In total, 18 of 166 patients met the composite endpoint of a poor outcome (11%); transfer for escalation of care occurred in 10 (6%), whereas mortality was eight (5%).

Lung ultrasound examinations and interobserver agreement. A total of 383 LUS examinations, median two (2–3) LUS/patient, were performed. All 166 patients were scanned at the day of admission, 121 also after 24 hours, and 86 also after 48 hours. Ten additional LUS examinations were performed in patients who deteriorated in between these planned examinations. Of all potential lung regions, 39 (< 1%) regions could not be examined because of surgical dressings or patient position. Agreement between the two study sonographers and the expert scorer in recording the LUS score for individual lung fields was kappa 0.77. Kappa statistics for anterior, lateral, and posterior lung zones were 0.76, 0.75, and 0.78, respectively.

Prevalence and timing of pulmonary complications. Overall, 21% (95% CI: 15–28) of patients had at least one pulmonary complication detectable by LUS during HDU stay. The incidence of pulmonary complications was higher in patients with respiratory distress versus in patients not having respiratory distress (21 of 57 [37%] versus 14 of 109 [13%]; $P = 0.001$).

Timing of occurrence of pulmonary complications was similar between patients with respiratory distress (67% on admission, and 24% and 10% in the first 24 hours or thereafter) and patients not having respiratory distress (57% on admission, 36% and 7% in first 24 hours or thereafter).

Types of pulmonary complications and patient characteristics. Types and frequency of pulmonary complications are detailed in Table 2. Clinical characteristics are reported in Table 3. Patients with respiratory distress who had pulmonary complications detected by LUS were commonly hypoxemic and more often transferred for escalation of care. Patients with respiratory distress in the absence of pulmonary complication frequently had hemodynamic compromise in terms of higher heart rate and capillary lactates. The few patients who had a complication in the absence of respiratory distress usually had higher body mass index (BMI) and

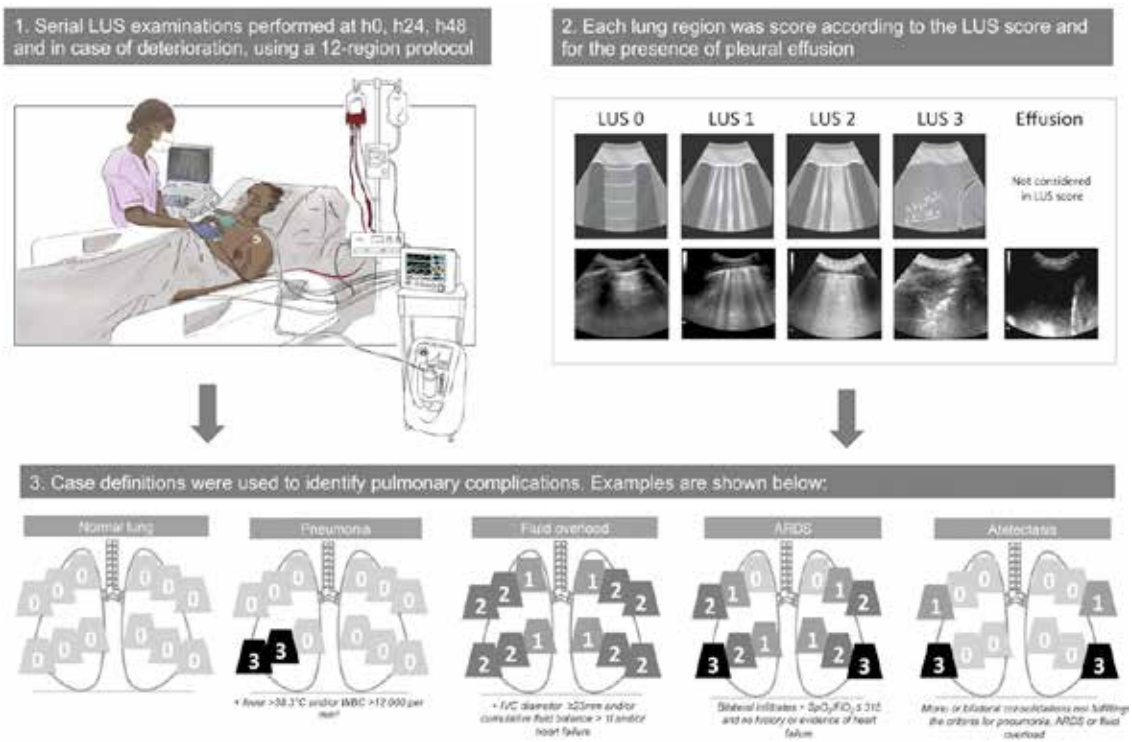

FIGURE 2. Lung ultrasound protocol including the LUS score assessment and predefined case definitions of pulmonary complications integrating LUS and clinical data. One example for each pulmonary complication case definition is shown. Lung ultrasound images were drawn from the study saved clips, with additional details in the text. FiO_2 = fraction of inspired oxygen; IVC = inferior vena cava; LUS = lung ultrasound; SpO_2 = peripheral pulse oximetry oxygen saturation. This figure appears in color at www.ajtmh.org.

TABLE 1
Patient characteristics at baseline

Variable	Number
General epidemiology	
Age (years)	25 (22, 30)
Gestation age (weeks)	36 (32, 38)
Gravidity	3 (2,4)
Parity	1 (0,3)
Body mass index (kg/m^2)	23.9 (22.2, 25.7)
Clinical features	
Obstetric early warning score total score	3 (2, 4)
Altered sensorium, *n* (%)*	16 (9.6)
Mean arterial blood pressure (mmHg)†	95 (82, 110)
Heart rate (beats/minute)‡	105 (95, 120)
Respiratory features	
Respiratory rate (movements/minute)	24 (22, 28)
SpO_2	99 (98, 99)
SpO_2/fraction of inspired oxygen	467 (462, 471)
Oxygen therapy, yes, *n* (%)	29 (17.4)
Biology	
Hemoglobin (g/dL)§	7.9 (6.3, 9.8)
Capillary lactates levels (mmol/L)‖	4.5 (2.6, 7.1)
Positive to malaria, *n* (%)	12 (7.2)
Reason of admission, *n* (%)	
Antepartum hemorrhage	45 (28.7)
Postpartum hemorrhage	14 (8.9)
Uterine rupture	22 (14)
Severe preeclampsia	30 (19.1)
Obstructed labor	15 (9.6)
Ectopic pregnancy	7 (4.5)
Sepsis	11 (7.0)
Sickle cell disease	5 (3.2)
Type of delivery/surgery, *n* (%)	
Spontaneous vaginal delivery	17 (10.8)
Cesarean section	68 (43.3)
Surgery (other than cesarean)	37 (23.6)
Type of anesthesia, *n* (%)	
General anesthesia	84 (53.5)
Spinal anesthesia	18 (11.5)

SpO_2 = peripheral pulse oximetry oxygen saturation. Data are presented as median (interquartile range) or proportion (%).
* Patients only responsive to painful stimulus or unresponsive on admission.
† Missing in three patients.
‡ Missing in one patients.
§ Missing in five patients.
‖ Missing in 46 patients.

suffered from atelectasis. Most patients never developed respiratory distress and had negative LUS examinations.

Lung ultrasound score. Overall, LUS examinations in which a pulmonary complication was detected had higher global LUS score than negative LUS examinations (four [3–9] versus zero [0–1]; $P < 0.001$). The baseline global LUS score was different in the four patient groups, and for different pulmonary complications (Figure 3).

Association with outcome. The occurrence of a poor outcome was highest in patients with respiratory distress and pulmonary complications detected by LUS (Table 2). The occurrence of one or more pulmonary complication was associated with poor outcome (odds ratio: 5.0; 95% CI: 1.7–14.6; $P = 0.003$).

DISCUSSION

In this study of critically ill obstetric patients in a resource-limited HDU in Africa, pulmonary complications detectable by LUS were frequent, affecting one of five patients. Most of these pulmonary complications had an early onset. Acute respiratory distress syndrome and fluid overload occurred with equal prevalence. Presence or development of pulmonary complications diagnosed by LUS was associated with increased risk of poorer outcome.

Strengths of this study include the use of clear case definitions integrating clinical parameters with LUS variables. The prospective design and serial LUS follow-up allowed capturing complications that were not present on admission. Examinations were performed using an abdominal ultrasound probe that is widely available in obstetric units. The stratification by respiratory distress allowed investigation of the clinical meaning of LUS findings in critically ill parturients in a setting where resources are extremely limited.

Patients with abnormal lung findings identified through LUS and respiratory distress frequently had ARDS. The period prevalence of ARDS mirrors previous findings in a hospital-wide study in Rwanda.[12] Whereas the absence of blood gas analysis and chest radiography did not allow to verify the diagnosis of ARDS against the current Berlin definition for ARDS,[21] the used criteria were individually validated.[12,22] Patients were exposed to ARDS risk factors such as sepsis, surgery, malaria, and whole blood transfusions,[23,24] whereas pneumonia was rare.

Pulmonary edema was another diagnosis in patients with pulmonary complications and respiratory symptoms. The incidence of pulmonary edema in the current cohort is in line with estimates ranging from 0.1% in normal pregnancy to 10% in patients with preeclampsia.[25] Physiologic changes of

TABLE 2
Types of pulmonary complications detected by LUS in patients with and without respiratory distress, and associated patients' outcomes

	Respiratory distress (*n* = 57)		No Respiratory distress (*n* = 109)		
	With LUS complication (*n* = 21)	No LUS complication (*n* = 36)	With LUS complication (*n* = 14)	No LUS complication (*n* = 95)	*P*-value
Pulmonary complications,* *n* (%)					< 0.001
Acute respiratory distress syndrome	6 (28.6)	–	0 (0)	–	
Fluid overload	6 (28.6)	–	0 (0)	–	
Effusion	8 (38.1)	–	3 (21.4)	–	
Pneumonia	2 (9.5)	–	1 (7.1)	–	
Atelectasis	6 (28.6)	–	11 (78.6)	–	
Outcomes					
Length of stay (days)	3.0 (2.0,3.2)	3.0 (2.0, 4.2)	3.5 (3.0, 4.0)	3.0 (2.0, 4.0)	0.541
Poor outcome, *n* (%)	6 (28.6)	5 (13.9)	3 (21.4)	4 (4.2)	0.004
Death, *n* (%)	0 (0)	5 (13.9)	1 (7.1)	2 (2.1)	–
Transfer, *n* (%)	6 (28.6)	0 (0)	2 (14.3)	2 (2.1)	–

LUS = lung ultrasound. Data are presented as median (interquartile range) or proportion (%).
* Nonexclusive categories.

TABLE 3
Patient characteristics in the different study groups

	Respiratory distress (n = 57)		No Respiratory distress (n = 109)		
	With LUS complication (n = 21)	No LUS complication (n = 36)	With LUS complication (n = 14)	No LUS complication (n = 95)	P-value
Clinical features					
Obstetric early warning score total score	3 (2, 5)	4 (2, 6)	2 (2, 3)	3 (2, 4)	0.003
Body mass index (kg/m^2)	23.4 (22, 25)	24.2 (23.3, 25.9)	25.1 (23.4, 28.8)	23.4 (21.5, 25.3)	0.03
Respiratory rate (movements/minute)	28 (24, 34)	31 (24, 36)	23 (22, 25.5)	24 (22, 25)	< 0.001
Oxygen therapy, yes, n (%)	14 (66.7)	15 (41.7)	0 (0)	0 (0)	< 0.001
Peripheral pulse oximetry oxygen saturation/fraction of inspired oxygen	275 (269, 452)	462 (274, 471)	467 (467, 470)	471 (467, 471)	< 0.001
Altered sensorium, n (%)*	5 (23.8)	14 (40.0)	3 (21.4)	18 (19.4)	0.114
MAP (mmHg)	85 (81, 112)	95 (78, 105)	89 (82, 108)	95 (83, 109)	0.87
Heart rate (beats/minute)	105 (90, 125)	115 (103, 130)	98 (81, 114)	102 (95, 113)	0.012
Biology, n (%)					
Hemoglobin (g/dL)	9.4 (7, 10.4)	7.1 (5.7, 10.0)	7.6 (5.9, 8.9)	8.0 (6.4, 9.6)	0.466
Cap. lactates, (mmol/L)†	3.5 (2.5, 5.0)	4.8 (3.2, 8.2)	2 (1.9, 3.7)	4.8 (2.9, 7.3)	0.023
Positive to malaria	5 (23.8)	4 (11.1)	2 (14.3)	2 (2.1)	0.004
Reason of admission, n (%)					
Antepartum hemorrhage	14 (66.7)	16 (44.4)	3 (21.4)	14 (14.7)	< 0.001
Postpartum hemorrhage	1 (4.8)	1 (2.8)	1 (7.1)	12 (12.6)	0.291
Uterine rupture	1 (4.8)	4 (11.1)	0 (0)	18 (18.9)	0.112
Severe preeclampsia	5 (23.8)	6 (16.7)	5 (35.7)	15 (15.8)	0.301
Obstructed labor	2 (9.5)	4 (11.1)	0 (0)	11 (11.6)	0.61
Ectopic pregnancy	0 (0)	2 (5.6)	0 (0)	5 (5.3)	0.581
Sepsis	1 (4.8)	4 (11.1)	2 (14.3)	4 (4.2)	0.319
Sickle cell disease	1 (4.8)	4 (11.1)	0 (0)	0 (0)	0.009
Procedures, n (%)					
Type of delivery					0.155
Spontaneous vaginal delivery	3 (14.3)	4 (11.1)	1 (7.1)	10 (10.5)	
Cesarean section	6 (28.6)	9 (25)	6 (42.9)	51 (53.7)	
Surgery (other than cesarean section)	1 (4.8)	7 (19.4)	1 (7.1)	30 (31.6)	0.019
General anesthesia	3 (14.3)	13 (36.1)	8 (57.1)	66 (69.5)	< 0.001
Management features first 24 hours, n (%)					
Transfusion	8 (38.1)	12 (33.3)	9 (64.3)	51 (53.7)	0.084
Fluids administered (mL)‡	2,500 (1725, 3,775)	2,100 (1,500, 2,700)	1,700 (1,250, 2,450)	1,975 (1,413, 2,450)	0.266
Use of vasopressors	3 (14.3)	4 (11.1)	0 (0)	1 (1.1)	0.013

LUS = lung ultrasound; MAP = mean arterial pressure. Data are presented as median (interquartile range) or proportion (%).
* Patients only responsive to painful stimulus or unresponsive on admission.
† Measurement available in 120 patients.
‡ Assessed in 126 patients.

pregnancy, preeclampsia, and puerperal cardiomyopathy predispose parturients to pulmonary oedema.[5] The combination of nifedipine use and magnesium sulfate, acute kidney injury related to severe preeclampsia and iatrogenic fluid overload may have contributed to pulmonary congestion.[26]

Lung ultrasound excluded a pulmonary complication in more than half of patients with respiratory distress. Lung ultrasound high negative predictive value is supported by findings in previous studies and allows to swiftly exclude parenchymal involvement in the dyspneic patient.[8,27] These patients likely had other reasons to develop respiratory symptoms, such as metabolic acidosis and hemorrhagic anemia. Malaria may also induce compensatory tachypnea and represents a risk factor for lung injury.[28] The exclusion of a pulmonary complication in dyspneic parturients was a key finding of this study and may provide the most added value in daily clinical practice in the obstetric population, which generally has a low pretest probability of pulmonary findings. Respiratory distress in combination with a negative LUS may also suggest a pulmonary embolism, which could have been captured with compression ultrasonography.[29] However, to keep burden of the study acceptable, compression ultrasonography was not part of the study protocol.

Patients with a positive LUS in the absence of respiratory symptoms did not require oxygen and had normal oxygenation. Previous studies documented how diffuse B-lines may be present in asymptomatic parturients.[11,30] The finding of frequent atelectasis in this group may be explained by the exposure to risk factors such as higher BMI and general anesthesia.[27,31]

Pulmonary complications were significantly associated with poorer outcome, confirming findings in non–obstetric patients in Africa[12] and Asia.[32] This does not imply a causal relationship with mortality, as parturients largely die of direct obstetric complications such as hemorrhage, eclampsia, and sepsis.[3,33] Yet, pulmonary complications led to frequent escalation of care. Although most obstetric critical illness can be treated in medium care units,[3,34] intensive care unit beds and mechanical ventilators are scarcely available in Africa.[3,35] Identifying patients with complications may help the caregivers to allocate the scarce monitoring, oxygen, and ventilation resources.

This study faces limitations. A considerable number of patients were missed as died before recruitment or when it was not possible to perform LUS within 6 hours from admission because of logistical reasons. However, this strict predefined inclusion window was designed to pinpoint

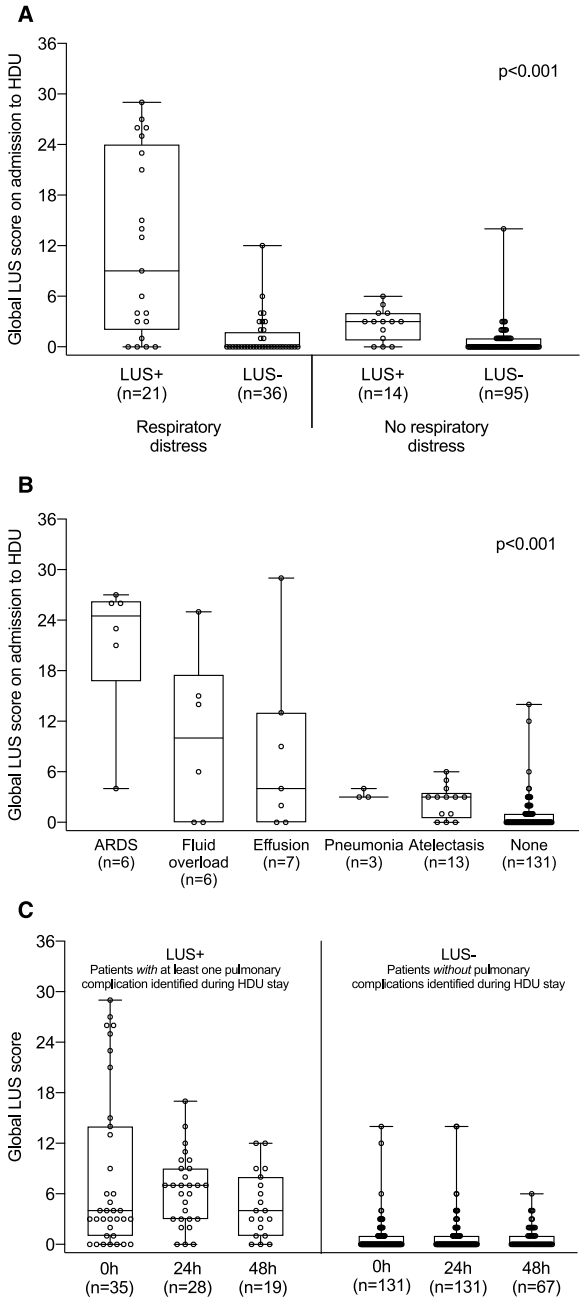

FIGURE 3. Baseline global lung ultrasound score on patient admission expressing loss of lung aeration in the different patient groups (**A**) and across different pulmonary complications (**B**). Individual global lung ultrasound scores are also represented at admission, at 24 hours and 48 hours (**C**). The middle line represents the median, the lower hinge represents the first quartile, the upper hinge represents the third quartile, and the whiskers extend to the minimum and maximum values. ARDS = acute respiratory distress syndrome; LUS = lung ultrasound.

pulmonary conditions observed early in the course of obstetric critical illness. Pulmonary case definitions were defined from granular data at study completion. Although this minimizes observation bias, it may lead to under or overestimation of complications. No other radiological imaging techniques were available in this setting to confirm the LUS findings. This limitation is mitigated by the body of literature validating LUS against reference methods for the conditions

investigated.[8,31,36] Echocardiography was not available to definitively exclude a peripartum cardiomyopathy; thus, patients with a history of cardiac failure were excluded a priori from the diagnosis of ARDS. Similarly, compression ultrasonography for the exclusion of deep vein thrombosis was not performed. Finally, the analysis regarding impact of pulmonary complications was limited by the unknown survival status of transferred patients.

CONCLUSION

In this cohort of critically ill obstetric patients in a resource-limited HDU, LUS was a useful and safe imaging tool to identify or exclude pulmonary involvement in patients with or without respiratory distress. Pulmonary complications occurred early, and their presence or development was associated with poor outcome.

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Research can provide tools to help
us better familiarize ourselves with
and interpret the facts, potentially
bringing us even closer to communities
as we respond to their needs,
and pointing the way to innovations
– sometimes unexpected
and inexpensive, yet key, ones.

La ricerca può permettere di avere
chiavi di entrata e interpretative
dei fatti, può creare percorsi di coesione
per rispondere alle necessità delle
popolazioni e può diventare un modo
per fare innovazione, anche frugale,
dove meno te l'aspetti.