

Assisting Birth Attendants in Providing Acceptable Care under Unacceptable Clinical Realities

The PartoMa Intervention Study at Zanzibar's Tertiary Hospital

Nanna Maaløe



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PhD Thesis

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October 2018

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Title and subtitle: Assisting Birth Attendants in Providing Acceptable Care under Unacceptable Clinical Realities - The PartoMa Intervention Study at Zanzibar's Tertiary Hospital

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Submitted: This thesis has been submitted to the Graduate School of the Faculty of Health and Medical Sciences, University of Copenhagen, 22 October 2018

Series: This thesis is part of the International Safe Motherhood and Reproductive Health working party's 'Safe Motherhood Series' (page 230)

Photos: Photos by Tarek Meguid, Jurre Rompa, Nanna Maaløe, and Rune Maaløe Andersen. All identifiable people have given oral consent.
Cover photo is by Nanna Maaløe and shows birth attendants with the PartoMa Pocket Guide.

Acknowledgements

This PhD is dedicated to Zanzibari women giving birth, their families, and their birth attendants. I have either met you in Zanzibar or read your birth stories in the study's more than 1000 included case files. Without this knowledge of your lived experiences, the study would not have been possible. I want to express my deepest gratitude for teaching me, and I humbly hope that this work will play a part in raising your voices and influencing your future.

While this PhD is awarded to me, the journey has been a joint venture with strong engagement from so many enthusiastic and generous people. I owe gratitude to all of you, for your support, inspiration, joy, and contributions to my learning.

Natasha Housseine, your bright personality, intelligence, commitment, and strength have been a tremendous inspiration since we first met in Zanzibar in 2014. It has been a gift to share intellectual, clinical, and life curiosity with you. Thanks a million for being an extraordinary research assistant, and now an impressive fellow PhD student – and for your friendship.

I am grateful for the supervision and mentoring I have received. Ib Christian Bygbjerg, I am thankful for your persistent enthusiastic interest and always encouraging support, though maternal health was off the beaten track for both you and me when you first started supervising me a decade ago. Thank you for passing on your deep and wide-reaching knowledge and experiences in the field of international health, and for introducing me to your important perspectives on fragile health care systems and the need for health system doctors. Jos van Roosmalen, I feel immensely lucky that I bumped into you at the FIGO World Congress in Rome in 2012. Thank you for believing in me. You have devoted countless hours to the study with punctual, thorough, and encouraging reviews. Your legacy of studies to learn from and your always creative suggestions to this pragmatic research have been invaluable. Tarek Meguid, you have introduced me to the complex real world of conducting implementation research in a low-resource setting, with countless stakeholders and agendas that, unfortunately, rarely are aligned. Thank you for passing on precious tools on how to navigate this, philosophical reflections, and thought-provoking stories from your more than 20 years in Africa. Birgitte Bruun Nielsen and Britt Pinkowski Tersbøl, thank you for inspirational talks, encouragement, and advice – Birgitte, thank you also for your work with the PartoMa Pocket Guide, and Britt, for your passionate and catching introduction to the social sciences.

Among the many hard working and committed doctors and nurse-midwives that I have met, I owe a special thanks for strong collaboration to the following: Alawiya Abubakar Ahmed, Ashura Amour Mwinyi, Dhuria Abdallah Ahmed, Kamilya Aly Omar, Lamlat Hassan Nondo, Margaret Tayari, Maryam Ahmed, Maryam Mchenga, Mishi Juma Ali, Mohamed Mussa Ahmad, Msafiri Marijani, Mubina Rajhy, Naufal Kassim, Saada

Juma Amour, Sabra Salum Masoud, Salma Abdi Mahmud, Saida Abukabar, Sanura Abdalla, Shahizma Abdul Hakim Omar, Tatu Fundi Salum, Wahida Rashid Abdi, and Zuhura Abdallah Balozi. Also, thank you to the administration at Mnazi Mmoja Hospital for supporting this study.

In addition to Natasha Housseine, thank you to Rashid Saleh Khamis, Ali Gharib Mohamed, Mbweni Makame Ali, Said Mzee Said, Fatma Mrisho Haji, Camilla Byskou Andersen, and Camilla Thomsen, who have provided crucial help with data collection and recording at different stages of the study. It has been stimulating, reassuring, and fun working together. Particularly Rashid Saleh Khamis has devoted an incredible number of hours and reflection to this study – thank you.

We, the study team and the users of the intervention, owe a sincere thank you to the external specialists for generously reviewing the PartoMa Pocket Guide multiple times and providing invaluable feedback: Antke Zuechner, Barbara Kwast, Ben Mbwele, Bjarke Lund Sorensen, Brenda D’Mello, Charles Ameh, Gaynor Maclean, Hussein Lesio Kidanto, Josephine Obel, Karen Odberg Pettersson, Klaas Koop, Mike English, Rachel Macleod, and Tom Weber. Barbara Kwast, your contribution needs particular acknowledgement. Your Asian multi-centre trial from 1994 on partograph use provided crucial guidance to this research. It was an honour, inspiration, and tremendous help when you visited us in Zanzibar in 2015.

Thank you to Director General Jamala A. Taib and the Zanzibar Ministry of Health for their recent decision to continue and upscale the PartoMa intervention in Zanzibar, the United Nations Populations Fund in Zanzibar for supporting this financially, the World Health Organization in Zanzibar for interest and engagement, and Suhaila Yusufu for her hard work organizing it all. I look forward to continuing this collaboration.

There are many more who deserve a special thanks: Jane Brandt Sørensen for sharing office, laughs, thoughts, frustrations, qualitative know-how, and engagement in the study; Jutta Jørgensen and Henrik Friis Juhl for your friendship and inspirational talks – I love visiting you in Zanzibar; Lara Meguid for beautifully filming the PartoMa study; Aksel Karl Georg Jensen for assisting on statistics; Kanga Maternity Trust for collaboration and support; Poppy Farrow and DTree for assistance with arranging community visits; Sangeeta Mookherji for your course in program theory and complex interventions, which was crucial for the study design; Jonas Søndergaard-Jepsen for assistance on the graphics; Centre for Online and Blended Learning at University of Copenhagen for currently developing the PartoMa e-book; Randi Iversen and editors at Munksgaard Publishing for the illustrations; Dorcas Paul Jidayi and Brenda D’Mello for translating the pocket guide to Swahili; Britt Ingeborg Eide, Siv Storøy, Stine Marie Noe Nielsen, and Tanneke Herklots for help at some of the PartoMa seminars; Caroline Clemens Egeland for patiently and thoroughly assisting with accounting and the website; Dan Meyrowitch, Thomas van den Akker, Flemming Konradsen, and Morten Skovdal for your recent engagement in the study, which, hopefully, will lead to a

new research journey on the basis of the PartoMa study; and my colleagues at the Global Health Section, University of Copenhagen, for nice working days and interest in my research.

I am grateful to the main donors of this PhD: The Lundbeck Foundation, The Laerdal Foundation, The Augustinus Foundation, and University of Copenhagen. Your flexibility when the study changed its course was paramount. This enabled allowing the concerns of the Zanzibari birth attendants – and through them the labouring women – shape the study.

I owe the warmest gratitude to my loving family and friends. I am particularly indebted to my parents and parents-in-law for their continuous supportive, caring, and happy participation in our everyday life. It has been pivotal for being able to balance the study with parenthood.

Rune, Selma, and August, you are the most important people in my world. Rune, thank you for doing this together with me – for making the happy moments twice as happy, and the hard times half as hard. Selma and August, you have taught me how deep parental love is.

Asanteni sana,

Nanna Maaløe

Copenhagen, October 2018

Research contributions

This thesis is written as a synopsis with scientific papers and additional research contributions in the Appendix (page 120). Unpublished study parts are included to supplement and triangulate the published data, and thereby strengthening the overall study design.

Peer-reviewed scientific papers

- Paper I: Maaløe N, Housseine N, Bygbjerg IC, Meguid T, Khamis RS, Mohamed AG, Nielsen BB, van Roosmalen J. Stillbirths and quality of care during labour at the low resource referral hospital of Zanzibar: a case-control study. *BMC Pregnancy Childbirth*. 2016;16(351).
- Paper II: Maaløe N, Housseine N, van Roosmalen J, Bygbjerg IC, Tersbøl BP, Khamis RS, Nielsen BB, Meguid T. Labour management guidelines for a Tanzanian referral hospital: The participatory development process and birth attendants' perceptions. *BMC Pregnancy Childbirth*. 2017;17(175).
- Paper III: Maaløe N, Housseine N, Meguid T, Nielsen BB, Jensen AKG, Khamis RS, Mohamed AG, Ali MM, Said SM, van Roosmalen J, Bygbjerg IC. Effect of locally-tailored labour management guidelines on intrahospital stillbirths and birth asphyxia at the referral hospital of Zanzibar: A quasi-experimental pre-post-study (The PartoMa study). *BJOG*. 2018;125:235–45.
- Paper IV: Maaløe N, Andersen CB, Housseine N, Meguid T, Bygbjerg IC, van Roosmalen J. Effect of locally-tailored clinical guidelines on intrapartum management of severe hypertensive disorders at Zanzibar's tertiary hospital (The PartoMa study). *Int J Gynecol Obstet*. 2019;144(1):27-36.
- Paper V: Maaløe N, Meguid T, Housseine N, Nielsen KK, Bygbjerg IC, van Roosmalen J. Clinical Guidelines for Maternal Health versus Clinical Realities in Low-Resource Settings: Closing the Gap. Re-submitted to *WHO Bulletin*, 2018.

Letter to the editor

- Letter I: Maaløe N, Meguid T, Kwast B, van Roosmalen J. Re: Cervical dilatation over time is a poor predictor of severe adverse birth outcomes: a diagnostic accuracy study. *BJOG*. 2018;125:1341-1342.

The PartoMa intervention

- Pocket guide: PartoMa Pocket Guide for Best Possible Safe and Respectful Childbirth Care. Mnazi Mmoja Hospital and University of Copenhagen, 2018.
- Seminar case histories: PartoMa Case Histories for Best Possible Safe and Respectful Childbirth Care. Mnazi Mmoja Hospital and University of Copenhagen, 2018.
- Background document: PartoMa Pocket Guide 2.0 – Development, Implementation and Evaluation. Mnazi Mmoja Hospital and University of Copenhagen, 2018.

Table of Content

Abbreviations and definitions	1
Summary.....	2
Muhtasari (Swahili summary).....	4
Resumé (Danish summary).....	6
1. Introduction.....	10
2. Background.....	16
i. Shortages of supplies, space, staff, skills, supervision, and system support.....	16
ii. Birth attendants' perceptions, motivations, and aspirations.....	17
iii. Clinical decision-support for birth attendants.....	18
iv. Participatory development of clinical guidelines and training	21
3. Objectives, Study Team, and Position in Scientific Disciplines.....	26
Objectives	26
Primary investigator, study team, and local steering group	27
Study position in scientific disciplines	27
4. Study Setting and Context	32
Maternal health care in Zanzibar	32
Mnazi Mmoja Hospital	34
5. Ethical Considerations	40
6. Baseline Quality of Care Study	44
Methodology	44
Results and target areas for improvement	45
7. The PartoMa Intervention	52
The PartoMa Pocket Guide.....	52
The PartoMa Seminars	57
Intervention running costs	58
8. Methodology for the Evaluation	62
Kirkpatrick level 1: Perceptions and reaction.....	64
Kirkpatrick level 2: Learning	65
Kirkpatrick levels 3 and 4: Quality of care and birth outcomes	66
Structural mediators and confounders	69
9. Results of the Evaluation	72
Kirkpatrick level 1: Perceptions and reaction.....	72
Kirkpatrick level 2: Learning	75

Kirkpatrick levels 3 and 4: Quality of care and birth outcomes	79
Possible structural mediators and confounders.....	83
10. Discussion of Main Findings and Related Research by Others.....	90
i. Getting to the hospital was not enough.....	90
ii. Act globally while thinking locally, in guidelines development and beyond.....	92
iii. The PartoMa intervention's likely behavioral effects, active ingredients, and dilemmas	93
11. Discussion of Methodological Issues.....	104
i. Participatory development process.....	104
ii. Assessment design.....	106
12. Conclusion and Perspectives	112
References	115
Appendix.....	120
PartoMa Pocket Guide version 2.0, March 2018	122
Paper I.....	142
Paper II.....	156
Paper III.....	176
Paper IV	192
Paper V	204
Letter I	210
Timeline	214
Additional information for Kirkpatrick level 1: Perceptions.....	218
Additional information for Kirkpatrick level 2: Learning	220
The Safe Motherhood Series	230

Abbreviations and definitions

Birth attendant	A nurse-midwife, doctor, assisting medical officer, or clinical officer assisting women during birth
BP	Blood pressure
CI	Confidence interval
CS	Caesarean section
FHR	Foetal heart rate
OR	Odds ratio
PartoMa	Derives from ‘partogram kwa mama’ (English: Partogram for Mother)
PartoMa intervention	The integrated intervention of PartoMa pocket guides with clinical guidance on care during birth and related quarterly seminars
RR	Relative risk
SD	Standard deviation
SDG	Sustainable Development Goal
sHDP	Severe hypertensive disorders in pregnancy
UNFPA	United Nations Populations Fund
WHO	World Health Organization

Summary

Background

Globally, 300,000 women and five million babies die each year around birth. The vast majority of deaths occur in the world's poorest countries. With proper care, most would survive. However, particularly in sub-Saharan Africa, while facility births are increasing, quality of care often does not follow. Generating evidence-based, safe and respectful care at birth is, therefore, a key priority to reach the Sustainable Development Goal (SDG) targets 1.1, 1.2, 3.1, 3.2 and 5.1. As a response, the international community's production of clinical guidelines for maternal health is extensive, including related electronic partographs and other algorithms for surveillance and management of childbirth. However, discrepancies with contextual realities in under-resourced health systems limit implementation of these mostly top-down developed fixed interventions. While advocating for adaptation of health systems to reach acceptable realities, research is warranted on contextually tailored clinical guidelines and related interventions that take the actual unacceptable realities into account.

Overall aim and objective

This thesis presents participatory, action-oriented implementation research for strengthening overworked birth attendants' ability to deliver quality of intrapartum care in a high-volume, low-resource tertiary referral hospital in the United Republic of Tanzania. The study was carried out between October 2014 and July 2018 with the objective to create locally acceptable, achievable, and applicable intrapartum clinical guidelines and associated in-house training; and analyse the intervention's pathway to possible effects on quality of care and, ultimately, survival at birth.

Setting

In the maternity unit of Zanzibar's tertiary Mnazi Mmoja Hospital, each birth attendant simultaneously cares for an average of three to six labouring women. Bed occupancy is around 200%. The workforce is dominated by young, non-specialized providers and massive staff-turnover. At baseline, a stillbirth rate was revealed as 59 per 1000 total births, of which approximately half died in the hospital, often due to substandard care.

The PartoMa intervention

In collaboration with birth attendants in Mnazi Mmoja Hospital, best possible clinical recommendations on safe and respectful care during birth were developed, while taking the resource-constrained setting into account. This resulted in the '*PartoMa Pocket Guide*' on common routine and emergency intrapartum care, which was initially launched in 2015. To realistically reflect the context,

international guidelines' frequency of clinical assessments, information load, ambiguity, and safety of management regimens were modified. The pocket guide underwent multiple rounds of internal testing and feedback as well as external peer-review. The implementation strategy was based on birth attendants' individual motivation to learn and improve care. Every three months, in-house, problem-based training was conducted outside working hours with discussions of contextually-tailored case histories. These '*PartoMa seminars*' were mainly facilitated by birth attendants working in Mnazi Mmoja Hospital. During the study, no allowances, or 'per diems', were paid to birth attendants for attendance at seminars.

Evaluation methodology and results

The '*PartoMa intervention*' of pocket guides and training follows principles of complex public health interventions. A program theory was developed to specify the expected pathway from intervention to birth outcomes, and to tailor associated research assessments. When comparing four months baseline with the ninth to 12th intervention months, criterion-based case file audits suggested the need for broad improvements in intrapartum care and in survival at birth. Time from last recorded foetal heart rate to delivery reduced by 40% ($p < 0.01$), use of oxytocin augmentation nearly halved (relative risk (RR) 0.54, 95% confidence interval (CI) 0.37–0.81) and it was applied more timely, and, among women with severe hypertension, administration of antihypertensives increased from 47% to 64% (RR 1.37, 95% CI 1.14–1.66). Stillbirths were reduced by 33% (RR 0.66, 95% CI 0.53–0.82) and newborns with an Apgar score 1–5 almost halved (RR 0.53, 95% CI 0.41–0.69). The pathway from the PartoMa intervention to changes in quality of care was strengthened by analysing birth attendants' perceptions, reactions, knowledge, and skills. Around two-third of the staff attended each quarterly round of seminars. Paired comparisons of pre-post seminar tests showed significant improvements in related knowledge and partograph skills, and with further significant improvements at the following seminar round.

Conclusion and perspectives

Although clinical realities remained unacceptable, the PartoMa intervention appeared associated with improvements in knowledge, partograph skills, and intrapartum care, leading to reductions in stillbirths and birth asphyxia. The suboptimal staff numbers and massive staff-turnover did not improve during the study years, no additional medical technology was introduced, and staff were not paid for attending PartoMa seminars. After four years, demand for the PartoMa intervention remains high among Zanzibari birth attendants, indicating profound motivation to learn and improve. Locally useful clinical guidance is pivotal and warranted for strengthening health system accountability, and should be a basic, fundamental right and precondition for health workers holding lives of others in their hands. Birth attendants demand access to such professional development and decision support (SDG targets 3c, 5.1, and 8.8), but current international guidelines appear far from effectively suiting their needs.

Muhtasari (Swahili summary)

Usuli

Ulimwenguni, wanawake 300,000 na watoto milioni 5 hufa kila mwaka wakati wa uzazi. Vifo vingi hutokea katika nchi zilizo masikini duniani. Kwa huduma nzuri, wengi wangeweza kuishi. Hata hivyo, hasa Kusini mwa Jangwa la Sahara, wakati wazazi wanapooongezeka kituoni, ubora wa huduma mara nyingi hupungua. Kuzalisha kwa misingi usalama na heshima ni kipaumbele muhimu kufikia Malengo ya Maendeleo Endelevu ya meliniumu (malengo ya SDG 1.1, 1.2, 3.1, 3.2 na 5.1). Mwitikio wa jamii wa kimataifa wa miongozo ya kliniki kwa afya ya uzazi ni pana, ikiwa ni pamoja na vifupisho vinavyolingana na elektroniki na taratibu nyingine za ufuatiliaji wa matibabu wakati wa kuzaliwa. Hata hivyo, kutofautiana na hali halisi ya mazingira katika mifumo ya afya iliyopunguzwa hupunguza utekelezaji wa ufumbuzi ulioendelea zaidi, na unaoendelea. Wakati wa kutetea marekebisho ya mifumo ya afya ili kufikia hali halisi, uchunguzi unahitajika kwenye miongozo ya kliniki inayofaa na kuhusiana na hatua zinazohusiana na hali halisi ambazo hazikubaliki.

Lengo zima

Thesis (hoja) hii inatoa utafiti shirikishi, kwa ajili ya utekelezaji wa hatua kwa ajili ya kuimarisha uwezo wa wahudumu kwa kutoa huduma bora katika hospitali za juu zenye msongamano mkubwa ndani ya Jamhuri ya Muungano wa Tanzania. Utafiti huo ulifanyika kati ya Oktoba 2014 na Julai 2018 kwa lengo la jumla la kuongoza mwongozo wa kliniki wa kukubalika, kufikia, na ufanisi wa kliniki na kuhusishwa na mafunzo ya ndani, na kuchambua njia ya kuingilia kati kwa athari zinazoweza kuonekanaili kuboresha huduma, hatimaye kuishi baada ya kuzaliwa.

Kuweka

Katika kitengo cha uzazi katika Hospitali ya Mnazi Mmoja ya Zanzibar, kila mhudumu anahudumia wanawake wastani wa watatu hadi sita. Hospitali ina uwezo wa vitanda asilimia 200%. Kazi kubwa inafanywa na wahudumu wenye ujuzi mdogo wasio na utaalaamu wa kutosha. Kati ya vizazi 1000, 59 hufa hospitalini kwa kukosa huduma iliyo bora.

Ushiriki wa PartoMa

Kwa ushirikiano wa wahudumu katika Hospitali ya Mnazi Mmoja, kupitia uongozi bora wa kliniki juu ya uangalizi salama na wa heshima wakati wa kuzaliwa ulianzishwa, na kuzingatia hali iliyozuliwa na rasilimali. Hii ilisababisha 'Mwongozo wa Pocket wa PartoMa' juu ya huduma ya kawaida ya utaratibu wa dharura na ya dharura, ambayo ilizinduliwa mwanzoni mwaka 2015. Ili kutafakari ukweli, mwongozo wa kimataifa wa miongozo ya tathmini ya kliniki, mzigo wa habari, usawa, na usalama wa matibabu yalibadilishwa, na

mwongozo wa PartoMa ulipata muda mwingi wa kupima na kupata maoni ya ndani na ukaguzi wa rika. Mkakati wa utekelezaji ulikuwa msingi wa nia ya wahudumu kujifunza na kuboresha. Kila baada ya miezi mitatu, ndani ya kituo, mafunzo ya msingi ya matatizo yaliyojitokeza yalijadiliwa nje ya muda wa kazi kwa kutumia historia zilizojitokeza. 'Semina za PartoMa' zilifanywa hasa na wahudumu wanaofanya kazi katika Hospitali ya Mnazi Mmoja. Wakati wa utafiti, hakuna malipo yaliyotolewa kwa wahudumu kwa ajili ya utendaji wa kliniki au kuwawezesha kuhudhuria kwenye semina na mikutano inayohusiana.

Mbinu za tathmini na matokeo

Uingiaji wa 'PartoMa' wa mafunzo kufuata kanuni na taratibu za afya ya jamii. Nadharia ya mpango ilianzishwa ili kutaja njia inayotarajiwa kutoka kuingilia kati kwa matokeo ya kuzaliwa, na kuunda tathmini ya utafiti inayohusishwa. Unapofananisha miezi minne ya msingi na mwezi wa kumi na tisa wa kuingilia kati, ukaguzi wa faili unaozingatia makadirio ya kigezo ulipendekeza maboresho makubwa katika utunzaji wa intrapartamu na kuishi wakati wa kuzaliwa. Hasa, muda kutoka mwisho wa kiwango cha moyo wa fetal kwa utoaji wa kupunguzwa kwa 40% ($p < 0.01$), matumizi ya oxytocin augmentation karibu nusu (hatari ya jamaa (RR) 0.54, 95% ya kujiamini interval (CI) 0.37-0.81 na ilitumika zaidi wakati, na kati ya wanawake walio na shinikizo la damu kali, ubora wa kuhudumia shinikizo la damu uliongezeka kutoka 47% hadi 64% (RR 1.37, 95% CI 1.14-1.66). Vilivyojaliwa bado hupungua kwa asilimia 33 (RR 0.66, 95% CI 0.53-0.82) na watoto wachanga na Apgar alama 1-5 karibu nusu (RR 0.53, 95% CI 0.41-0.69) Baada ya PartoMa kuingiakulikuwa na mabadiliko katika ubora wa huduma, na uliimarishwa kwa kuchunguza mawazo ya wahudumu, athari, na mafunzo. Karibu theluthi mbili ya wafanyakazi walihudhuria kila semina ya robo mwaka. Ukilinganisha vipindi vya kwanza vya semina na semina zilizofuatia zilionyesha kuna ubora mkubwa uliopatikana.

Hitimisho na mitazamo

Ingawa hali halisi ya kliniki haikubaliki, kuingia kwa PartoMa ilionekana inahusishwa na maboresho katika ujuzi, stadi za kazi, na utoaji wa huduma, na kusababisha wepesi katika kuzaliwa kwa asphyxia. Kwa dhahiri, namba kubwa ya wafanyakazi hawakuboreshwa wakati wa miaka ya utafiti, hakuna teknolojia ya ziada ya matibabu iliyoanzishwa, na wafanyakazi hawakuwahi kulipwa kwa ajili ya utendaji wa kliniki au mahudhurio ya semina. Baada ya karibu miaka minne, kuingia kwa PartoMa ulileta ubora wa juu kati ya wahudumu wengi wa kuzalisha na kuonyesha nia kubwa ya kujifunza na kuboresha. Uongozi wa kliniki ni muhimu kuhakikisha kuimarisha uwajibikaji wa mfumo wa afya, na inapaswa kujua kuwa ni haki ya msingi kwa wafanyakazi wa afya kubeba maisha ya wengine mikononi mwao. Wahudumu wanahitaji upatikanaji wa maendeleo ya kitaaluma na msaada wa uamuzi (SDG malengo ya 3c, 5.1, na 8.8), lakini miongozo ya kimataifa ya sasa inaonekana inakuwa mbali na mahitaji yao kwa ufanisi.

Resumé (Danish summary)

Baggrund

Globalt dør 300.000 kvinder og fem millioner børn hvert år omkring fødselstidspunktet, og størstedelen af dødsfaldene sker i verdens fattigste lande. Med bedre fødselshjælp og behandling ville de fleste have overlevet. En stigende andel af fødsler i Afrika syd for Sahara finder sted på hospitaler, men kvaliteten af fødselshjælp og behandling er ofte uacceptabel. Forbedring af behandlingskvaliteten er derfor en nøgleprioritet for at nå verdens sundhedsorganisations bæredygtige udviklingsmål (1.1, 1.2, 3.1, 3.2, 5.1). I tråd hermed er den internationale udfærdigelse af kliniske retningslinjer inden for mødresundhed anseelig, inklusive elektroniske algoritmer til overvågning og behandling ved fødslen. Uoverensstemmelser mellem de ekspertbaserede retningslinjer og den faktiske ressourcefattige kontekst begrænser imidlertid anvendeligheden. Det er derfor yderst vigtigt, at der sideløbende med den større kamp for forbedring af de uacceptable sundhedssystemer, forskes i at skræddersy kliniske retningslinjer og interventioner, så de er opnåelige og brugbare for de overbebyrdede fødselshjælpere i den aktuelle uacceptable kontekst.

Studiets overordnede mål

Denne ph.d.-afhandling præsenterer implementeringsforskning udført mellem oktober 2014 og juli 2018 på fødegangen på et stort og overbelastet hospital i Tanzania. I samarbejde med fødegangens fødselshjælpere var studiets overordnede mål at udvikle lokalt opnåelige og relevante kliniske retningslinjer og tilhørende træning til forbedring af fødselshjælp og behandling under de uacceptable forhold. Interventionens vej til mulige virkninger på kvaliteten af fødselshjælp og fødselsoverlevelse blev evalueret.

Zanzibar's hovedhospital

Fødegangen på Mnazi Mmoja Hospital er overbelastet. Sundhedspersonalet, som inkluderer læger, sygeplejersker og jordemødre, assisterer hver i gennemsnit tre til seks kvinder i fødsel på samme tid, og sengebelægningsgraden er 200%. Arbejdsstyrken domineres af unge, ikke-specialiserede fødselshjælpere, der ofte udskiftes. Ved studiets start viste det sig, at 59 babyer var dødfødte per 1000 fødsler, og heraf døde halvdelen efter indlæggelse grundet dårlig eller manglende fødselshjælp.

PartoMa-interventionen

I samarbejde med fødegangens fødselshjælpere blev kliniske retningslinjer for bedst mulig sikker og respektfuld fødselsbehandling udviklet under hensyntagen til den ressourcefattige situation. Dette resulterede i '*PartoMa Lommebogen*' om rutinepleje og akutbehandling under fødslen. Den første version blev lanceret i 2015. Retningslinjerne har siden da gennemgået adskillige revisioner på baggrund af afprøvning blandt sundhedshjælperne og ekstern fagfællebedømmelse blandt eksperter. For at sikre

opnåelighed og brugbarhed i den ressourcefattige kontekst måtte internationale retningslinjers hyppighed af observationer og undersøgelser, informationsmængde, ofte tvetydige anbefalinger og behandlingsregimer modificeres. Den relaterede træning baseredes på fødselshjælpernes individuelle motivation til at forbedre fødselshjælp og behandling. Hver tredje måned blev træning udbudt ulønnet og uden for arbejdstid. Disse '*PartoMa seminarer*' med lokalt realistiske patienthistorier blev hovedsageligt faciliteret af lokale fødselshjælpere.

Evalueringsmetode og -resultater

PartoMa-interventionen, bestående af lommebog og seminarer hvert kvartal, følger principperne for komplekse interventioner i folkesundhedsvidenskab. En programteori blev udviklet ved studiets start til at specificere den forventede kausale sammenhæng fra interventionens implementering til mulig virkning på fødselsoverlevelse, og baseret herpå blev forskningsmetoderne fastlagt. Journalgennemgang i fire måneder før implementering og i den niende til tolvte interventionsmåned viste adskillige forbedringer i fødselshjælp og behandling. Eksempelvis blev tiden fra sidste registrerede hjertelydsmåling af barnet til fødslen reduceret med 40% ($p < 0,01$), brug af ve-stimulerende medicin blev næsten halveret (relativ risiko (RR) 0,54, 95% konfidensinterval (CI) 0,37-0,81) og den ve-stimulerende medicin blev anvendt mere rettidigt, og blandt kvinder med svær hypertension steg brug af antihypertensiv medicin fra 47% til 64% (RR 1,37, 95% CI 1,14-1,66). Dette var associeret med 33% reduktion i dødfødsler (RR 0,66, 95% CI 0,53-0,82) og halvering i nyfødte med tegn på iltmangel under fødslen (RR 0,53, 95% CI 0,41-0,69). Den mulige kausale sammenhæng mellem PartoMa-interventionen og forbedringerne i fødselshjælp og behandling blev desuden forskningsmæssigt belyst. Omkring to tredjedel af alt sundhedspersonale deltog i hver runde seminarer. Ved sammenligning af viden- og færdigheds-tests før og efter seminardeltagelse sås betydelige forbedringer, som vedblev indtil næste seminarrunde, hvor der igen blev fundet signifikante forbedringer.

Konklusion og perspektivering

Om end de grundlæggende forudsætninger er uændrede og utilstrækkelige for at fødselshjælperne kan yde en acceptabel fødselshjælp og behandling, tyder forskningsresultaterne på, at PartoMa-interventionen var relateret til forbedringer i sundhedshjælpernes viden, færdigheder, overvågning og behandling, hvilket resulterede i fald i dødsfødsler og nyfødte med tegn på iltmangel under fødslen. Efter fire år er efterspørgslen efter PartoMa-interventionen fortsat høj blandt fødselshjælpere på Zanzibar, hvilket tolkes som en dyb motivation for at lære og forbedre fødselshjælpen. Lokalt opnåelige kliniske retningslinjer og relateret træning bør være en grundlæggende ret og forudsætning for sundhedsfaglige med andres liv i deres hænder. Fødselshjælpere i Afrika syd for Sahara kræver adgang til sådan faglig udvikling og beslutningsstøtte (jævnfør de bæredygtige verdensmål 3c, 5,1, 8,8) – men de nuværende internationale retningslinjer svigter deres behov.



Entrance to Mnazi Mmoja Hospital, Zanzibar's tertiary hospital. Photo by Nanna Maaløe.

Chapter 1

Introduction

1. Introduction

Globally, approximately 300,000 women and five million babies die each year related to pregnancy and childbirth.¹⁻³ Many more women suffer from physical and mental morbidities, and an estimated one million survivors of birth asphyxia suffer from more or less severe disabilities and premature death annually.⁴ The major cause is obstetric complications around birth, including prolonged or obstructed labour, severe hypertensive disorders, and haemorrhage.^{1-3,5} Adding to the tragedy, women and their families suffer from the 'epidemic of grief' as a result of traumatic birth experiences, with long-lasting psychosocial and economic consequences.⁶⁻⁹ With proper care, many women and babies would survive and be healthy.¹⁰

The highest burden of maternal and perinatal deaths is in the world's poorest countries.¹⁻³ In sub-Saharan Africa, a woman's lifetime risk of maternal death is estimated at 1:36. In Scandinavia, the risk is less than 1:10,000.¹¹ While considerable progress has occurred during recent decades, the Millennium Development Goals were not met for maternal and child mortality, with neonatal deaths decreasing the least.^{1,3} Add to that the neglected 2.6 million babies who are born dead.² While more than half of stillbirths share causes of birth asphyxia and infection with early neonatal deaths,^{2,5} and stillbirths were already mentioned in the United Nations' 1966 declaration on human rights,¹² stillbirths remain a largely neglected epidemic, absent in both the Millennium and the Sustainable Development Goals.¹³ It is estimated that more than 160 years will pass before an average woman in Africa has the chance of giving birth to a live baby equal to a woman in high-income countries at present.²

In the millennium's first decade, the global strategy for improving maternal health mainly focused on expanding coverage of skilled birth attendance by campaigns for women to give birth in health facilities. However, particularly in sub-Saharan Africa, the increasing proportion of facility births has yet to be matched with intra-facility quality care. The vast majority of sub-Saharan African countries have severe shortages of human resources for health, and there is widespread discrepancy between the knowledge and competency levels of health professionals and the needs of the populations that they serve – not only in the peripheral health centres, but also at the referral levels.¹⁴⁻²⁰ As reported from 42 of Nigeria's 46 public tertiary hospitals, getting to the hospital was not enough. Maternal mortality ratios were unacceptably high, and clinical management of women with life-threatening complications was often severely sub-standard with alarming delays of clinical care.¹⁸ Similar reports are emerging from referral hospitals in other sub-Saharan African countries,^{17,21-28} and a dangerous double-burden often exists of care provided 'too little, too late' and 'too much, too soon'.²⁹ Inside these overcrowded maternity units, women and babies are reported to suffer from shortages of supplies, few and poorly skilled providers, neglect, risky procedures, under- and over-prescription of medicines, absence of birth companions, and disrespectful and

abusive practices.^{17,21–29} To quote Margaret Chan, “what good does it do to offer free maternal care and have a high proportion of babies delivered in health facilities if the quality of care is sub-standard or even dangerous?”.³⁰

Considering such current quality challenges, how can the continually increasing number of women prompted to give birth in hospitals be overcome? Notably, overall fertility rate in sub-Saharan Africa persists at 4.8, urban populations grow 4.1% annually, and obstetrics is in transition towards complex double-burdens of disease.^{11,20,31,32} Further, the highest level of the health care sector, the tertiary hospitals, is often where most of the countries’ future health care workers are trained. If the tertiary hospitals’ ability to provide quality care is strengthened, they can possibly facilitate nationwide improvements – and thus support what should be a positive momentum of increasing the number births in health facilities.

Unsafe and disrespectful care during birth is a human rights’ violation that affects women and babies, their families, and societies, and negatively impacts on gender equality.^{33–35} Generating evidence-based and respectful care at birth is a key priority to reach the Sustainable Development Goals, particularly birth-related survival and gender equality,^{17,36,37} and also on societal development and poverty reduction (targets 1.1, 1.2, 3.1, 3.2, and 5.1).^{7,38} There are no shortcuts – the route to achieve the maternal health related development goals is through the birth attendants.^{39,40}

This thesis presents the PartoMa study’s participatory, action-oriented implementation research for strengthening overworked birth attendants’ ability to deliver quality care in a high-volume, low-resource tertiary referral hospital in the United Republic of Tanzania. The study was carried out between October 2014 and July 2018 in collaboration with the birth attendants at Zanzibar’s Mnazi Mmoja Hospital. The ultimate goal of the study was to improve perinatal survival by assisting nurse-midwives and doctors in providing best possible safe and respectful care in their resource-constrained context and, through the process, to achieve a better understanding of their challenges. The overall structure of the thesis is presented in Figure 1, and the study’s timeline in the Appendix (page 214).

**Assisting Birth Attendants in Providing Acceptable Care under Unacceptable Clinical Realities
The PartoMa Intervention Study at Zanzibar's Tertiary Hospital**

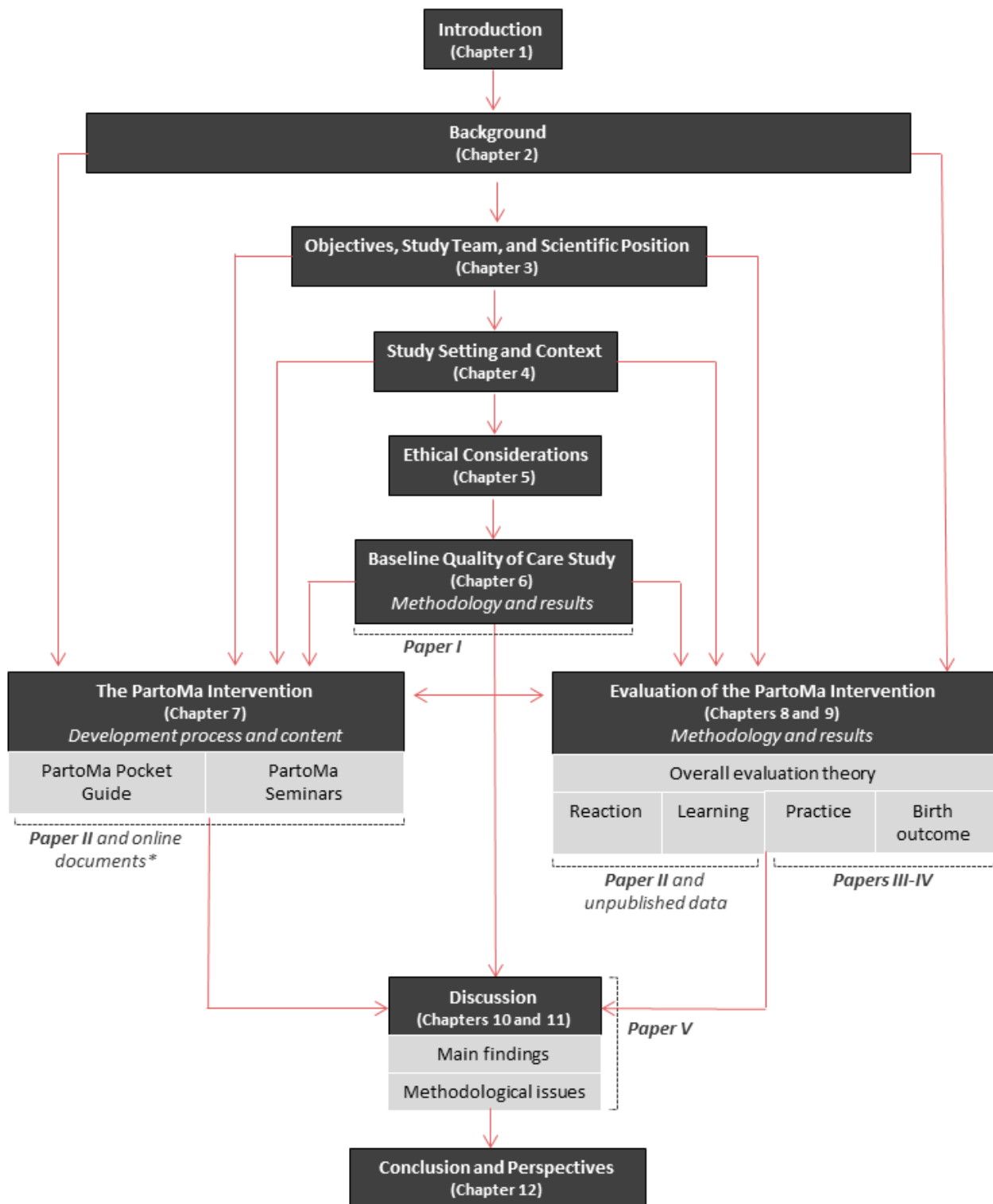


Figure 1 A guide to the reader: Structure and flow in the PhD thesis. *Latest version of the PartoMa background document, the case histories for training, and a background document on the development process are available on the study website: publichealth.ku.dk/partoma/



Entrance to the maternity unit in the old building, Mnazi Mmoja Hospital. Photo by Tarek Meguid.

Chapter 2

Background

2. Background

This chapter reflects on birth attendants' ability to deliver safe and respectful care in busy, low-resource maternity units, including the resource constraints they are faced with *(i)*, their perspectives, motivations, and aspirations *(ii)*, and their access to clinical decision-support *(iii)*. In addition, the chapter touches upon possibilities of bottom-up, participatory intervention development to possibly optimize the usefulness of clinical decision support tools within resource-constrained realities *(iv)*. With the exception of more recently added research, this theoretical overview fed in to the program theory that specifies the expected causal pathway from the intervention to the desired ultimate goal of improved perinatal survival (Figure 7, page 63).⁴¹

i. Shortages of supplies, space, staff, skills, supervision, and system support

Providing safe and respectful care at all births is central to the post-2015 agenda and entails that women and babies “should be protected from unnecessary interventions, practices, and procedures that are not evidence-based, and from any practices that are not respectful of their culture, bodily integrity, and dignity”.⁴² Yet, reports from maternity units carrying the highest rates of adverse outcomes question their readiness to deliver these goals.¹⁷ The reasons are manifold.

Shortages in functional, basic, essential equipment and medicine are repeatedly reported, such as blood pressure (BP) machines, gloves, water, ultrasound gel, reliable laboratory tests, or high-quality medicines.^{43–45} Particularly in high-volume facilities, there is a shortage of space, leading to overcrowded maternity units that challenge the birth attendants' ability to prioritize properly, and compromise hygienic standards and women's privacy.^{26,31,45} In a secondary analysis of the Tanzanian 2014-2015 Service Provision Assessment, a significant decrease in delivery beds was found with increasing numbers of labouring women in maternity facilities.^{46,47}

The human resource crisis for health is paramount, causing health providers to carry extreme and often complex workloads with unachievable demands and unofficial task shifting. Birth attendants, including nurse-midwives, doctors, clinical officers, and assisting medical officers, are typically paid little and sometimes inconsistently, which may challenge their own living conditions, and they are frequently moved around in the health system.^{43,48} Out-migration of health workers is a challenge, and the few birth attendants are often young and non-specialized with inadequate pre-graduate education and little access to post-graduate training and supervision.^{40,43,48–50} As reported in numerous maternal and perinatal death audits from sub-Saharan Africa, as well as in knowledge and skills assessments, birth attendants too often fail to make timely, effective, and respectful clinical decisions.^{17,18,51–53} Furthermore, the Tanzania Service Provision Assessment found that clinical care guidelines were only available in one-third of the country's

maternity units, and only one-quarter had at least one provider with adequate training in the application of these guidelines.⁴⁶ This is similar to service provision assessments from Kenya, Uganda, and Rwanda where only 40%, 36%, and 41% of interviewed birth attendants had received training related to delivery services during the past 12 months.^{54–56}

Adding to these challenges, resource-constrained health care systems may often reduce birth attendants' ability to provide proper care even further due to steep hierarchies of authority and power, with health officials at the top and frontline health workers too often at the bottom.^{28,57,58} Too often, birth attendants' ability to provide proper quality of care is severely limited in systems where they are personally blamed and shamed for system failures, accountability is unclear, their efforts are not recognized, promotion and employee benefits are opaque, and disrespectful and unsafe care is routinized, or even expected.^{48,57–60}

ii. Birth attendants' perceptions, motivations, and aspirations

Poor working conditions as described above may result in exhaustion, demotivation, demoralization, and burnout, with impaired performance, negative attitudes, illness, absenteeism, and escape from the health care system – thus worsening maternal health care further.^{27,45,48,59,61–63}

Birth attendants are at risk of being stereotyped as unprofessional, cold, non-empathic, and apathetic, which might then be seen as the cause for disrespectful and abusive lack of quality care.²⁸ On the other hand, analyses point to how birth attendants are often deeply affected by adverse pregnancy outcomes and their unacceptable working conditions, causing feelings of guilt, anger, and sadness.^{48,61,64} Burnout, for example, is the negative response to chronic job-related emotional stress. In a study in a Malawian referral hospital, between 43% and 74% of the maternal health providers experienced moderate to high levels of burnout, according to different burnout scales.⁶¹ Another feeling often expressed is fear of poor birth outcomes as well as fear of blame and disciplinary actions, which may cause non-evidence-based decision-making, false reporting, and withdrawing from responsibilities.^{60,65}

Like the women giving birth and their families, birth attendants in resource-constrained health systems are often aware of the flaws in care provision, and they call for improvements of their working conditions. They wish for teamwork, professional development, staff support, and supervision, and for predictability and transparency, trust, and recognition within the health care system.^{43,48,62,64,66} This is in line with the Sustainable Development Goal's targets 3c and 8.8 on increasing recruitment, development, training, and retention of the health workforce, as well as protecting labour rights and promoting safe and secure working environments.

iii. Clinical decision-support for birth attendants

The use of partographs, clinical guidelines, and continual medical education are key interventions provided to strengthen evidence-based intrapartum decision support in low-resource settings and thereby survival at birth. The World Health Organization's (WHO's) partograph, a sheet of paper providing a pictorial overview of labour, is often emphasized as pivotal in this,⁶⁷⁻⁷¹ just like the production of clinical guidelines for maternity care and training interventions.^{29,72} However, as set out below, for each of these three intervention strands, evidence is limited to show the associated effects on quality of clinical care.

WHO's partograph

The 50 year old partograph is widely available in low-resource maternity units. It is a single-paper-sheet tool where labour observations of maternal vital signs, foetal heart rate (FHR), and labour progress are recorded. By indicative lines, it alerts birth attendants if deviations occur from what is considered normal. For labour progression, the partograph includes two lines to assist in decision making. The 'alert line' represents a cervical dilatation of 1 cm per hour, and the 'action line' is parallel to the alert line, but four hours later.^{67,73} However, controversy remains on what actions are to be taken when the progress of labour is crossing each of these lines (Letter I, page 210).

In low-resource maternity units, proper use of the partograph is often limited, and its effectiveness is questioned. Multiple reasons have been suggested, such as the partograph being associated with limited flexibility to treat each woman as an individual, being time consuming and difficult to fill in, being retrospectively used after delivery and thereby not aiding in clinical decision support, stimulating individual responsibility and risk of blame for possible substandard care, and being considered unnecessary due to the assumption that labour outcomes are outside of the birth attendants' control or meaningless due to lack of competencies to manage any detected complication.^{53,60,74,75} Consistently, a Cochrane review concluded that experimental comparisons failed to demonstrate the effect of partographs in improving birth outcomes.⁷³ A recent WHO study by Oladapo/Souza et al. of progression of labour in Nigeria and Uganda also revealed crucial variations in uncomplicated labour progress, which led the authors to challenge the alert line's one-centimetre-per-hour rule for uncomplicated labour.^{76,77}

In contrast, partograph use is also often emphasized as fundamental for timely intrapartum surveillance and decision-making, and characterized as user-friendly, highly useful, and vastly teachable.⁶⁷⁻⁷¹ The WHO's quality standard for care at birth emphasizes use of the partograph, which can be reviewed at a glance, as one of two essential interventions for routine care, to ensure monitoring and clinical decision-support during first and second stage of labour, including parameters of the woman, foetus, and progression of labour.⁷⁸ It is remarkable that the Cochrane review on partograph use neglected WHO's Asian multi-centre trial from 1994.⁷³ Among 35,484 deliveries, the trial found significant effects of partograph use combined

with a clinical protocol for what to do with the recorded assessments. Reductions were found in prolonged labour, proportion of labours treated with oxytocin augmentation, emergency caesarean sections (CSs), and intrapartum stillbirths.⁶⁹ This is also similar to successful Tanzanian and Norwegian pre-post studies of partograph use combined with clinical guidance.^{79,80} If used correctly and action taken accordingly, the low-cost partograph could influence quality of care positively.

Clinical guidelines

As knowledge exists on the often preventable nature of maternal and perinatal deaths, clinical practice guidelines are repeatedly suggested as pivotal in ensuring appropriate use of evidence in health care in low-resource settings.²⁹ Thus, the global production of maternal health guidelines, and associated critical care pathways and other algorithms, are excessive. They are usually based on expert consensus and implemented top-down by diffusion, while encouraging local adaptation or adoption.^{81–83} However, the path for effective large-scale guidelines development and, subsequently, adaptation and implementation at targeted facilities within fragile health care systems are ineffective with unaddressed barriers (Paper V, page 204).

As presented in Paper II (page 156), a systematic literature search was conducted in PubMed for studies on clinical guidelines development, modifications, use, or effectiveness with a focus on intrapartum care in Africa (1st January 2000 – 6th July 2016). The vast majority of included studies concerned comparisons of actual clinical practice with the recommended best practices in international guidelines, predominantly from WHO, and found de facto practices to be alarmingly suboptimal. Many of the studies concluded that simpler and more achievable clinical guidance was warranted. However, while local adaptations are typically encouraged in the international guidelines,⁸³ the literature search indicated that only in few instances have large-scale guidelines been matched with reviews of local modifications or with assessments of use and effect in African maternity units (Additional file 3 in Paper II).

Similarly, a review of national Ugandan health guidelines described how the process of local adaptations was unrealistically resource-demanding as international recommendations were too far from the targeted clinical realities. It would depend heavily on time, funding, access to evidence, knowledge on synthesizing and applying evidence, and coordination of partners. Consequently, as such processes were not feasible within the Ugandan health care system, health providers from the grass root level typically did not participate in developing national guidelines. This was identified as a key contributor to ineffective, impractical, or too complex recommendations.⁸²

Not only may poorly fitting, non-realistic clinical guidelines waste resources and demoralize health workers, they may result in either no use or unpredictable and potentially harmful individual adaptations and selective use.⁸⁴ For instance, the thesis writer and colleagues previously conducted a study of emergency

CSs in two district hospitals in Tanzania. The findings suggested how simple, basic obstetric practices were abandoned, while guidelines for preventing vertical HIV transmission over-influenced care. Though the HIV prevalence among pregnant women was below five percent, the fear of transmission explained the reluctant use of artificial rupture of membranes and vacuum extraction for all labouring women, causing unnecessary CSs.^{53,85}

Continuous medical education

There has, for many years, been a global focus on strengthening competencies among birth attendants in low-resource health systems through continuous medical education. It has been common practice to invite a subgroup of health workers for training, away from their clinical environment and for an intensive period of time. For example, essential obstetric care training is often taught in a two or three week off-site course,⁸⁶ and workshops are typically conducted with massive per diems where the daily so-called 'sitting allowance' may equal two weeks' or even two months' salary from the government.⁸⁷ Evidence is not very convincing whether this one-time workshop-approach is effective in translating gained knowledge and skills into practice, and in transferring knowledge and skills to co-workers at the facilities.^{88,89} The workshop approach has also been criticized for dangerously leaving health facilities with too few health workers and, due to the considerable economic incentives, raises a culture where training is perceived as an opportunity to supplement income, rather than an opportunity to build professional competencies.^{87,90} Thereby, it is argued that the workshop approach with per diems may decrease intrinsic motivation among participants as well as their demands for high-quality, effective training. As observed in a multi-country study of maternity services, there were endless conflicts among staff and managers about who received training, resulting in training content not always being fed back to colleagues at the maternity unit, and in unsuitable staff receiving the training.⁹¹ A possible root cause is donor organizations outbidding each other, paying increasingly higher per diems and drawing impressive attendance rates, while the urgent clinical and management tasks are left unaddressed.⁸⁷

The workshop alternative of recurring, in-house training is increasingly becoming the recommended approach for strengthening competencies in both low- and high-resource clinical practices.^{88,92} The concept of 'low-dose, high-frequency' training is emerging with the aim of optimizing retention of clinical knowledge, skills, and attitudes through recurring, short, in-service, competency-focused, simulation- and case-based learning activities that are spaced and elaborated on over time. Such training focusses on the most essential information needed and is typically multidisciplinary to enhance teamwork.⁸⁶ This approach is supported by evidence suggesting that: 1) recurring targeted training is correlated to higher retention of knowledge and skills; 2) having the same setting for training as clinical practice is correlated with higher gains in skills and performance as well as lower costs than off-site, one-time training; 3) simulation- and case-based interactive methods are more effective than didactic lectures; 4) multidisciplinary team training

enhances the possibility for knowledge and skills to be translated into clinical behaviour.^{93–98} However, there is variation in what is defined as low-dose, high-frequency training, evidence is limited on applicability and effects in low-resource settings, and the approach may still include per diems and pull birth attendants away from their clinical work for considerable periods of time. In a Ghanaian study, ‘low-dose’ was a twice repeated four-days, full time, in-house course in basic and emergency obstetric care, followed by intensive clinical supervision.⁹⁹ Conversely, the whole program of an American paediatric CPR course was four trainings over six months, each lasting five minutes.⁹³ A systematic review of costs related to emergency obstetric care training with the majority of studies from low-resource settings revealed that per diems and resource person allowances accounted for between one- and two-thirds of the overall training implementation costs, both at off-site and in-house training.⁹⁴ However, for instance, as proven effective in a one-day, in-house obstetric training course in Zimbabwe, per diems can be eradicated.⁹⁰

iv. Participatory development of clinical guidelines and training

When comparing ‘de jure systems’ of official policies and programmes with the grass root level’s ‘de facto systems’ that are implemented by health workers and experienced by health system users, an apparent gap often exists. It may be argued that the key to understanding challenges in connecting de jure with de facto systems lies in the reflexive, complex, and dynamic responses to policies and programmes of health workers and health system users. Strategies and interventions that have been evaluated as effective elsewhere are a starting point, but not an end point in getting what works to happen.⁹¹ However, this conflicts with how health intervention development and implementation for low-resource settings are often framed at the global level. As described for clinical guidelines, study evidence and expert consensus from high income countries and top-down waterfall implementation are still vastly dominant (Paper V, page 204).^{100–102}

Participatory development of clinical guidelines and related interventions with end-users are an important alternative.¹⁰¹ In relation to clinical guidelines development, evidence from high-income countries suggests that a focus on local barriers to implementation, including end-users’ level of knowledge and time and their acceptance and agreement, is effective.^{103–106} From the field of occupational health interventions, it appears that the degree of participation in intervention development is negatively related with resistance to change and stress, and positively with achievement of goals, commitment, and job-satisfaction.¹⁰⁷ This reorientation from top-down waterfall diffusion may be an opportunity for health workers at the frontline to enhance control and influence how problems and solutions are framed in the future at both local and global levels.

Andrews et al. propose four overarching principles for ‘problem-driven iterative adaptation’ of development interventions in low-resource settings. First, it is important to solve locally nominated and

defined problems instead of adopting pre-made 'best practice' solutions. Second, the development environment must encourage positive deviance and experimentation, as opposed to fixed, non-adjustable interventions. Third, feedback loops are introduced, which facilitate rapid experimental learning throughout development and implementation. Fourth, engaging a broad set of stakeholders is crucial to ensure that reforms are viable, legitimate, relevant, and supportable.¹⁰⁸ These principles appear in line with the Paris Declaration and Accra Agenda for aid harmonisation and effectiveness where the recipient countries set the priorities.¹⁰⁹ Also, they are in line with the aim of context-appropriate implementation strategies in maternal health,¹¹⁰ and WHO's aspiration to develop "conditional recommendations" when interventions are suitable for some locations only.⁸³



Delivery bed, ready for use. Photo by Tarek Meguid.

Chapter 3

Objectives, Study Team, and Position in Scientific Disciplines

3. Objectives, Study Team, and Position in Scientific Disciplines

Objectives

The study proposal's overall aim was to strengthen birth attendants' ability to deliver best possible care at birth at the resource-constrained tertiary hospital of Zanzibar. With this aim, the PhD set off to implement and evaluate an externally-derived and fixed electronic partograph. Through the first baseline months' learning about the birth attendants' work realities and quality of care challenges (page 42), the study design was adjusted to a more participatory, bottom-up, iterative, and dynamic approach. As the study evolved further, disclosed incompatibility with the contextual realities led to declining the possibility of implementing the electronic partograph altogether. Hence, by incorporating the birth attendants' lived experiences and the quality of care challenges found at baseline, the understanding of the main problems changed, as did the overall objectives presented below. It appeared that the most crucial challenges in translating evidence into intrapartum practice were not difficulties in filling in the paper partograph, but in the associated clinical decision-making on best possible timely action and triage.

Overall objective of the PhD (the PartoMa study)

To create locally acceptable, achievable, and applicable intrapartum clinical guidance and associated in-house training for birth attendants at a high-volume, low-resource maternity unit and analyse the intervention's pathway to possible effects on quality of care and, ultimately, perinatal survival at birth.

Specific objectives

- a. To disclose clinical determinants for unsafe birth, by analysing baseline quality of intrapartum care in a case-control study of stillbirths.
(Paper I, page 142)
- b. Through participatory development of locally-tailored intrapartum guidance, to assess modifications needed for key international maternal health guidelines to reach usefulness at the study site.
(Paper II, page 156, and Paper V, page 204)
- c. To evaluate effects of the modified clinical guidance and associated in-house training on quality of record keeping, intrapartum surveillance and treatment, and birth outcomes.
(Paper III, page 176, and Paper IV, page 192)
- d. To evaluate the causal pathway from implementation of the PartoMa intervention to the possible changes in quality of care, by assessing birth attendants' perceptions and reactions to the guidance and training intervention, and possible related changes in knowledge and partograph skills.
(Unpublished, data available on page 75 and in the Appendix, page 220)

Primary investigator, study team, and local steering group

The PartoMa study's core research team included the thesis author as primary investigator (Nanna Maaløe), a senior specialist in obstetrics and a junior doctor at the obstetric department of Mnazi Mmoja Hospital (Tarek Meguid, MD, Associate Professor in obstetrics and gynaecology, and Natasha Housseine, MD, PhD student), the main supervisor (Ib Christian Bygbjerg, MD, Professor in International Health), and the co-supervisors (Jos van Roosmalen, MD, Professor of Safe Motherhood and Health Systems, Britt Pinkowski Tersbøl, Associate Professor in Anthropology, and Birgitte Bruun Nielsen, MD, Associate Professor in Obstetrics). As the intervention and implementation developed, a local PartoMa steering group was formed to further strengthen the partnership with the birth attendants, to ensure the continuous running and modifications of the intervention.ⁱ

Understanding the birth attendants' needs was crucial not only for the initial change of the study's intervention plan, but throughout the iterative process of intervention development and implementation. During the study years, the thesis author spent a total of one year at the study site, divided into multiple short and long stays. She primarily focused on development and implementation of the PartoMa intervention in collaboration with Zanzibari nurse-midwives and doctors. She actively participated in daily clinical meetings and informal and formal teachings and conversations, and on some days participated more passively as an observer of the clinical work. The thesis author maintained a reflexive journal – either on a daily or weekly basis.

Study position in scientific disciplines

The initiative for the PartoMa study originated in a post-positivistic epistemology, which distances itself from positivism and recognises the multiplicity and complexity of social phenomena, and thereby that context-free experimental design is insufficient and impossible. However, the knowledge generation in post-positivism is still largely based on pre-structured data collection and controlled measurements, and objectivity is the ideal to which the researcher strives.¹¹¹ The interactions between the health system, birth attendants, labouring women, community, and research team, and the participatory development and uptake of the PartoMa intervention in these realities, appeared better understood from a pragmatist action-oriented approach. According to pragmatism, knowledge is a tool for action and the criteria for judging 'good' epistemologies, methodologies, and results are whether they are supportive to a research process closely associated to solving health system challenges, and possibly in creative new ways.¹¹² While biomedicine is classically grouped with positivistic and post-positivistic epistemologies, the pragmatist

ⁱ The current PartoMa Steering Group at Mnazi Mmoja Hospital: Alawiya Abubakar Ahmed (MD), Dhuria Abdallah Ahmed (Maternity Theatre Nurse), Fatma Mrisho Haji (MD), Lamlat Hassan Nondo (MD), Naufal Kassim (MD, Chief Medical Consultant), Maryam Ahmed (Nurse-midwife, nurse supervisor), Mubina Rajhy (MD), Rashid Saleh Khamis (Intern Doctor), Saada Juma Amour (Midwife), Salma Abdi Mahmud (MD, PhD, MMed OBGYN) and Zuhura Abdallah Balozi (MD, Head of Maternity Department).

approach seems close to being a clinician, be it in Denmark or Zanzibar: To reach diagnosis and optimal management plans for individual patients, qualitative history taking and subjective impressions are continuously combined with more objective test results – and the real-life scenarios are typically a little different than the textbook examples or clinical guidelines.



Supplies in the delivery room. Photo by Tarek Meguid.

Chapter 4

Study Setting and Context

4. Study Setting and Context

Maternal health care in Zanzibar

Zanzibar is a low-income semiautonomous archipelago of the United Republic of Tanzania, consisting of two main islands, Unguja and Pemba (Figure 2). The Zanzibari population is rapidly approaching 1.5 million,¹¹³ of which 30% live below the basic-needs poverty line.¹¹⁴ It is a young population with a total fertility rate of 5.1 children per woman.¹¹⁵

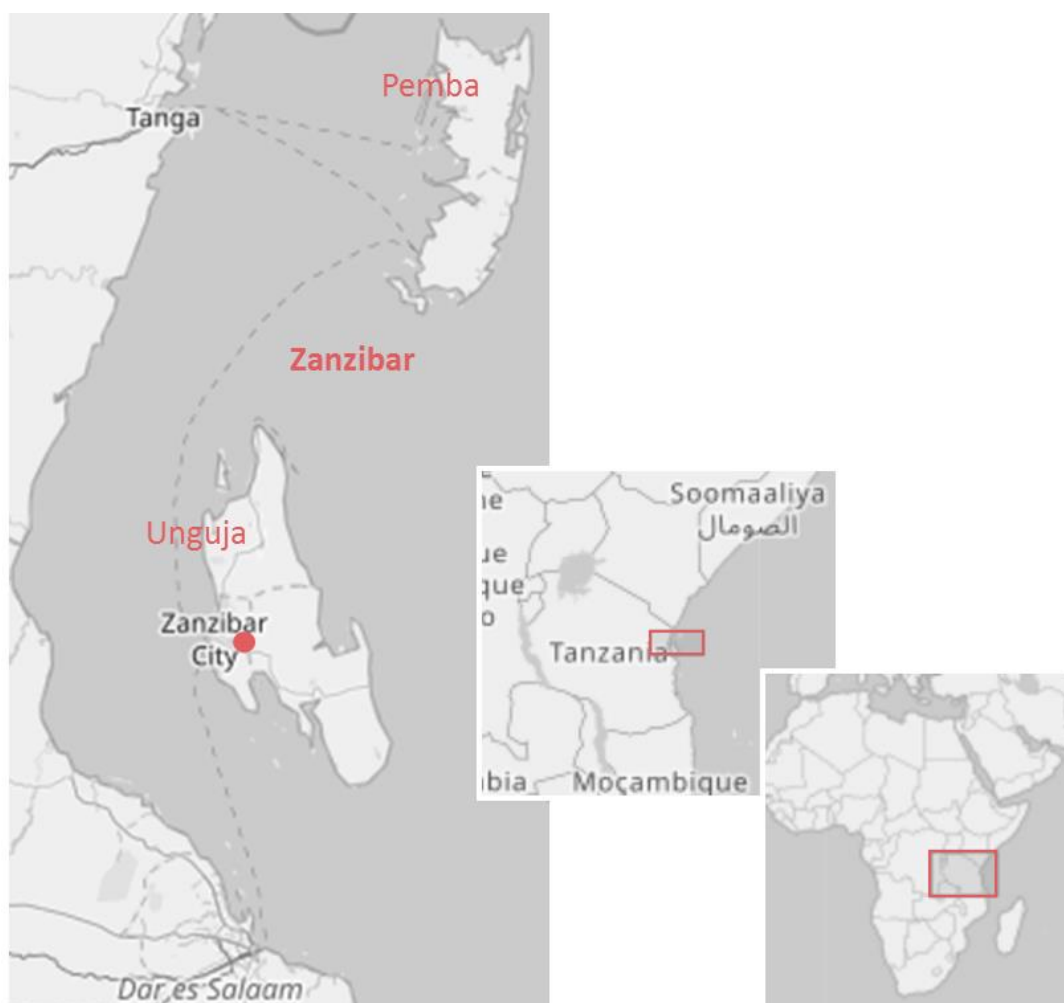


Figure 2 Map of the Zanzibar archipelago with the main islands of Unguja and Pemba. Mnazi Mmoja Hospital, the study site, is located in Zanzibar City. Zanzibar is a semiautonomous part of the United Republic of Tanzania. Source: Open Street Map.

Zanzibar is autonomous in internal matters, such as health, which is governed by its Ministry of Health. In alignment with the objectives of the PartoMa study, the health sector strategic plan includes reduction of maternal and neonatal mortality, gender mainstreaming, improved human rights in health, human resources development and retention, and better adherence to standard protocols and guidelines.¹¹⁶

Zanzibar's health sector receives support from global development partners, the private sector, and faith-based and nongovernmental organizations. The government encourages donor commitment to the Paris Declaration and Accra Agenda for aid harmonisation and effectiveness.^{109,116}

In Zanzibar, most health services are delivered by public facilities, though private facilities are increasing in urban areas. Basic emergency obstetric and neonatal care is provided at approximately 40 primary maternity units. Comprehensive obstetric care with CSs and blood transfusions are provided in Zanzibar's tertiary referral hospital, Mnazi Mmoja Hospital, and in four other maternity units in Unguja and in three in Pemba.¹¹⁷ Although the government tries to decongest Mnazi Mmoja Hospital and other bigger maternity units by enhancing more primary health care units to provide childbirth care, it seems that women prefer the bigger facilities. Of Zanzibar's total yearly facility births, Mnazi Mmoja Hospital attends to 33%.¹¹⁸

Parallel with the formal health care sector, the Zanzibari population often consults traditional healers and use herbal medicine. Officially, maternal and neonatal care is free in the public sector. However, lack of supplies and low salaries often cause unpredictable user fees and informal payments for these services.

The first antenatal care visit coverage is approximately 80%, but less than half of pregnant women complete four visits and the facility delivery rate is around 55%. Data on ante- and intrapartum health in Zanzibar is limited. Among Zanzibari women aged 25-44 years, an estimated 19% suffer from hypertension,¹¹⁹ with risk of gestational aggravation and superimposed pre-eclampsia.^{120,121} Of the approximately 35,000 women delivering in health facilities annually, less than 10% are delivered by CS, and the use of vacuum extraction is rare.¹¹⁸ In 2016, Zanzibar's institutional maternal mortality ratio was estimated at 276 per 100,000 live births,¹¹⁸ and in a 24 month maternal mortality study exclusively at Mnazi Mmoja Hospital (2016-2018), a ratio of 361 per 100,000 live births was recorded.¹²² Among intra-facility maternal deaths, the leading causes were obstetric haemorrhage (around 46%) and severe hypertensive disorders (23%-30%).^{118,123} Community-based maternal and perinatal mortality statistics are unavailable.

Human resources for health crisis are alarming. The 2017 Zanzibari maternal, neonatal, and child health workforce was estimated at 6.3 per 10,000 population, which falls substantially short of the WHO-recommended threshold of 23 per 10,000 population for 80% of births to be attended by skilled personnel. The shortage of skilled attendants results in unregulated and unprepared task-shifting to lower cadres of staff.^{49,124} Moreover, a quality assessment at five Zanzibari governmental hospitals found key issues in providing comprehensive obstetric care to be high staff-turnover, insufficient salaries, bleak career options, and weak clinical training. On-the-job training was scarce and, as reported from other low-resource health systems (page 15), off-the-job training by non-governmental organizations was often given to staff not providing the trained tasks. Moreover, newly trained staff members were poorly prepared for their clinical work, as pre-graduate nursing and medical training were not aligned with post-graduate work realities.¹¹⁷

The 2017 survey of human resources for health in Zanzibar found that clinical supervision was not regularly done, and staff members were unclear on their job descriptions. No effective feedback mechanisms for improving professional performance were in place, and continuous and significant migration of health workers away from the Ministry of Health was observed.⁴⁹

Mnazi Mmoja Hospital

Fieldwork for this thesis was conducted at the Department of Obstetrics and Gynaecology in Mnazi Mmoja Hospital, Zanzibar's tertiary university hospital, between October 2014 and July 2018. The hospital is located in the capital district of Unguja and is by far the biggest hospital in Zanzibar. It is the highest level referral facility for all – except those referred to Dar es Salaam and beyond, which is a rare possibility for pregnant women or women in labour.¹¹⁷

Approximately 11,500 women delivered at Mnazi Mmoja Hospital annually during the study years.¹¹⁸ Of these, around 5% were referrals from other facilities. In 2014, the hospital was the only facility in the capital district performing CSs at night. Now, three private urban facilities also aim at providing the service around the clock. However, Mnazi Mmoja Hospital is the only facility in Zanzibar with adult and neonatal intensive care units. Hence, while the labouring women are primarily from lower socioeconomic groups, the hospital takes care of women from all socioeconomic groups when critical care is needed.¹¹⁸

During the study years, 35-40 birth attendants assisted the approximately 11,500 yearly deliveries. This is only half of the WHO's 2005 benchmark for supply-side needs, which recommends 20 birth attendants for 3600 deliveries.¹²⁵ While the number of labouring women remained steady, the birth attendants' unequal shift distribution between days, evenings, and nights resulted in an average of between three and six labouring women per birth attendant.⁴⁵ A varying proportion (16-30%) of these birth attendants were intern doctors conducting their initial six week clinical rotation in obstetrics. During evenings, nights, and weekends, there were between two and three nurse-midwives for women in labour – one in the admission room, and one or two for all admitted labouring women. They collaborated with a non-specialized doctor and an intern doctor who were also positioned in the obstetric department. In addition, a non-specialized doctor in the gynaecological division was added to the evening and night shifts in 2017 and would sometimes assist. A specialized doctor in obstetrics and gynaecology was on call.

Staff-turnover was high throughout the study – not only for intern doctors, but also for doctors and nurse-midwives who worked in permanent positions (page 83). Consequently, at any time, a considerable proportion of staff had limited experience in maternity care. In March 2018, a total of 23 nurse-midwives were employed in the obstetric department, of which eight (35%) had less than three months' experience with maternity care, and only three (13%) had a master in midwifery. In the same month, 15 medical

doctors were employed for the whole department, of which 10 (67%) had less than three years' obstetrical experience and two (13%) were specialists in obstetrics and gynaecology.

When initiating the PartoMa study in 2014, no clinical practice guidelines were routinely applied for intrapartum care. For more than a decade, use of WHO's composite partograph had been recommended for all women in labour, and the partograph paper sheets were available.⁶⁹ Clinical meetings for doctors were held daily, and intern doctors received a one-hour partograph training each week. Otherwise, formalized on-the-job training was scarce, and only few staff were invited for off-the-job workshops (page 83).¹¹⁷

The department carried a massive teaching obligation. In 2016, more than 200 Tanzanian nurse-midwifery and medical students conducted their pre-graduate midwifery or obstetric training in the department.

All comprehensive obstetric and neonatal care signal functions were usually available.ⁱⁱ However, there were frequent shortages in functioning, essential equipment and medicine for routine and emergency care, and none replenishment of the department's storage room added to the problem. Intermittent shortages in supplies included, for instance, foetoscopes, ultrasound gel, oxygen, working thermometers, parts for the vacuum extractor, and antihypertensives. It was often reported that there was only one functioning BP machine available for the entire department (Paper III, page 176).⁴⁵

There was an urgent need for space. Until January 2017, the department was located in an old hospital building where two rooms were available for women in childbirth, as depicted in Figure 3 and in the thesis pictures. In the labour room's 19 beds, women were supposed to be attended to during the first stage of labour. Severely ill postpartum women were also cared for there. In the second stage of labour, women were supposed to walk 15 meters to the delivery room that had three delivery beds. The new building contained three labour rooms with a total of 24 beds and a separate room with four delivery beds. With approximately 11,500 annual deliveries, this equals a total of nine beds per 3600 deliveries. For comparison, WHO's 2005 benchmark for supply-side needs recommend 60-80 beds for 3600 deliveries.¹²⁵ Hence, though six extra beds were added in the new building, the number of beds was too few in both buildings. This resulted, on average, in two women sharing a bed, and due to staff shortage and lack of overview, many women ended delivering in the shared beds. An observational study by a collaborating research group of 161 deliveries in 2016 found that 56% of deliveries took place in the crowded labour room, only 28% in the three-bed delivery room, and 16% in the theatre.⁴⁵

ⁱⁱ Parenteral antibiotics, oxytocic, magnesium sulphate, equipment for manual removal of placenta and for removal of retained products, vacuum extractor, bag and mask for neonatal resuscitation, surgical theatre with surgical staff ready for caesarean section, and blood transfusion service.

In the old building, there was one obstetric theatre and there were two in the new building. Throughout the study, a designated theatre nurse was available around the clock and anaesthetists were on call. During the evening and night shifts, two anaesthetists covered the whole hospital. In the old building, the neonatal intensive care unit was adjacent to the labour and delivery rooms, and in the new building, staff had to walk 40 meters with asphyxiated newborns, including using a staircase.

Maternal and perinatal delivery statistics are provided in the results section where challenges in structural resources are also further clarified (pages 42 and 70).

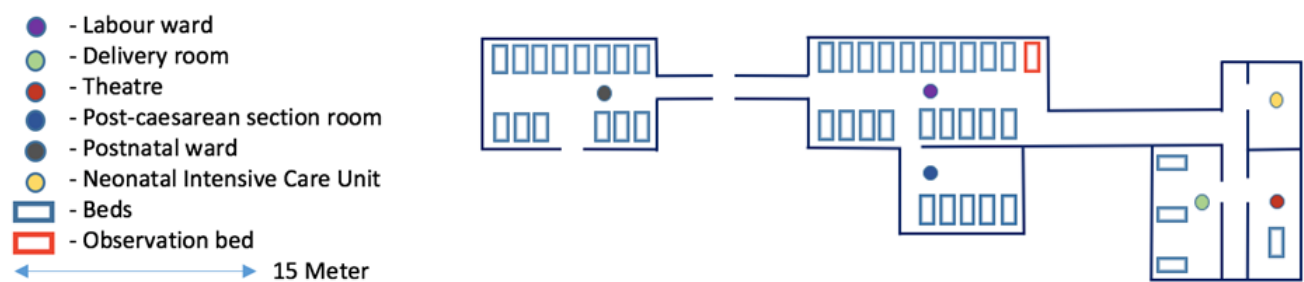


Figure 3 Layout of the maternity unit in the old building. Reproduced with permission from Natasha Housseine.⁴⁵



Resuscitaire in the delivery room. Photo by Tarek Meguid.

Chapter 5

Ethical Considerations

5. Ethical Considerations

The goal of the PartoMa study was a participatory quality improvement process for enhancing intrapartum care to the best achievable practice, while avoiding exposure and reprimands of individual birth attendants. Identities of women and newborns whose admissions were investigated as well as of health providers involved in their care were kept confidential. Keeping personal data safe was paramount and secured. Furthermore, taking staff away from clinical duties, both for participation in the intervention and for research, was avoided throughout the study.

Through the recurring peer-review cycles by external experts in obstetrics, midwifery, and neonatology (Figure 5, page 54), the study team believe that it have taken all reasonable precautions to verify the information contained in the PartoMa Pocket Guide.

Clearance to conduct the PartoMa study was obtained from Mnazi Mmoja Hospital and the Zanzibar Medical and Research Ethical Committee (ZAMREC/0001/JUNE/014, 7 October 2014), and the study is in line with the strategy formulated by Zanzibar's Ministry of Health.^{46,116} Oral informed consent was obtained from all respondents to questionnaires, tests, and the qualitative data collection. They volunteered to respond anonymously, and were informed that they could withdraw their consent without consequences on their care or career.

The PartoMa study is listed in ClinicalTrials.org (NCT02318420, 4 November 2014).



Woman suffering from severe pre-eclampsia and stillbirth. Photo by Tarek Meguid.

Chapter 6

Baseline Quality of Care Study

6. Baseline Quality of Care Study

Intrapartum stillbirths are considered a sensitive indicator of quality of care,² and an unblinded case-control study of stillbirths was conducted, with data collection between October 2014 and January 2015. The data were published in Paper I (page 142) and applied in intervention development (page 50) and as baseline for the intervention evaluation (page 66).

Qualitative data were also collected during the baseline months, by participatory observations, informal conversations, and in-depth interviews. While the final qualitative analysis is still in progress and the ethnographic study not included in the thesis, preliminary findings informed the intervention design and research plan.

Methodology

Study population

We sought to count all late foetal deaths with birthweight ≥ 1000 g, of which stillbirths from singleton pregnancies with birthweight ≥ 2000 g were included for further analysis in the criterion-based case-control study. These were divided into 'intra-hospital stillbirths' with FHR present on admission, and 'pre-hospital stillbirths' without a recorded positive FHR during the entire admission. Reasons for excluding multiple pregnancies and for the 2000 g cut-off are presented in Paper I (page 142).

For the control group, every tenth delivery was selected from the same time period, of which singletons with birthweight ≥ 2000 g and an Apgar score ≥ 7 were included. No power calculations were conducted as it was impossible to expand the baseline period – due to the absence of patient files in the hospital's storage system and start of the intervention. To optimize the study's power, a ratio between intra-hospital stillbirths and controls of 1:4 was aimed at.¹²⁶

Data retrieval

Both case and control women were identified in the admission, delivery, and theatre registers at the maternity unit. All case files from the four month period were then intensively searched. This also allowed searching for additional stillbirths not recorded in the official registers. Identification of and searches for cases and controls were conducted part time by Zanzibari intern doctors and medical studentsⁱⁱⁱ. They had weekly meetings with the thesis author or Tarek Meguid to assure quality retrieval, and all searches were repeated at least twice. The thesis author attended a final re-search and afterwards checked all case files individually to determine whether the inclusion criteria were met for in-depth criterion-based review.

ⁱⁱⁱ Research assistants: Natasha Housseine, Rashid Saleh Khamis, Ali Gharib Mohamed, Mbweni Makame Ali, and Said Mzee Said (intern doctors and final year medical students at Mnazi Mmoja Hospital).

Criteria of realistic best practice

The audit criteria, or care indicators, were formulated with the aim of representing unambiguous standards for the low-resource setting, which were sensitive in monitoring progress and limited to the available information in case files. Final drafts of the audit criteria were reviewed by the study team's three specialists in obstetrics (Jos van Roosmalen, Tarek Meguid, and Birgitte Bruun Nielsen), of whom Tarek Meguid worked at Mnazi Mmoja Hospital, and by the study team's non-specialized doctor at Mnazi Mmoja Hospital (Natasha Housseine). The criteria were developed in parallel to tailoring the initial pilot version of the PartoMa Pocket Guide (page 50). The resulting key criteria are presented in Figure 8 (page 68).

Analyses

The thesis author extracted all available background characteristics and birth outcome data, and analysed intrapartum practice against the preselected criteria. In cases of doubt when classifying data, the study team was consulted. As recommended for criterion-based auditing, if a practice was not documented, it was assumed to have not been performed.¹²⁷ Background characteristics were compared by Fisher's exact test, and care indicators individually by odds ratio (OR) with 95% confidence interval (CI). Logistic regression was done in SAS Enterprise Guide 6.1 (SAS Institute, Inc., Cary, NC).

Results and target areas for improvement

Stillbirth rate

During the four month baseline, a total of 216 stillbirths occurred out of 3690 total births, corresponding to a hospital-based stillbirth rate of 59 per 1000 total births. Of these, 139 of 186 (75%) retrieved case files had a birthweight ≥ 2000 g and were included in the case-control study, with 72 (52%) having positive foetal heart on admission (intra-hospital stillbirths). In only one case, a congenital anomaly was described. Of the controls, 249 met the inclusion criteria. Sample size flow is presented in Paper I's Figure 1 (page 142).

Background and outcome characteristics

Background and outcome characteristics of intra-hospital stillbirths, pre-hospital stillbirths, and controls are presented in detail in Paper I's Tables 1 and 2 (page 142). In short, among the women included in the criterion-based case file review, 54% with intra-hospital stillbirths were nulliparous, which was similar to the controls, but different from women suffering from pre-hospital stillbirths, where only 22% were nulliparous (OR 4.22, 95% CI 1.99-8.96). All women, except one, had attended antenatal care at least once. Of the multiparous women experiencing stillbirth, 36% had also previously suffered from the loss of one or more children, versus 22% among controls (OR 1.96, 95% CI 1.07-3.59). Of women experiencing intra-hospital stillbirths, 59% were admitted before active phase of labour, versus 28% controls (OR 3.79, 95% CI 2.19-

6.57). There were three maternal deaths in the study population, all associated with stillbirth and suffering from severe delays in intrahospital management.

Quality of care

Seven key findings were extracted, which led to seven target areas for improving intrapartum quality of care (Box 1). Overall, quality of care was found to be suboptimal among both cases and controls, leading to profound perinatal and maternal risks.

First, admission assessment was suboptimal causing missed opportunities for detecting risks. For instance, 70% of all women in the study had no information recorded on gestational age, and around 40% had no temperature recording from admission till delivery. Of intrahospital stillbirths, 59% were admitted before active phase of labour with multiple hours for proper assessments.

Second, routine surveillance during latent and active phase of labour was delayed or neglected for all key parameters. Take FHR for example. In 81% of the intrahospital stillbirths, there was no documentation of foetal distress or foetal death prior to delivery, and for each one-hour increase in duration from last FHR assessment till delivery, the odds of stillbirth increased by 20% (OR 1.20; 95% CI 1.08-1.34).

Third, women in the prehospital stillbirth group received less care than labouring women with living foetuses on admission. Significantly more did not have a partograph filled in, when compared to both intrahospital stillbirths (OR 9.78, 95% CI 2.56-37.42) and controls (OR 3.39, 95% CI 1.52-7.56). Also, women admitted in latent phase with prehospital foetal death suffered from the highest risk of having no cervical assessments recorded during active labour (61% versus 35% controls; OR 2.85, 95% CI 1.08-7.55).

Fourth, diagnosing prolonged labour was delayed due to infrequent assessments of cervical dilatation, and management was equally substandard. Take oxytocin use for labour augmentation for example. When excluding induced women, oxytocin augmentation was administered in 36% of intrahospital stillbirths, versus 23% controls (OR 1.86, 95% CI 1.06-3.27). In 31% of these stillbirth cases, progress in cervical dilatation was at least one centimetre per hour when oxytocin was initiated, and in an additional 27% the infusion was started between the partograph's alert and action lines with the membranes still intact. Among controls receiving oxytocin, 59% had the infusion started before crossing the alert line. None of the women receiving oxytocin augmentation, cases or controls, had information on oxytocin titration and maintenance doses documented, and FHR and contractions were never assessed half hourly after starting the infusion (Figure 4).

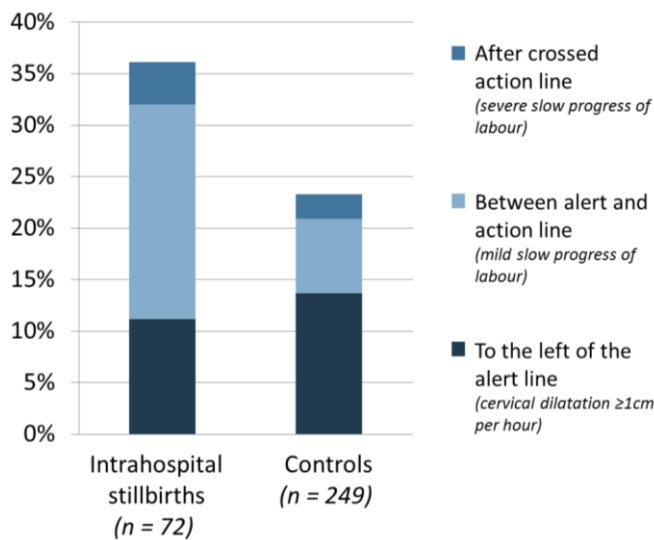


Figure 4 Initiation of oxytocin for labour augmentation, according to labour progression. The difference in overall use of oxytocin for labour augmentation between intra-hospital stillbirths and controls was significant with the stillbirth cases receiving oxytocin more often (OR 1.86, 95 % CI 1.06–3.27). Intra-hospital stillbirths: Documented positive FHR on admission, birthweight ≥ 2000 g. Controls: Apgar score ≥ 7 , birthweight ≥ 2000 g. The figure is reprinted from Paper I.

Fifth, 26% of all stillbirths were delivered by CS, versus 11% of babies among controls (OR 2.94, 95% CI 1.68–5.14). Only one baby was delivered by vacuum extraction. A quarter of the CSs after foetal death or resulting in stillbirth were performed in the second stage of labour.

Sixth, prevalence of severe hypertensive disorders in pregnancy (sHDP) was 19% among women experiencing stillbirth, versus 4% among controls (OR 5.76, 95% CI 2.70–12.31), and their care was suboptimal. For instance, in 67% of the 27 stillbirth cases with maternal sHDP there were no recordings of antihypertensive treatment.

Seventh, intrapartum documentation and record keeping were substandard. For example, the overall case file retrieval revealed that 25 % of stillbirths were not reported in the hospital's official registers.

For an example of the multifaceted quality of care shortages detected, please see Saada's birth story in Box 2.

Box 1 Seven target areas for improving intrapartum quality of care at the study site, informed by the baseline case-control study of stillbirths and developed by the study team (October 2014 – January 2015). The box is reprinted from Paper I.

1. Strengthened risk assessment on admission, with particular focus on foetal heart rate (FHR), blood pressure (BP), temperature, and previous obstetric history.
2. Improved routine surveillance during latent and active phase of labour, regarding all key parameters (FHR, dilatation of cervix and descent, contractions, maternal vital signs, and urinary output).
3. Increased prioritization of women with already diagnosed intrauterine foetal death for routine assessments during labour.
4. Timely prevention and management of prolonged labour, with focus on alternative and less harmful interventions than oxytocin infusion for labour augmentation (e.g. artificial rupture of membranes and emptying of bladder), and more restrictive dosages and improved surveillance when oxytocin is administered.
5. Reduction of caesarean sections after intrauterine foetal death, by improved management of prolonged labour, and enforcement of vacuum extraction and craniotomy use.
6. Improved management of severe hypertensive disorders, with particular focus on antihypertensive treatment.
7. Better intrapartum documentation as well as record keeping.

Box 2 Saada's story (fictitious name), pieced together through review of her case file, direct observations, and informal conversations. She was included in the baseline's case-control study of stillbirths.

Saada, a 23 years old woman expecting her first child, was admitted in the evening in the latent phase of labour and quickly referred to a nearby waiting ward. BP on admission was noted to be normal and exactly identical to the four measurements from antenatal care visits. BP was again assessed two hours later due to unspecified complaints and was 220/130 mmHg. Severe proteinuria was then disclosed but foetal heart rate (FHR) was normal. Saada was asked to walk to the crowded labour room, where an intern doctor initiated hydralazine, methyldopa, and magnesium sulphate treatment and also monitored urinary output.

During the next four hours, surveillance was infrequent and not documented. Subsequently, the FHR was recorded as "very low" and the intern doctor called his supervisor. Due to severe hypertension, the supervisor was in doubt whether to decide on a caesarean section. Saada was still in the latent phase.

Thereafter, Saada was left alone for another four hours without surveillance till early morning, when FHR could no longer be heard and BP was 150/100 mmHg. At this time, she was in active phase of labour. One hour later, Saada's situation was presented at the clinical morning meeting, where a senior obstetrician criticised the management of Saada, who still was in labour, and reminded the staff that in severe pre-eclampsia "*the woman is running to her grave*". The only comment from the supervisor of the night shift was: "*We are busy, what can we do?*".

Thirteen hours after admission, Saada delivered her stillborn baby vaginally. The birth weight was 2300 gram. Vital signs were assessed five times in the first 12 hours postpartum. BP fell rapidly and the urinary output increased.

Although her baby was stillborn, Saada was placed in the labour room for the next four days, surrounded by women giving birth. She was cared for by her mother who was allowed to visit for a few minutes twice daily with food and tea. Saada and her mother whispered together, unhappy and isolated without any interaction with the staff.



The PartoMa seminars. Photos by Jurre Rompa and Nanna Maaløe.

Chapter 7

The PartoMa Intervention

7. The PartoMa Intervention

Having observed how externally-derived clinical guidelines were rarely applied and that more clinical knowledge and guidance were urgently needed, a participatory development process was initiated to create locally-tailored guidance and associated training.

The PartoMa Pocket Guide

The key aim of the PartoMa Pocket Guide was to assist birth attendants in routine and emergency intrapartum care associated with using the WHO partograph. Besides being evidence-based, the clinical recommendations should be easy-to-use and locally applicable and achievable when taking the resource-constrained context into account. Evidence on clinical guidelines indicate that participatory development of standards that are simple and easy to understand have a greater chance of implementation.^{105,128} In alignment, regional, national, and subnational adaptations are encouraged by WHO for “taking into account local circumstances and resource considerations”.⁸³

The WHO’s ‘Managing Complications in Pregnancy and Childbirth’ was applied as the main guidelines frame for the development process, but supplemented and cross-checked by other evidence-based guidelines. When modifications were made to well-established international recommendations, systematic literature searches were conducted for overview of related scientific evidence. As depicted in Figure 5, recommendations were modified through repeated evaluations by local birth attendants and a panel of external specialists in midwifery, obstetrics, and neonatology, the vast majority of which had intensive experience working with maternity care in low-resource settings.^{iv} In 2015, the development process resulted in the first version of the PartoMa Pocket Guide, which focused on intrapartum partograph-related care. This version was pilot tested by all 46 birth attendants at the department, 32 (70%) of whom were available to provide written questionnaire feedback on designated evaluation days (response rate 100%). They found the pilot version useful, achievable, and easy to understand, and their free text comments only necessitated minor changes, primarily in wording.

In response to birth attendants’ wishes, an expanded second version was launched with additional recommendations in 2018 (Appendix, page 122). Additional topics included labour induction, obstetric

^{iv} External reviewers: Antke Zuechner (MD, neonatologist, Tanzania), Barbara Kwast (Midwife, epidemiologist, PhD, Fellow of the Royal College of Obstetricians and Gynaecologists), Ben Mbwele (MD, PhD, epidemiologist, Tanzania), Bjarke Lund Sorensen (MD, PhD, OBGYN, Denmark), Brenda D’Mello (MD, MMed OBGYN, Tanzania), Charles Ameh (MBBS, PhD, MPH, FWACS (OBGYN), FRCOG, United Kingdom), Gaynor Maclean (Midwife, PhD, United Kingdom), Hussein Lesio Kidanto (MD, PhD, MMed OBGYN, Tanzania), Josephine Obel (MD, PhD, MMed OBGYN, Yemen), Karen Odberg Pettersson (Midwife, PhD, Sweden), Klaas Koop (MD, PhD, pediatrician, Netherlands), Mike English (MD, neonatologist, Kenya), Rachel Macleod (Midwife, United Kingdom), and Tom Weber (MD, PhD, OBGYN, Denmark).

manoeuvres (vaginal breech delivery, delivery of second twin, and shoulder dystocia), antepartum and postpartum haemorrhage, and neonatal resuscitation. Again, the pocket guide was pilot tested and evaluated. This time, 40 birth attendants pilot tested the pocket guide and provided written questionnaire feedback (response rate 100%), which again was encouraging. As requested by birth attendants, the second version is currently being made available in both English and Swahili, both in paper form and online.¹²⁹ For both rounds of pilot testing, a questionnaire similar to the 12 month evaluation was applied (page 64).

Both versions of the PartoMa Pocket Guide aimed at providing simple and brief guidance, and the guide covered an integrated continuum of common care at birth, based on three key principles (Paper II, page 156):

- 1) Triage: Guidelines on monitoring and treatment of the individual woman took into account that each birth attendant cared for between three and six labouring women simultaneously.
- 2) Routine and emergency care in one: Basic and emergency obstetric care were integrated, because obstetric complications were often preceded by suboptimal basic care.
- 3) Partograph use: The partograph was emphasized as an integrated early warning tool to assess FHR, labour progression, and maternal condition throughout the latent and active phase of labour, including second stage.

In the development process, it was often necessary to deviate considerably from established international clinical guidelines, as discussed in Paper V (page 204). Substantial reductions in frequency of assessments, information load, and ambiguity were necessary to bridge clinical realities, which are further described for pocket guide version 1 in Paper II (page 156), and for version 2 in the online background document at the study website.¹²⁹

In Box 3, guidance for management of women with slow labour progress in the first stage of active phase is presented as an example of the reflections behind the modifications made.

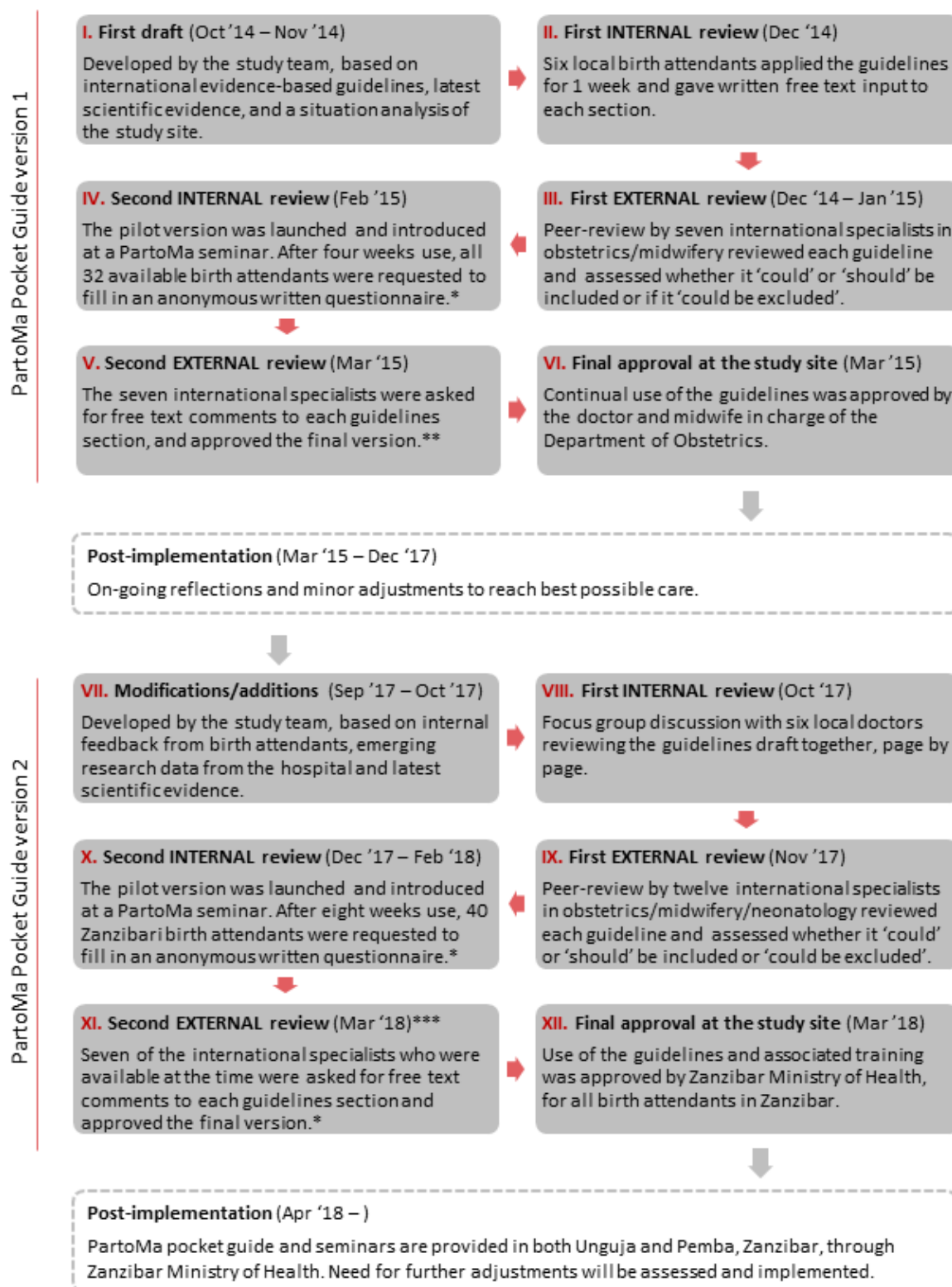


Figure 5 The participatory and internationally peer-reviewed development process of the PartoMa Pocket Guide version 1 and 2. Elaborated from Paper II's Figure 2. *Questionnaire evaluation after pilot testing version 1 was responded to by 16 nurse-midwives, 8 medical doctors, and 8 intern doctors, and version 2 by 15 nurse-midwives, 7 medical doctors, 2 clinical officers, 9 intern doctors, and 7 medical students (response rate 100% for both versions). **The reviewers were asked to divide their feedback into major concerns (if the reviewer feared that a specific guideline or graphic presentation could be dangerously used or misunderstood in clinical work) and minor comments (any additional ideas for changes, including the graphical presentation, typos, etc.). ***At this time point, the newly published WHO guidelines on 'intrapartum care for a positive childbirth experience' were incorporated.⁹²

Box 3 Example of reflections in the development of PartoMa guidance. The example concerns managing slow labour progress, and the latest version of the resulting page 7 of the PartoMa Pocket Guide is depicted in Figure 6.

PartoMa guidance for managing slow labour progress

1. Creating time for managing complications

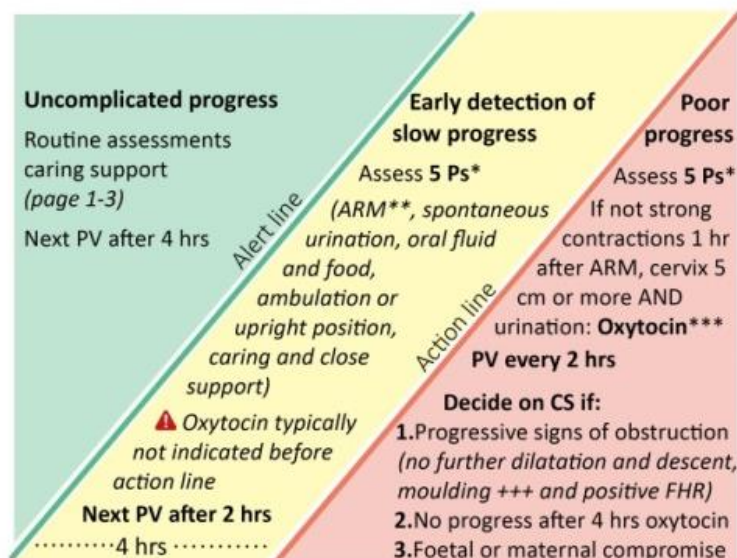
In line with the key principle of triage, it was considered how to create extra time for birth attendants to spend on women with labour complications, such as slow labour progress, while still providing essential monitoring and care for women with uncomplicated labours. It was calculated that simply following WHO's recommendations for basic assessments of foetal heart rate (FHR), contractions, blood pressure (BP), pulse, and vaginal examination during four hours of uncomplicated first stage of active labour would take 120 minutes per woman.⁶⁷ Notably, this is excluding additional time for providing caring support. As one birth attendant typically attended at least three labouring women simultaneously, the birth attendant inevitably was forced to prioritize even these basic tasks when caring for three women with uncomplicated first stage labour. Adding to the challenges, levels of knowledge, skills, and experiences on basic obstetric care were limited among birth attendants, which could compromise the ability to provide optimal prioritization in the complex and hectic provision of care. To create time for managing complications and assist in best possible prioritization, it was therefore obvious to reduce frequencies of routine assessments. This resulted in a minimum of 33 minutes per woman for routine assessments over 4 hours, and extra time for managing complications and providing caring support.

2. Safe management of slow labour progress in the first stage of active labour

The PartoMa guidance was based on the partograph's alert and action lines and an infographic was developed of all crucial information, with colours for urgency (Figure 6). Before implementation of the pocket guide, 22% of labouring women received oxytocin augmentation and most often on doubtful indications, which appeared associated with increased risk of stillbirth (Figure 4, page 47). Oxytocin is categorized as one of 12 medications with a heightened risk of significant harm during labour. There is risk of blind intravenous titration as steady-state plasma levels are first reached after 40 minutes, and effects of any dose may range from unchanged hypotonic to sustained hypertonic uterus.¹³⁰ Oxytocin augmentation is, however, also suggested crucial to reduce the likewise harmful epidemic of caesarean sections (CSs) due to poor labour progress.⁵³ Hence, cautious oxytocin use during labour was warranted with close monitoring of drip count, contractions, and FHR. To achieve safe use at Mnazi Mmoja Hospital, it was evident that the potent drug had to be saved for women most in need. It was necessary to withdraw from the inconsistent WHO guidelines, which, as further described in Paper V and Letter I, would either cause injudicious overuse,⁶⁷ or were too unspecific to assist the busy birth attendants.^{92,131} In alignment with promising results of an Asian multicentre trial conducted by WHO in the 1990s,⁶⁹ consensus was reached for a restrictive oxytocin regimen where oxytocin was saved for women crossing the action line with ruptured membranes for ≥ 1 hour and less than four contractions in 10 minutes. Simultaneously, a '5 Ps mnemonic' drew attention to less dangerous interventions to boost labour progress (Figure 6).¹³² After crossing the action line, no clear guidelines or evidence for when to decide on CS were found. However, women at Mnazi Mmoja Hospital often suffered from severe delays in management of poor progress, and it was found crucial to develop clear indications, as provided in Figure 6.

ACTIVE FIRST STAGE OF LABOUR

(Cervix 4-5 cm or more AND regular painful contractions)



⚠ WHO (2018) recommends not to start active phase before 5 cm

SECOND STAGE OF LABOUR

(Cervix fully dilated)

Duration less than 1 hr AND Pushing less than 30 min Caring and continuous support ARM if membranes still intact** ⚠ Never leave woman alone and monitor FHR closely (page 5)
Duration 1-2 hrs OR Pushing 30-60 min Exclude malposition If presenting part not visible at vulva, consider 5 Ps* and oxytocin augmentation*** PV every 15-30 min
Duration more than 2 hrs OR Pushing more than 1 hr ⚠ For nulliparous, normal second stage can last up to 3 hrs Vacuum extraction if possible (page 12). CS as last resort.

* 5 Ps - why poor progress?

Power:

If less than 4 strong contractions per 10 min, enhance labour:

- ARM**
- Oral fluid and food intake
- Ambulation, upright position
- Oxytocin augmentation***

Passenger:

- Malposition or malpresentation?
- Foetal weight (*large baby?*)

Pass urine:

- Encourage spontaneous emptying every 2 hrs
- Catheterize as last resort

Psyche:

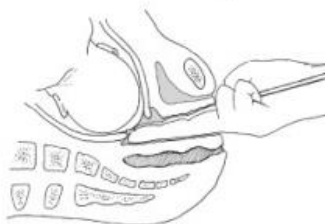
- Reduce anxiety (page 1)

Pelvis:

- Severely contracted pelvis?

** ARM

1. Foetal head engaged in pelvis?
2. On back, legs bent, feet together, knees apart
3. Place two fingers against membranes and GENTLY rupture membranes with clamp



4. After rupture, fingers remain in place (*umbilical cord prolapse?*)
5. Remove fingers slowly, note colour of liquor (page 5)
6. FHR after contraction

⚠ If HIV positive, wait till action line is crossed or cervix 7 cm dilated

*** OXYTOCIN AUGMENTATION

Indications: No previous scar, and less than 4 contractions per 10 min, each lasting less than 40 sec.
Latent phase: 12 hrs or more OR induction (page 6)

Active first stage: Action line crossed, cervix 5 cm or more, membranes ruptured for 1 hr

Second stage: 1 hr or more OR pushing 30 min or more

Start dose: IV Oxytocin 2.5 units in 500 ml Normal Saline or Ringer's Lactate, 10 drops per min

Every 15 min: FHR, contractions, Oxytocin drops per min

Every 30 min: Increase by 5-10 drops per min until 4 contractions in 10 min, each lasting more than 40 sec. Maintain this rate until delivery. Maximum 60 drops/min.

Stop Oxytocin: If more than 5 contractions in 10 min

Figure 6 Page 7 of the PartoMa Pocket Guide version 2 (2018) on management of slow labour progress. The entire pocket guide is available in the Appendix (page 120). ARM, artificial rupture of membranes; BP, blood pressure; bpm, beats per minute; CS, caesarean section; FHR, foetal heart rate; PV, vaginal examination; Temp, temperature. © 2018 The PartoMa Study, University of Copenhagen. All Rights Reserved.

The PartoMa Seminars

By developing structured recurring training sessions, it was aimed to strengthen use of the PartoMa Pocket Guide in clinical work and during daily clinical meetings. Considering the high staff-turnover, adult learning theories, and the limited budget, a 'low-dose, high-frequency training' regimen of in-house seminars every three months were tailored. These 'PartoMa seminars' were conducted quarterly. Particularly during the first rounds, feedback from participants led to several minor adjustments to make the training as acceptable and effective as possible. Each seminar took four hours and was held twice so that staff could attend outside working hours. At the seminars, use of the PartoMa Pocket Guide and the partograph were practiced by discussing case histories at five learning stations. The case histories were based on real accounts from the department and concerned the transition from uncomplicated to complicated labour, but most often with wellbeing of mother and baby at discharge. While the case histories differed between seminar rounds, all concerned the topics included in the PartoMa Pocket Guide. One station always focused on triage among multiple women in labour and, after implementing the second version of the pocket guide in 2017, another station included brief simulation-based training in neonatal resuscitation. Moreover, overarching themes in both the pocket guide and seminars were to strengthen critical, analytical clinical decision-making and respectful, caring support for both labouring women and colleagues, with teamwork, timely and well-prioritized care, and reliable documentation in the centre. Examples of peer-reviewed PartoMa case histories are available at the study website.¹²⁹

The PartoMa seminars were non-hierarchical and groups were multidisciplinary, consisting of nurse-midwives, doctors, assisting medical officers, intern doctors, and students with different levels of authority and status. The stations were facilitated by similar multidisciplinary teams of experienced birth attendants, predominantly from Mnazi Mmoja Hospital. Seminars commenced after work in and around a meeting room in the hospital. No per diems or facilitator allowances were paid, but free food, the PartoMa Pocket Guide, and a certificate of attendance were provided. Names of participants were not disclosed to the hospital administration. The aim was that the main incentive for attending should be the birth attendants' intrinsic motivation to learn and improve in a safe and positive environment, and to spend a social afternoon with colleagues. To maintain an atmosphere of hospitality, staff were never turned away. Group sizes at each station therefore varied considerably (attendance rates are presented in the result section, page 72). There was no official train-the-trainers course, but it was a rule that facilitators had attended seminars multiple times and started by co-facilitating with an experienced facilitator.

In February 2016, a local PartoMa steering group of voluntary clinicians from Mnazi Mmoja Hospital was established and took over arranging the PartoMa seminars (page 27). Case histories were continuously provided by the PartoMa study team, and funding for pocket guides and snacks for seminars secured.

Intervention running costs

As an economical evaluation was not conducted, only direct running costs are known. Indirect costs were not estimated, such as opportunity costs for the numerous hours of voluntary time spent by the facilitators and participants outside working hours.

Training 80 people over two days of PartoMa seminars in Mnazi Mmoja Hospital costed approximately 800 USD (10 USD per person). This included distribution of laminated pocket guides (produced in Zanzibar, 4.80 USD per booklet), snacks, photocopies, and stationery.

In addition, a big-size poster for the maternity unit costed 30 USD, and due to modifications of the guidance, it was reprinted eight times during the nearly four years studied. One-time expenses for the seminars included purchasing four reusable whiteboard partographs at 45 USD per piece. A mannequin for neonatal resuscitation was already available when a resuscitation station was included in the seminars in 2017.



Training at a PartoMa seminar, with use of a partograph case history and the pocket guide. Photo by Nanna Maaløe.

Chapter 8

Methodology for the Evaluation

8. Methodology for the Evaluation

The PartoMa intervention is a complex clinical, educational intervention.⁴¹ As proposed by Craig et al., the complexity refers to several characteristics of the intervention:¹⁰² *First*, the intervention's multiple interacting components caused complexity (i.e. the pocket guide, training, and partograph use), and the number of evaluation indicators on multiple levels (see below). *Second*, the intervention demanded multiple skills by the birth attendants, who were simultaneously considered co-creators of the intervention as well as implementers and receivers. *Third*, both the intervention development and implementation were flexible, with a 'self-directed approach' where participation in seminars, use of the pocket guide, and supervision of others relied on individual motivation. Hence, a potential lack of effect in the ultimate outcome of birth survival could be caused by multiple failures on multiple levels on the pathway from implementation to birth outcomes.

A theoretical understanding of the likely pathway of change was outlined by the study team during baseline (Figure 7). This program theory, or logical pathway, was vital in developing the mixed-methods evaluation design to explore the implementation pathway and how the implementation did, or did not, differ from intention.^{41,133} The four-level program theory was primarily based on the theoretical background (page 14), the contextual understanding (page 30), and two overlapping and widely applied causal pathway models. By combining Kirkpatrick's model for evaluating training programs with Donabedian's model for evaluating quality of clinical care, the evaluation included indicators for the *structure* within which care was provided, the *process* of delivering proper care, and the related *birth outcomes*. Particularly, process evaluation is considered central to answering the question at hand, "whether medicine is properly practiced",¹³⁴ and according to Kirkpatrick's model, process was subdivided into birth attendants' initial perceptions and reactions to the intervention (level 1), followed by possible changes in knowledge and skills (level 2) and in clinical practice (level 3), leading to possible improvements in birth outcome (level 4).¹³⁵ Structure was included in an overarching context assessment, which more broadly comprised possible mediators and confounders affecting the implementation pathway (Figure 7).⁴¹

Research methodologies applied for evaluating each Kirkpatrick level and the study's related scientific publications are summarized in Figure 7 and described in the following sections. A timeline of the study is provided in the Appendix (page 214), including the intervention development and implementation, the evaluation's assessment levels, and related key structural changes. To achieve a richer description of the context and a deeper understanding of the possible 'active ingredients' in transferral between the levels, and of possible non-linear feedback loops between them, an inductive ethnographic assessment was conducted.^{102,136} This overarching qualitative component is not included in the thesis and its analysis is yet to be finalized.

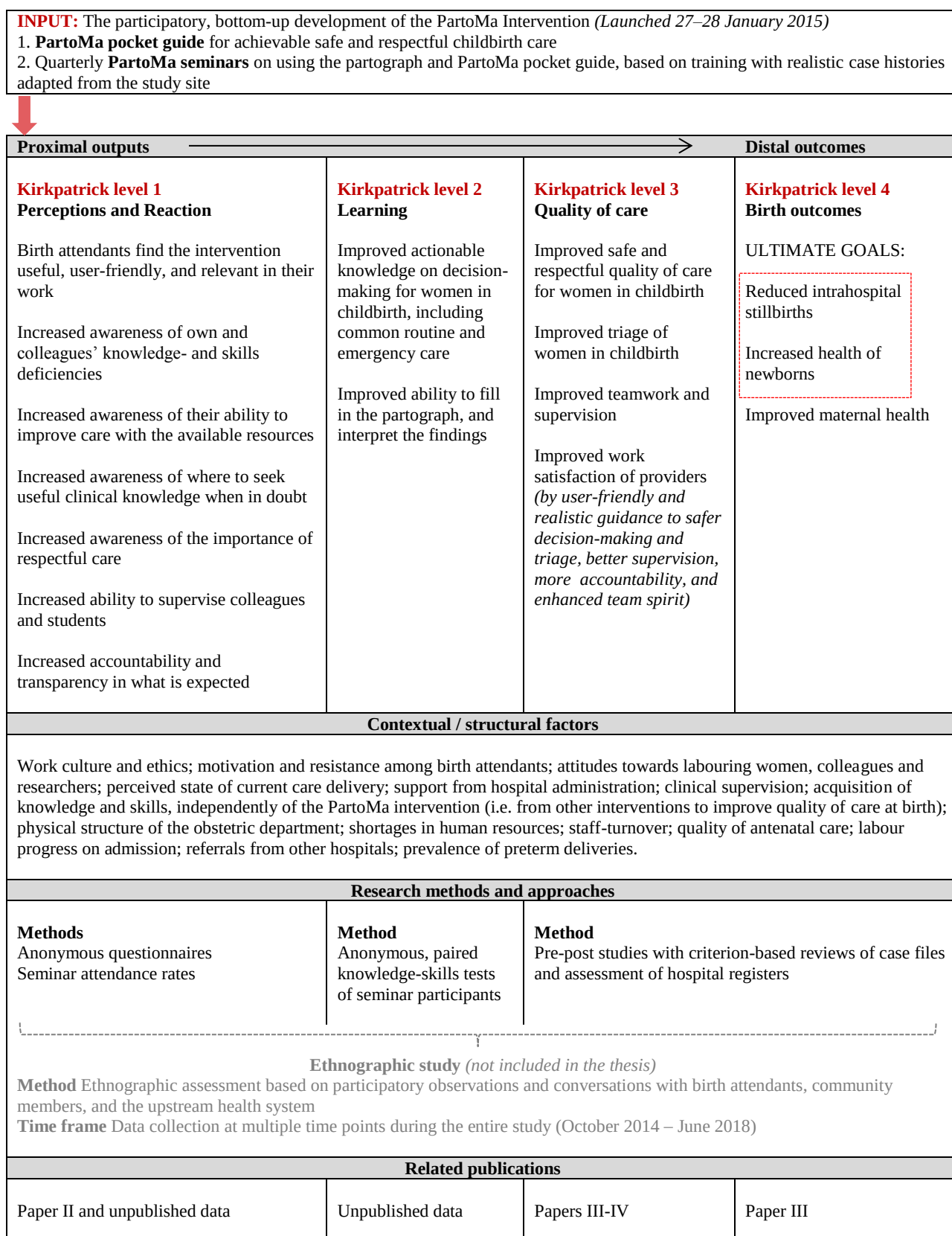


Figure 7 Program theory and related research evaluation design for the PartoMa study. Based on the theoretical background (page 14), the contextual understanding (page 30), the baseline quality of care study (page 38), and Kirkpatrick and Donabedian's causal pathway models for evaluating training interventions and quality of medical care.^{134,135}

Kirkpatrick level 1: Perceptions and reaction

This section concerns evaluation of conductance, attendance, and participants' perceptions at the PartoMa seminars (unpublished data), as well as a 12-months evaluation of birth attendants' perceptions of the PartoMa Pocket Guide (Paper II), independently of whether they used the intervention.

Seminar conductance

After the 12th intervention month (February 2016), a local PartoMa steering group took over arranging the seminars. Continuation of the intervention was followed by observing timeliness of conducting seminars.

Seminar attendance

As no per diems or allowances were paid for seminar participants and the seminars happened outside working hours, attendance was considered an indicator of interest in and motivation to learn about the PartoMa intervention. It was the aim to obtain attendance rates during each round of seminars throughout the study (timeline, page 214).

Birth attendants' perceptions

Immediately after each PartoMa seminar, it was the aim that all participants filled in written questionnaires on satisfaction with the seminar, critique, and suggestions for improvements. Similarly, after the 12th intervention month (February 2016), all birth attendants in Mnazi Mmoja Hospital's obstetric department were invited to complete in an anonymous questionnaire on satisfaction with and use of the PartoMa Pocket Guide version 1. Invited respondents included all nurse-midwives and doctors currently employed in permanent positions, as well as intern doctors conducting their clinical rotation in the department the preceding 10 months.

For both questionnaire evaluations, a five-point Likert scale was applied (1 = strongly disagree, 5 = strongly agree), with each question in both English and Swahili. Additional free text comments on facilitators and barriers to use of the intervention and recommendations for improvements were welcomed. Prior to use, the questionnaires were reviewed by health providers from other departments in Mnazi Mmoja Hospital to avoid ambiguity and misunderstandings. The seminar questionnaire's content is presented in Figure 10 (page 75) and the 12-months evaluation questionnaire is available in Paper II's Additional File 1 (page 156).

Analyses

Questionnaire responses were translated into English and entered by a research assistant at Mnazi Mmoja Hospital.^v The thesis author analysed questionnaire and attendance data independently by descriptive statistics.

^v Research assistant: Rashid Saleh Khamis (medical student/intern doctor)

Kirkpatrick level 2: Learning

Knowledge-skills test development

During the first study year, anonymous tests of knowledge and partograph skills were developed that were similar to those described here, and their findings added to the continuous modifications of the PartoMa intervention. However, with the seminar concept being new and primarily facilitated by voluntary Zanzibari birth attendants who needed supervision, it was too time-consuming at the time to assure individual coding of the tests. Thereby, evaluation of the tests on individual level was impossible and the design too weak for statistical evaluations.

From October to November 2017, the previously developed test was applied as a pilot for recommencing the learning evaluation. A structured checklist was applied for modifying and validating the test,¹³⁷ and distribution with individual coding of tests was planned for the following three rounds of PartoMa seminars.

In line with the seminars' goal of giving participants 'value for participation', a test-response time of more than 20 minutes was agreed to be unacceptable. The 'one-best-answer principle' was applied, aiming for the distracting multiple choice answers to represent typical errors in clinical practice. As the correct answers followed the PartoMa guidance, they were already externally peer reviewed and internally accepted as best possible care (Chapter 3, page 38). The wrong answers were inspired by Kirkpatrick level 3's quality of care results (page 79). Two external obstetricians, one external midwife, and two internal doctors, all familiar with the PartoMa intervention, reviewed the test for initial face and content validity. This included the relevance of the test for evaluating the PartoMa intervention, wording in English and Swahili, and whether the distracting answers were within the same category and represented common errors. The revised test was then sent for a second face and content validity check by six external experts, including three consultant obstetricians and three consultant midwives. They were asked to particularly focus on accuracy and generalizability of content and clinical relevance of the test inside and outside the Zanzibari setting. This led to a few and minor changes. Construct validity was then explored by comparing the test results of four external experts with eight local non-specialized young doctors and nurse-midwives. While the groups were too small for statistical comparison, a tendency of diversity was apparent in total test scores, with the experts scoring >13 of 15 (87%) correct, versus approximately eight of 15 (53%) among the non-specialists. For the latter group, test-time was assessed to ensure that the test did not exceed the 20 minutes limit.

The final test version included three parts: simple multiple choice, partograph interpretation, and partograph recording. The two former parts were printed in different order to avoid the possibility that

respondents could look at answers of the person sitting next to them. The total test score ranged from 0-15 with 0 being the lowest and 15 the highest score. The test is available in the Appendix (page 220).

Data collection and analysis of pre- and post-seminar tests

Before commencing and after finalizing each of the PartoMa seminars in December 2017, April 2018, and June 2018, all participants were requested to fill in the test (timeline, page 214). A research assistant entered all tests electronically and applied an unambiguous correction key with a maximum test score of 15 points.^{vi} Descriptive statistics were calculated for participant characteristics, knowledge, and partograph skills. Paired-sample t-test was calculated for overall test scores between pre- and post-seminar tests. For participants who had attended two or three of the rounds, paired sample t-test was also applied to compare first round test scores with the following round. Participants were stratified according to professional background, years of experience with maternity care, and attendance at PartoMa seminars or use of the pocket guide prior to inclusion in the knowledge and skills study.

Kirkpatrick levels 3 and 4: Quality of care and birth outcomes

Audit and feedback, have shown the potential to improve clinical practice, whether criterion-based or by expert panels.¹³⁸ In the present study, criterion-based audit was applied as a pre-post assessment comparing pre-intervention baseline months (1st October 2014 to 31st January 2015) with the ninth to 12th intervention months (1st October 2015 to 31st January 2016).

Study populations for Kirkpatrick level 3 – Quality of care

Quality of care related to key content of the PartoMa Pocket Guide version 1 was analysed, covering basic intrapartum care as well as management of frequent complications related to FHR, labour progress, and maternal vital signs with focus on sHDP and fever. It was not time- and budget-feasible to conduct these in-depth analyses on all women (n = 6601), and evaluation level 3's pre-post study included two separate and smaller study populations.

- For a general evaluation of quality of care (Paper III, page 176), women were quasi-randomly selected by identifying every tenth delivery in the department's admission, delivery, and operation theatre registers. Similar to the controls for the baseline study (page 38), all women among these who delivered singletons with birthweight ≥ 2000 g were included. Reasons for excluding multiple pregnancies and the 2000 g cut-off are presented in Paper III.
- Quality of care was also evaluated among women with sHDP (Paper IV, page 192). Case files were retrieved of all women suffering from sHDP prior to delivery, defined as systolic BP ≥ 160 mmHg and/or diastolic BP ≥ 110 mmHg and/or eclampsia pre-delivery. A power calculation was conducted, which is presented in Paper IV.

^{vi} Research assistant: Camilla Thomsen (Master of science in public health)

Study population for Kirkpatrick level 4 – birth outcomes

For evaluation of birth outcomes between baseline and the ninth to 12th intervention months (Paper III, page 176), all labouring women were included. A power calculation was conducted on intrapartum stillbirths, which is presented in Paper III.

Case files retrieval

Case file retrieval was similar to the baseline study (page 44). For Paper III, case files were collected prospectively each week and birth outcomes were assessed for all labouring women.^{vii} Paper IV's case files of women with sHDP were collected retrospectively from November to December 2016. The thesis author attended the final file searches for Paper III and afterwards checked all case files individually to determine whether the inclusion criteria were met for in-depth criterion-based audit. A research assistant conducted these tasks for paper IV's data.^{viii}

Audit criteria

Indicators of improvement in realistic best quality of care were adapted and modified from the baseline study (page 38), and key criteria are presented in Figure 8. In contrast to the PartoMa Pocket Guide, it was not the aim that the unambiguous criteria should represent acceptable quality of care. The criteria should be sensitive in monitoring progress of care at the low-resource study site and be possible to retrieve from the information limited case files.

The PartoMa study's combined ultimate outcome were stillbirths (foetal deaths ≥ 1000 g) and living newborns with Apgar score between 1 and 5 (Paper III, page 176). Furthermore, as in the baseline study, a sub-analysis of FHR on admission was conducted on all available case files of singleton stillbirths to identify the proportion with positive FHR on admission (intra-hospital stillbirths). Only these stillbirths could possibly be reduced by the study. Five-minute Apgar score between 1 and 5 was applied as an indicator of birth asphyxia, with known risk of serious adverse consequences.¹³⁹ If the 5-minute Apgar score was not available, the 1- or 10-minute score was applied. At baseline, as presented in Paper I (page 142), substantial underreporting was revealed of very early neonatal deaths in all registers, and neonatal deaths were therefore not included. Similarly, categorization in fresh and macerated stillbirths proved unreliable and was therefore not applied.

Secondary birth outcomes included maternal deaths and rates of CSs and vacuum extractions.

^{vii} Research assistants: Natasha Housseine, Rashid Saleh Khamis, Ali Gharib Mohamed, Mbweni Makame Ali and Said Mzee Said (intern doctors and final year medical students at Mnazi Mmoja Hospital).

^{viii} Research assistant: Camilla Byskou Andersen (midwife and global health master student)

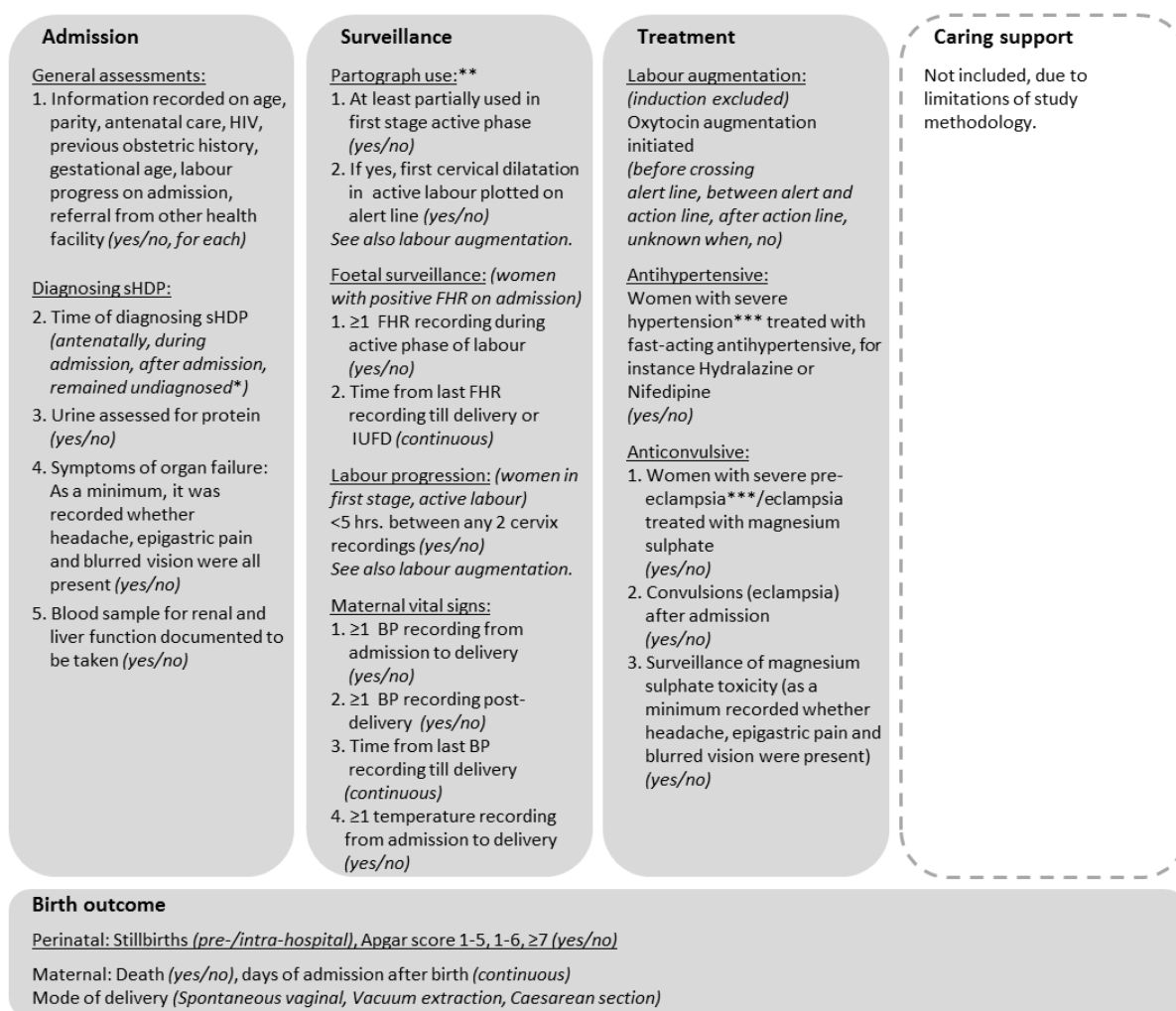


Figure 8 Key criteria analysed to assess intrapartum quality of care and birth outcomes through reviews of case files. The criteria are related to key content of the PartoMa Pocket Guide and represent unambiguous research indicators that were sensitive in monitoring progress of care at the low-resource study site and possible to retrieve from the case files. These criteria do not aim at representing acceptable quality of care. *Severe hypertension: systolic BP ≥ 160 mmHg and/or diastolic BP ≥ 110 mmHg. **Severe pre-eclampsia: Severe hypertension on at least one reading and urine-protein $\geq 2+$, or recorded eclampsia/convulsions before or during admission. BP, blood pressure; FHR, foetal heart rate; IUFD, intrauterine foetal death; sHDP, severe hypertensive disorder in pregnancy.

Analyses

For paper III, the thesis author extracted all available background and birth outcome data, and analysed intrapartum practice against the preselected criteria. In case of doubt when classifying data, the study team was consulted. As recommended for criterion-based audit, if a practice was not documented, it was assumed to be not performed.¹²⁷ For paper IV, this was done by Camilla Byskou Andersen, supervised by the thesis author. For both papers, the thesis author conducted all statistical analyses, which included descriptive statistics and statistical comparisons. Background characteristics were compared by Fisher exact test. For the quality of care and birth outcome data, relative risk (RR) with 95% CI for dichotomous variables

and Mann-Whitney test for time intervals were applied. Information on software used is provided in the papers (pages 176 and 192).

Structural mediators and confounders

During the baseline and first intervention year, structural changes that potentially could be contextual mediators or confounders to practice and outcome changes were assessed quarterly by the thesis author following a structured checklist (October 2014 – January 2016). As presented in Paper III's Supplementary File 3 (page 176), the indicators included availability of emergency obstetric and neonatal care signal functions, number of births, number of health care providers in each cadre of staff, and whether other interventions were introduced to enhance maternal and perinatal health (for instance, teaching in neonatal resuscitation or maternal and perinatal death audits).

In 2018, possible structural mediators and confounders in 2016-2018 were retrospectively assessed through enquiries with staff, including the ethnographic study's in-depth interviews, and through two collaborating research teams that both started their data collections in 2016 (timeline, page 214).^{ix}

^{ix} Natasha Housseine, research assistant on the PartoMa study, is primary investigator on a study on intrapartum care with particular focus on foetal surveillance and admission test, and Tanneke Herklots is primary investigator on a study on maternal mortality and near misses. The two studies are both primarily observational and are collaborations between Mnazi Mmoja Hospital and University Medical Centre Utrecht, The Netherlands.



Quality of care. Photos by Tarek Meguid.

Chapter 9

Results of the Evaluation

9. Results of the Evaluation

This chapter presents key findings for each of the four evaluation levels (Figure 7, page 62), followed by a brief overview of possible structural confounders and mediators. Within the total study period (October 2014 to July 2018), each analysis concerned smaller data collection intervals as depicted in the timeline (Appendix, page 214).

Kirkpatrick level 1: Perceptions and reaction

The sections below concern unpublished data on conducting *(i)*, attendance rates *(ii)*, and written evaluations of the PartoMa seminars *(iii)*, as well as Paper II's 12-months questionnaire evaluation of birth attendants' perceptions of the PartoMa Pocket Guide *(iv)*.

i. Conducting seminars

Since the first round of seminars on 27-28 January 2015, 14 rounds were conducted at Mnazi Mmoja Hospital, with the latest in September 2018 (timeline, page 214). Due to time limitations, the latest round was not included in the thesis' findings. After the local PartoMa steering group took over arranging the PartoMa seminars in February 2016, the thesis author was not present for the following five rounds of seminars, but still provided case histories for the training. Also, the PartoMa study continued to provide intervention running costs. All seminar rounds at Mnazi Mmoja Hospital have been held with approximately three months intervals, except for 2017. Due to a continuous wish from birth attendants working at the neighbouring island, Pemba, the PartoMa steering group decided to conduct the April 2017 round of seminars in Pemba and raised funding for transport of the facilitators. The following round of seminars was delayed, after which the quarterly interval was re-established (timeline, page 214). No seminars with a set date were cancelled during the 42 intervention months studied. At each seminar, there were enough voluntary facilitators, and afternoon snacks and pocket guides had been organized and were available to the participants.

In June 2018, the Zanzibar Ministry of Health took over the continuation of the PartoMa intervention, with quarterly rounds of seminars in both of Zanzibar's main islands, Unguja and Pemba, and with support from United Nations Populations Fund (UNFPA). Until June 2018, primarily staff members from Mnazi Mmoja Hospital were invited for seminars, through posters in the department of obstetrics and by email and WhatsApp groups. For the June 2018 seminars, additional advertising to birth attendants at other Zanzibari maternity units was done, and a part time secretary was employed to assure timely organizing and reporting. As indicated by missing data in the sections below, this had previously proven challenging for the PartoMa steering group comprising of voluntary busy clinicians.

ii. Seminar attendance

Seminar attendance data were available from 11 of 13 rounds of seminars (85%) (Figure 9). Between 45 and 120 participated in each round, with an average of 67. Participants encompassed on average 20 nurse-midwives, seven doctors, and 13 intern doctors from Mnazi Mmoja Hospital, as well as 14 birth attendants from other Zanzibari maternity units, nine Zanzibari medical and nursing students, and five others. As depicted in Figure 9, there were, however, considerable variations between rounds of seminars. According to response rates of available seminar evaluations, a conservative estimate is that at least 82% of participants stayed for all three hours of training.

Throughout the 42 intervention months, an average of 64% of doctors and 62% of nurse-midwives from the Department of Obstetrics, Mnazi Mmoja Hospital, participated in each round of seminars. The percentage of all intern doctors at the hospital who attended fluctuated between 8% and 58%. During the initial five rounds of seminars (the first intervention year), 50% of doctors and 46% of nurse-midwives from the obstetric department, as well as 43% of all intern doctors at the hospital, returned for one or more rounds of seminars. According to the knowledge test data from the 11th round of seminars, 38% were returners (page 75).

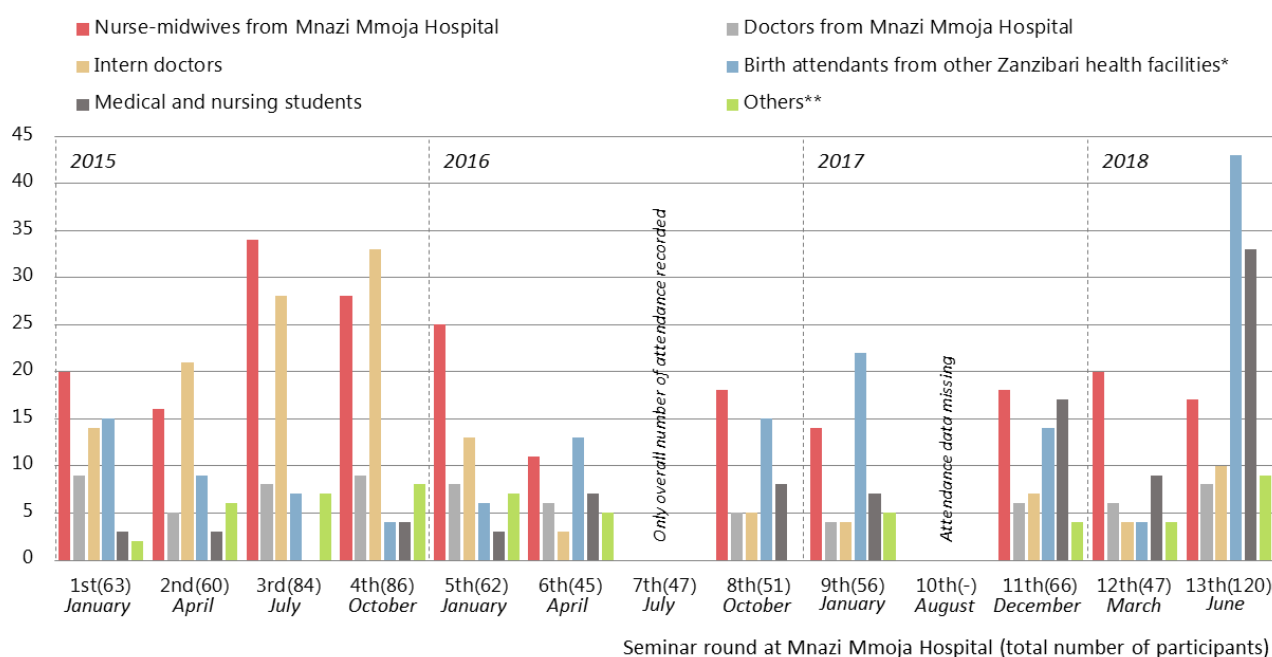


Figure 9 Attendance at the PartoMa seminars, divided into cadres of staff, with total number of seminar participants provided in parenthesis. * Nurse-midwives, doctors, assisting medical doctors, and clinical officers. **Representatives from Ministry of Health and non-governmental organizations, foreign aid workers, and foreign health students.

iii. Birth attendants' written evaluations of seminars

At 10 of the 13 rounds of seminars, a total of 532 participants responded to the evaluation questionnaire, with an overall response rate of 82%. They comprised of 151 (28%) doctors, including intern doctors, 270 (51%) nurse-midwives, 93 (17%) medical and nursing students, and 18 (3%) others. Similar to the distribution of all birth attendants at Mnazi Mmoja Hospital's obstetric department (page 70), 272 (55%) of all respondents had less than one year and 91 (18%) more than five years' experience with maternity care.

As there were no considerable differences in the responses between seminar rounds, results from all 10 rounds are combined in Figure 10. Overall, 89% found that the training had been a good experience (mean point 4.6 out of 5.0), 91% would recommend the next round of seminars to fellow birth attendants (mean point 4.7), 86% agreed that case histories and discussions represented the current situation at their maternity unit (mean point 4.5), and more than 90% found that the seminar helped to improve their knowledge and care for laboring women (mean point 4.7 for both). Free text comments in questionnaires continuously described the respondents' motivation to attend the PartoMa seminars as to gain knowledge and improve quality of care. Responding to suggestions for future improvements of the PartoMa intervention, the main proposals were that the training should be for all birth attendants in Zanzibar and conducted at multiple health facilities. Others proposed that it should be mandatory so that less interested colleagues would be forced to learn as well; the seminars should be conducted in morning hours; there should be planned breaks for prayer; and seminars should be longer and conducted more frequently. Of all 532 respondents, five suggested per diems for seminar participants, and some birth attendants from other Zanzibari health facilities wished for transport reimbursement.

iv. 12-months evaluation of the PartoMa Pocket Guide

A total of 12 (92%) doctors and 23 (89%) nurse-midwives who were employed at the obstetric department at the time responded to the anonymous questionnaire, as well as 49 (80%) intern doctors who had worked at the department during the past ten months. Hence, this also included staff who did not attend the PartoMa seminars and possibly did not use the PartoMa Pocket Guide. The results are presented in Paper II's Figure 4 (page 156). In brief, 93% of the respondents agreed that the PartoMa Pocket Guide helped to improve care. They found the guidance attainable (89%), and that the graphics worked well (90%). Doctors, including interns, more often than nurse-midwives responded to using the pocket guide daily (89% versus 74%). Similarly, when asked about colleagues' use, responses indicated that some staff did not apply the guidance on a regular basis. All groups of staff found 'FHR and foetal distress' to be one of the most useful pages. In addition, doctors, including interns, particularly emphasized the 'hypertensive disorders' page, while nurse-midwives found the 'labour progress and poor progress' page to be a favourite (Paper II). The latest version of the pocket guide is available in the Appendix (page 122).

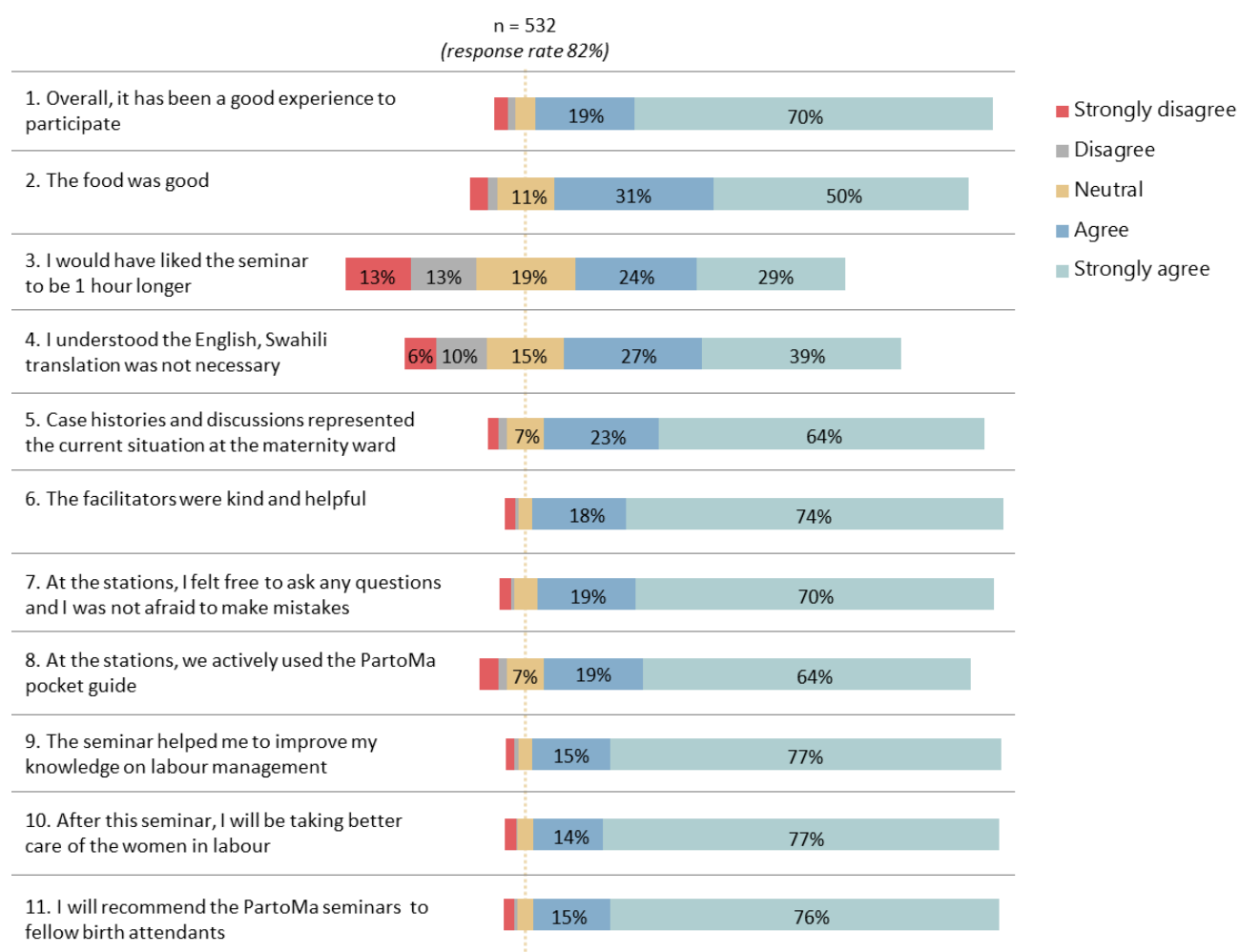


Figure 10 Five-point Likert scale evaluation of seminar participants' perceptions of the PartoMa seminars, conducted at 10 of 13 seminar rounds. The respondents included 151 (28%) doctors, including interns, 270 (51%) nurse-midwives, 93 (17%) medical and nursing students, and 18 (3%) others.

Kirkpatrick level 2: Learning

This section concerns the recently collected, unpublished data on knowledge and partograph skills among participants in the 11th to 13th round of PartoMa seminars (35th to 41st intervention month, December 2017 – June 2018). The test and additional data are available in the Appendix (page 220).

A total of 166 seminar participants completed one pre- and one post-seminar test, of which 26% had attended PartoMa seminars prior to the 11th round of seminars. Of the 86 total respondents from the 11th and 12th rounds of seminars, 29 (34%) returned for a second round during the 12th and 13th rounds of seminars, and their knowledge retention could be analysed during two rounds. Of the returners, the period between seminars was three months for all, but one. Fifteen attended all three rounds of seminars. A detailed sample size flow is presented in Figure 11.

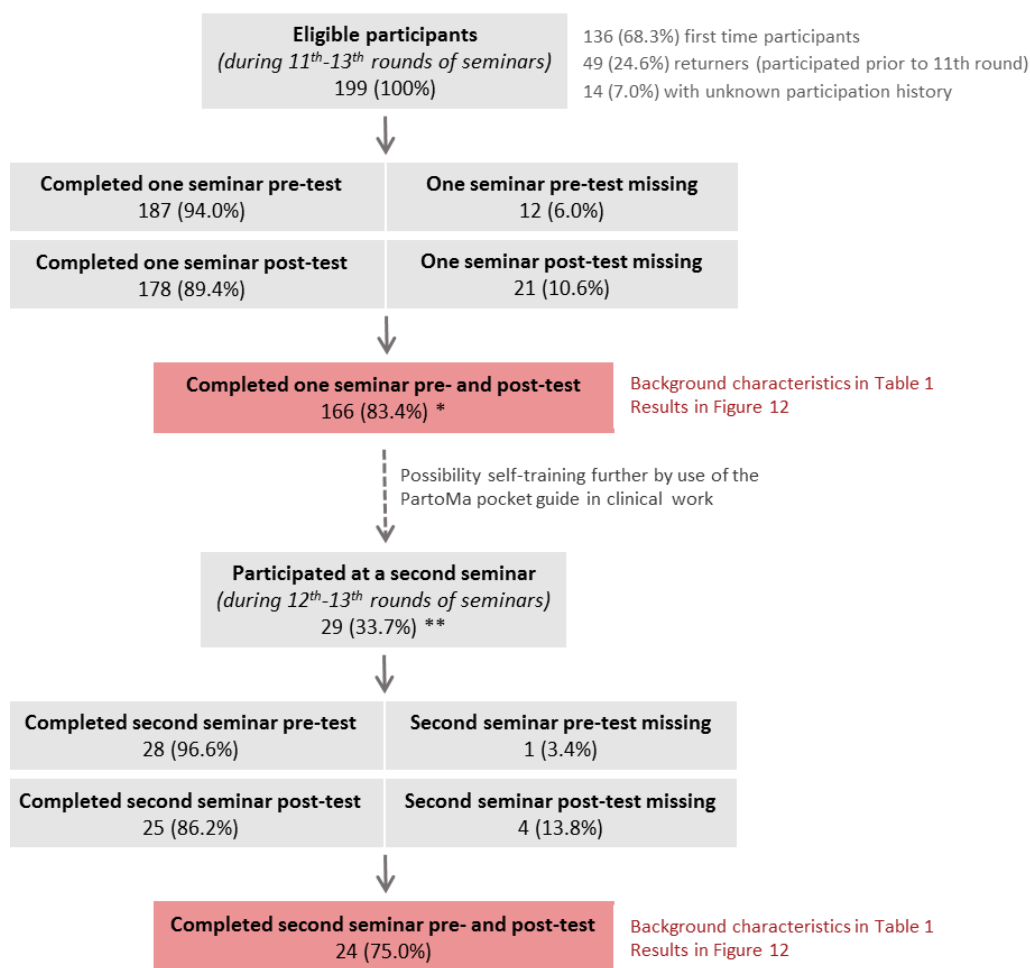


Figure 11 Flow chart of sample size for the knowledge and skills study during the 11th to 13th rounds of PartoMa seminars, i.e. the 35th to 41st intervention month. Fifteen participants out of 199 were present for all three successive rounds. * Only 143 (86.1%) had also the test's partograph filled in and were included in the test score evaluation. **29 of the 86 total respondents at the 11th or 12th seminars returned during the 12th or 13th round of seminars.

The 166 respondents to at least one seminar round's pre- and post-tests consisted of 18 (11%) doctors, 84 (51%) nurse-midwives, and 17 (10%) intern doctors, of which 54% worked at Mnazi Mmoja Hospital. In addition, 47 (28%) final year medical students attended. Of these respondents, 87 (52%) had less than one year and 28 (17%) more than five years' experience in maternity care. Before inclusion in this study, 43 (26%) had previously attended PartoMa seminars and 107 (64%) informed of having previously applied the PartoMa Pocket Guide at least once a week (Table 1).

Table 1 Background characteristics of respondents to the knowledge and skills tests.

	Participants completing only one seminar pre- and post-test, within the study period, n (%)	Participants completing two seminar pre- and post-test, within the study period, n (%)
	(n=166)	(n=24)
Professional background		
Doctors*	18 (10.8)	2 (8.3)
Nurse-midwives	84 (50.6)	10 (41.7)
Intern doctors	17 (10.2)	2 (8.3)
Final year medical student	47 (28.3)	10 (41.7)
Others	-	-
Years of experience with care at birth		
<1 year	87 (52.4)	16 (66.7)
1-5 years	38 (22.9)	2 (8.3)
>5 years	28 (16.9)	4 (16.7)
Information missing	13 (7.8)	2 (8.3)
Affiliation**		
Mnazi Mmoja Hospital	64 (38.6)	11 (45.8)
Other governmental maternity units	52 (31.3)	3 (12.5)
Private sector maternity unit	3 (1.8)	0 (0.0)
Medical school	47 (28.3)	10 (41.7)
Other affiliation	2 (1.2)	0 (0.0)
Information missing	1 (0.6)	0 (0.0)
Attended PartoMa Seminars prior to the 11th-13th rounds		
Yes	43 (25.9)	8 (33.3)
No	122 (73.5)	16 (66.7)
Information missing	1 (0.6)	-
Use of PartoMa Guidelines before inclusion in the study		
Every day when working in maternity unit	91 (54.8)	15 (62.5)
At least once a week	16 (9.6)	1 (4.2)
Less than once a week	13 (7.8)	2 (8.3)
Never	44 (26.5)	6 (25.0)
Information missing	2 (1.2)	-

* Doctors included 14 medical doctors, 3 clinical officers, and 1 Assistant Medical Officer (AMO). Intern doctors are presented separately. ** Multiple answers allowed.

Among the 166 respondents of the first pre-test in the study period, the mean total score was 10.9 out of 15 (standard deviation (SD) 1.9), with nurse-midwives scoring the lowest (10.0, SD 2.5), final year medical students and intern doctors in the middle (10.5, SD 1.8 and 1.3), and registrar doctors the highest (11.3, SD 2.6) (Appendix, page 220). In this pre-test, common errors were: 65 (39.2%) responded that if postpartum bleeding exceeds 500 milliliters, after delivery of placenta, misoprostol per rectum is the most important immediate care, as compared to continual uterine massage; 63 (38%) responded that a cervical dilatation between the partograph's alert and action lines and three brief contractions in 10 minutes are signs of obstruction, not of insufficient uterine contractions; 61 (36.7%) responded that a FHR of 108 beats per

minute is an indication for immediate caesarean section; and 47 (28.3%) responded that if FHR is 80 beats per minute and cervix is fully dilated with the foetal head below the ischial spine, immediate caesarean section is indicated. Among the 143 who had filled in the blank partograph on the last page of the test, errors in recording time (36.6%), cervical dilatation (29.7%), and contractions (27.6%) were most common.

As depicted in Figure 12, significant improvement was found when conducting paired comparison of pre- and post-test scores among the 143 respondents with all test parts filled in (mean test scores 10.4 to 12.6, $p<0.001$). Filling in the partograph was always the last page of the test, and some participants lacked time due to late arrival at the seminars. For the 24 who participated at a second round of seminars during the three rounds studied, and with the second pre- and post-tests filled in, test scores between first seminar post-test and second seminar pre-test reduced (mean test scores 13.0 to 12.2, $p=0.090$), but the second seminar pre-test still significantly improved compared to the first seminar pre-test (mean test scores 10.9 to 12.2, $p=0.006$). The second pre-post-test comparison again showed significant improvement (mean test scores 12.2 to 13.6, $p<0.001$). As depicted in the Appendix (page 220), the pre-post-test differences persisted in all subgroups, when stratifying for professional background, years of experience with maternity care, and attendance of seminars or use of the PartoMa Pocket Guide prior to this knowledge and skills study. Improvements were also observed in each of the test's parts.

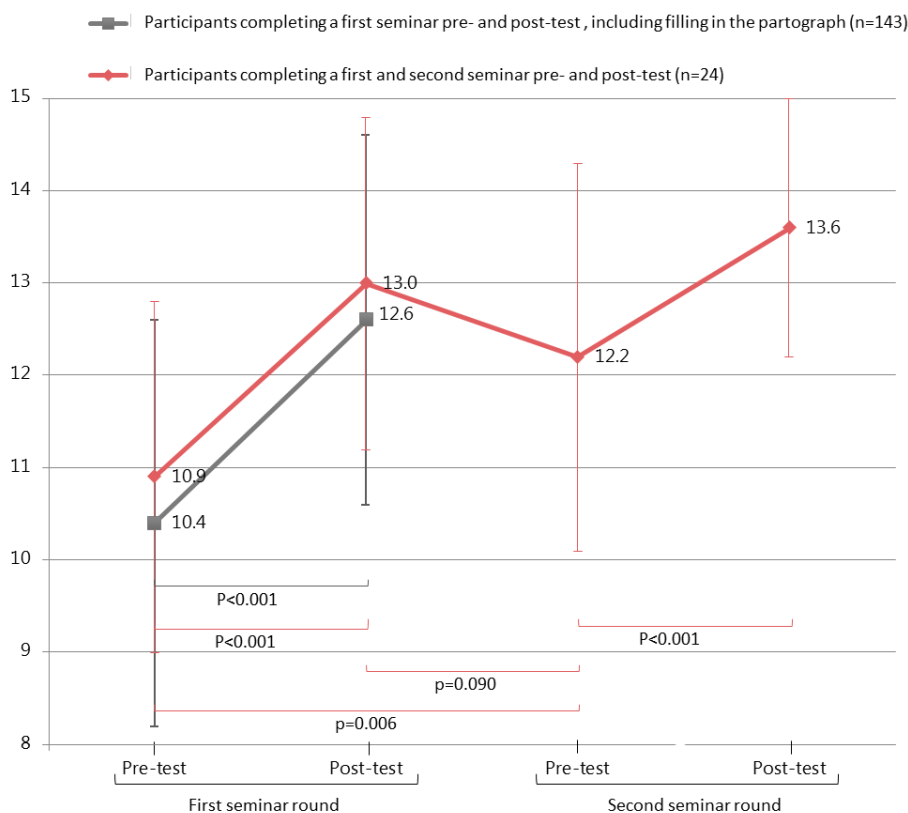


Figure 12 Learning curve at the group level for mean test scores during the 11th-13th rounds of the quarterly PartoMa seminars (December 2017 – June 2018). The y-axis reflects mean test scores, where 15 are maximum. The x-axis reflects the round of seminars. P-values were calculated by paired-sampled t-test.

Kirkpatrick levels 3 and 4: Quality of care and birth outcomes

The sections below concern background characteristics (*i*), quality of care (*ii*), and birth outcomes (*iii*) for the women included in the pre-post study comparing baseline (1st October 2014 to 31st January 2015) with the ninth to 12th intervention months (1st October 2015 to 31st January 2016). The data are published in Papers III and IV (pages 176 and 192).

i. Sample flow and background characteristics

According to hospital registers, a total of 3599 women gave birth and 3690 babies were born during baseline, and 3002 women and 3087 babies in the ninth to 12th intervention months.

For the quasi-random group, 364 (10%) from baseline and 315 (10%) from intervention months were identified in the registers. It was possible to retrieve case files of 83% and 90% of these, of which 283 and 264 were singletons with a birthweight ≥ 2000 gram. Sample size flow is presented in Paper III's Figure 1.

Women with sHDP were searched for in all available case files from the study months. The search revealed that 22% of all women during both baseline and the ninth to 12th intervention months had no BP recorded from admission to delivery. Among the women with BP or eclampsia recorded, 188 (7%) at baseline and 196 (8%) in intervention months fulfilled the sHDP criteria and were included. Sample size flow is presented in Paper IV's Figure 2.

In both the quasi-random and sHDP groups, background characteristics were largely comparable between baseline and intervention months, without statistical significant differences (Paper III's Table 1 and Paper IV's Supplementary Table S1). Notably, when comparing background characteristics between the two groups, sHDP women were older and admitted earlier in labour, more women were referred from other health facilities, and more women had a history of previous child death (Table 2).

ii. Kirkpatrick level 3 - Quality of care

While still suboptimal, significant improvements were observed in multiple of the pre-selected audit criteria (Figure 8, page 68). Others remained unchanged, and none of the indicators worsened (Papers III and IV). Missing information in admission assessments remained largely unchanged (Papers III and IV). Among women in the quasi-random group, more than 90% in active first stage of labor had the partograph started during both baseline and intervention months. More than 90% of these had first cervical dilation correctly plotted on the alert line (Paper III). Around 70% of the sHDP women had a partograph filled in during first stage of labor (Paper IV).

Table 2 Background characteristics of quasi-randomly selected women (Paper III) and of all women suffering from severe hypertensive disorders (Paper IV). Data are combined from baseline (October 2014–January 2015) and the ninth to 12th intervention months of the PartoMa study (October 2015–January 2016).

	Quasi-random group of women (Paper III)	Women with severe hypertensive disorders (Paper IV)	p-values ^a
	N (%)	N (%)	
<i>Of all women in the studies</i>	<i>(n = 547)</i>	<i>(n = 384)</i>	
Age			
< 20 years	54 (9.9)	25 (6.5)	<0.01
20-29 years	290 (53.0)	189 (49.2)	
30-39 years	176 (32.2)	136 (35.4)	
≥ 40 years	23 (4.2)	33 (8.6)	
Information missing	4 (0.7)	1 (0.3)	
Parity on admission			
Para 0	230 (42.0)	148 (38.5)	0.21
Para 1-4	236 (43.1)	168 (43.8)	
Para ≥ 5	67 (12.2)	62 (16.1)	
Information missing	14 (2.6)	6 (1.6)	
Antenatal care			
≥ 4 visits	246 (45.0)	152 (39.6)	0.68
1-3 visits	240 (43.9)	165 (43.0)	
Not attended	1 (0.2)	0 (0.0)	
Information missing	60 (11.0)	67 (17.4)	
HIV			
Negative	485 (88.7)	308 (80.2)	0.16
Positive	4 (0.7)	0 (0.0)	
Information missing	58 (10.6)	76 (19.8)	
<i>Of multiparous women in the groups:</i>	<i>(n = 296)</i>	<i>(n = 230)</i>	
Previous obstetric history			
Previous death of child/children ^b	58 (19.6)	70 (30.4)	<0.01
1 previous caesarean section	25 (8.4)	22 (9.6)	0.76
≥ 2 previous caesarean sections	18 (6.1)	10 (4.3)	0.44
<i>Of all women in the studies</i>	<i>(n = 547)</i>	<i>(n = 384)</i>	
Progress on admission			
Before active phase of labour	160 (29.3)	189 (49.2)	<0.0001
First stage of active phase of labour	332 (60.7)	158 (41.1)	
Second stage of labour	50 (9.1)	7 (1.8)	
Information missing	5 (0.9)	30 (7.8)	
Referrals			
Referral from smaller health centre	24 (4.4)	57 (14.8)	<0.0001

^a Fisher exact test.

^b Documentation was inadequate to distinguish perinatal deaths from deaths later in life.

Concerning foetal surveillance, women with at least one FHR recorded during active labour increased significantly in the quasi-random group (82% to 92%; RR 1.12, 95% CI 1.05-1.20)(Paper III). There was not a significant increase for sHDP women (79% to 86%; RR 1.10, 95% CI 0.99-1.23)(Paper IV). In both groups, median time from last FHR recording till delivery, or till detected intrauterine foetal death, decreased by approximately 40% (Mann Whitney test for difference, $p < 0.01$ for both groups)(Figure 13)(Papers III and IV).

In the quasi-random group, 80% at baseline and 88% in intervention months had cervical dilatation recorded with intervals of less than five hours (RR 1.10 95% CI 1.01–1.19). Overall oxytocin use for labour augmentation decreased significantly (21% to 12%; RR 0.54, 95% CI 0.37-0.81). Oxytocin use before crossing the action line fell (20% to 4%; RR 0.23, 95% CI 0.12-0.41) and its use increased after crossing the line (2% to 8%; RR 3.57, 95% CI 1.46-8.76) (Figure 13). Meanwhile, 11% crossed the partograph's action line at baseline, versus 19% in intervention months (RR 1.83, 95% CI 1.16–2.90)(Figure 13)(Paper III).

The finding of approximately 22% of all labouring women in both time periods without BP recorded from admission till birth (Paper IV) was supported by no improvements in routine BP and temperature recordings in the quasi-random group (Paper III). However, women diagnosed with sHDP more often received the diagnosis at antenatal care or on admission during intervention months (48% to 61%; RR 1.25, 95% CI 1.04-1.51), more had proteinuria tested (83% to 90%; RR 1.09, 95% CI 1.01-1.18), more had blood sample taken for liver and renal function (12% to 31%; RR 2.54, 95% CI 1.65-3.93), and more had at least one recorded BP post-delivery (67% to 77%; RR 1.15, 95% CI 1.01-1.30). At baseline, 13% had a physical examination of headache, vision, and abdomen recorded, which was the case for 21% in intervention months (RR 1.57, 95% CI 1.00-2.48). Among sHDP women with vaginal birth ($n=126$ at baseline and $n=130$ in intervention months), median time from last BP until delivery decreased from 162 minutes (IQR 80–328) to 129 minutes (IQR 60–245)(Mann–Whitney test for difference, $p = 0.02$). Consistently, initiation of antihypertensive treatment for severe hypertension increased, from 47% to 64% (RR 1.37, 95% CI 1.14-1.66)(Figure 13). In baseline and intervention months, 90% with severe pre-eclampsia/eclampsia had magnesium sulphate initiated. Among these, surveillance for magnesium sulphate toxicity increased (18% to 35%; RR 1.91, 95% CI 1.20-3.03)(Figure 13)(Paper IV).

iv. Kirkpatrick level 4 – Birth outcomes

As presented in the pre-intervention study (page 45), 216 babies at baseline were born dead, out of 3690 total births (59 per 1000 total births)(Paper I). During the ninth to 12th intervention months, 119 of 3087 were born dead (39 per 1000 total births; RR 0.66, 95% CI 0.53-0.82). Consistently, rate of babies with Apgar score 1-5 reduced from 52 to 28 per 1000 live births (RR 0.53, 95% CI 0.41-0.69)(Figure 14)(Paper III).

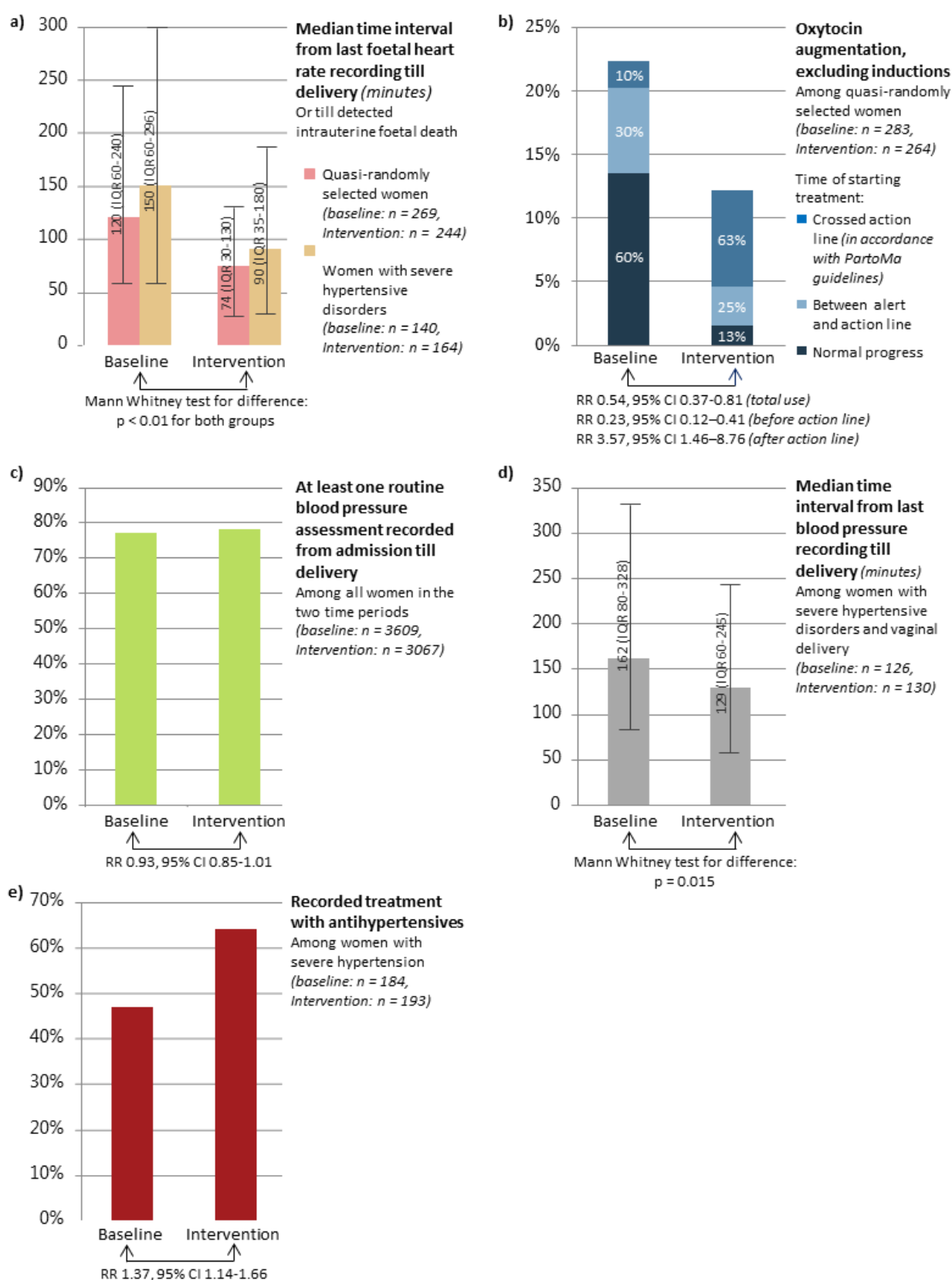


Figure 13 Key findings on quality of care, when comparing baseline (October 2014–January 2015) and the ninth to 12th intervention months of the PartoMa study (October 2015–January 2016). The results are presented in Papers III and IV and relate to the three main parts of the partograph: foetal heart surveillance (a), labor progress (b), and maternal vital signs (c-e). CI, confidence interval; FHR, foetal heart rate; IQR, interquartile range; RR, relative risk. The figure is based on Figure 2 in Paper III, but further elaborated to include data from Paper IV.

As presented in Paper III (page 176), we succeeded in retrieving case files of 175 (81%) singleton stillbirths at baseline and 92 (77%) in intervention months, of which 84 (48%) and 35 (38%), respectively, had positive FHR recorded during admission (RR 0.79; 95% CI 0.59-1.07). Of the remaining stillbirths, 67 (38%) at baseline and 51 (55%) in intervention months had intrauterine foetal death clearly documented, while 24 (14%) and six (7%) stillbirths had no documentation of FHR during admission and could potentially also be intrapartum stillbirths (Figure 14). The proportion of intrahospital stillbirths among retrieved and the approximately 20% non-retrieved case files might differ. However, if assuming similar proportions, this suggests an almost halving of intrahospital stillbirths, from 28 to 15 per 1000 total births (RR 0.52; 95% CI 0.37-0.73)(Paper III).^x

As presented in Paper IV (page 192), stillbirth rate also reduced significantly among sHDP women, from 42 in 201 (21%) to 23 in 196 (12%) (RR 0.56, 95% CI 0.35-0.90), and Apgar score ≥ 7 increased from 65% to 76% (RR 1.17, 95% CI 1.03-1.33). Although not reaching statistical significance, the stillbirth reduction among women with sHDP likewise predominantly occurred in intrahospital stillbirths. Among sHDP women, there was no significant change in the use of oxytocin augmentation, with 24% receiving oxytocin augmentation at baseline and 18% during intervention months (RR 0.77, 95% CI 0.52-1.13)(Figure 14)(Paper IV).

Maternal deaths were largely unchanged between baseline and the ninth to 12th intervention months, from 15 in 3474 live births to 16 in 2968 (RR 1.25, 95% CI 0.62-2.52). Maternal mortality causes are listed in Paper III's Supplementary Table S1 (page 176).

Among all women, the proportion of vacuum extractions increased from 0.3% to 1.2% (RR 4.42, 95% CI 2.20-8.88), and CSs from 11.7% to 15.8% (RR 1.36, 95% CI 1.20-1.53)(Paper III). Among sHDP women, approximately 30% in both baseline and intervention months were delivered by CS (Paper IV).

Possible structural mediators and confounders

This section presents a brief overview of likely central structural confounders related to numbers of labouring women (*i*), human resources (*ii*), supplies and space (*iii*), and introduction of additional interventions and research that may have influenced the PartoMa study's findings (*iv*). A brief overview of key structural changes is provided in the timeline (page 214), and specifically for the first intervention year in Paper III's Supplementary Table S3 (page 176). Possible non-structural contextual factors that may have interacted with the intervention implementation are discussed in chapter 10 (page 93) and will be further analysed in the ethnographic study, which falls outside this thesis. The overall structural constraints are described in more details in chapter 4 (page 34).

^x (59/1000)*0.48 at baseline and (39/1000)*0.38 in the ninth to 12th intervention month

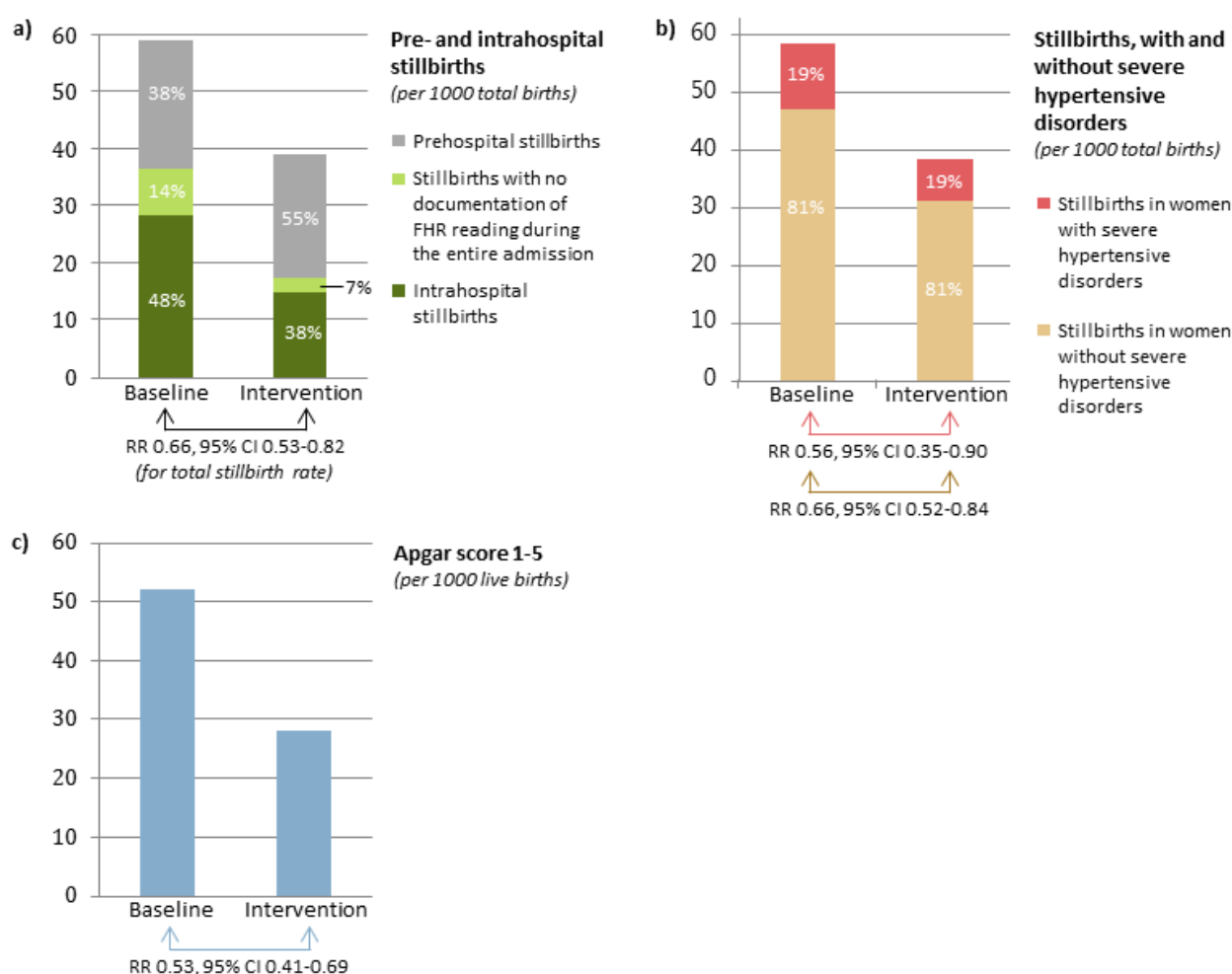


Figure 14 Key findings on perinatal outcomes, when comparing baseline (October 2014–January 2015, 3690 total births) and the ninth to 12th intervention months of the PartoMa study (October 2015–January 2016, 3087 total births). (a) Stillbirths (foetal deaths ≥ 1000 g) among all laboring women in the two time periods. The division into prehospital (no FHR on admission) and intrahospital (positive FHR during admission) stillbirths is based on extrapolation from an analysis of singleton stillbirths with retrievable case files. (b) Stillbirths with and without maternal severe hypertensive disorders. (c) Signs of birth asphyxia among all laboring women in the two time periods. CI, confidence interval; FHR, foetal heart rate; IQR, interquartile range; RR, relative risk. The figure is based on Figure 2 in Paper III, but further elaborated to include data from Paper IV.

i. Numbers of women delivering

During the total study period of October 2014 to July 2018, approximately 42,000 women gave birth in Mnazi Mmoja Hospital's obstetric department. Monthly numbers varied, and the total number of women delivering in the ninth to 12th intervention months ($n = 3002$) was found to be 17% lower than during baseline ($n = 3599$). As the human resources were similar between the two four month periods, it indicates a slight improvement in the attendant-to-labouring-women ratio.

ii. Human resources

During the total study period, the number of employed doctors at the maternity unit varied between nine and 11, and the number of intern doctors in their six weeks obstetric rotation between one and six. The number of nurse-midwives varied between 21 and 26.

Though little variation was found in overall staff numbers, staff-turnover was evident throughout the study. Of doctors and nurse-midwives who worked in permanent positions during the initial six months of the PartoMa intervention in 2015, 40% and 25%, respectively, were no longer working in the department when finalizing the 12th intervention month in February 2016 (Paper III). One year later, in February 2017, 80% of doctors and 60% of nurse-midwives had left the department, as compared to the initial six months. They most often rotated to other departments in Zanzibari health facilities, went for further studies outside Zanzibar, or stopped working in the governmental health sector.

During the years studied, the total number of intern doctors at Mnazi Mmoja Hospital varied between 20 and 65, and they all worked as birth attendants at the obstetric department for six weeks as part of their one-year internship.

In February 2016, approximately five (42%) doctors and five (22%) nurse-midwives in permanent positions in the department of obstetrics had less than one year of experience with maternity care, and only two doctors and four nurse-midwives had more than five years of experience (Paper II). This did not improve during the study period. In March 2018, 67% of doctors in the department had less than three years of experience and 35% of nurse-midwives had less than three months of experience.

iii. Supplies and space

There were no improvements observed in emergency obstetric and neonatal care signal functions available during the first intervention year (Paper III). In February 2017, the department moved to a new building, as further described in chapter 4 (page 34). While this resulted in a few extra beds, an extra theatre for obstetrics, and better possibilities for ensuring women's privacy, the urgent need for space remained. There continued to be an average of two labouring women sharing one bed. The hospital's anaesthetic personnel did not increase to cover the extra theatre. With the too few birth attendants it may even be questioned whether more walls and curtains weakened their ability to keep an overview of the labouring women for proper triage.

iv. Introduction of additional interventions

Daily clinical meetings with supervision by a senior doctor were launched seven months prior to the baseline and were similar throughout the study, and mainly attended by doctors. While maternal death

audits commenced in August 2015, presentations of findings were first initiated in March 2016, after ending the 12th intervention month (timeline, page 214).

The first research dissemination event of the PartoMa study was in March 2016. Audit criteria to be measured and findings of the PartoMa study, including baseline data, were not presented during the first intervention year. The two collaborating research teams started their observational data collection after the 12th intervention month. No other studies had been conducted in the department in the years prior to starting the PartoMa study or in the first intervention year. As part of Housseine et al.'s study, an admission assessment test was implemented in October 2017, prior to initiating the knowledge-skills test study.

Introduction of other formalized on-the-job training was scarce throughout the nearly four study years. In 2017, a total of five senior nurse-midwives were given on-the-job training on mentoring and supervising junior nurse-midwives during labour care, for instance by use of PartoMa. One birth attendant received off-the-job clinical training in intrapartum care in 2015, one in 2016, eight in 2017, and none in 2018 (until October 2018). This included one-time workshops, either limited to basic emergency obstetric care or more broadly focusing on life-saving skills in obstetrics. Six of these ten attendants still worked in the department in October 2018. Besides that, no additional formalized training was organized in neonatal resuscitation or immediate management of postpartum haemorrhage before 2018 when helping babies breathe training was initiated.



Participants at a PartoMa seminar. Photo by Jurre Rompa.

Chapter 10

Discussion of Main Findings and Related Research by Others

10. Discussion of Main Findings and Related Research by Others

This thesis presents new evidence on participatory development, implementation, and mixed-methods evaluation of a clinical educational intervention with the aim of strengthening birth attendants' ability to deliver best possible care at a high-volume maternity unit in East Africa. The PartoMa Pocket Guide on best possible intrapartum care and the related quarterly, in-house seminars were developed with inputs from the birth attendants at Zanzibar's tertiary hospital, and the guidance was endorsed by a panel of international specialists. In a context where externally-derived clinical guidelines were rarely applied, though available and supposed to target maternal health in low-resource settings, demand for the PartoMa Pocket Guide was high. Furthermore, in a context where birth attendants' motivation to engage in performance enhancing activities often has been linked to personal financial gains,^{87,140} the participation of approximately two-thirds of staff during seminars occurred outside working hours and without payment. In the ninth to 12th intervention months, stillbirths had decreased by 33%, when compared to baseline. In the same time period, newborns with birth asphyxia had almost halved. According to data from a collaborating research group, the stillbirth rate remained at this lower level during the following two years, accompanied by trends of reduction in maternal deaths.¹²² Through enhanced knowledge and partograph skills and multiple care improvements, it appears likely that the PartoMa intervention was an enabler for the birth attendants' improved ability to save lives. Notably, the effects occurred in spite of the continuous understaffing and high staff-turnover, and without introducing additional medical technology.

The discussion below starts by unfolding the persistently unacceptable structures of the health care system with unsafe care at birth, at baseline as well as after implementing the intervention (*i*), followed by discussions of the disclosed gap between externally-derived clinical guidelines and local achievability and applicability (*ii*) and, finally, the PartoMa intervention's likely effects, active ingredients, and dilemmas (*iii*). Both the participatory development approach and the pragmatic evaluation design carry limitations that demand methodological discussion, which is provided in chapter 11 (page 100).

i. Getting to the hospital was not enough

As concluded in a study from 42 Nigerian tertiary hospitals, getting to the hospital was not enough for the labouring women to ascertain proper, basic care at birth – even at this tertiary level of the health sector.¹⁸ Though improvements were observed during the PartoMa study, substandard quality of risk assessments on admission, intrapartum surveillance, and record keeping were repeatedly documented throughout the study, with severe delays of care and neglect of women and babies. As presented in Paper III, even after the intervention, more than an hour passed (74 minutes on average) from last recorded FHR till delivery, and Paper IV reported how 22% of women delivered without having BP recorded throughout admission. Birth

attendants often referred to late admission or referral of women as major causes of adverse labour outcomes. However, more than half of the women with intrahospital stillbirth (Paper I) or with sHDP (Paper IV) were admitted before the active phase of labour, and 85% in each of these groups sought care directly at Mnazi Mmoja Hospital. As reported from maternal health care in numerous low- and middle-income countries, the two extreme situations of too little, too late and too much, too soon care coexisted at the study site.^{17,21–29} This led to unnecessary risks, as well as time- and resource-consuming situations. The dangerous coexistence was particularly apparent when reviewing injudicious use of oxytocin augmentation at baseline, as further discussed in Letter I (page 210).

A key challenge in providing quality care in low-resource maternity units has been referred to as a ‘know-do gap’. However, the definition of ‘know’ is unclear. It might refer to the international *de jure* knowledge, evidence, and expert consensus of how to provide safe and respectful care, as represented in clinical guidelines, or to the birth attendants’ knowledge and thereby their inability to do what they know is right for labouring women, due to high workload and lack of supplies, or due to poor attitudes.^{141,142} While some birth attendants at Mnazi Mmoja Hospital were observed to react to high workload by decreasing work moral,⁴⁵ the knowledge-skills tests suggested that even on less busy days and with supplies available, many birth attendants were restricted in their ability to provide proper care. Test scores suggested that a core of the relatively few birth attendants at this tertiary hospital were not trained adequately to fulfil the definition of a skilled birth attendant: an accredited health professional “who has been educated and trained to proficiency in the skills needed to manage uncomplicated pregnancies, childbirth and the immediate postnatal period, and in the identification, management and referral of complications in women and newborns”.¹⁴³

It is warranted that lack of knowledge, skills, and quality care are not viewed as individual birth attendants’ faults, but that the non-conducive health systems are intensively addressed. As experienced in the PartoMa study and reported in other Tanzanian studies, birth attendants’ ability to provide best possible care is lessened due to poor socio-economic conditions, work organization shortcomings, lack of colleagues and supervision, and poor priority setting at the political level, including governance of human resource management.^{60,65,66,144} Without changes in the current resource constraints at Mnazi Mmoja Hospital, the PartoMa study showed that some improvements could happen by strengthening the birth attendants’ clinical decision support. However, counting on birth attendants’ intrinsic motivation to provide safe and respectful care without adequately addressing the larger health system challenges is not an acceptable response to one of the most disturbing and preventable public health disasters of our time. Adding to the challenge, the quantity of women prompted to give birth in facilities is increasing not only in Zanzibar, but globally.³¹ Particularly in sub-Saharan Africa, with a fertility rate at 4.8, urban population growth at 4.1%

annually, and obstetrics in transition towards complex double-burdens of diseases, the pressure on low-resource, urban mega-hospitals is expected to increase dramatically.^{11,20,31,32}

ii. Act globally while thinking locally, in guidelines development and beyond

In a previous mixed-methods study at two Tanzanian district hospitals, the thesis author and colleagues explored why birth attendants performed many CSs without obvious medical reasons.^{53,85} Birth attendants appeared to construct actionable knowledge for clinical practice that was influenced by opinions, rumours, and fears, as much as by evidence-based guidelines. The birth attendants were asked why they seldom applied available, international guidelines. One midwife replied by asking, how could she follow guidelines that for instance recommended standing with each labouring woman for 10 minutes half-hourly counting contractions, when simultaneously caring for several labouring women.⁵³

Drawing on this and similar experiences, the study team expected inconsistencies between internationally-derived clinical guidelines and what would be attainable in Mnazi Mmoja Hospital. However, the gap widened during the lengthy and resource demanding development of the PartoMa Pocket Guide. Major alterations were necessary in frequency of clinical assessments, information load, ambiguity in recommendations, and safety of treatment regimens, as in the example in Box 3 (page 55). Some barriers were obvious, such as financial limitations and unavailable supplies. Other barriers were less predictable and the birth attendants' experiences were pivotal. These included aligning guidance with attendant-to-labouring-women ratio and professional competencies, avoiding contradictive recommendations or a counterproductive guidelines overload, and integrating and aligning routine and emergency management within the continuum of care.

The effects and unforeseen side effects of poorly matched international clinical guidelines in low-resource settings may be amplified through the guidelines' use in other interventions, such as electronic solutions with decision-support, algorithms, and critical care pathways. The originally planned intervention for this PhD was an externally-derived electronic partograph with alarms to indicate when to assess labouring women, but without clinical decision-support for what to do on the basis of the assessments. However, during the initial months of the baseline study, it became apparent that strengthening partograph-associated decision-making was urgently needed, irrespective of whether the partograph was low- or high-tech. While the resulting peer-reviewed PartoMa intervention was well accepted and used among many birth attendants, the PartoMa guidance turned out not to be aligned with the high frequencies of alarms in the electronic partograph. The electronic partograph was at this point supposed to be the next implementation step, but the developers did not allow contextual modifications and highlighted that the fixed clinical rules in the software were based on WHO guidelines and global best practices. Contrary to

WHO's encouragement of local adaptations,⁸³ and to evidence on guidelines effectiveness from high-income countries,^{103–106} the developers stressed that they would only alter the clinical rules based on global standards and 'emerging evidence'. This apparently did not include single-hospital study findings. Such lack of flexibility and alignment with local clinical processes have also been reported as a barrier in implementing electronic health tools in other settings, and too high costs for context specific modifications may be a central underlying cause.¹⁴⁵

In the 2016 Lancet Maternal Health Series, a review of the global production of international maternal health guidelines was conducted. The authors reported major disagreement in guidance, even between what was rated as high-quality guidelines.²⁹ This emphasizes the inevitable limitations, biased selectivity, and ambiguity in experimental studies and therefore the strong influence of values, culture, and professional tradition in guidelines development.^{29,146–148} Translating evidence into clinical recommendations inevitably requires judgments about the balance between benefits and risks, and it involves weaving the selective and narrow experimental study findings together.¹⁴⁷ On this basis, it is astonishing that the bulk of internationally-derived clinical guidelines targeting low-resource settings are published with little, if any, inputs from frontline health workers, and without pilot testing or post-implementation evaluation (Paper II's Supplementary File 1, page 156).^{82,147,149}

Inspired by successful, large-scale, participatory guidelines development in high-income countries,¹⁰⁵ three interactive steps are proposed in Paper V (page 204) of how international, regional, and national clinical guidelines may become better attuned to input from the targeted healthcare workers in low-resource settings, and thereby pave the way for simple facility-level adaptations and effective use (Paper V, page 204).

iii. The PartoMa intervention's likely behavioral effects, active ingredients, and dilemmas

Likely behavioral effects

When comparing quality of care at baseline with the ninth to 12th intervention months, significant progress had occurred – particularly concerning foetal heart surveillance and management of slow labour progress and of women suffering from sHDP. Improvements were in alignment with the three pages of the PartoMa Pocket Guide that birth attendants found most useful (Paper II), seminar case histories, and content of the knowledge and skills test that has recently shown promising results. These care improvements offered likely explanations for the simultaneous reductions in stillbirths and asphyxiated newborns. Thereby, the PartoMa intervention most likely moved through all four levels of the Kirkpatrick model (page 63).¹³⁵ This apparent bridge-building from knowledge and skills improvements to behavioral changes is encouraging.

The translation from enhanced knowledge and skills into practice is often reported to be challenging, both in high- or low-resource settings.^{98,150}

When combining the findings from Papers III and IV, it appeared not to be one magic bullet in the PartoMa intervention that caused improved survival at birth: while decrease in over-use of oxytocin augmentation appeared to be a major contributor among non-sHDP women, this did not explain stillbirth reduction among sHDP women. Overall, it appeared to be the multiple behavioral changes in quality of care that had effect, which is similar to the results of the Asian multi-centre trial from 1994 where partograph use was similarly combined with a simple clinical protocol for how to act according to clinical assessments.⁶⁹

Paper III presented a simultaneous increase in CSs from 12% to 16%. CS indications in the quasi-random group did not raise concerns about an increase in unnecessary surgeries, and if timely performed, the increased rate may have aided further in reducing maternal and perinatal risks. However, though the rate of vacuum extractions also increased (0.3% to 1.2%), it remained far below optimal rates, which might have caused unnecessary CSs during both baseline and intervention months.¹⁵¹

While the knowledge and skills evaluation was conducted in the 35th to 41st intervention months, the post-implementation data on quality of care and birth outcomes were from the ninth to 12th intervention months (timeline, page 214). However, based on participatory observations in the department and informal discussions and in-depth interviews with birth attendants, it appears that the improvements in care have largely persisted after the 12th intervention month. This falls well in line with the 2016-2018 stillbirth rate of 35 per 1000 total births, and a simultaneous tendency of reduction in maternal mortality.¹²² In addition, a structured observational study, based on the PartoMa guidance, was conducted by Housseine et al. in the department in October to November 2016. Direct observations of 161 labouring women showed a similar interval from last FHR assessment to delivery as in the ninth to 12th intervention months. Also, the data showed signs of proper triage in accordance with the PartoMa guidance: presence of abnormal FHR, use of oxytocin, or crossing the action line led to systematic increase in the number of FHR assessments.⁴⁵

Active ingredients in the PartoMa intervention

The idea that a pocket guide combined with relatively infrequent short training sessions could assist in improving knowledge and quality of care may seem over-optimistic, when considering the limited effects often reported of long-lasting, high-intensity training,⁸⁶⁻⁸⁹ and the challenges in translating evidence into clinical practice in both high- and low-income countries.^{29,84,91,110} However, if considering the principles of participatory, problem-driven, bottom-up intervention development (*a*), the multifaceted integrational approach (*b*), adult learning theory (*c*), and the decision to avoid payment for attendance (*d*), the success of the PartoMa intervention appears less surprising. This is further discussed below and summarized in Box 4.

Likely active ingredients	Description	Plausible associated effects
Participatory development	Clinical guidance and associated training were developed and modified based on wishes and inputs from the birth attendants, through multiple rounds of feedback	Feeling of being heard and understood among end-users
External peer-review	Clinical guidance underwent multiple reviews by an external panel of 12 specialists in obstetrics, midwifery, and neonatology, with experience working in low-resource maternity units	Realistic blue-stamped guidance by specialists understanding the unique challenges of providing maternity care in low-resource settings
Multifaceted intervention with integrated implementation strategy	The intervention integrated pocket guide with essential clinical guidance, recurring training, and partograph use	Strengthened effect through synergy and bridge-building between training and clinical work
Integration of routine care and emergency management	Basic and emergency obstetric care was integrated	Enabled better practice in the continuum of care, and prevention of emergencies by improved routine care
Triage	Guidance and training on monitoring and treating individual women took triage into account, as each birth attendant care for 3-6 labouring women simultaneously	Enabled better adherence to guidance and strengthened triage
Partograph as an integrated early warning tool	The partograph was emphasized to capture the well-being of the woman, baby, and labour progress at a glance throughout latent and active phase of labour, including second stage	One integrated assessment and warning tool, rather than the common exclusive focus on the partograph for foetal surveillance and labour progress in first stage of labour
Pocket guide as advisor in the clinic	The pocket guide aimed at being locally achievable, practical, relevant, unambiguous, brief, and easy to understand (“a friend in the pocket”)	Support in clinical decision-making, both individual and within the team, and for supervising students and colleagues, as well as for transparency in what is best possible care
Staff-friendly, positive, and safe learning environment	Seminars aimed at being a positive, welcoming, safe, and non-blaming place for learning and sharing experiences (“therapeutic afternoons”)	Staff- and student-friendly learning, blame free, encouraging active participation with critical reflections on own limitations in knowledge and skills, and with spill-over to better woman- and baby-friendly care
In-house, realistic team training	The seminars were conducted in-house, recurring, and non-hierarchical in multi-disciplinary teams	Strengthening interdisciplinary teamwork and common understanding of key management
Reward-driven training	The ultimate reward to the participants for achieving the training goals was intended to be the ability and confidence to provide better care at birth	Improved safety at birth, as well as appreciation and recognition of birth attendants and improved mental wellbeing at work
No economic incentives	No additional payment for clinical performance, or per diems or allowances for attending seminars	Ensured that motivated staff were trained, amplified experience of self-directed learning, urged the voluntary facilitators to make extra effort to ensure ‘value for participation’, and avoided the department being left without staff

Box 4 The plausible active ingredients in the PartoMa approach that interacted effectively with the context at the low-resource Mnazi Mmoja Hospital. The ethnographic study aims at exploring this further.

a. Participatory, problem-driven, bottom-up intervention development

The degree of participation in intervention development is found to be negatively related to resistance to change and stress, and positively to achievement of goals, commitment, and job-satisfaction.¹⁰⁷ However, as the group of birth attendants was largely replaced shortly after developing the first version of the PartoMa intervention, the direct participation in the intervention development was unlikely to cause the motivation to use the pocket guide and attend seminars. More likely, the pocket guide and seminars' locally achievable guidance addressing locally defined key problems motivated its use, by creating a feeling of being heard and understood, and a sense of ownership. Signs of ownership were often observed within the local steering group that worked hard on a voluntary basis to organize and conduct seminars. Maintaining ownership, however, was a challenge because members frequently changed due to the staff-turnover. While the copyright claimer still writes "© The PartoMa Study, University of Copenhagen", it is encouraging that the Zanzibar Ministry of Health has recently taken over the continuation and upscaling of the intervention at the national level, with support from UNFPA. Their engagement and effort in taking over the ownership are yet to be evaluated.

b. Multifaceted, integrational approach

Multifaceted interventions have shown to more likely improve performance than single issue interventions.¹⁵² The PartoMa intervention may be considered multifaceted – or integrated – as it consists of associated pocket guides, trainings, and use of the partograph with an integrated implementation strategy, and contains multiple integrated guidance and multiple associated assessment indicators.

Pinnock et al.'s standards for reporting implementation studies divide intervention and implementation strategies into two strands.¹³⁶ In the PartoMa study, the seminars may be seen as the implementation strategy for the pocket guide and partograph, but the pocket guide may also be regarded as the seminar curriculum and implementation tool to translate the training into clinical realities. The components were seen as parts of one complex intervention where the aim was to interact in synergy. Although Pinnock et al.'s division may be reasonable for clarity and simplicity in study designing and reporting, it may discourage intervention development with embedded implementation strategies, which in the PartoMa study seemed to be an active ingredient for effectiveness.

The guidance in the PartoMa Pocket Guide aimed at being simple and brief while covering an integrated continuum of common care at birth based on three key principles. *First*, guidance on monitoring and treatment of the individual woman took into account that each birth attendant on average cared for three to six labouring women simultaneously, which is in contrast to common guidelines development principles. *Second*, basic and emergency obstetric care were integrated in the PartoMa intervention. Management of complications appears often to over-influence local practice in maternity units, and in training

interventions, resulting in risk of neglecting basic, routine care that could prevent many severe complications.^{53,60} *Third*, the PartoMa intervention emphasized the partograph as an integrated early warning tool capturing the well-being of the mother, baby, and progress of labour at a glance throughout latent and active phase of labour, including the second stage.

Understanding the integrated role of the partograph in intrapartum care needs further discussion. In evaluations of care at birth, partograph use is sometimes evaluated as a simple procedure in line with, for instance, hand hygiene or clean towels.⁷⁰ At other times, the partograph is described as a complex intrapartum decision-support tool helping providers to act timely and correctly.¹⁵³ Simultaneously, as unfolded in chapter 2 (page 18), the partograph is often criticized for being suboptimally applied in low-resource settings.⁷³ As the partograph is an early warning tool capturing the complex, combined routine care and emergency management during labour, it is hard to see how partograph use could be optimal before human resources are adequate and governed adequately in busy low-resource maternity units. While fighting for conducive health care systems in low-resource settings, research on how to simplify the partograph further and make it even easier to use for birth attendants are relevant. Further, in line with the findings in this thesis and results of the successful Asian multi-centre trial from the early 1990s,⁶⁹ it is warranted that future partograph solutions are closely combined with realistic guidance on what to do with the assessments – only with such guidance will the partograph be a decision support tool.

c. Adult learning theory

The PartoMa intervention follows the principles of relevant, focused, self-directed, and practical training.⁹⁷ The implementation strategy was based on birth attendants' individual motivation to learn and improve care, and, as disclosed in Kirkpatrick's level 1, the need for obtaining the intervention's information appeared apparent among many birth attendants. The ultimate reward to the participants for achieving the training goals seemed to be the ability and confidence, or self-efficacy, to provide better care. According to Bandura's theory of self-efficacy, people's judgements of their own ability to deal with difficult situations is central to what they choose to do, how much effort they invest, how long they persist, and whether they approach the tasks anxiously or assuredly. The seminar case histories ending with healthy mothers and babies were one example of attempting to strengthen self-efficacy.¹⁵⁴ Some birth attendants described the seminars as 'afternoons of therapy'. In what they characterized as a safe and non-blaming environment for critical thinking, the knowledge gains appeared to give new energy and motivation for care provision. Some birth attendants went on to explain how clinical care supported by the PartoMa Pocket Guide, their "friend in the pocket", was less stressful or terrifying.

As described in chapter 2 (page 14), low-dose, high-frequency, in-house training is increasingly becoming the recommended approach for strengthening competencies in both low- and high-resource clinical

practice, and results on knowledge retention are promising.^{88,92,93,96} For instance, while a locally accepted, interactive, half-day course in postpartum bleeding at a Tanzanian district hospital resulted in an immediate increase in knowledge, the knowledge decayed to the pre-training level after nine months.¹⁵⁵ In contrast, the quarterly 'dose' of PartoMa seminars combined with possible use of the pocket guide in daily practice resulted in promising knowledge and skills improvements that were refreshed after three months, where the knowledge and skills levels already showed signs of decrease (Figure 12, page 78). Interestingly, the knowledge and skills results point to lowest improvements among birth attendants with more than five years of experience (Appendix, page 220). The predominantly young group of birth attendants with limited years of professional experience may thereby be considered a possible important contextual factor for the effects of the PartoMa intervention. In alignment, a multi-country assessment of knowledge and skills before and after training in emergency obstetric care disclosed that birth attendants who had been in post for more than 10 years were less able to improve their test scores, and the proportion of work-time spent providing maternity care was not associated with an improvement in scores.⁵²

d. A non-per-diem training culture

The seminar attendance rates emphasized that in this Zanzibari setting, the perceived need for paying per diems to ensure attendance at trainings and related meetings could be counteracted.⁸⁷ The average of two-third of birth attendants from the obstetric department participating at PartoMa seminars, together with birth attendants from other facilities and health students, was a crucial indicator of satisfaction with the intervention and of motivation to gain knowledge and improve quality of care. If birth attendants would not find the PartoMa seminars relevant or satisfying, it is unlikely that attendance rates would remain high. Related to adult learning theory, it may even be argued that attending in free time without allowances amplified the birth attendants' experience of self-directed learning where the gain in knowledge and skills were largely within their control and a free choice, thereby enhancing their striving and acceptance of a personal responsibility for own learning.⁹⁷ Furthermore, as touched upon in chapter 2 (page 18), per diems may decrease intrinsic motivation, as the main focus becomes securing salary.⁹¹ Non-per-diem workshops and meetings may thereby push the organizers to put extra efforts into the content and listen to the demands of the participants. In the PartoMa study, it was a continual focus to ensure 'value for participation' at each seminar. Moreover, there was consistency between participants at seminars and health care workers attending births, which is not necessarily so if per diems are paid.⁹¹

Dilemmas

As previously touched upon, an ethical dilemma in the PartoMa intervention is that it did not directly address the broader health system challenges. The intervention may be seen as a small band aid at the bottom level of a health system suffering from much bigger disabilities. Yet, as Freedman and Kruk argue, and in line with the Paris Declaration and Accra Agenda for aid harmonisation and effectiveness,¹⁰¹ “if we are serious in saying that quality starts with what women need and want, then quality of care efforts must start where women live and labour”.⁵⁹ The PartoMa study may indirectly influence the bigger ‘health system disease’, and it has in fact moved from the grass root level at Mnazi Mmoja Hospital and upstream gaining increasing support by the Zanzibar Ministry of Health and from UNFPA and WHO in Zanzibar. Full effect and sustainability of the PartoMa intervention at the national level now depends on the health care system’s ability to integrate the intervention in the horizontal continuum of care and in vertical depths of specific conditions. It is questionable whether the Zanzibari health care system is strong enough to conduct such integration – for instance by avoiding overload and confusing disagreements in national guidelines and training packages offered with support by multiple aid organizations.

It may be argued that the label of ‘evidence-based best practices’ requires evidence generated through experimental study designs, while controlling for the contextual factors that, however, are crucial to understanding the possible translation of evidence into clinical practice. It might also be argued that the alternative of contextually-tailored guidance, as the PartoMa Pocket Guide, may unprofessionally promote non-best-practice solutions, inefficiently ‘reinvent the wheel’, or fail to meet global standards.¹⁰⁸ Rightly, the ethical dilemmas in producing achievable and acceptable guidance for unacceptable realities must be acknowledged. However, in accordance with the PartoMa study’s promising findings, WHO emphasizes the relevance of ‘conditional recommendations’ when interventions are appropriate for some locations only, and the Lancet Maternal Health Series call for context-appropriate implementation strategies with clinical guidelines that are formulated in ways that facilitate understanding and use.^{29,67,83} At the grassroots level, Zanzibari birth attendants involved in PartoMa, as well as birth attendants in Tanzania mainland, Malawi, and Mozambique, all demand access to professional development, staff support, and supervision, for which context-tailored clinical guidance is central.⁶⁴ At the national level, as Andrews et al. argue, the ‘isomorphic mimicry’ of adopting poorly fitting ‘best practices’ that may enhance external legitimacy and financing, but do not correspond with internal constraints, may cause ‘capability traps’: most of the resources within a resource-constrained health care system are used to ensure ongoing flows of external support through adopting poorly fitting ‘best practices’, while leaving the internal pre-existing constraints further underresourced.¹⁰⁸

Another concern may be the unambiguous “assembly line” of care that the PartoMa guidance promotes, which possibly minimizes attention to individual variations in the birth process. With low levels of

knowledge and skills among many birth attendants, little professional experience, excessive workloads, and limited access to supervision, it seemed justified to keep individual clinical judgements of individual clinical cases at a minimum. It was emphasized in the pocket guide and at seminars how guidelines offer a guiding line that typically is preferably for the labouring woman and her baby, but if in doubt, the care should be discussed with colleagues and further information sought before acting.

It is a dilemma to train health care workers in their free time where participation takes away time from other duties in their private lives, and perhaps is impossible for some due to private obligations. In the evaluations, birth attendants continuously mentioned how attending the seminars and applying the pocket guide should be mandatory for all birth attendants in Zanzibar. As disclosed in seminar evaluations, it was a repeated frustration how non-participating colleagues hindered team work, and non-participants in the PartoMa study may have counteracted quality care improvements to its full potential. As found among English birth attendants, variation in patient safety and team efficiency during emergency care were predominantly correlated with the quality of teamwork, not with individual knowledge and skills, which training together in realistic scenarios could improve.⁹⁸ It would seem fair that relevant in-house training, such as PartoMa, was an inherent part of working and thereby conducted on-the-job with the usual salary, not per diems, and by the senior health workers as a part of inherent work responsibilities. With the current human resources and system constraints, the work environment, however, did not appear conducive for such an approach. The study team and local steering group feared how participation would disrupt clinical tasks or cause risk of neglecting labouring women.



Data collection. Photos by Tarek Meguid and Nanna Maaløe.

Chapter 11

Discussion of Methodological Issues

11. Discussion of Methodological Issues

Since the Millenium Development Goals, awareness has increased remarkably on the need for assessing the broader impact of aid. With the Paris Declaration and Accra Agenda for aid harmonisation and effectiveness, and latest with the Sustainable Development Goals, participatory development at the grass root level and creative, mixed-method evaluations are gaining recognition.^{57,156} There is, however, a long way to go to reorient the conventional, and some might add colonising,¹³³ ways of designing, implementing, and assessing interventions for health care in low-resource settings . At a small scale, the one-hospital PartoMa study may be seen as an example of a broader-based intervention, which, over time, has moved in the direction from vertical to more horizontal in guidance and training focus. As touched upon in chapter 10, the PartoMa intervention has also moved from the grass root level to upstream in the system. The study may therefore be seen as a simple case of iterative, participatory, bottom-up development of a low-cost intervention and also a low-cost, mixed-methods assessment, which fulfill the global goals and priorities for effective aid. The overall pragmatic study approach evolved to contain principles from implementation science's program theory models, participatory action research, and classical criterion-based clinical audits.^{41,127,138,156,157} This resulted in the PartoMa study's cycle of iterative, participatory development, implementation, assessment, and further development (Figure 15).

i. Participatory development process

While the PartoMa study took off as implementation science aiming at assessing a complex intervention, the flexible, participatory approach at the grass root level evolved in the initial study months. Observations of clinical care and reflections on inputs from birth attendants led to redefining the central problem and the core intervention for strengthening birth attendants' ability to provide best possible care at birth. Since then, the intervention modifications continued to be influenced by cycles of participatory development, implementation, assessment, and further development (Figure 15). According to the promising findings, at the study site, this approach appeared well suited for bridging the gap between evidence and practice.

Without the birth attendants' motivation to participate voluntarily in the intervention and share perspectives with the study team, the study would have failed. The motivation to learn and improve among the majority of birth attendants was a major strength of the study, and it would be relevant to further explore causes as to why some birth attendants did not participate. As discussed in chapter 10, non-participants may have counteracted improvement to its full potential.

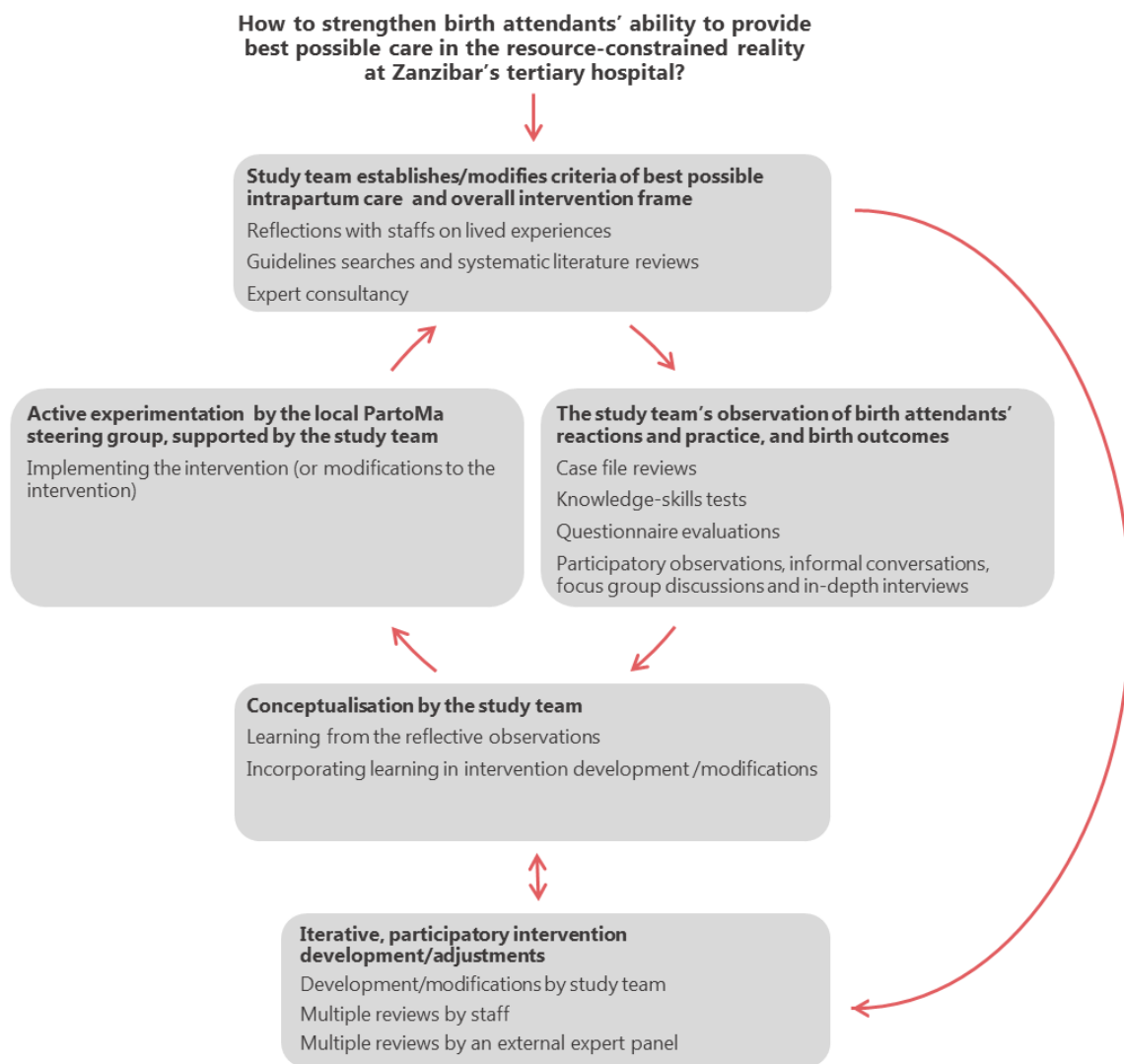


Figure 15 The PartoMa study's cycle of active experimentation and assessment for iterative, participatory development of clinical guidance and associated training. The cycle is based on the classical criterion-based audit cycle, participatory action research's action-reflection learning cycle and implementation science's application of program theory.^{41,127,138,156,157}

Also for engaged and enthusiastic birth attendants, there were limitations to what could be expected from the partnership. They were over-worked clinicians and surplus energy was often limited. Classical participatory action research advocates that those being studied are actively involved in all stages of the process, through a clearly defined cooperative inquiry group and with workshops for building consensus of the group's ongoing learning.¹⁵⁷ The PartoMa study's participatory approach evolved pragmatically to suit an obstetric department with severe resource and capacity constraints and a detailed process of participatory development was not pre-defined. Furthermore, with the high turnover of staff, birth attendants participating in the intervention and providing formal and informal feedback changed over time.

Seminar attendance was high, and most facilitators were local birth attendants volunteering. Although at times it demanded persistent reminders and re-bookings, the study continually succeeded in collecting feedback from birth attendants, by questionnaires, focus group discussions, in-depth interviews and informal conversations. It may be questioned, however, to what degree the study followed the participatory action research's principle of always working *with* rather than *for* the people in focus.¹⁵⁷ Although the cyclic process in the PartoMa study may be seen as genuinely respectful and open, the overall intervention outline of guidance and training and the evaluation assessments were predominantly established and conducted by the study team, including only two birth attendants from the department. Under the busy and resource-constrained circumstances, birth attendants could hardly have devoted more time for evaluation and reflectory activities, without influencing their ability to perform their clinical work.

ii. Assessment design

This pragmatic and low-cost, mixed-methods study was designed to suit limitations in data and budget, while still enabling a more thorough understanding of the likely pathway from the intervention to possible changes in survival at birth than a classical pre-post study, or a so-called 'black-box' evaluation.¹⁰⁷ In achieving this, the pragmatic research paradigm without a predetermined association between epistemology and research methods was well supported by the program theory model (Figure 7, page 62). The combined findings of the mixed-methods evaluation with multiple indicators on four levels of causality indicate that the actual process of causality largely followed the proposed program theory. Thus, it is likely that the PartoMa intervention contributed to the observed changes in perinatal survival, through many birth attendants' satisfaction and engagement with the intervention and associated improvements in knowledge, skills, and quality care.⁴¹

Such program theory approach has, however, been criticised for assuming linear causality and for failing to test for all plausible alternative hypotheses.⁴¹ The study presented here does, to some extent, leave us uncertain of alternative explanations for the apparent causal association and does not provide us with rich descriptions of the context and deeper understanding of the possible 'active ingredients' in transferral between the causality levels.¹⁵⁶ It cannot be excluded that slightly lower numbers of admissions after baseline and PartoMa-independent self-learning and supervision of peers may have allowed for better time and thereby for improved care. The unpublished ethnographic study aims at exploring such non-linear feedback loops and alternative pathways further.

This PhD focused particularly on quality of care during childbirth and the birth attendants' perspectives, and leaving out the labouring women's perspectives on care received is a crucial limitation. Community

visits with focus group discussions were, in fact, conducted in 2016 on perceived quality of care during childbirth and will be included in the ethnographic study.

Another restriction is the lack of an economic evaluation. Considering direct running costs, the intervention is low-cost, overall (page 58), when compared to other in-service clinical training interventions in low-income countries.^{90,94} However, a cost-effectiveness analysis would, particularly, have been interesting if including indirect costs, such as opportunity costs for the numerous hours of voluntary time spent by the participants and facilitators outside working hours.

Key limitations to each assessment method applied are touched upon below.

Birth attendants' perceptions and reactions

Limiting birth attendants' perceptions in pilot-testing of the pocket guides and evaluations to written questionnaires may be too narrow to capture all dimensions. The ethnographic study aims to explore this further, through in-depth interviews and focus group discussions.

Paired tests of knowledge and partograph skills

A key limitation was that the same test was applied to all testing points. Although it was assured that the respondents did not take the test home after the seminars nor were informed of the correct answers, they may have learned from retaking the test and thereby the test alone may have added to the learning effect. Such knowledge gain due to testing has been shown, and that knowledge is better retained if a test is conducted.¹⁵⁸ Testing of a control group of birth attendants not offered the training would have demonstrated a stronger cause-effect relationship, but this was not feasible.

While it appeared that face, content, and construct validity were acceptable after the development phase, it had only been tested on a small sample. With more time and resources, a more elaborate pilot testing would have been relevant.¹³⁷ However, the learning results strengthen the test's construct validity, as it clearly discriminated between groups of participants expected to perform differently due to whether or not they had attended PartoMa seminars and applied the guidance.

Though the test had to be short to be acceptable during the seminars, it captured birth attendants' abilities to fill in the partograph, make clinical diagnosis and treatment plans based on the partograph, and their partograph-independent knowledge on central topics in the PartoMa Pocket Guide. Notably, the respondents were not looking in the pocket guide during test time. However, the test did not evaluate the

birth attendants' ability to prioritize the labouring women. Directly observed simulation-based skills tests would have allowed for testing of obstetric maneuvers, management of postpartum hemorrhage, and neonatal resuscitation. This was unachievable within the budget- and time-limited one-PhD study.

Criterion-based auditing of case files and reviews of birth registers

Considering the resource-constrained study site with no functioning system for case file storage, the high proportion of case files that were retrieved was reassuring.

Intrahospital stillbirths would have been a more delineated primary outcome than overall stillbirths. However, case files of multiple gestations often did not allow clear assessment of FHR monitoring, and in approximately 20% of singleton stillbirth cases, the available information did not allow analyzing whether death occurred pre- or intrahospital. Hence, the pre- versus intrahospital stillbirth proportions are an extrapolation from 80% of singleton stillbirths with risk of bias. Nevertheless, as presented in Paper III, the reduction in the intrahospital stillbirth proportion from 48% to 38% between baseline and the ninth to 12th intervention months is a promising indication of the likelihood that the overall stillbirth reduction was associated with improved intrapartum care. Encouragingly, this is triangulated by the simultaneous reduction in birth asphyxia, the consistency between the baseline study's disclosed determinants for intrahospital stillbirths and the pre-post improvements in quality of care, and the comparable challenges and improvements in care within the quasi-random and the SHDP groups. Furthermore, the collaborating research group's observational maternal mortality and near miss study (2016 – 2018) found a stillbirth rate of 35 per 1000 total births.¹²² Hence, the perinatal data in the ninth to 12th intervention months were apparently not a random fluctuation. However, two baseline time points would have strengthened the study further, to explore possible time-related changes and fluctuations before implementation. This was not possible owing to the broken hospital case file storage system.

For the ninth to 12th intervention months, the hospital's admission, delivery and theatre registers disagreed on total number of births, which ranged from 3087 to 3209. For Paper III's evaluation in early 2016, it was decided to apply the lowest value, as this would give the most conservative change in rates of stillbirth and low Apgar score. Later in 2016, the repeated assessment of all available case files for Paper IV's retrospective retrieval suggested, however, that 3209 may be closer to the truth. Hence, the true stillbirth rate in the ninth to 12th intervention months appeared to lie within the interval of 37-39 per 1000 total births. Such discrepancy was not found at baseline.

Intensive efforts were made to understand why only 82-90% of the randomly-selected case files used for Paper III could be found, while the total number of case files from the two periods were around the total numbers in the registers. This may be caused by some labouring women not being recorded in the hospital

registers, and, as no patient registration numbers existed, by sluggishness in writing names and dates. This is strengthened by the baseline study revealing 25% underreporting of stillbirths in the registers.

The varying quality of data in case files limited the study. There may be a tendency of staff to over-report or to forget reporting given care, or to under-report mismanagement. In alignment with observations by study team members working in the department, this did not change considerably during the first intervention year.

An important weakness is that case file reviews will never allow evaluation of the interactions between birth attendants and labouring women and the level of respectful care, which was central in the PartoMa guidance and seminar content (page 27 and the Appendix, page 122). More resource demanding, direct, structured clinical observations would have overcome these limitations, though it would have simultaneously increased the risk of the Hawthorne effect.¹⁵⁹ In addition, while qualitative, participatory observations were conducted, direct structured observations would possibly have enabled a better assessment of the clinical decision making, and how, why, and when the PartoMa Pocket Guide assisted in this, or was not applied.



Eid celebration at a beach in Zanzibar. Photo by Rune Maaløe Andersen.

Chapter 12

Conclusion and Perspectives

12. Conclusion and Perspectives

Unsafe and disrespectful care during childbirth is a human rights violation that affects women and babies, their families and societies, as well as the birth attendants. Generating evidence-based safe and respectful care remains a key priority in the post-2015 agenda. Increasing numbers of facility births in low-income countries are currently causing additional pressure on already fragile health care systems, with risk of further impairment in quality care. It is urgent that the increasing proportion of facility births evolves to a positive momentum for ending the epidemic of preventable deaths, disabilities, and grief at birth. From resource-rich maternity units, we know ‘what works’, but evidence is scarce on ‘how’ to make this happen in poor-resource maternity units. Context-appropriate implementation strategies are therefore a global key priority.

This thesis presented the PartoMa study’s innovative, participatory, action-oriented implementation research for strengthening overworked birth attendants’ ability to deliver acceptable quality of care under the unacceptable circumstances at the high-volume, low-resource tertiary hospital of Zanzibar. In collaboration with Zanzibari birth attendants, international clinical guidelines were adapted and modified to be achievable, acceptable, and applicable, taking into consideration available resources, the immense workload carried out by the birth attendants, and their often suboptimal levels of knowledge, skills, and experience. An associated training intervention of quarterly recurring, three-hour, in-house seminars was developed, where the pocket guide’s content was practiced through case histories. The seminars were conducted outside working hours, without per diems or allowances.

The PartoMa study’s mixed-methods assessment suggested how birth attendants found the intervention relevant and helpful and that it improved and retained related knowledge and skills. In the ninth to 12th intervention months, multiple related indicators of quality care had improved, when compared to baseline. Moreover, stillbirths had decreased by 33%, and newborns with birth asphyxia had almost halved. According to data from a collaborating research group, the stillbirth rate remained at this level during the following two years, and there appears to be a simultaneous tendency of reduction in maternal deaths.¹²² Through this causal pathway assessment, the PartoMa intervention appeared to be an enabler for the birth attendants’ improved ability to save lives at birth. Notably, the effects occurred without increasing the suboptimal staff numbers, halting staff-turnover, or introducing additional medical technology.

Additionally, the study proved useful to gain insights into the unacceptable quality of intrapartum care and underlying health system weaknesses, which caused profound risks for women and babies throughout the study. The study also gained insights into hidden strengths within the system, for instance: the persisting demand for the PartoMa Pocket Guide among birth attendants; attendance rates of approximately two-

third of all birth attendants at the PartoMa seminars outside working hours; and the continuous efforts of the PartoMa steering group of busy Zanzibari birth attendants who voluntarily organized and facilitated the seminars without pay. The majority of birth attendants in Mnazi Mmoja Hospital showed profound intrinsic motivation to learn and improve care, which is rarely portrayed in the global health literature.

The findings of the PartoMa study are from one hospital only and whether these are generalizable to other low-resource hospitals, within and across countries, need further study. It seems that structural constraints at Mnazi Mmoja Hospital are highly similar to the wider concerns of urban low-resource ‘mega-hospitals’ with high volumes of labouring women. Thus, at baseline, Mnazi Mmoja Hospital appeared structurally comparable to other Tanzanian high-volume maternity units, related to shortage of maternity beds and overall hospital human resources, as well as of use of partographs and clinical maternal health guidelines, and post-graduation training of staff.⁴⁶ However, the wider social, cultural, political, organisational, financial, and historical characteristics are not that easily compared between apparently similar settings. Expanded studies and follow-up are crucial to move beyond ‘pilotism’ and explore whether both the intervention development approach and the resulting PartoMa intervention were designed with sufficient flexibility to work across a range of low-resource, high-volume maternity units. For instance, a pragmatic stepped-wedge design would be relevant in multiple high-volume maternity units. It should contain an embedded qualitative component to further explore mechanisms that strengthen or limit birth attendants’ ability to deliver best possible care, including opportunities and barriers in participatory development, implementation, and upscaling of the PartoMa intervention.

As a result of the high and increasing interest among Zanzibari birth attendants for the PartoMa intervention, and the promising study findings, the Zanzibar Ministry of Health took over upscale and continuous support of the PartoMa intervention in June 2018. With financial support from UNFPA, the PartoMa intervention’s seminars will now be held every three months in both of Zanzibar’s main islands. Further, a Swahili version of the pocket guide is under development by the thesis author and Zanzibari colleagues, as well as a simple, electronic e-book with the guidance for free downloading on birth attendants’ personal smart phones. Similar to exploring acceptance and applicability in ‘PartoMa-naïve’ settings, it is important to qualitatively study the PartoMa intervention’s upscale and continuation, or discontinuation, in Zanzibar. It would also be interesting to study if a pre-service, participatory developed, PartoMa-related curriculum module could strengthen the young trainees’ ability to provide acceptable care.

This PhD grew into a critical analysis of the applicability of leading international guidelines targeting maternity care in low-resource settings. Developing the PartoMa clinical guidance emphasized crucial obstacles for international maternal health guidelines to be easily adaptable to realities in maternity units carrying the highest burden of adverse outcomes. It was a time- and resource-consuming process that

appeared unfeasible as a process to be conducted routinely within fragile health care systems. Compared to international guidelines targeting maternity care in low-resource settings, alterations were necessary in frequency of clinical assessments, information load, ambiguity, and safety of treatment regimens. It is mind-boggling that the bulk of internationally-derived clinical guidelines targeting low-resource settings are published with little, if any, inputs from health workers at the grass root level, and often without pilot testing or post-implementation assessment. Research is warranted on alternative interactive steps to ensure that large-scale guidelines development targeting low-resource settings is better attuned to inputs from the end-users, and thereby easier to adapt and use effectively.

As argued in paper V, “with the art of the possible, we can co-create decision-support that assists health workers in saving lives in facilities with the highest burden of death and disabilities, rather than the blockage, which the desire for perfectionism may cause. Within and beyond maternal health, realistic clinical guidelines and associated training are conditional for translating evidence into practice, pivotal in strengthening health systems’ accountability, and a basic, fundamental right and precondition for health workers with the lives of others in their hands”.

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Appendix

PartoMa Pocket Guide version 2.0	122
Paper I.....	142
Paper II.....	156
Paper III.....	176
Paper IV	192
Paper V	204
Letter I	210
Timeline	214
Additional information for evaluation level 1: Perceptions	218
Additional information for evaluation level 2: Learning	220
The Safe Motherhood Series	230

PartoMa Pocket Guide version 2.0, March 2018

A background document on the development process and seminar case histories are available at: <https://publichealth.ku.dk/partoma/>

VERSION 2.0 | March 2018

PartoMa

A Pocket Guide for Best Possible
Safe and Respectful Childbirth Care



Approved by Zanzibar Ministry of Health

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The guidelines represent achievable essential care at
the low-resource referral hospital of Zanzibar,
where each birth attendant takes care of 3 or more
women in childbirth simultaneously.

PartoMa Homepage: publichealth.ku.dk/partoma

PartoMa Background Document: In-depth information on the development process, implementation and evaluation is available at the PartoMa homepage.

PartoMa Practice-Based Training: Case stories are available in the background document.

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Reviewers: PartoMa Pocket Guide 2.0 is internally reviewed by 40 Zanzibari birth attendants, and externally peer-reviewed by a panel of 11 specialists in obstetrics, midwifery, neonatology and epidemiology.

Supporters: Zanzibar Ministry of Health and University of Copenhagen

References: World Health Organization's 'Managing Complications in Pregnancy and Childbirth: A Guide for Midwives and Doctors' (2017) is used as main frame, but supplemented by other guidelines and evidence reviews. References are listed in the background document. They have been adjusted to what is realistic at Mnazi Mmoja Hospital. Mnemonics for shoulder dystocia and vacuum extraction are adapted with permission from ALSO guidelines (Copyright: © American Academy of Family Physicians. All Rights Reserved).

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All reasonable precautions have been taken to verify the information contained in this publication, and both text and graphical presentations are internationally peer-reviewed. PartoMa guidelines are primarily developed to guide health providers in providing best possible care in the low-resourced referral hospital of Zanzibar, Mnazi Mmoja Hospital. The material is being distributed without warranty of any kind, and responsibility for interpretation and use of the material lies with the reader.

INDEX

Safe and respectful care	page 1
Partograph and PartoMa use	page 2
Routine maternity care	
Assessments during labour	page 3
Post-delivery care	page 4
Partograph decision-support	
FHR, liquor	page 5
Latent phase, PROM, labour induction	page 6
Cervix, contractions	page 7
High BP, urine protein	page 8
Low BP, high pulse, high temperature	page 9
Obstetric maneuvers	
Vaginal breech delivery	page 10
Second twin, shoulder dystocia	page 11
Vacuum extraction	page 12
Caesarean section decision-support	page 13
Vaginal bleeding	
Before birth (APH)	page 14
After birth (PPH)	page 15
Neonatal resuscitation	page 16

ABBREVIATIONS

APH antepartum haemorrhage (bleeding)
ARM artificial rupture of membranes
BP blood pressure
Bpm beats per minute
CS caesarean section
FHR foetal heart rate
GCS Glasgow Coma Scale
HIV human immunodeficiency virus
Hr hour
IM intramuscular
IV intravenous
Min minutes
MmHg millimetres of mercury
PPH postpartum haemorrhage (bleeding)
PROM pre-labour rupture of membranes
PV per vaginal examination
RR respiratory rate
Sec seconds
SRM spontaneous rupture of membranes
Temp temperature
TR transfer
UTI urinary tract infection

⚠ These are not all aspects of safe and respectful care, but represent key expectations



Caring support and kind communication

Treat every woman with respect and empathy, and involve in care decisions.



Teamwork

If uncertainty, discuss with colleagues.
If emergency, call for help.



Timely and complete partograph use

How is mother?
How is baby?
How is progress?



Clinical guidelines

Provide evidence-based care for every woman.
If in doubt, discuss with colleagues.



Encourage eating and drinking freely



Encourage ambulation

Position is the woman's choice, and upright position is encouraged.



Urination

Encourage spontaneous urination every 2 hrs during childbirth.



Privacy and confidentiality



Baby skin-to-skin on mother's chest

Immediately after birth for all babies without complications.



Encourage early breastfeeding

Start within 1 hr after birth.



Cleanliness

Clean birthing area.
Always clean hands (*handrub with alcohol-based solution is best*).



Birth companion of choice

Throughout labour and childbirth.

PAIN RELIEF

Routine pain relief for all childbirths

For most women, this is enough to cope with pain:

- Respectful caring support
- Ambulation

If distressed by pain

- Assess FHR, contractions, PV (*cervical dilatation*) (*if pain between contractions, see page 14*)
- Encourage ambulation (*walking or most comfortable position*)
- Encourage breathing techniques

If severely distressed by pain AND more than 4 hrs to birth

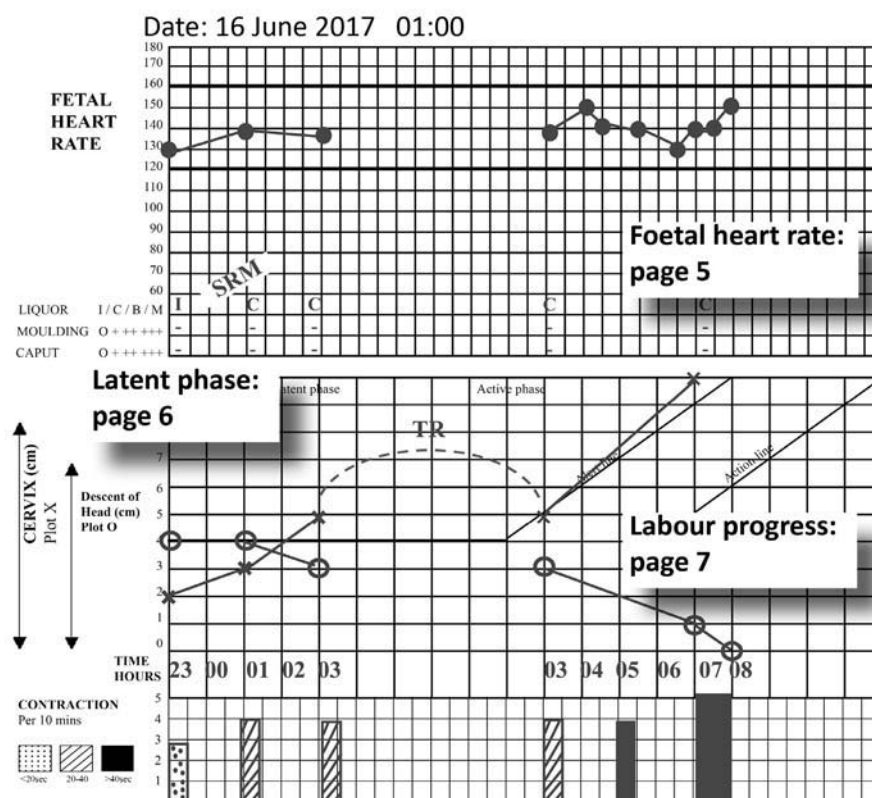
Offer medication:

- IM Morphine 0.1 mg per kg body weight

If needed, Morphine may be repeated after 4 hrs

⚠ **DANGER:** If Morphine is given within 4 hrs before birth, baby may suffer from poor breathing at birth (page 16). Antidote: IV Naloxone 0.1 mg/kg body weight.

CORRECTLY USED PARTOGRAPH (the composite partograph, which is applied in Zanzibar)

**When to use the partograph**

The partograph must be used for ALL women in labour, and also in second stage.

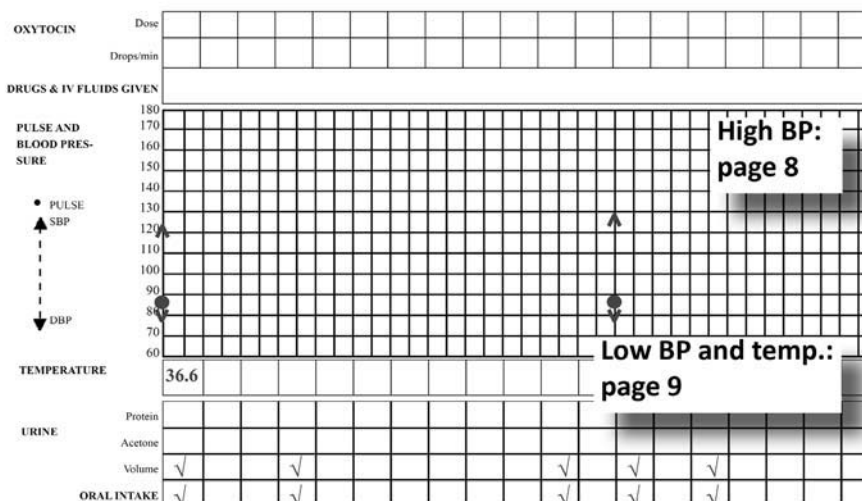
First recording in active phase

Active phase of labour starts when cervix is dilated 4-5 cm AND regular painful contractions.

If the woman is admitted in active phase, start by plotting cervical dilatation on the Alert line. Only use the latent area of the partograph if the woman is admitted in latent phase.

When to re-assess

Please see routine assessments during latent and active phase of labour on page 3.

**3 diagnostic questions**

Each assessment of a woman in labour requires analysis of the partograph as a whole by:

1. Is mother in a good condition?
2. Is baby in a good condition?
3. Is progress as expected?

Actions needed

On pages 5-9, partograph decision-support is presented.

⚠ In all cases of uncertainty, consult senior colleagues AND obstetric text books

PartoMa COLOUR CODES

- UNCOMPLICATED** Routine assessments and supportive care
- WARNING** Attention and treatment
- DANGER** IMMEDIATE ACTION!

PartoMa SYMBOLS

- ⚠ This exclamation mark means special attention
- * This asterisk indicates that there is more information further down on the same page in a grey field

FOR UNCOMPLICATED BIRTH:

ON ADMISSION

History: Obstetric risks in previous or present pregnancy/childbirth? For example:

- Vaginal bleeding (APH or PPH, page 14-15)
- Previous CS (trial of scar, page 13)
- Maternal age and parity
Parity 5 or more has increased risk of complications (low Apgar score, placenta praevia, uterine rupture)
- Twin pregnancy (page 11)
- Maternal illness
For example hypertension (page 8), obesity, anaemia, diabetes, HIV
- Concerns for the baby
For example preterm labour, meconium (page 5) PROM (page 6), breech (page 10)

Assess: FHR, Pulse, BP, Temp, Contractions, Lie, Presentation, Descent, PV

Start partograph for all women in labour (page 2)

⚠ *When preterm birth is expected, it is unclear whether corticosteroids do more harm than good in low resource settings*

LATENT PHASE

Regular painful contractions, cervix less than 4-5 cm

Every 4 hrs AND when changes occur:

(for example SRM or increasing contractions)

FHR, Pulse, BP, Abdominal exam (*lie, presentation*), contractions, PV

⚠ *WHO guidelines (2018) recommend not to start active phase before 5 cm cervical dilatation*

FIRST STAGE, ACTIVE PHASE

Cervix 4-9 cm AND regular painful contractions

Every ½ hr (every 1 hr as a minimum): FHR

Every 2 hrs: Urine output (*spontaneously is best*)

Every 4 hrs: Contractions, PV, Pulse, BP

SECOND STAGE, ACTIVE PHASE

Cervix fully dilated (10 cm)

Monitor FHR closely:

Before pushing: Every 15 min

When pushing: After every contraction

Contractions, PV: Every ½ hr

Pulse, BP: Assess if 4 hrs since last assessment

⚠ *Empty bladder before pushing (spontaneous is best)*

FOETAL HEART RATE (FHR)

Auscultate with Doppler ultrasound or Pinard foetal stethoscope at the end of a contraction for 1 min.

⚠ *Confirm that it is FHR, and not maternal pulse*

⚠ *In second stage of labour, always have delivery set and ambu bag ready (page 16)*

PER VAGINAL EXAMINATION (PV)

⚠ *No PV if abnormal vaginal bleeding and position of the placenta is unknown (page 14)*

What to assess:

1. Cervical dilatation
Do not stretch cervix more open than it is
2. State of cervix
Effacement, thin/thick, rigid/soft, oedematous
3. State of membranes (*intact or ruptured*)
4. Descent of presenting part
Vaginally in relation to ischial spines (station 0) (descent can also be assessed abdominally, in fifths of head palpable above brim)
5. Presentation and position
6. If membranes have ruptured, assess:
Colour of liquor, moulding and caput

CONTRACTIONS

Contractions are assessed prior to every vaginal examination, by palpating the abdomen for 10 min and carefully registering frequency and duration of each uterine tightening.

Strong contractions: 3-5 contractions per 10 min, each lasting more than 40 sec

BLOOD PRESSURE (BP)

Assess BP every 4 hrs during labour.

Woman should sit upright for BP assessment, no crossed legs.

No physical activity for 5 min prior to BP.

Measure twice:

- If readings no more than 5 mmHg apart, accept measure
- If readings more than 5 mmHg apart, repeat until 2 readings are within 5 mmHg from each other

If abnormal BP, see pages 8 and 9.

FOR UNCOMPLICATED BIRTH:

AFTER BIRTH OF BABY

- Mother: **Active management of third stage**
(*IM Oxytocin 10 units, controlled cord traction, uterine massage*)
- Baby: **Not crying or not breathing?** (*page 16*)
Apgar score* (*after 1 min and 5 min*)
Cord clamping (*if baby is well, delay 2 min*)
Skin-to-skin with mother (*for at least 1 hr*)
Breastfeeding (*should start within 1 hr*)

AFTER DELIVERY OF PLACENTA

- Mother: **Vaginal bleeding above 500 ml?** (*page 15*)
Perineal/genital trauma? (*rectal exam*)
Placenta and membranes complete?

1 HR AFTER BIRTH

- Baby: **Head-to-toe examination**
Exclude malformations (*for instance cleft palate, spina bifida, anorectal malformation*)
IM Vitamin K 1 mg
(*if weight less than 1500g, give 0.5 mg*)

EVERY 30 MIN IN THE FIRST 2 HRS AFTER BIRTH

- Mother: **General condition**
Pulse, BP
Uterus firmly contracted? (*fundal height*)
Vaginal blood loss (PPH, page 15)
Bladder full? (*encourage urination*)
- Baby: **Breathing, colour and temperature,**
Cord bleeding?
(*teach mother to also observe*)

BEFORE DISCHARGE

- Mother: **Pulse, BP**
Vaginal discharge (blood loss and lochia)
Ensure urination
Give instructions**
- Baby: **General condition**
Birth weight
Assure good breastfeeding
- ⚠ **Keep baby skin-to-skin on mother's chest as much as possible. Mother and baby should not be separated if at all possible**

*APGAR SCORE

	0	1	2
Appearance	Blue/pale all over	Blue/pale limbs and pink body	Pink body and limbs
Pulse (bpm)	Absent	less than 100	100 or more
Grimace	No response to stimulation	Grimace when stimulated	Cry when stimulated
Activity	None	Some flexion	All limbs flexed
Respiration	Absent	Weak	Strong

⚠ **5 min Apgar score less than 7 indicates asphyxia and the baby needs close monitoring**

** INSTRUCTIONS TO MOTHER

1. Danger signs for mother

- severe bleeding
- fever
- severe pain
- difficult or fast breathing

2. Danger signs for baby

- inactivity
- not feeding
- difficult or fast breathing

3. Advice on breastfeeding

4. Advice on good hygiene for mother and baby

5. Family planning

FOETAL HEART RATE (FHR)

⚠ *Pushing is the most dangerous time for baby:
FHR at the end of each contraction*

FHR bpm	Abnormal FHR (<i>continuous FHR more than 180 bpm</i>) Suspect foetal distress and/or maternal infection: Pulse, BP, Temp (<i>fever: page 9</i>) Intrauterine resuscitation*, FHR every 15 min If no improvement after 1 hr: Immediate delivery by vacuum extraction (<i>page 12</i>) or CS (<i>page 13</i>)
180	
170	Non-reassuring FHR (<i>continuous FHR 161-180 bpm</i>) Assess Pulse, BP, Temp Intrauterine resuscitation* FHR every 15 min
160	
150	Normal FHR (<i>FHR 110-160 bpm</i>) First stage of active labour: FHR every 30 min Second stage: FHR every 15 min when descending to pelvic floor FHR at the end of every contraction when pushing
140	
130	
120	
110	
100	Non-reassuring FHR (<i>FHR 100-109 bpm</i>) Intrauterine resuscitation* FHR every 15 min
90	Foetal distress (<i>FHR less than 100 bpm</i>) Intrauterine resuscitation*
80	After 5 min: If FHR still below 100 bpm: Immediate delivery by vacuum extraction or CS (<i>pages 12-13</i>) If FHR not heard, quickly confirm absent FHR**
70	

LIQUOR (amniotic fluid)

Clear (C)

Reassuring.
No specific actions to be taken.

Meconium (M)

Can be a sign of foetal distress:
- Assess FHR every 15-30 min
⚠ *At delivery with meconium:
Immediate suction of mouth and
nose if signs of obstruction or
weak baby. Do not suction if baby
is nicely crying or breathing*

Vaginal bleeding (B)

See page 14.
⚠ *No PV before placenta praevia
is ruled out (by ultrasound, or in
theatre ready for CS)*

*** INTRAUTERINE RESUSCITATION**

- Woman on left side
(*if no improvement, then right side*)
- Stop oxytocin if administered
- Assess Pulse, BP, FHR, PV, Temp
- ⚠ *Always ensure that it is FHR
and not maternal pulse, by
checking FHR and maternal
radial pulse at the same time*

**** FHR NOT HEARD****Confirmation of absent FHR:**

Ask colleague to reassess FHR (*with Doppler*) and perform ultrasound

If confirmed intrauterine foetal death, plan for vaginal birth:

- Induce (*page 6*) or augment (*page 7*) labour if necessary
- Craniotomy (*if obstructed labour and cervix fully dilated*)
- Observe for signs of infection and treat (*page 9*)
- Provide emotional support (*page 1*)
- ⚠ *CS after foetal death is dangerous for the mother, and must only be
performed as last option, or if severe maternal compromise (for example
uterine rupture, page 14)*

LATENT PHASE OF LABOUR

(Cervix less than 4-5 cm, painful uterine contractions and variable changes of the cervix)

Latent phase less than 12 hrs

Assess every 4 hrs if admitted (page 3)

Signs of infection? (page 9)

Rupture of membranes, PROM (speculum exam)?*

Need for pain relief? (page 1)

Latent phase more than 12 hrs

Check for urinary tract infection (dipstick)

If poor progress in latent phase, consider either rest with pain relief (page 1) or induction of labour**

⚠ Prolonged latent phase is often confused with false labour where contractions cease after a while.

* PRE-LABOUR RUPTURE OF MEMBRANES (PROM) ⚠ Limit PVs due to risk of infection. If FEVER, see page 9

37 weeks gestation or more:PROM less than 18 hrs in total:

Routine assessments and supportive care in hospital

PROM more than 18 hrs in total:

Start antibiotics, for example (if not allergic):

Oral Erythromycin 250mg every 6 hrs for 10 days (or until birth)

Plan for delivery within 12 hrs

Induce** or augment (page 7) if necessary

Less than 37 weeks gestation: (Preterm PROM)

Start antibiotics, for instance (if not allergic):

Oral Erythromycin 250 mg 4 times a day for maximum 10 days or until active labour

Expectant management in hospital, with close observation. Induce labour at 37 weeks gestation

Induce immediately if high risk, for instance severe hypertension (page 8) or fever (page 9).

** INDUCTION OF LABOUR (artificial stimulation of the uterus to start labour)

Indication:

Delivery needed soon.

For example due to PROM (page 6), Intrauterine foetal death (page 5), Abruptio placenta (page 14), Severe pre-eclampsia (page 8), fever (page 9)

⚠ Always keep mother ready for CS during induction

Examine cervix and calculate the score:

Cervix:	0	1	2	3
Dilatation (cm)	Closed	1-2	3-4	5 or more
Length (cm)	5 or more	3-4	1-2	Less than 1
Consistency	Firm	Average	Soft	Effaced
Position	Posterior	Mid	Anterior	Effaced

Score 5 or less (cervix unfavourable):

Induce by Misoprostol OR Balloon and Oxytocin

Score 6 or more (latent phase in progress):

ARM if possible and Oxytocin (page 7)

⚠ If previous CS (page 13) or parity 5 or more, do **not** use misoprostol⚠ If history of bleeding OR PROM OR obvious vaginal infection, do **not** use Balloon catheter**MISOPROSTOL****Dose:** Tabl. Misoprostol 25 microgram ORAL

(dissolve one 200 microgram tablet in 200 ml of water and administer 25 ml of that solution as a single dose)

⚠ Fat-free diet. Otherwise no effect.

Every 1 hr: FHR and contractions**After 2 hrs:** PV and repeat Misoprostol if required:

If score 5 or less: Repeat Misoprostol

If score 6 or more OR membranes ruptured:

Stop Misoprostol and consider Oxytocin (page 7)

After 12 hrs: If no progress and delivery needed fast, consider CS. Otherwise, repeat Misoprostol regimen for 12 hrs (immediately or the following day)**BALLOON AND OXYTOCIN****1. Balloon catheter (or foley catheter):**

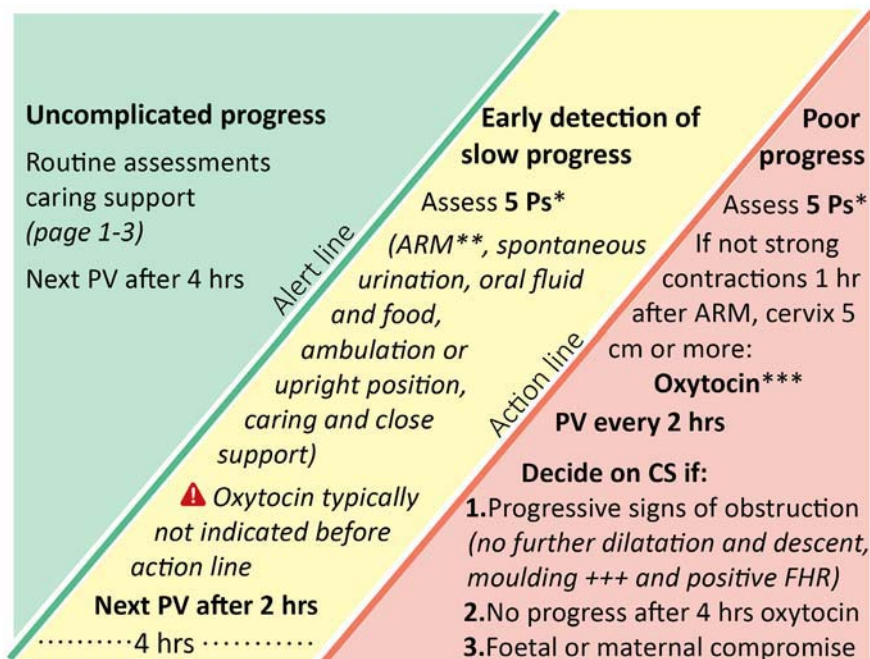
- Gently introduce balloon catheter through cervix (inflatable bulb must be beyond internal cervical os)
- Inflate bulb with 30–50 mL of water
- Leave catheter in place for 12-24 hrs or until contractions begin or membranes rupture

2. When catheter is removed or falls out:

ARM and start oxytocin (page 7)

ACTIVE FIRST STAGE OF LABOUR

(Cervix 4-5 cm or more AND regular painful contractions)



⚠ WHO (2018) recommends not to start active phase before 5 cm

SECOND STAGE OF LABOUR

(Cervix fully dilated)

Duration less than 1 hr AND Pushing less than 30 minCaring and continuous support
ARM if membranes still intact**

⚠ Never leave woman alone and monitor FHR closely (page 5)

Duration 1-2 hrs OR Pushing 30-60 min

Exclude malposition

If presenting part not visible at vulva, consider 5 Ps* and oxytocin augmentation***

PV every 15-30 min

Duration more than 2 hrs OR Pushing more than 1 hr

⚠ For nulliparous, normal second stage can last up to 3 hrs

Vacuum extraction if possible (page 12). CS as last resort.

*** 5 Ps - why poor progress?****Power:**

If less than 4 strong contractions per 10 min, enhance labour:

- ARM**
- Oral fluid and food intake
- Ambulation, upright position
- Oxytocin augmentation***

Passenger:

- Malposition or malpresentation?
- Foetal weight (large baby?)

Pass urine:

- Encourage spontaneous emptying every 2 hrs
- Catheterize as last resort

Psyche:

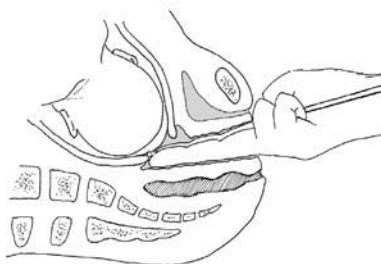
- Reduce anxiety (page 1)

Pelvis:

- Severely contracted pelvis?

**** ARM**

1. Foetal head engaged in pelvis?
2. On back, legs bent, feet together, knees apart
3. Place two fingers against membranes and GENTLY rupture membranes with clamp



4. After rupture, fingers remain in place (umbilical cord prolapse?)
5. Remove fingers slowly, note colour of liquor (page 5)
6. FHR after contraction

⚠ If HIV positive, wait till action line is crossed or cervix 7 cm dilated

***** OXYTOCIN AUGMENTATION****Indications:** No previous scar, and less than 4 contractions per 10 min, each lasting less than 40 sec.**Latent phase:** 12 hrs or more OR induction (page 6)**Active first stage:** Action line crossed, cervix 5 cm or more, membranes ruptured for 1 hr**Second stage:** 1 hr or more OR pushing 30 min or more**Start dose:** IV Oxytocin 2.5 units in 500 ml Normal Saline or Ringer's Lactate, 10 drops per min**Every 15 min:** FHR, contractions, Oxytocin drops per min**Every 30 min:** Increase by 5-10 drops per min until 4 contractions in 10 min, each lasting more than 40 sec. Maintain this rate until delivery. Maximum 60 drops/min.**Stop Oxytocin:** If more than 5 contractions in 10 min

HYPERTENSION AND PRE-ECLAMPSIA / ECLAMPSIA

⚠️ Guidelines only involve treatment during childbirth

↑ Systolic BP 160 or more and/or ↓ Diastolic BP 110 or more (mmHg)	SEVERE Hypertension / Pre-eclampsia*: Medication (SLOWLY) (use specific treatment sheet): Antihypertensive** AND Anticonvulsant*** Strict fluid balance: - Catheterize bladder (<i>fluid intake-output, proteinuria</i>) - Urine output less than 30mL/hr: Stop Magnesium Sulphate. Start IV Ringer's Lactate 1L in 8 hrs - Be careful with IV fluid (<i>risk of pulmonary oedema</i>) Plan for delivery within 12-24 hrs of admission: - Vaginal delivery is preferable. Induce (<i>page 6</i>) or augment (<i>page 7</i>) if necessary Assess every 30 min (use specific observation sheet): - Pulse, BP, RR, Temp, FHR, GCS, signs of organ failure or Magnesium Sulphate toxicity (<i>assess lungs, urine output, urine dipstick, patellar reflexes</i>)	Convulsions (eclampsia): ⚠️ Convulsions are always treated as eclampsia until other diagnosis is confirmed 1. CALL FOR HELP 2. Airway and Breathing 3. Position on left side and protect from injuries 4. Insert IV lines 5. Magnesium Sulphate SLOWLY** 6. Oxygen if available (mask or nasal) ← Additional management as for severe hypertensive disorders
↑ Systolic BP 140-159 and/or ↓ Diastolic BP 90-109 (mmHg)	MILD-MODERATE Hypertension / Pre-eclampsia*: Ask and observe for symptoms of organ failure* Assess lungs, urine output, proteinuria, patellar reflexes Reassess Pulse and BP every hr FHR every 30 min	

* DIAGNOSING PRE-ECLAMPSIA

MILD-MODERATE pre-eclampsia:

Hypertension on 2 consecutive readings **AND** Proteinuria 2+ or more (*dipstick*)

SEVERE pre-eclampsia:

Pre-eclampsia **AND**

Severe hypertension **OR** Symptoms of organ failure:

Persistent severe headache, Blurred vision,
Persistent upper abdominal pain, Low urine production (*less than 30 ml/hr*), Breathlessness

** ANTIHYPERTENSIVE

HYDRALAZINE:

Dose: IV 5 mg bolus **SLOWLY** over 10 min

Repeat: IV 5 mg bolus every 20 min until SBP less than 160 mmHg

Maximum dose: 20 mg per 24 hrs

If this regimen fails to control BP, consider sublingual nifedipine, IV labetalol or IV hydralazine infusion

⚠️ Diastolic BP should not fall below 80 mmHg

⚠️ Observe closely: Hydralazine may cause low BP and foetal distress

*** ANTICONVULSANT

MAGNESIUM SULPHATE (50% solution):**Loading dose**

IV 4 g in 200 mL Normal Saline **SLOWLY** over 10 min
In each buttock: IM 5 g **AND** 1 mL 2% Lignocaine in same syringe

Maintenance dose:

IM 5g **AND** 1mL 2% Lignocaine every 4 hrs, alternate buttocks

Duration: Continue dose for 24 HRS AFTER BIRTH OR LAST CONVULSION, whichever occurs last

If convulsions while on maintenance dose:

IV 2 g in 100 mL Normal Saline **SLOWLY** over 10 min

Check for signs of toxicity before each dose:

- Patellar reflexes diminished or absent
- RR less than 12 breaths per min

⚠️ Urinary output less than 30 ml per hr increases risk of Magnesium Sulphate toxicity

In case of toxicity: Stop Magnesium Sulphate.

If RR less than 12 breaths per min:

IV Calcium Gluconate 1 gram (10 ml of 10% solution) over 3 min (immediately if heart arrest). Bag-mask ventilation if necessary.

LOW BP OR LOW/HIGH PULSE RATE

↑ Systolic BP less than 100 mmHg ↓ or ● Pulse more than 110 bpm or ● Pulse less than 60 bpm	Immediate danger signs: - Systolic BP less than 90 mmHg (<i>SHOCK</i>) - Unconscious <i>Convulsions</i> (page 8), severe bleeding (pages 14-15), sepsis* - Cardiac arrest: START CARDIAC MASSAGE VENTILATION (consider perimortem CS) Stabilizing care (<u>A</u>irways, <u>B</u>reathing, <u>C</u>irculation) Stop bleeding if any Oxygen if available (by mask or nasal cannulae) Elevate legs Vital signs every 15 min: Pulse, BP, RR, temp, vaginal blood loss, FHR, urine output Collect blood: Haemoglobin, blood group, cross-match and clotting-test 2 IV lines (<i>wide bore cannula</i>): IV Normal Saline or Ringer's Lactate 2L in 20-40 min Catheterize bladder (<i>fluid intake-output</i>) Find and manage cause: <table border="0"> <tr> <td>1. Bleeding (<i>APH or PPH: page 14-15</i>)</td><td>4. Trauma</td></tr> <tr> <td>2. Magnesium Sulphate toxicity (<i>page 8</i>)</td><td>5. Cardiac</td></tr> <tr> <td>3. Sepsis*</td><td>6. Other</td></tr> </table>	1. Bleeding (<i>APH or PPH: page 14-15</i>)	4. Trauma	2. Magnesium Sulphate toxicity (<i>page 8</i>)	5. Cardiac	3. Sepsis*	6. Other
1. Bleeding (<i>APH or PPH: page 14-15</i>)	4. Trauma						
2. Magnesium Sulphate toxicity (<i>page 8</i>)	5. Cardiac						
3. Sepsis*	6. Other						
● Pulse 100-110 bpm or FHR more than 160 bpm	Consider maternal infection OR dehydration OR bleeding? - Pulse, BP, RR, Temp, FHR every 15-30 min - PV (<i>blood loss, foul smelling vaginal discharge</i>) - Uterine pain? - Sufficient fluid intake?						

HIGH TEMPERATURE DURING CHILDBIRTH (fever)

Temp 38°C or more ⚠ <i>Chorioamnionitis causes risk of neonatal sepsis and maternal death</i>	Start broad spectrum intravenous antibiotics until delivery, for instance (<i>if not allergic</i>): IV Ampicillin 2g every 6 hrs AND IV Gentamicin 5 mg per kg once daily Tablet Paracetamol 1 gram every 6 hrs Pulse, BP, RR, FHR every 15-30 min. Temp hourly Consider diagnosis and order relevant tests: (<i>adjust treatment accordingly</i>) For example: Foul-smelling watery discharge, uterine tenderness (<i>chorioamnionitis</i>), Urinary dipstick testing (<i>UTI</i>), Flank pain (<i>Acute pyelonephritis</i>), Auscultation of lungs (<i>Pneumonia</i>), Malaria, Sepsis* Plan for delivery within 12 hrs: Induce (<i>page 6</i>) or augment (<i>page 7</i>) if necessary Observation of the baby for 24 hrs after birth: Feeding, pulse, RR and temp
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* MATERNAL SEPSIS ⚠ Call for HELP and consider referral to the Intensive Care Unit

Symptoms:	Slurred speech or confusion, Extreme shivering or muscle pain (fever), Passing NO urine all day, Severe breathlessness, It feels like you are going to die, Skin mottled or discolored
Management:	- Stabilizing care: <u>A</u>irways (<i>oxygen</i>), <u>B</u>reathing, <u>C</u>irculation - IMMEDIATE identification of the cause (<i>remember blood cultures</i>) - IMMEDIATE treatment of infection (<i>broad spectrum IV antibiotics</i>) - IV lines (<i>wide bore cannula</i>): IV Normal Saline or Ringer's Lactate 2L in 20-40 min - Every 15 min: Pulse, BP, RR, FHR - Strict fluid balance (<i>urine output</i>) - Assess lactate

⚠ *The following obstetric manoeuvres need hands-on training with supervision. These notes cannot replace that.*

VAGINAL BREECH DELIVERY

Recommendable if:

- Previous vaginal delivery **AND**
- No previous caesarean section **AND**
- No footling breech **AND**
- Estimated birthweight below 4 kilogram **AND**
- A health provider experienced with the procedure present

Management of first stage of labour:

Routine management as for cephalic presentation (page 3), but FHR every 30 min.

Avoid Oxytocin augmentation in first stage of labour. If action line is crossed (page 7), decide on CS.

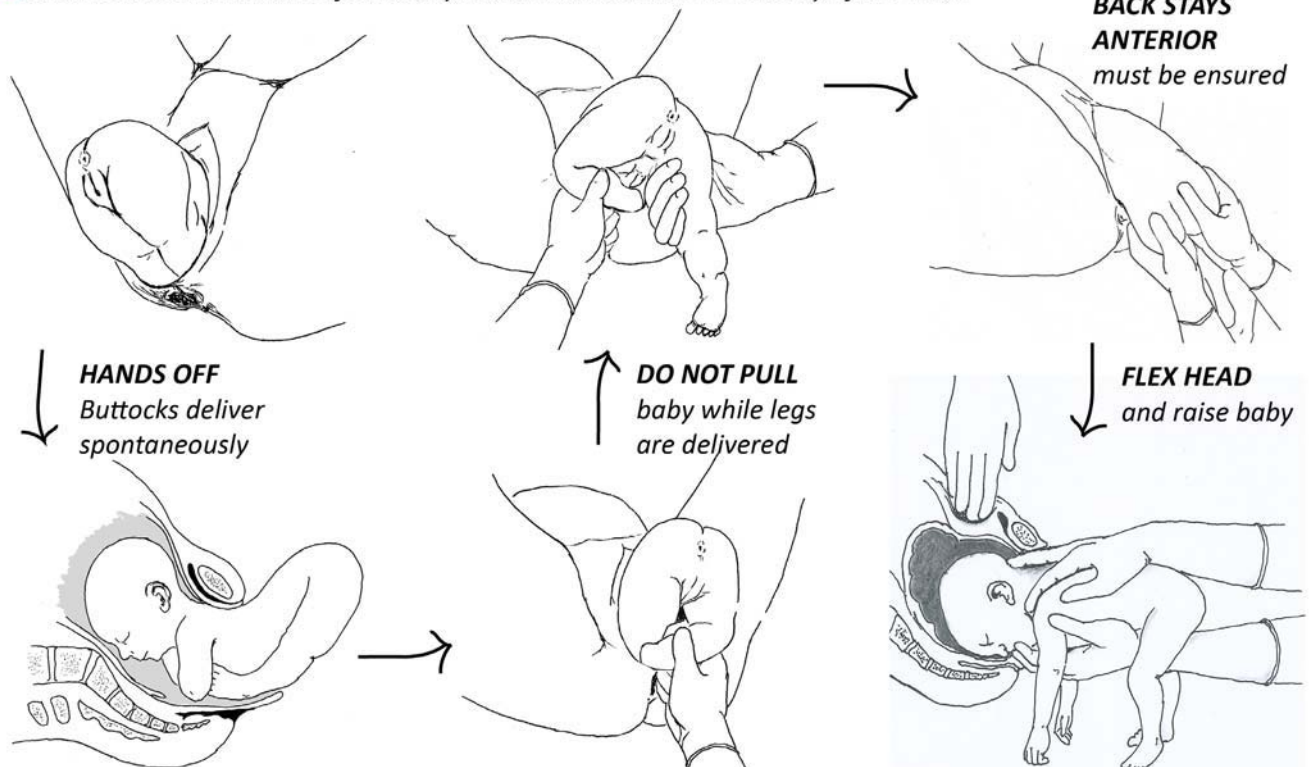
Management of second stage of labour:*

⚠ *Maximum 2 hrs duration of second stage*

1. **Oxytocin augmentation should be ready** if contractions not strong in second stage (page 7)
2. **Buttocks deliver spontaneously**
3. If legs not delivered spontaneously, deliver one leg at a time: Push behind knee to bend leg, grasp ankle, deliver foot and leg.
4. **Hold baby by the hips** with thumbs along spine. Do not pull. No pressing on abdomen.
5. **Allow arms to disengage spontaneously** one by one. After first arm, lift baby's belly towards mother's belly to enable second arm to deliver.
6. **Let the head descend to pelvic floor for maximum 30 seconds** before assisting delivery of the head.
7. **Deliver head:** Lay baby's face down with length of its body over your hand and arm. Place fingers on baby's cheekbones to **flex head**. Fingers of the other hand help to flex head from the occiput. Raise baby, until mouth and nose are free.

* VAGINAL BREECH DELIVERY - OBSTETRIC MANEUVERS

⚠ *Maximum 3 min duration from baby's umbilicus is visible to delivery of the head*



⚠ The following obstetric manoeuvres need hands-on training with supervision. These notes cannot replace that.

DELIVERY OF SECOND TWIN

Immediately after first baby is born:

- Palpate abdomen to determine lie
- Correct to longitudinal lie by hands on abdomen (assistant holds baby in position until delivery)
- Check FHR

PV:

- Cord prolapsed?
- Membranes ruptured?
- Presentation?

Leave clamp on mother's end of umbilical cord

⚠ Do not deliver placenta until last baby is born

Oxytocin infusion should be ready for augmentation if contractions are not strong (page 7)

If breech, Vaginal breech delivery (page 10)

ARM if membranes are intact and baby well engaged (page 7)

FHR at the end of each contraction

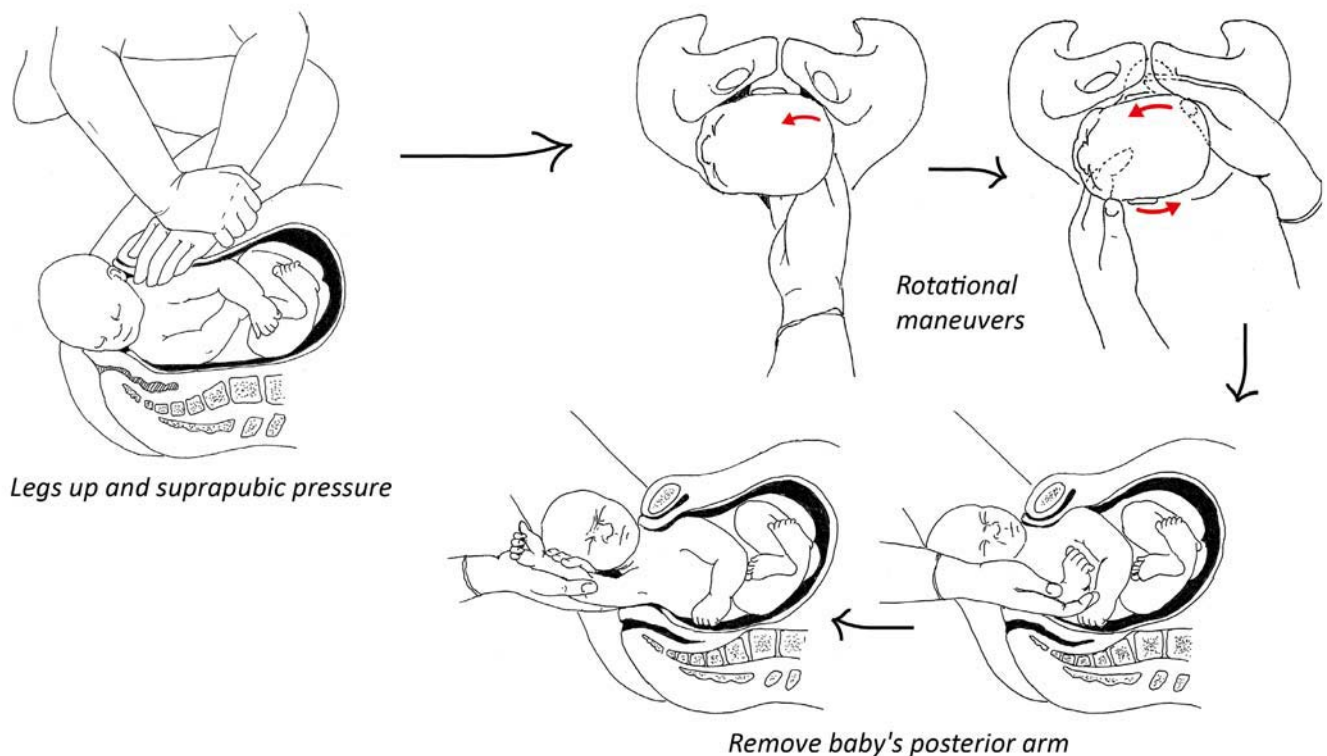
⚠ **If immediate delivery needed:** Internal podalic version with breech delivery, or vacuum extraction. CS is last option and should be done IMMEDIATELY

SHOULDER DYSTOCIA (HELPERR mnemonic)

- H** Call for HELP! Always at least **3 health providers**
- E** Evaluate if episiotomy is needed
- L** Legs up* (McRoberts: 2 people push flexed knees firmly onto chest by flexion of hips)
- P** Suprapubic Pressure* downwards to assist delivery of baby's shoulder
- E** Enter vagina and do rotational maneuvers*:
 - apply pressure to baby's anterior shoulder in direction of sternum
 - if not working, apply pressure to baby's posterior shoulder in direction of sternum
- R** Remove the baby's posterior arm*
 - grasp arm at humerus, keep arm flexed at elbow and sweep arm across baby's chest
- R** Roll patient to her hands and knees and repeat E and R

⚠ Do not apply fundal pressure. This will further impact the shoulder

* SHOULDER DYSTOCIA - OBSTETRIC MANEUVERS



VACUUM EXTRACTION

Most important indications:Foetal distress in second stage of labour (*page 5*)Poor progress in second stage of labour (*page 7*)

Maternal exhaustion

⚠ *If the procedure is not possible or fails, CS should be performed IMMEDIATELY*

Required beforehand:

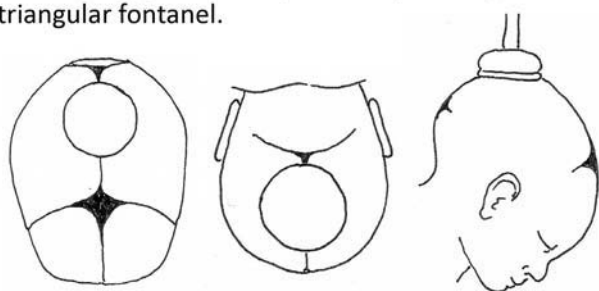
1. Cervix fully dilated
2. Vertex presentation, membranes ruptured
3. Foetal head at or below ischial spines (PV: stations 0, +1, +2, +3. Abdominal: levels 2/5, 1/5, 0/5)
4. Gestational age 34 weeks or more
5. Birth attendant trained in vacuum extraction

The A-J approach to vacuum extraction:

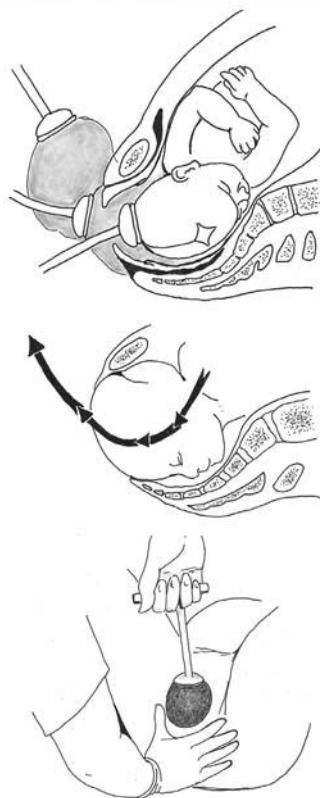
- A** Ask for help
Address the patient
(inform that you need patient to cooperate and keep pushing when there is contraction)
Abdominal Palpation (*descent of head*)
- B** Bladder is empty?
- C** Cervix must be fully dilated
Contractions are needed (*Oxytocin needed? Page 7*)
- D** Determine position of the head assess **D**escent
(locate the posterior triangular fontanel)
- E** Equipment ready?
(delivery tray, towels, neonatal resuscitator, vacuum extractor)
- F** Flexion point* must be located
Feel for vaginal tissue between cup and foetal skull to avoid perineal trauma (*before and after suction*)
- G** Gentle, steady traction during contractions**
- H** HALT traction between contractions
HALT and STOP if: - 3 pop-offs
 - 3 pulls with no progress
 - After 20 min of use
- I** Intact perineum! Protect perineum with one hand when head is delivered.
 During last contraction: Hold back head with the other hand, and ask mother to push gently
- J** When reachable Jaw: Release vacuum, remove cup

*** FLEXION POINT**

Place the edge of the cup at the tip of the posterior triangular fontanel.



⚠ *To avoid vaginal and perineal trauma, and minor trauma to the head of the baby: Feel for vaginal tissue between cup and foetal skull, and protect perineum*

**** TRACTION**

Axis for traction changes according to the pelvic curve.

⚠ *Gentle, steady traction during contractions. No rocking pulls*

For first contractions downward traction. During following contractions more upward.

One hand protects perineum while completing delivery. During last contraction, ask mother to push gently and hold back head with other hand.

DECIDING ON EMERGENCY CS - a few notes

Most common indications for CS

- Foetal distress (*see specific criteria on page 5*)
- Prolonged labour (*see specific criteria on page 7*)
- 2 or more previous CSs

In second stage of labour

Vacuum extraction should always be considered before deciding on CS (*page 12*).

Contraindications for CS

If the woman is medically unstable (*for example severe hypertension*), the maternal condition is stabilized first, and delivery considered only for obstetric indications.

CS after foetal death is generally unnecessary and dangerous for the mother, and must only be performed as last option, or if severe maternal compromise.

⚠ *Check FHR just before starting surgery, and reconsider CS's indication if foetal death*

Maximum time from decision to delivery by CS

If foetal or maternal compromise:
30 minutes

(for example foetal distress, cord prolapse with pulsating cord, severe bleeding)



If no maternal or foetal compromise, but early delivery is needed:
75 minutes

(for example poor progress of labour, 2 or more previous CSs, placenta previa without heavy bleeding)

VAGINAL BIRTH AFTER CS (trial of scar)

Plan for vaginal birth when

Only 1 previous low segment CS **AND**
no previous uterine rupture **AND**
current pregnancy singleton, cephalic presentation

⚠ *FHR abnormalities might be the first sign of impending uterine scar rupture (*page 5*)*

Special management

Due to risk of scar rupture:

- 2 IV lines
- Urinary catheter
- FHR every 15-30 min throughout active labour
- Follow labour progress closely
- Do **not** use Misoprostol or Oxytocin

BLEEDING IN LATE PREGNANCY OR DURING CHILBIRTH ⚠️ APH also causes increased risk of PPH (page 15)

1. Check maternal vital signs: Pulse, BP, Temp

See page 9 if:

- Systolic BP less than 100 mmHg OR
- Pulse less than 60 bpm OR
- Pulse more than 110 bpm

2. Blood type, X-match and haemoglobin

3. Determine the cause and manage accordingly*

- Blood volume?
- (if heavy bleeding, see also page 9)
- Pain?
- FHR?
- Ultrasound to rule out placenta previa

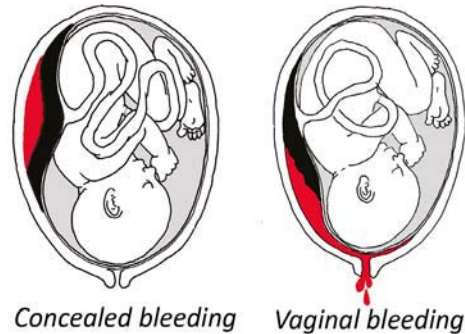
⚠️ No PV before placenta praevia is ruled out (by ultrasound or gentle speculum exam)

4. Measure blood loss and replace accordingly:

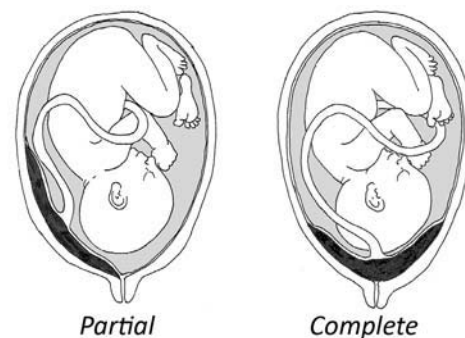
2-3 times estimated blood loss

⚠️ Early blood replacement saves lives

Abruptio placenta*



Placenta praevia*



*** MOST COMMON DANGEROUS CAUSES OF APH**

ABRUPTIO PLACENTA

(placenta separates too early)

Typical symptoms:

- Vaginal bleeding (might be hidden in uterus)
- Intermittent or constant abdominal pain
- Tender uterus
- Low/absent FHR

Heavy bleeding OR foetal distress:

DELIVER IMMEDIATELY

Vacuum extraction (page 12), otherwise CS.

Mild-moderate bleeding AND FHR normal:

Vaginal delivery within 12 hrs
FHR every 15-30 min
Induce (page 6) or augment (page 7) if necessary.

PLACENTA PRAEVIA

(placenta covers internal os of cervix)

Typical symptoms:

- Bleeding
- No pain
- Relaxed uterus
- Foetus not in pelvis
- Normal foetal condition

If 37 weeks gestation or more OR heavy bleeding:

DELIVER IMMEDIATELY

If internal cervical os not covered, consider vaginal delivery. Otherwise CS.

If premature AND mild bleeding AND normal FHR:

Expectant management, admitted in hospital with close observation

RUPTURED UTERUS

Typical early symptoms:

- Low/absent FHR
- High maternal pulse
- Blood in urine
- Tender abdomen
- Vaginal bleeding (might be in peritoneal cavity)

Typical late symptoms:

- Abdominal distension (free fluid)
- Abnormal shape of uterus
- Loss of station (foetal head goes up)
- Shock

Resuscitate and restore blood volume:

Crystalloids 2-3 litres fast

THEATRE IMMEDIATELY:

Laparotomy (uterine repair or hysterectomy)

BLEEDING AFTER BIRTH (*exceeding 500 ml, or less if severe anaemia*)

⚠ CALL for HELP! Always be at least 3 health providers

1 PERSON AT **UTERUS**:

- Rub-up contraction by **CONTINUAL UTERUS MASSAGE**
 - **Catheterise bladder** (*leave catheter in place*)
 - If uterus still atonic, apply **BIMANUAL COMPRESSION** or aortic compression.**
 - Review bleeding cause by **the 4 Ts***
 - **If bleeding continues:**
Transfer early to theater (*with bimanual or aortic compression*)**
- Examination under anesthesia:
suture tears, balloon tamponade,
laparotomy (*B-lynch' brace suture, hysterectomy*)

1 PERSON AT **HEAD**:

- Lie woman flat
- Check **airways and breathing**
- Give oxygen if available
- Talk to patient, reassure

1 PERSON AT **ARMS**:

- **2 IV lines** (*large bore cannula into each elbow pit*) and **X-match**
- **Order 6 units of whole blood**
- Start **IV-fluids** (2L Normal Saline or Ringer's Lactate)
- Give **3 drugs** at once to reverse atony (*not in sequence*):
IV Oxytocin 20 IU in 500 ml Normal Saline, 250 ml per hr
IV Tranexamic acid 1 gram slowly (*can be repeated after 30 min*)
Rectal Misoprostol 800 microgram
- Check **pulse, BP**
- **Blood transfusion** AND IV fluids if blood loss 1 L or more
- If still bleeding, and BP below 140/90 mmHg: **SLOW bolus of IV Ergometrine** 0.2 mg (*can be repeated after 15 min*)

* 4 Ts - WHY PPH?

TONE:

Atony of uterus is the most common cause

TISSUE:

Is placenta complete?

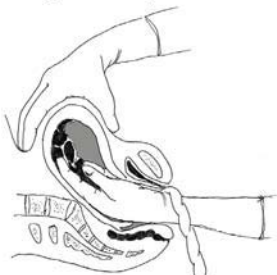
Always do intrauterine palpation if bleeding exceeds 1000 ml

TRAUMA:

Tears, episiotomy, ruptured uterus

THROMBIN:

Coagulation problems secondary to severe bleeding



Manual removal of placenta

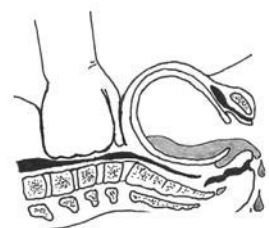
⚠ After bleeding stops:
24 hrs of close observation

** BIMANUAL AND AORTIC COMPRESSION

⚠ Keep compression until bleeding stops



Bimanual compression



Aortic compression



⚠ Palpate femoral pulse to assess effect of aortic compression: Femoral pulse must disappear

NEONATAL RESUSCITATION ⚠️ *Always have ambu bag ready before delivery*

CALL for HELP! Always be at least **2 health providers**

All newborns

- Dry and warmth

If baby not crying

- If obvious obstruction of airways: QUICKLY and gently clean or suction mouth and nose (*do not spend more than 10 sec on this*)
- Stimulate by rubbing the baby's back
- Is baby breathing?

If baby not breathing

- **START BAG-MASK VENTILATION IMMEDIATELY, WITHIN THE FIRST 1 MIN AFTER BIRTH ***

- If baby's heart rate is 60 bpm or more:
Continue ventilation until normal breathing
- If baby's heart rate is less than 60 bpm:
Give cycles of 1 EFFECTIVE breath for every 3 chest compressions. Reassess heart rate every 1-2 min

⚠️ THE GOLDEN MINUTE

The first 60 seconds of life is the most important for saving the baby
If not breathing, bag-mask ventilation must be started within the first minute



⚠️ *Only suction if obvious obstruction of airways. Suction should never delay bag-mask ventilation*

⚠️ *How is the mother? Mothers of asphyxiated babies are at increased risk of PPH (page 15)*

* BAG-MASK VENTILATION AND HEART RATE

⚠️ *Bag-mask ventilation needs hands-on training with supervision. These notes cannot replace that*

1 person ventilate:

- Remember to position the baby's neck for adequate airway
- 40 breaths per minute
- Use air, not ox



Position of the head is slightly extended to open airways. If too extended, airways will not be open.

1 person assess baby's heart rate:

- Palpate the umbilical stump or auscultate heart
- If heart rate is increasing, the bag-mask ventilation is working

** AFTER SUCCESSFULL RESUSCITATION

⚠️ *For all babies admitted to Neonatal Intensive Care Unit, a handover sheet should be filled in*

After successful resuscitation of an asphyxiated baby, the baby is at risk for hypothermia and hypoglycemia. Therefore:

1. Skin-to-skin with mother (page 4)

2. Assure good breastfeeding

If not, give cupfeeding
or insert nasogastric tube (NGT)



**Achievable guidance is a basic, fundamental right for
health workers having lives of others in their hands**

PartoMa

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Paper I

Stillbirths and quality of care during labour at the low resource referral hospital of Zanzibar: a case-control study

Maaløe N, Housseine N, Bygbjerg IC, Meguid T, Khamis RS, Mohamed AG, Nielsen BB, van Roosmalen J. BMC Pregnancy Childbirth. 2016;16(351).

Additional files 1 and 2 are available on the journal homepage.

RESEARCH ARTICLE

Open Access



Stillbirths and quality of care during labour at the low resource referral hospital of Zanzibar: a case-control study

Nanna Maaløe^{1*} , Natasha Housseine^{2,3}, Ib Christian Bygbjerg¹, Tarek Meguid^{2,4}, Rashid Saleh Khamis², Ali Gharib Mohamed², Birgitte Bruun Nielsen⁵ and Jos van Roosmalen⁶

Abstract

Background: To study determinants of stillbirths as indicators of quality of care during labour in an East African low resource referral hospital.

Methods: A criterion-based unmatched unblinded case-control study of singleton stillbirths with birthweight ≥ 2000 g ($n = 139$), compared to controls with birthweight ≥ 2000 g and Apgar score ≥ 7 ($n = 249$).

Results: The overall facility-based stillbirth rate was 59 per 1000 total births, of which 25 % was not reported in the hospital's registers. The majority of singletons had birthweight ≥ 2000 g ($n = 139$; 79 %), and foetal heart rate was present on admission in 72 (52 %) of these (intra-hospital stillbirths). Overall, poor quality of care during labour was the prevailing determinant of 71 (99 %) intra-hospital stillbirths, and median time from last foetal heart assessment till diagnosis of foetal death or delivery was 210 min. (interquartile range: 75–315 min.). Of intra-hospital stillbirths, 26 (36 %) received oxytocin augmentation (23 % among controls; odds ratio (OR) 1.86, 95 % confidential interval (CI) 1.06–3.27); 15 (58 %) on doubtful indication where either labour progress was normal or less dangerous interventions could have been effective, e.g. rupture of membranes. Substandard management of prolonged labour frequently led to unnecessary caesarean sections. The caesarean section rate among all stillbirths was 26 % (11 % among controls; OR 2.94, 95 % CI 1.68–5.14), and vacuum extraction was hardly ever done. Of women experiencing stillbirth, 27 (19 %) had severe hypertensive disorders (4 % among controls; OR 5.76, 95 % CI 2.70–12.31), but 18 (67 %) of these did not receive antihypertensives. An additional 33 (24 %) did not have blood pressure recorded during active labour. When compared to controls, stillbirths were characterized by longer admissions during labour. However, substandard care was prevalent in both cases and controls and caused potential risks for the entire population. Notably, women with foetal death on admission were in the biggest danger of neglect.

Conclusions: Intrapartum management of women experiencing stillbirth was a simple yet strong indicator of quality of care. Substandard care led to perinatal as well as maternal risks, which furthermore were related to unnecessary complex, time consuming, and costly interventions. Improvement of obstetric care is warranted to end preventable birth-related deaths and disabilities.

Trial registration: This is the baseline analysis of the PartoMa trial, which is registered on ClinicalTrials.org (NCT02318420, 4th November 2014).

Keywords: Tanzania, Low resource, Stillbirths, Labour, Quality of care, PartoMa, Caesarean section, Severe hypertensive disorders, Oxytocin, Criterion-based audit, Case-control study, Guidelines, Partograph

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Background

More than a quarter of a million women and 2.7 million newborn babies lose their lives during pregnancy and childbirth annually [1, 2]. Though often invisible in global estimates, an additional 2.6 million stillbirths add profoundly to the tragedy, of which half are estimated to occur during labour [3]. In all three groups, the vast majority of deaths are caused by largely avoidable obstetric complications with the highest risk at the time of birth [1–3]. Many more women continue to suffer from birth related injuries, infections, and disabilities, and an estimated one million survivors of birth asphyxia may end up with cerebral palsy, learning difficulties, or other disabilities [4, 5]. The world's highest burden of maternal and perinatal deaths and other birth-related complications remains in sub-Saharan Africa and Asia [1–3].

In the Millenium Development Goals' era, the global strategy mainly aimed at skilled birth attendance, which resulted in campaigns for women to deliver in health facilities. The increasing proportion of facility births, however, has not been matched with improvements in the quality of intra-facility labour care [6, 7]. Notably, reports from referral hospitals in sub-Saharan Africa suggest ample room for improvement even at the tertiary level of the health care sector [8–11]. Importantly, these are the facilities where most of the countries' future health care workers are trained, and if quality of care was improved, they could possibly be a lever for achieving nationwide health care improvements. Hence, in-depth insight into contextual challenges in delivering intrapartum quality of care is vital.

This paper is part of a baseline study for the PartoMa project, which aims at improving labour outcome for women and their offspring at the referral hospital of Zanzibar, Mnazi Mmoja Hospital. The project focuses on understanding direct and underlying determinants of substandard quality of care as well as strengthening monitoring and decision-making during labour [12]. We here present a case-control study of intrapartum management when the outcome was stillbirth. Although intrapartum stillbirths are considered a sensitive indicator of quality of care at the time of birth, there are few such studies from low income settings [3, 8, 11, 13, 14].

Methods

Setting

The Zanzibar archipelago, a semiautonomous part of Tanzania, struggles with poverty and a resource constraint health system. Half of the 1.3 million Zanzibarians live below the poverty line [15]. In 2011, the maternal mortality ratio was reported at 287 deaths per 100 000 live births, of which the majority occurs during or shortly after childbirth [16]. Though little is known about perinatal mortality,

estimates from 2010 suggest a rate of 50 perinatal deaths per 1000 total births, as opposed to 36 per 1000 in mainland Tanzania [17].

The governmental Mnazi Mmoja Hospital is the only tertiary care facility on the archipelago, and at the time of data collection, the only hospital on the biggest island providing comprehensive obstetric and neonatal care around the clock. In 2014, 13 291 women delivered in the hospital, corresponding with an average of 36 deliveries daily. Of these, 16 % were caesarean sections (CSs), and 44 maternal deaths were counted. According to the official registers, 41 babies were stillborn in 2014 per 1000 total births, and 17 neonatal deaths occurred up to discharge per 1000 live births.

The hospital plays a leading role in clinical training of future Tanzanian health care providers. Yearly, approximately 60 intern doctors do their initial clinical rotations at the department, and more than 200 Tanzanian nursing and medical students are trained.

Intrapartum care is located in two rooms only. In the labour room's 18 beds, women are assisted during the first stage of labour. Postpartum women needing extra surveillance stay in this room as well. When women reach the second stage of labour, they walk 15 m to the delivery room with only three beds. There is one, occasionally two, theatres available for obstetric surgery. For more than a decade, it has been the aim to apply the World Health Organization's (WHO's) composite partograph for all women in labour, which is a graphic monitoring sheet including foetal heart rate (FHR), labour progress, and maternal vital signs during latent and active phase of labour [18]. A treatment and observation sheet for severe hypertensive disorders has been available since June 2014 and includes evidence-based guidelines on anticonvulsant and antihypertensive treatment [19].

After uncomplicated delivery, the woman and baby are usually observed in the labour room for two hours before referral to the postnatal ward for another four hours where no routine observations are done. Babies with birth asphyxia, with birthweights <1500 gram (g), or delivered by CS are admitted to the Neonatal Intensive Care Unit, which is adjacent to the delivery room.

At day time, there are on average three nurse-midwives and two registrar doctors on duty in the labour and delivery rooms as well as a fluctuating number of intern doctors. During evenings and nights, there are two or three nurse-midwives on duty for all obstetric patients and one registrar doctor assisted by two interns are in charge of the entire department, which also includes an average of 30 gynaecological patients. A second doctor is on call from home. At the department, there are two specialist obstetricians, of which one is member of the study team (TM).

Study population

All stillbirths defined as late foetal deaths ≥ 1000 g [20] were identified between 1st October 2014 and 31st January 2015 in the admission, delivery, and theatre registers, and their case files were searched for. In addition, to give the best possible estimate of the actual hospital-based stillbirth rate, non-registered stillbirths were sought by systematically going through all case files from the four months. Due to a breakdown in the hospital's storage system of case files prior to October 2015, four months was the maximum feasible period for the study. The control group was identified in the same registers and from the same time period. The first control included in October 2014 was selected by throwing dices and afterwards every tenth delivery was identified, resulting in a case control ratio of approximately 1:4. These tasks were conducted by three research assistants (NH, RSK, and AGM), who had weekly meetings with TM or NM to assure quality of files retrieval.

Afterwards, all case files were checked individually by NM to determine whether the inclusion criteria were met for in-depth criterion-based audit (Fig. 1).

All singleton stillbirths were included for the audit and divided into three groups: birthweight 1000–1999 g (very preterm stillbirths) [21]; birthweight ≥ 2000 g without positive FHR on admission (pre-hospital stillbirths), and birthweight ≥ 2000 g with positive FHR on admission

(intra-hospital stillbirths). Hence, pre-hospital stillbirths included not only cases in which the stillbirth diagnosis was made on admission, but also cases where there was no documentation of FHR (neither present nor absent) during the admission. While deliveries from multiple gestations were included in the overall estimation of the stillbirth rate, they were not included in the further audit process as their case files were often too ambiguous; e.g. frequently only one FHR was registered throughout labour. The 2000 g cut-off was decided as this reflects gestational age of 32–34 weeks, where lung maturity no longer plays a major role in survival, and the newborn is less dependent on dexamethasone treatment prior to delivery as well as advanced intensive neonatal care [22]. Data on the very preterm stillbirths are only presented in Additional file 1.

Inclusion criteria for controls were singletons with birthweight ≥ 2000 g and Apgar score ≥ 7 ; hence a group with immediate good neonatal outcome. It varied whether one, five or 10 min (min.) Apgar scores were recorded. It was therefore decided to use the latest. The case-control study was unblinded.

Criteria of realistic best quality of care

Criteria reflecting locally best possible labour management with the available resources were formulated and

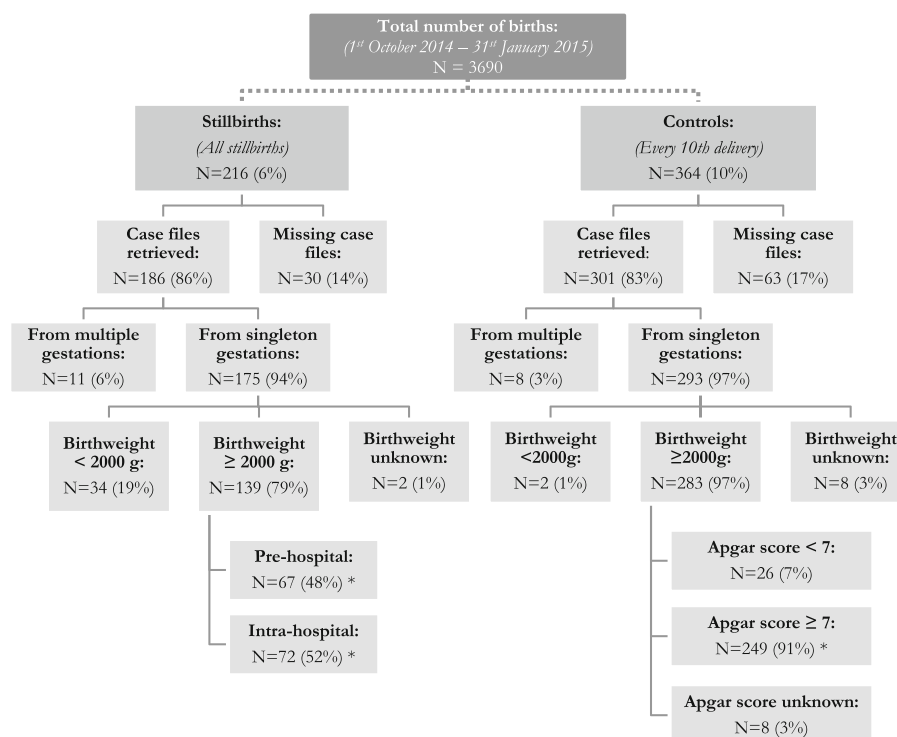


Fig. 1 Sampling of case files. Facility-based stillbirth rate was 59 per 1000 total births. Stillbirths: All late foetal deaths with birthweight ≥ 1000 g. Pre-hospital stillbirths: No documented positive foetal heart rate on admission. Intra-hospital stillbirths: Documented positive foetal heart rate on admission. *Groups compared by the case-control study

agreed upon. This developmental process was conducted by a participatory approach including both local skilled birth attendants and seven external specialists in midwifery and obstetrics. It was decided that the standards should include routine labour care as well as management of frequent complications of labour, related to FHR and foetal distress, labour progression by dilatation and descent, and maternal vital signs with specific focus on severe hypertensive disorders and fever. Selected criteria were adapted from the Active management of labour package, modified by WHO, and supplemented with other evidence-based guidelines [23–31]. Frequency of routine assessments was reduced to reflect local reality. For example, FHR assessments every 30 min. for all women in active labour were kept as optimal practice, but assessments within intervals of <90 min. were applied as an acceptable audit criterium.

In addition, information was collected on background and admission characteristics as well as outcome parameters. Finally, if information was available, time from last FHR assessment till delivery or diagnosis of intrauterine foetal death was calculated, as well as the admission to delivery interval.

Data extraction and analysis

Data was extracted into a structured entry form based on the pre-selected audit criteria, using EPI INFO 7 software (Centres for Disease Control and Prevention, Atlanta, GA, USA). Differences were analysed by logistic regression in SAS Enterprise Guide 6.1 (SAS Institute, Inc., Cary, NC). *P*-values <0.05 were considered statistically significant.

Results

During the four months studied, 216 stillbirths occurred out of 3690 total births. This corresponds to an overall hospital-based stillbirth rate of 59 per 1000 total births, of which 53/216 (25 %) were not reported in the hospital's official registers. Case files of 186/216 (86 %) stillbirths and 301/364 (83 %) controls could be retrieved, of which 175/186 (94 %) and 293/301 (97 %) were from singleton gestations. Of the singleton stillbirths, 139/175 (79 %) had a birthweight ≥ 2000 g and were included in the case-control study. Of these, 72/139 (52 %) had a positive foetal heart rate on admission (intra-hospital stillbirths), with only one having a congenital abnormality that may have been incompatible with life. Of the 67 pre-hospital stillbirths, 20/67 (30 %) had no documentation of FHR readings during the admission. Classification in 'fresh' and 'macerated' stillbirths was not recorded in 77/139 (55 %) stillbirths, and it was therefore not useful for determining the rate of intrapartum deaths. Of controls, 249 met the inclusion criteria (Fig. 1).

Background characteristics

Among intra-hospital stillbirths, 39/72 (54 %) were nulliparous versus 14/64 (22 %) pre-hospital stillbirths (odds ratio [OR] 4.22, 95 % confidence interval [CI] 1.99–8.96) and 105/239 (44 %) controls (OR 1.51, 95 % CI 0.89–2.56). All women, except one, had attended antenatal care at least once. Of women experiencing stillbirth, 69/119 (58 %) had attended at least four visits, versus 103/214 (48 %) controls (OR 1.49, 95 % CI 0.95–2.34). Cases with missing information are excluded from these comparisons (Table 1).

Of multiparous women experiencing stillbirth, 30/83 (36 %) had also previously experienced the loss of one or more children, compared to 30/134 (22 %) controls (OR 1.96, 95 % CI 1.07–3.59). A history of previous CS occurred in 19/83 (23 %) compared to 18/134 (13 %) controls (OR 1.91, 95 % CI 0.94–3.90; Table 1).

Of stillbirths, 35/135 (26 %) were delivered by CS, compared to 26/244 (11 %) controls (OR 2.94, 95 % CI 1.68–5.14). While 10/35 (26 %) of the CSs resulting in stillbirth were performed in the second stage of labour, this was never the case for controls. Only one baby was delivered by vacuum extraction. Of intra-hospital stillbirths delivered by CS, 10/20 (50 %) had FHR documented at the time of deciding on CS. In five of these ten women, FHR were absent. Foetal distress was recorded as an indication for CS in only one case. Indications for CSs resulting in stillbirth were: 21/35 (60 %) for prolonged labour, of which one was also due to foetal distress; 8/35 (23 %) due to antepartum haemorrhage, of which three had severe pre-eclampsia; an additional 2/35 (6 %) solely due to severe pre-eclampsia; 2/35 (6 %) due to cord prolapse; and 2/35 (6 %) due to ≥ 2 previous CSs. Concerning the prolonged labour group, 1/21 (5 %) had signs of obstructed labour on admission and another 6/21 (29 %) developed uterine rupture; half had signs of rupture on admission, of which two were referrals, and three ruptures occurred at the study site. Four of the women with uterine rupture had a history of previous CS (Table 2).

There were three maternal deaths in the study population. They were all associated with stillbirth and suffered from severe delays in intrahospital surveillance and management (Additional file 2).

Admission and partograph use

Women experiencing intra-hospital stillbirths were admitted particularly early; 42/71 (59 %) before the active phase of labour, compared to 68/246 (28 %) controls (OR 3.79, 95 % CI 2.19–6.57). Their median time from admission to delivery was 11 h and 36 min. (interquartile range (IQR): 5 h and 42 min. to 21 h and 55 min.). Rates of referrals were similar among pre- and intra-hospital stillbirths. The referral rate among stillbirths (21/139; 15 %) was higher than the

Table 1 Characteristics of delivering women

	Case-control study BW ≥ 2000 g		
	Cases Pre-hosp. Stillbirths N (%)	Cases Intra-hosp. Stillbirths	Controls Apgar 7–10 (n = 249)
<i>Of all women in the study:</i>	<i>(n = 67)</i>	<i>(n = 72)</i>	<i>(n = 249)</i>
Age			
<20 years	2 (3.0 %)	7 (9.7 %)	26 (10.4 %)
20–29 years	26 (38.8 %)	35 (48.6 %)	122 (49.0 %)
30–39 years	27 (40.3 %)	28 (38.9 %)	83 (33.3 %)
≥ 40 years	8 (11.9 %)	2 (2.8 %)	15 (6.0 %)
Information missing	4 (6.0 %)	0 (0.0 %)	3 (1.2 %)
Parity on admission			
Para 0 ^a	14 (20.9 %)	39 (54.2 %)	105 (42.2 %)
Para 1–4	33 (49.3 %)	23 (31.9 %)	99 (39.8 %)
Para ≥ 5	17 (25.4 %)	10 (13.9 %)	35 (14.1 %)
Information missing	3 (4.5 %)	0 (0.0 %)	10 (4.0 %)
Antenatal care			
≥ 4 visits	31 (46.3 %)	38 (52.8 %)	103 (41.4 %)
1–3 visits	23 (34.3 %)	26 (36.1 %)	111 (44.6 %)
Not attended	0 (0.0 %)	1 (1.4 %)	0 (0.0 %)
Information missing	13 (19.4 %)	7 (9.7 %)	35 (14.1 %)
HIV			
Negative	54 (80.6 %)	62 (86.1 %)	211 (84.7 %)
Positive	0 (0.0 %)	2 (2.8 %)	0 (0.0 %)
Information missing	13 (19.4 %)	8 (11.1 %)	38 (15.3 %)
Gestational age			
No information on LMP/gestation weeks	46 (68.7 %)	49 (68.1 %)	181 (72.7 %)
Previous obstetric history			
<i>Of multiparous women:</i>	<i>(n = 50)</i>	<i>(n = 33)</i>	<i>(n = 134)</i>
Previous death of child/children ^{b,c}	18 (36.0 %)	12 (36.4 %)	30 (22.4 %)
1 previous CS	7 (14.0 %)	8 (24.2 %)	8 (6.0 %)
≥ 2 previous CSs	2 (4.0 %)	2 (6.1 %)	10 (7.5 %)

BW birthweight, CI confidence interval, CS caesarean section, LMP last menstrual period, OR odds ratio

^aDifference between pre- and intra-hospital stillbirths: OR 4.22, 95 % CI 1.99–8.96

^bDocumentation was insufficient to clearly distinguish perinatal deaths from deaths later in life

^cDifference between stillbirths and controls: OR 1.96, 95 % CI 1.07–3.59

rate among controls (12/249 (5 %); OR 3.52, 95 % CI 1.67–7.39; Table 3).

Of women reaching active labour and admitted before second stage, significantly more in the pre-hospital stillbirth group did not have a partograph filled in, when compared to both intra-hospital stillbirths (OR 9.78, 95 % CI 2.56–37.42) and controls (OR 3.39, 95 % CI 1.52–7.56; Fig. 2). In all groups, 237/276 (86 %) women with a partograph applied had the first cervical dilatation appropriately plotted on the alert line (Table 3).

Foetal heart rate (FHR)

In all intra-hospital stillbirths, FHR was reassuring on admission. However, in 60/72 (83 %) >90 min. elapsed between FHR assessments during active phase of labour, which was the case for 137/204 (67 %) controls (OR 2.45, 95 % CI 1.23–4.85; Fig. 2). Among 63 intra-hospital stillbirths, median time from last FHR recording till delivery or detected intrauterine foetal death was 3 h and 30 min. (IQR: 1 h and 15 min.–5 h and 15 min.), compared to 2 h and 0 min. in 176 controls (IQR: 1 h

Table 2 Mode of delivery, maternal outcome, and appearance of stillborn babies

	Case-control study BW ≥ 2000 g		
	Cases Pre-hosp. Stillbirths N (%)	Cases Intra-hosp. Stillbirths	Controls Apgar 7–10
Mode of delivery			
<i>Of all women in the study:</i>	<i>(n = 67)</i>	<i>(n = 72)</i>	<i>(n = 249)</i>
Spontaneous vaginal	45 (67.2 %)	46 (63.9 %)	213 (85.5 %)
Vaginal breech	3 (4.5 %)	5 (6.9 %)	5 (2.0 %)
Vacuum extraction	1 (1.5 %)	0 (0.0 %)	0 (0.0 %)
Caesarean section ^{a,b}	15 (22.4 %)	20 (27.8 %)	26 (10.4 %)
Mode of delivery unknown	3 (4.5 %)	1 (1.4 %)	5 (2.0 %)
Maternal outcome			
<i>Of all women in the study:</i>	<i>(n = 67)</i>	<i>(n = 72)</i>	<i>(n = 249)</i>
Maternal deaths	2 (3.0 %)	1 (1.4 %)	0 (0.0 %)
Post partum haemorrhage ^c	7 (10.4 %)	10 (13.9 %)	14 (5.6 %)
Episiotomy/spontaneous tears ^{d,e}	6 (9.0 %)	19 (26.4 %)	79 (31.7 %)
<i>Of vaginal deliveries:</i>	<i>(n = 49)</i>	<i>(n = 51)</i>	<i>(n = 218)</i>
Prolonged admission, ≥ 1 day ^f	9 (18.4 %)	0 (0.0 %)	3 (1.4 %)
<i>Of caesarean sections:</i>	<i>(n = 15)</i>	<i>(n = 20)</i>	<i>(n = 26)</i>
Prolonged admission, ≥ 5 days	1 (6.7 %)	3 (15.0 %)	2 (7.7 %)
'Fresh' versus 'macerated' stillbirths			
<i>Of all women in the study:</i>	<i>(n = 67)</i>	<i>(n = 72)</i>	<i>(n = 249)</i>
Classification not recorded	36 (53.7 %)	41 (56.9 %)	NA

BW birthweight, CI confidence interval, NA not applicable; OR, odds ratio

^aOverall, 9/35 (26 %) of the caesarean sections with stillbirth were done prior to active labour, and 10/35 (29 %) in second stage. Among controls, this was the case for 13/26 (50 %) and 0/26 (0 %), respectively

^bDifference between stillbirths and controls: OR 2.94, 95 % CI 1.68–5.14

^cDifference between stillbirths and controls: OR 2.34, 95 % CI 1.12–4.90

^dInformation was insufficient to distinguish between spontaneous vaginal tears and episiotomies

^eDifference between pre-hospital stillbirths and controls: OR 0.21, 95 % CI 0.09–0.51

^fDifference between pre-hospital stillbirths and controls: OR 16.13, 95 % CI 4.18–62.17

and 3 min.–3 h and 58 min.). For each one-hour increase in duration from last FHR assessment, the odds of stillbirth increased 20 % (OR 1.20; 95 % CI 1.08–1.34). In 58/72 (81 %) of the intra-hospital stillbirths, there was no documentation of foetal distress or foetal death prior to delivery (Table 4).

Labour progress

The highest proportion of women admitted in the latent phase of labour with no cervical assessments recorded during active labour occurred among pre-hospital stillbirths: 14/23 (61 %) compared to 24/68 (35 %) controls (OR 2.85, 95 % CI 1.08–7.55; Table 5).

In 27/69 (39 %) women experiencing intra-hospital stillbirth, ≥ 5 h elapsed between any two vaginal examinations during active labour, compared to 40/207 (19 %) controls (OR 2.68, 95 % CI 1.48–4.86; Fig. 2). This resulted in delays in diagnosing poor labour progress,

which was a common complication among intra-hospital stillbirths when compared to controls (Table 5). After crossing the alert line, in 18/33 (55 %) and 9/51 (18 %), respectively, ≥ 3 h elapsed before next vaginal examination (OR 5.60, 95 % CI 2.07–15.13). After crossing the action line, in 2/16 (13 %) intra-hospital stillbirths and 9/21 (43 %) controls, membranes were still intact, and in an additional 3/16 (19 %) and 5/21 (24 %), there was no information regarding membranes. Moreover, severe delays in surveillance were found after crossing the action line.

Oxytocin for labour augmentation was administered in 26/72 (36 %) of intra-hospital stillbirths, compared to 58/249 (23 %) controls (OR 1.86, 95 % CI 1.06–3.27). However, in 8/26 (31 %) of those, there was no indication for augmentation, and in an additional 7/26 (27 %) the infusion was started between the alert and action line with the membranes still intact. Likewise, 34/58 (59 %) controls had the infusion started before crossing the alert line (Fig. 3). In

Table 3 Admission and partograph use

	Case-control study BW ≥ 2000 g		
	Cases Pre-hosp. stillbirths N (%)	Cases Intra-hosp. Stillbirths	Controls Apgar 7–10
Progress on admission and referrals			
<i>Of all women in the study:</i>	<i>(n = 67)</i>	<i>(n = 72)</i>	<i>(n = 249)</i>
Before labour pain ^a	5 (7.5 %)	2 (2.8 %)	12 (4.8 %)
Latent phase of labour ^{a,b}	18 (26.9 %)	40 (55.6 %)	56 (22.5 %)
First stage of labour	23 (34.3 %)	29 (40.3 %)	153 (61.4 %)
Second stage of labour	15 (22.4 %)	0 (0.0 %)	25 (10.0 %)
Stage of labour on admission unknown	6 (9.0 %)	1 (1.4 %)	3 (1.2 %)
Referral from smaller health centre ^c	10 (14.9 %)	11 (15.3 %)	12 (4.8 %)
Partograph use			
<i>Of women in first stage of labour:</i>	<i>(n = 39)</i>	<i>(n = 69)</i>	<i>(n = 207)</i>
The partograph at least partially applied ^d	27 (69.2 %)	66 (95.7 %)	183 (88.0 %)
<i>Of women with the partograph applied:</i>	<i>(n = 27)</i>	<i>(n = 66)</i>	<i>(n = 183)</i>
First cervical dilatation in active labour plotted correctly on the alert line	18 (66.7 %)	53 (80.3 %)	166 (90.7 %)

BW birthweight, CI confidence interval, OR odds ratio

^aDifference in women admitted before active labour between intra-hospital stillbirths and controls: OR 3.79, 95 % CI 2.19–6.57

^bCervical dilatation <4 cm

^cDifference between intra-hospital stillbirths and controls: OR 3.52, 95 % CI 1.67–7.39

^dDifference between pre-hospital stillbirths and both intra-hospital stillbirths and controls: OR 9.78, 95 % CI 2.56–37.42, and OR 3.39, 95 % CI 1.52–7.56, respectively

none of the cases, information on oxytocin titration and maintenance dose was documented, and FHR and contractions were never assessed half hourly after starting the infusion. Preceding 13/35 (37 %) of CSs resulting in stillbirth, oxytocin was started for labour augmentation. This was also the case in four of six uterine ruptures, of which three had a history of one previous CS.

Maternal vital signs

Prevalence of severe hypertensive disorders was significantly higher among women experiencing stillbirth (27/139, 19 %) than in controls (10/249, 4 %; OR 5.76, 95 % CI 2.70–12.31). An additional 33/130 (25 %) and 81/235 (35 %) of women reaching active phase of labour, had no recordings of blood pressure during active labour (OR

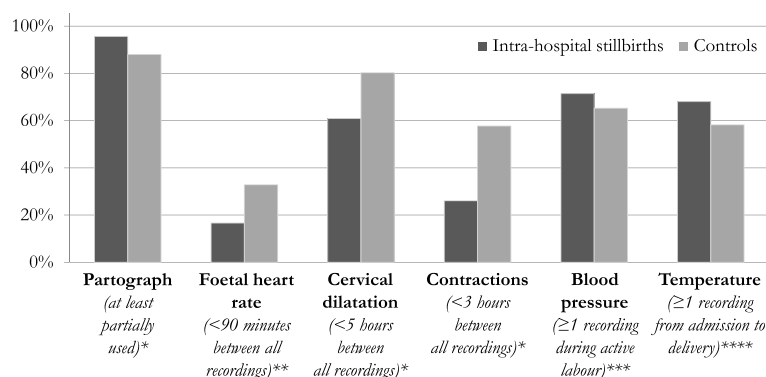


Fig. 2 Proportion of labouring women reaching each of six criteria for minimal acceptable routine surveillance during labour. Significant differences were found in FHR (OR 0.41, 95 % CI 0.21–0.81), cervical dilatation (OR 0.37, 95 % CI 0.21–0.68), and contractions (OR 0.26, 95 % CI 0.14–0.47). Intra-hospital stillbirths: documented positive FHR on admission, birthweight ≥ 2000 g. Controls: Apgar score ≥ 7 , birthweight ≥ 2000 g. * Of all women at the hospital during active first stage of labour ($n = 69$ and $n = 207$, respectively). ** Of women with at least one FHR reading ($n = 72$ and $n = 204$, respectively). *** Of women reaching active phase of labour ($n = 70$ and $n = 235$, respectively). **** Of all women in the study ($n = 72$ and $n = 249$, respectively). FHR, foetal heart rate; BP, blood pressure; Temp, temperature

Table 4 Intrapartum surveillance of the foetus

	Case-control study BW ≥ 2000 g	
	Cases Intra-hosp. Stillbirths N (%)	Controls Apgar 7–10 N (%)
Of women with at least one FHR reading:	(n = 72)	(n = 204)
FHR in normal range on admission (110–160 beats per min.)	72 (100.0 %)	202 (99.0 %)
Foetal distress detected prior to delivery	15 (20.8 %)	0 (0.0 %)
<90 min. between any 2 recordings of FHR ^a	12 (16.7 %)	67 (32.8 %)
Median time from last FHR till delivery or detected IUFD (min.) ^{b,c}	210	120

BW birthweight, CI confidence interval, FHR foetal heart rate, min. minutes, OR odds ratio

^aDifference between intra-hospital stillbirths and controls: OR 0.41, 95 % CI 0.21–0.81

^bIt was possible to calculate average time from last FHR till delivery in 63 (86 %) cases and 176 (86 %) controls. The interquartile ranges were 75–315 min. and 63–238 min., respectively

^cFor each one-hour increase in duration from last FHR assessment, the odds of stillbirth increased 20 % (OR 1.20; 95 % CI 1.08–1.34)

0.65, 95 % CI 0.40–1.04; Fig. 2). Overall, 13/27 (48 %) of all stillbirth cases with severe hypertension had significant proteinuria ($\geq 2+$ on urine dipstick). However, urine analysis was not recorded in an additional 6/27 (22 %) cases, and information about clinical symptoms were too sparse to analyse for signs of organ failure. In 18 (67 %) of all 27 stillbirth cases with severe hypertension, there were no recordings of relevant antihypertensive treatment. Of the

severe pre-eclampsia cases, 4/13 (31 %) had no documentation of having received magnesium sulphate.

In 43/139 (31 %) stillbirths and 104/249 (42 %) controls, there was no maternal temperature recording from admission till delivery (OR 0.63, 95 % CI 0.40–0.97; Fig. 2). Intrapartum fever or infection were rare diagnoses with five stillbirths related to infection and none among controls.

Discussion

The overall facility-based stillbirth rate was 59 per 1000 total births. Approximately 80 % of the singleton stillbirths had a birthweight ≥ 2000 g. In half of these, the FHR was still present after admission to hospital. In all groups, major challenges were identified in intrapartum surveillance, timely decision-making, and documentation. This resulted in stillbirths as well as unacceptable maternal and neonatal risks for all women and babies. The findings are largely in line with the limited number of other stillbirth studies from sub-Saharan Africa [3, 11, 13, 14]. Our study provides a more in-depth assessment of intrapartum care, which may contribute to effectively target interventions to reduce risks through improved quality of care (Table 6).

Causes of stillbirths

As suggested in other studies, the high number of intra-hospital stillbirths appeared primarily to be a sensitive indicator of substandard quality of care [3, 32, 33]. For instance, primigravid women suffered an increased risk of intra-hospital stillbirths, which may be associated with

Table 5 Intrapartum surveillance of labour progress

	Case-control study BW ≥ 2000 g		
	Cases Pre-hosp. Stillbirths N (%)	Cases Intra-hosp. Stillbirths N (%)	Controls Apgar 7–10 N (%)
Surveillance in latent phase of labour			
Of women admitted before active labour:	(n = 23)	(n = 42)	(n = 68)
Assessment of cervical dilatation during active labour ^{a,b}	9 (39.1 %)	37 (88.1 %)	44 (64.7 %)
Assessment of labour progression			
Of women in first stage of active labour:	(n = 39)	(n = 69)	(n = 207)
<5 h. between any 2 recordings of cervical dilatation in active labour ^c	39 (100.0 %)	42 (60.9 %)	167 (80.3 %)
<3 h. between any 2 recordings of uterine contractions ^d	33 (84.6 %)	18 (26.1 %)	120 (58.0 %)
Alert line crossed ^e	2 (5.1 %)	33 (47.8 %)	51 (24.5 %)
Action line crossed ^f	1 (2.6 %)	16 (23.2 %)	21 (10.1 %)

BW birthweight, CI confidence interval, OR odds ratio

^aIf a vaginal examination was done in latent phase ≤ 4 h prior to delivery, this was registered as acceptable

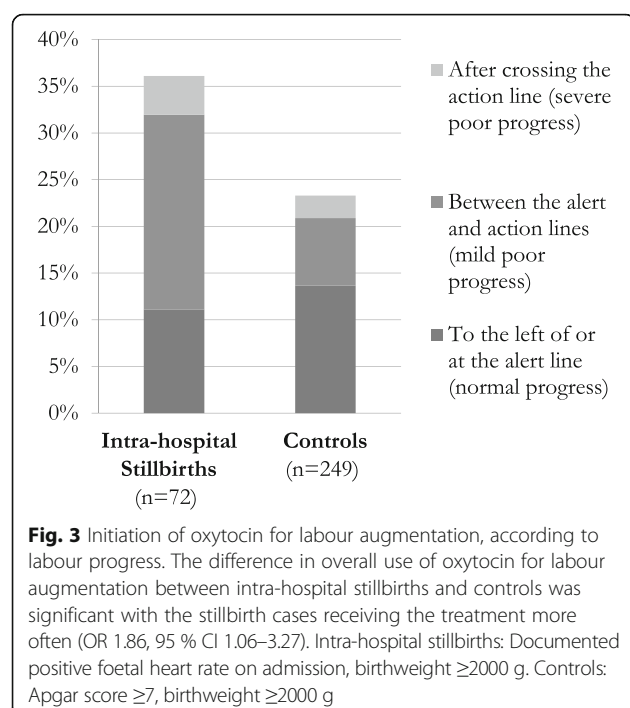
^bDifference between pre-hospital stillbirths and controls: OR 0.35, 95 % CI 0.13–0.93

^cDifference between intra-hospital stillbirths and controls: OR 0.37, 95 % CI 0.21–0.68

^dDifference between intra-hospital stillbirths and controls: OR 0.26, 95 % CI 0.14–0.47

^eDifference between intra-hospital stillbirths and controls: OR 2.80, 95 % CI 1.59–4.95

^fDifference between intra-hospital stillbirths and controls: OR 2.67, 95 % CI 1.30–5.49



their admission earlier in labour, and longer and more complicated labour duration [34]. In addition, increased vulnerability and need for quality care among all women experiencing intra-hospital stillbirth is emphasized by the association with severe hypertension and prior loss of child.

While staff often referred to late referral of women as a major cause to adverse labour outcome, 85 % of women experiencing intra-hospital stillbirth directly sought care

at the study site, and 58 % were admitted before active labour.

As found in other East African studies [8, 11, 35], not only was correct management often delayed, unnecessary and even harmful management was sometimes initiated. The presence of under- as well as over-treatment became particularly apparent when reviewing cases with poor progress of labour, where CSs often were found unnecessary. Yet, as only 4 % of foetuses had a documented positive FHR when deciding to perform CS, it is doubtful how big an impact e.g. possible delays in the decision-to-delivery interval for CS had on causing stillbirths; the unnecessary CSs may rather have caused avoidable maternal risks. In contrast, the under-use of vacuum extraction may be seen as an indicator of poor FHR monitoring, leading to undisclosed foetal distress in the second stage of labour.

Likewise, there appeared to be a dangerous over-use of oxytocin for labour augmentation. This is similar to studies from Bangladesh and Pakistan, where misuse of oxytocin was associated with stillbirth and birth asphyxia [36, 37]. Notably, the Pakistani study draws attention to the danger of insufficiently trained healthcare workers administering this highly potent drug [36].

Similar to intrapartum care, antenatal visits did not appear consistent with effective antenatal surveillance and treatment, and as in other studies this appeared to be a central determinant of both pre- and intra-hospital stillbirths [33]. For instance, while nearly all women attended antenatal care at least once, a severe hypertension prevalence of 19 % among stillbirths suggests missed opportunities [38]. Furthermore, the fact that less than half of the study population had attended four antenatal care visits indicate a lost chance for continuity in care [39].

Maternal risks

Substandard quality of risk assessment on admission as well as poor intrapartum surveillance and decision-making were associated with profound maternal risks and appeared to be major determinants of the death of three women (Additional file 2). Women with foetal death on admission were the most neglected. While they were in particular high intrapartum risk due to the often underlying morbidity and further at increased postpartum risk of e.g. obstetric fistula, labour progress and vital signs were often undocumented throughout active labour [40, 41].

CS is generally not indicated when there is foetal death [42]. However, a high proportion of CSs were done on doubtful indications, and many were related to insufficient management of prolonged labour. Thus, 26 % CSs among stillbirths is unacceptably high; in particular as the vast majority had either foetal death diagnosed or did not have FHR recorded prior to surgery. Except for an even higher

Table 6 Seven target areas for improving intrapartum quality of care at the study site

1. Strengthened risk assessment on admission, with particular focus on foetal heart rate, blood pressure, temperature, and previous obstetric history.
2. Improved routine surveillance during latent and active phase of labour, regarding all key parameters (foetal heart rate, dilatation of cervix and descent, contractions, maternal vital signs, and urinary output).
3. Increased prioritization of women with already diagnosed intrauterine foetal death for routine assessments during labour.
4. Timely prevention and management of prolonged labour, with focus on alternative and less harmful interventions than oxytocin infusion for labour augmentation (e.g. artificial rupture of membranes and emptying of bladder), and more restrictive dosages and improved surveillance when oxytocin is administered.
5. Reduction of caesarean sections after intrauterine foetal death, by improved management of prolonged labour, and enforcement of vacuum extraction and craniotomy use.
6. Improved management of severe hypertensive disorders, with particular focus on antihypertensive treatment.
7. Better intrapartum documentation as well as record keeping.

rate found at three hospitals in Mozambique [11], this is markedly higher than other studies from low- and middle-income countries [33]. A high proportion of CSs were done in the second stage of labour without an attempt of operative or destructive vaginal delivery. While short- and long-term maternal risks of suboptimally treated prolonged labour and unnecessary CSs are widely established [34, 43, 44], lack of transparency as to when to perform CS is found in other African studies too [11, 45, 46].

Six women suffered from uterine rupture. When considering the low level of surveillance in 14 % of stillbirth cases with one or more previous CSs, and the misuse of oxytocin, many more appeared at risk of rupture. Furthermore, while foetal bradycardia is an early sign of impending rupture [47], substandard FHR assessments made it less useful in timely detection.

Of the 19 % with severe hypertensive disorders experiencing stillbirth, more than half had severe pre-eclampsia or eclampsia. A Nigerian study found a similar prevalence and comparable insufficient antenatal and intrapartum surveillance and treatment of these dangerous conditions [48]. Recent data from well-resource settings emphasize suboptimally treated severe hypertension as an important contributor to maternal mortality [38]; in our study, 67 % of women with severe hypertension did not receive any antihypertensive treatment.

Clinical implications

At this East African referral hospital, facility births were frequently not accompanied by skilled intrapartum attendance. While widespread insufficiency in quality of routine and emergency labour care may partly be caused by massive structural constraints, suboptimal care often resulted in more risk associated, complicated, and resource draining interventions. Some of the revealed deficiencies may be addressed even without high costs in manpower and other resources, and the main risks and determinants are crucial in effectively designing low cost interventions (Table 6).

For many years, effectiveness of using the WHO partograph has been questioned [49, 50]. Yet, when analysing quality of intrapartum care at low resource facilities, partograph use for timely surveillance and decision-making appears central in ending preventable complications [11, 14, 18, 35]. In 86 % of all cases where the partograph was applied, first cervical dilatation in active phase of labour was plotted correctly on the alert line, and knowledge on accurate recording did not appear to be a major challenge. However, similar to other studies, WHO's recommendations for frequency of recordings were not followed and also did not seem achievable with the resources available [35, 51, 52]. In the present study, even though the majority of intrapartum decision-making did not seem influenced by partograph use or evidence-

based guidelines, it would be premature to conclude ineffectiveness of the WHO partograph. However, for the partograph to assist in surveillance and management, it must be coupled to a locally achievable and relevant labour management protocol. Although often not prioritised in evaluations of partograph use, this has previously proven effective [14, 18]. For instance, when considering the low resources at the study site, it seems unrealistic to assure close monitoring and titration of oxytocin augmentation if more than a few women are treated simultaneously [53].

This study identified 25 % underreporting of stillbirths in the official hospital registers, and even though a systematical surge was conducted through all piles of case files, a considerable number of files remained missing (Fig. 1). Initially, it was the intention also to include early neonatal deaths in the study. However, data collection revealed frequent default record keeping between the obstetric and neonatal units as well as substantial underreporting of very early neonatal deaths in all registers, which resulted in reluctance to include them. Furthermore, missing documentation in medical records – or “blanks” – was a frequent finding, which is likely to have affected patient care and labour outcomes. Incomplete health information systems are notoriously linked with poor health outcomes [3, 54]. It is warranted that the underlying factors for these “blanks” in medical recording are evaluated, and that quality of documentation and record keeping as well as use of the data are improved.

Strengths and limitations

The present pragmatic study was found suitable as a structured, simple, and low-cost method to identify central challenges in intrapartum care at this real-world setting with limited information available. Classification in pre- and intra-hospital stillbirths was a useful, more achievable, and simple alternative to ‘fresh’ versus ‘macrated’ stillbirths, which, as in a study from Ghana, was found unreliable [55]. Moreover, intra-hospital stillbirths may be seen as an even stronger indicator of intra-hospital quality of care than ‘fresh’ stillbirths. However, in 30 % of pre-hospital stillbirths there was no FHR documentation on or after admission, which may potentially hide an even higher proportion of intra-hospital stillbirths.

Selected audit criteria were unambiguously applicable. Yet, though intensive efforts were made for adapting international evidence-based guidelines to reach local reality, some criteria, such as <90 min. between FHR recordings, might be too optimistic as a sensitive audit standard for detecting quality improvements at this setting.

A central limitation to the study is that a criterion-based audit does not allow exploration of underlying determinants of substandard care, such as structural needs for supplies, space, and knowledge/skills among staff. Another limitation is the varying quality of data, which

might bias results; there may be a tendency of staff to forget reporting given care or to under-report mismanagement. Participant observations during the study period also identified the issues presented in the current paper, and qualitative analysis opened up to a complex tangle of both structural and process related underlying challenges influencing health providers' ability to deliver acceptable quality of care.

Conclusion

Stillbirths are both a devastating burden of avoidable lost lives in itself and a strong and easy to assess indicator of quality of antenatal and intrapartum care. Substandard care led to substantial maternal and perinatal risks, which furthermore were related to resource draining interventions that were not always necessary. Furthermore, 25 % underreporting of stillbirths in hospital registers indicates a poor health information system. These findings are largely in line with other reports from sub-Saharan Africa, and improvement of intra-hospital obstetric knowledge, care, and documentation is central to end preventable birth-related deaths and disabilities. Considering referral hospitals' major teaching tasks for future health providers, it is warranted to address the tertiary level in order to achieve quality improvement of the entire health care sector.

Additional files

Additional file 1: Very preterm stillbirths. Criterion-based audit data on very preterm stillbirths (birthweight <2000 g). (DOCX 49 kb)

Additional file 2: Maternal deaths. Intra-hospital management preceding the three maternal deaths within the study population. (DOCX 39 kb)

Abbreviations

CI: Confidence interval; CS: Caesarean section; FHR: Foetal heart rate; g: Grams; IQR: Interquartile range; min.: Minutes; OR: Odds ratio; WHO: World Health Organization

Acknowledgements

The research team would like to thank the many health providers at the study site who have kindly assisted in collecting the data here presented. The research team is also grateful for the fellow research assistants Mbweni Makame Ali and Said Mzee Said's high quality work. Finally, many thanks to Aksel Karl Georg Jensen, Section of Biostatistics, University of Copenhagen, for statistical consultation and review.

Funding

The present study was funded by grants from the Lundbeck, Laerdal, and Augustinus foundations.

Availability of data and materials

The datasets supporting the conclusions of this article are included within the article and its additional files.

Authors' contributions

NM formulated the study design, managed data acquisition, analysed and interpreted data, and drafted the paper. NH participated substantially in acquisition, analysis, and interpretation of data, and in critically revising the paper draft. ICB, JvR, TM, and BBN contributed substantially to the study design, analysis and interpretation of data, and they critically revised the paper draft. RSK and AGM participated substantially in acquisition of data and

in critically revising the paper draft. All authors have approved to the final version to be published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Competing interests

The authors declare that they have no competing interests.

Jos van Roosmalen is a Section Editor for BMC Infectious Diseases. Tarek Meguid is an Associate Editor for BMC Infectious Diseases.

Consent for publication

Not applicable.

Ethics approval and consent to participate

Ethical approval was obtained from the Zanzibar Medical and Research Ethical Committee (ZAMREC/0001/JUNE/014) and Mnazi Mmoja Hospital, and the PartoMa project is registered with ClinicalTrials.org (NCT02318420, 4th November 2014). In this baseline study of case files, all patient identities were anonymized and assigned a research number. Individually obtained informed consent was therefore not required.

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Received: 28 June 2016 Accepted: 1 November 2016

Published online: 10 November 2016

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Paper II

Labour management guidelines for a Tanzanian referral hospital: The participatory development process and birth attendants' perceptions

Maaløe N, Housseine N, van Roosmalen J, Bygbjerg IC, Tersbøl BP, Khamis RS, Nielsen BB, Meguid T. BMC Pregnancy Childbirth. 2017;17(175).

A systematic literature search is included after the paper: Labour and delivery guidelines for African low-resource settings (Additional file 3)

Additional files 1 and 2 are available on the journal homepage.

RESEARCH ARTICLE

Open Access



Labour management guidelines for a Tanzanian referral hospital: The participatory development process and birth attendants' perceptions

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Abstract

Background: While international guidelines for intrapartum care appear to have increased rapidly since 2000, literature suggests that it has only in few instances been matched with reviews of local modifications, use, and impact at the targeted low resource facilities. At a Tanzanian referral hospital, this paper describes the development process of locally achievable, partograph-associated, and peer-reviewed labour management guidelines, and it presents an assessment of professional birth attendants' perceptions.

Methods: Part 1: Modification of evidence-based international guidelines through repeated evaluation cycles by local staff and seven external specialists in midwifery/obstetrics. Part 2: Questionnaire evaluation 12 months post-implementation of perceptions and use among professional birth attendants.

Results: Part 1: After the development process, including three rounds of evaluation by staff and two external peer-review cycles, there were no major concerns with the guidelines internally nor externally. Thereby, international recommendations were condensed to the eight-paged 'PartoMa guidelines ©'. This pocket booklet includes routine assessments, supportive care, and management of common abnormalities in foetal heart rate, labour progress, and maternal condition. It uses colour codes indicating urgency. Compared to international guidelines, reductions were made in frequency of assessments, information load, and ambiguity. Part 2: Response rate of 84% ($n = 84$). The majority of staff (93%) agreed that the guidelines helped to improve care. They found the guidelines achievable (89%), and the graphics worked well (90%). Doctors more often than nurse-midwives (89% versus 74%) responded to use the guidelines daily.

Conclusions: The PartoMa guidelines ensure readily available, locally achievable, and acceptable support for intrapartum surveillance, triage, and management. This is a crucial example of adapting evidence-based international recommendations to local reality.

Trial registration: This paper describes the intervention of the PartoMa trial, which is registered on ClinicalTrials.org (NCT02318420, 4th November 2014).

Keywords: Guidelines, Labour, Partograph, Quality of care, Tanzania, PartoMa

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Background

An estimated 303,000 maternal deaths occur worldwide annually with the highest risk at the time of birth, and 3 million babies die as intrapartum stillbirths or early neonatal deaths [1–3]. Global efforts have focused on increasing facility births. However, these have not been matched with actual skilled care and this is an urgent post-2015 priority [4–8].

While promising interventions have been launched concerning e.g. postpartum bleeding and neonatal resuscitation, evidence on effective intrapartum interventions are limited [6, 9–11]. Meanwhile, many complications needing emergency postpartum/neonatal management could be prevented by basic and timely labour care [6, 12]. The World Health Organization's (WHO's) partograph is generally perceived to be central for improving intrapartum care [13–15]. However, as shown in the WHO's Asian multi-centre trial of 35,484 deliveries, partograph use should be coupled with realistic and simple management guidelines to achieve effect [16]. Moreover, guidance of health providers in best possible intrapartum care appears crucial [5, 8, 17]. Yet, a gap exists between international evidence-based guidelines for low resource settings and what is achievable and applicable locally [6, 18].

Since 2000, WHO integrated guidelines for managing complications in pregnancy and childbirth, called IMPAC [14], have been the internationally prominent obstetric standards for low income settings, underlying multiple training and intervention programmes [19–21]. They were developed and peer-reviewed by expert panels without field testing [14]. Later on, focus has increased on the need for contextually-tailored interventions to achieve effective implementation [6, 22]. However, since the IMPAC guidelines' first publication 16 years ago, a systematic literature search revealed that hardly any reviews on use and impact at the targeted low resource facilities have been conducted (Fig. 1). Simultaneously, quality assurance studies from low income settings call for more simple and achievable guidelines [23–28]. A review of Uganda's 137 health sector guidelines found lack of involvement of end users in the development process to be a key contributor to ineffective, impractical, unclear, or too complex recommendations [18].

The resource constrained referral hospital of Zanzibar is an example of this struggle. There is ample room for improvement in intrapartum care, and fundamental shortages in number and knowledge level of birth attendants, space and equipment, guidelines use, and accountability measures [12]. Within this context, the PartoMa project aimed at developing locally agreed, achievable, and acceptable intrapartum guidelines, supporting partograph use and based on evidence, but carefully modified to local reality. We here describe the participatory development

process and perceptions among staff 12 months post-implementation.

Methods

The PartoMa study took place at the government-run Mnazi Mmoja Hospital in Zanzibar, Tanzania. This is the only referral facility for the archipelago's population of 1.4 million, with 11–13,000 births and 50 maternal deaths annually. Our baseline study revealed a stillbirth rate of 59 per 1000 total births, of which half occurred intrapartum after admission to the hospital [12]. The average ratio of birth attendant to labouring women is 1:4 at daytime and 1:6 during evenings and nights. Notably, 30% of birth attendants are inexperienced intern doctors conducting their initial six-weeks obstetric rotation. When commencing the PartoMa project in 2014, obstetric guidelines were not routinely used, the locally promoted WHO composite partograph was hardly ever applied properly, and labour care was characterized by delays and inadequate management [12].

Guidelines development process

The goal was to modify international guidelines to ensure achievability and unambiguousness in its use at the resource constraint facility. More specifically, patient load, staff numbers, supplies, and knowledge level of staff should be taken into account, and the guidelines should assist the providers in prioritizing surveillance and procedures in the best possible way, for individual labouring women as well as across the needs at the labour ward. Thereby, we hypothesized that the guidelines would be accepted and used by staff.

In November and December 2014, an initial version of the guidelines was drafted by four members of the study team (NM, JvR, TM, and BBN). TM is consultant obstetrician at the study site, and all four have obstetric experience in low income countries. WHO IMPAC guidelines [14] were applied as the frame for the development process, but supplemented and cross-checked by other evidence-based guidelines [29–35]. When modifications were made to well-established international recommendations, a systematic literature search was conducted in PUBMED for an overview of related scientific evidence.

Afterwards, an elaborate modification process was sketched, including testing and feedback cycles by both local birth attendants applying the guidelines in their clinical work and external specialists. The external peer review panel included four midwives and three obstetricians with elaborate clinical experience in low-income settings.

Implementation process

Training in and awareness of the new guidelines were strengthened by associated PartoMa seminars, which were held quarterly, and have been continued by local

In a systematic search in PubMed, combining search terms related to clinical guidelines, intrapartum care, and low resource settings, with specific focus on Africa (1st January 2000 – 6th July 2016, English language), we identified 43 published studies on guideline development/modification, use, or effectiveness.

Four studies concerned development/modification of guidelines, and eight evaluated guideline implementation (one study was included in both of these categories). The remaining 32 publications compared actual clinical practice with expected best quality of care as recommended by well-established international evidence-based guidelines. All of the latter 32 analyses concluded clinical practice to be alarmingly suboptimal when compared to international guidelines; 15 of these, representing 11 sub-Saharan African countries, specifically called for simpler and more achievable guidance.

While international guidelines production for intrapartum care appears to have increased rapidly since 2000, literature suggests that it has been matched with reviews of local modifications, use, and impact at the targeted low resource facilities only in few instances.

Fig. 1 Systematic literature search: Labour and delivery guidelines for African low-income settings. A more detailed search description is available in Additional file 3

staff after finalizing this study. The seminars provide case-based training at five work stations concerned with central topics in the guidelines. They are held in a communal room at the hospital and facilitated by hospital staff and members of the study team. Each seminar lasts four hours, commences after work, and is conducted twice. The strategy is to motivate individual providers to improve their quality of care voluntarily. No per diems are paid, and facilitators work voluntarily. Free lunch and guidelines booklets are provided.

In addition, the guidelines are available on posters in the maternity ward and often used during discussions of intrapartum care at the department's daily clinical meetings.

Staff's perceptions and use

Twelve months after implementation, all birth attendants were requested to fill in an anonymous questionnaire on satisfaction with and use of the new guidelines, which is available in Additional file 1. Respondents included nurse-midwives and doctors in permanent positions at the Department of Obstetrics, as well as intern doctors. A five-point Likert scale was applied (1 = strongly disagree, 5 = strongly agree), and questions were in English and Swahili. Free text comments were welcomed on facilitators and barriers for use and recommendations for improvements. The questionnaire was modified from a previous Tanzanian study in which it was also found useful in evaluating a clinical educational intervention [36]. Two maternity theatre nurses not included among the study participants confirmed that the questionnaire was understandable. Questionnaire responses in Swahili were translated into English by RSK and all were

entered electronically. Data was analysed by descriptive statistics.

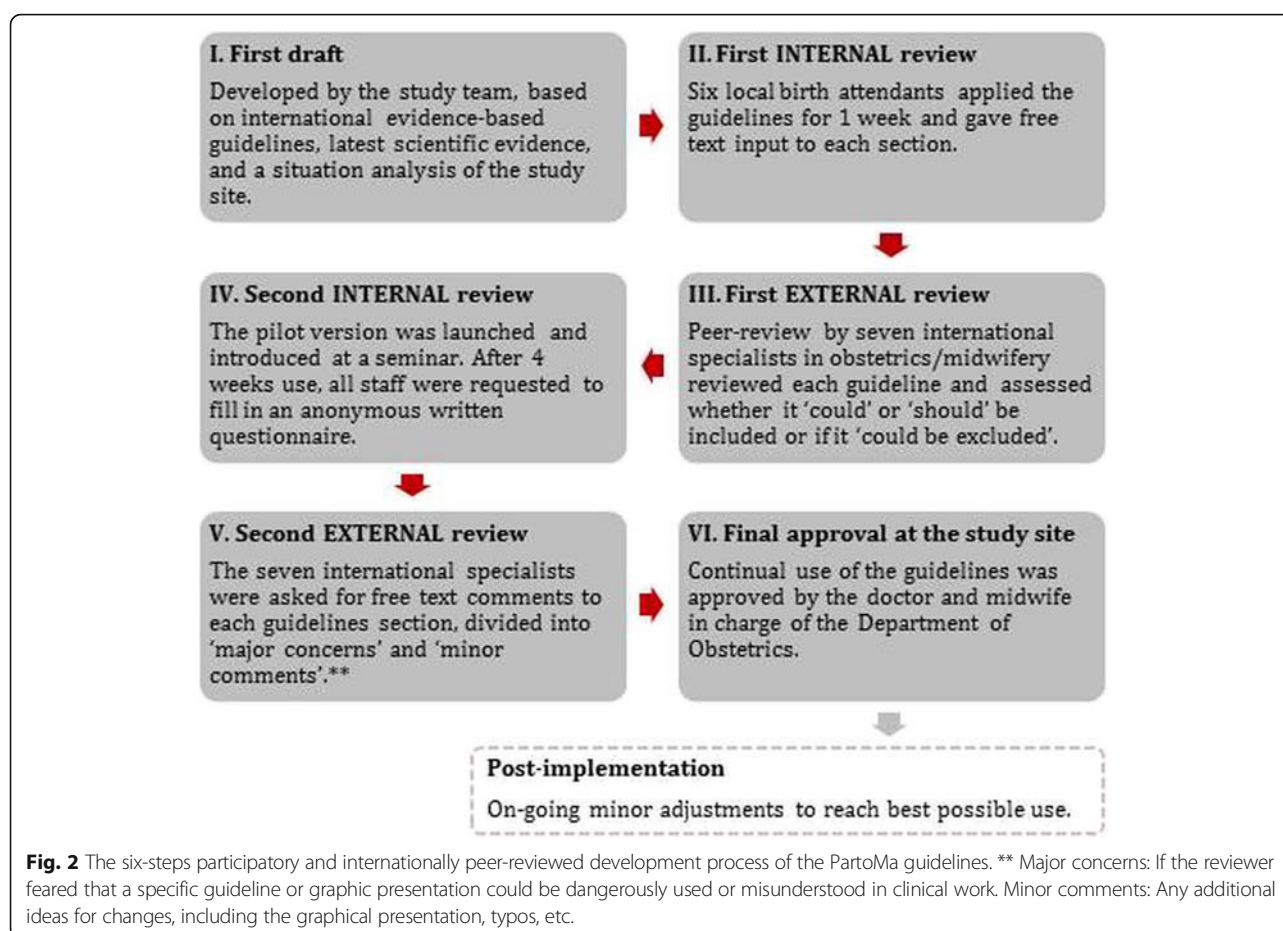
Results

Development process

Figure 2 provides an overview of what was eventually a six steps development process. By the end of December 2014, the initial guidelines draft (step I) was evaluated by six local staff, including the doctor and midwife in charge, another experienced nurse-midwife, two young medical doctors in permanent positions, and one intern doctor (step II). They applied the guidelines during 1 week's work and handed in written free text evaluations of each page. Overall, they found the draft understandable and useful, but multiple minor comments relating to content, wording, and graphical presentation were taken into account.

A first external peer-review was then conducted by the seven international specialists (step III). They received the guidelines both integrated graphically and in spread sheets with references and the rationale for modifications made. They were asked to evaluate if each guideline 'could' or 'should' be included or if it 'could possibly be left out'. Additional free text comments were welcomed. There was considerable diversity in comments, which resulted in discussions at length among the study team's specialists.

By the end of January 2015, a modified pilot version was introduced at the first round of PartoMa seminars and a 4 weeks testing conducted (step IV). This was followed by a semi-structured questionnaire of staff, similar to the 12-months evaluation. On the two evaluation days, 32/46 (70%) of the participants from the



launching seminars were present at work. Response rate among these was 100%. They found the pilot version useful, achievable, and understandable, and the evaluation only led to minor changes, primarily in wording.

The pilot-tested and re-modified version was thereafter sent for the second external peer-review (Step V). This time, the seven specialists were asked to comment in free text only, but divide their feedback into 'major concerns' (regarding a specific guideline or graphic presentation, which might be dangerously used in clinical work) and 'minor comments' (e.g. ideas for changes to graphics or wording). They raised no major concerns, and in March 2015 the guidelines were finally approved for internal use by the department's doctor and midwife in charge (Step VI).

In addition, through on-going/recurring stays and work in the department by three members of the study team (NM, NH, and TM), participatory observations and informal discussions with staff were taken into account in order to adjust the guidelines to reflect reality as accurately as possible. This was applied both during the development process and during continuous post-implementation-optimization of the guidelines. It mainly included simplifications of language and graphical presentations.

Guideline content

The development process resulted in the eight-paged PartoMa guidelines booklet on partograph-associated decision-support for common intrapartum management. The booklet is available in Additional file 2. It contains the following sections: routine assessments and supportive care during labour, delivery, and the first 2 h postpartum/neonatal; management of the most common intrapartum complications related to foetal heart rate (FHR), labour progression, and maternal condition (hypertensive disorders, hypotension, and fever); decision-to-delivery intervals for caesarean section; and vacuum extraction. To strengthen linkage to the WHO partograph, graphical presentations were developed based on the partograph's graphics (Fig. 3). As major deficiencies existed in basic labour care, both basic and emergency management were included [12]. Colour codes were applied as indicators of urgency (green, yellow, red). It was emphasized that while guidelines represent the best possible management for the majority of cases, there may be situations where alternative practice is preferable, and in such cases, management should always be discussed with colleagues. The final booklet fits into staff uniform pockets (10 × 15 centimetres each).

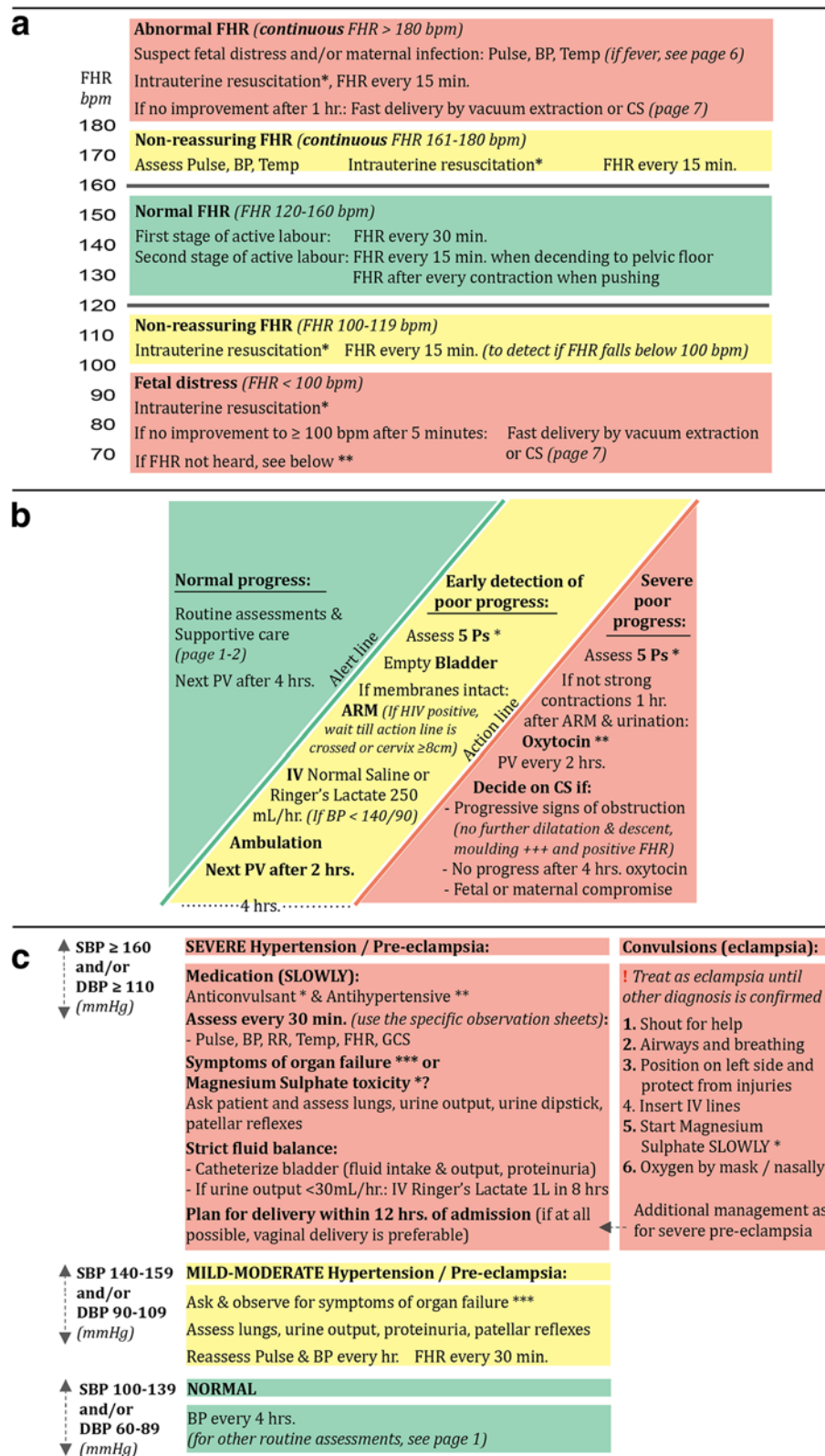


Fig. 3 (See legend on next page.)

(See figure on previous page.)

Fig. 3 The three parts of the PartoMa guidelines most appreciated by staff: **(a)** Management of abnormal foetal heart rate; **(b)** Management of poor progress in first stage of active labour (cervical dilatation ≥ 4 cm and regular painful contractions); **(c)** Management of hypertensive disorders. The graphics are based on the WHO partograph, and the star symbols (*) refer to recommendations further described on the page below in the guidelines. A full overview of the PartoMa guidelines is available in Additional file 2. ARM, artificial rupture of membranes; BP, blood pressure; bpm, beats per minute; CS, caesarean section; FHR, foetal heart rate; PV, vaginal examination; Temp, temperature. © 2015 The PartoMa Study, University of Copenhagen. All Rights Reserved

Three pages in the guideline were the most appreciated among staff (Table 1), and the main parts of these are presented in Fig. 3. Presentation of perspectives raised by staff, external reviewers, and study team members is delimited to these three pages.

A. Abnormal foetal heart rate (FHR)

No studies exist that compare different FHR auscultation intervals [37]. During first stage of active labour, the international benchmark of 30 min intervals was often hard to achieve, and 1 h was included as a minimum

acceptable interval. For second stage, due to high numbers of intrapartum stillbirths, and known risks of pushing on the foetus' oxygen supply, the importance of close monitoring was stressed (Additional file 2, page 1) [12, 32].

While it has internationally been suggested that FHR of 110–160 beats per minute (bpm) is normal, evidence is scarce [38]. Therefore, non-reassuring zones for both low and high FHR were kept in alignment with IMPAC and the partograph currently applied (100–119 bpm and 161–180 bpm; Fig. 3a) [14]. There was previously a common

Table 1 12 months evaluation of use and satisfaction with the PartoMa guidelines: Background characteristics of respondents, own use, and favorite guideline page(s)

	Doctors ^a <i>n</i> = 12	Nurse-midwives ^a <i>n</i> = 23	Intern doctors ^b <i>n</i> = 49
N (%)			
Years of obstetric/midwifery experience			
< 1 year	5 (41.7%)	5 (21.7%)	49 (100.0%)
1–5 years	6 (50.0%)	14 (60.9%)	0 (0.0%)
> 5 years	1 (8.3%)	4 (17.4%)	0 (0.0%)
Use of the PartoMa guidelines			
Every day when at work	11 (91.7%)	17 (73.9%)	43 (87.8%)
At least once a week	1 (8.3%)	3 (13.0%)	5 (10.2%)
Less than once a week	0 (0.0%)	1 (4.3%)	1 (2.0%)
Never	0 (0.0%)	2 (8.7%)	0 (0.0%)
PartoMa seminars attended			
0	1 (8.3%)	3 (13.0%)	9 (18.4%)
1	3 (25.0%)	12 (52.2%)	17 (34.7%)
≥ 2	8 (66.7%)	7 (30.4%)	23 (47.0%)
Information missing	0 (0.0%)	1 (4.3%)	0 (0.0%)
Favourite part(s) of the PartoMa guidelines			
Routine surveillance & supportive care	7 (58.3%)	16 (69.6%)	32 (65.3%)
Fetal heart rate and fetal distress	10 (83.3%)	17 (73.9%)	32 (65.3%)
Labour progression and poor progress	5 (41.7%)	17 (73.9%)	26 (53.1%)
Hypertensive disorders	9 (75.0%)	14 (60.9%)	39 (80.0%)
Fever, high pulse, low blood pressure	5 (41.7%)	7 (30.4%)	21 (43.0%)
Vacuum extraction ^c	8 (66.7%)	5 (21.7%)	24 (49.0%)

^aAll doctors and nurses/midwives in permanent positions at the obstetric division of the department by the end of January and beginning of February 2016 were requested to fill in the questionnaire (response rates: 92.3% and 88.5%, respectively). Doctors included 11 medical doctors and 1 assistant medical doctor

^bAll intern doctors who had conducted their six weeks obstetric clinical rotation since March 2015 were requested to fill in the questionnaire (response rate: 80.3%). At the time of data collection, some had finalized their internship and left for positions outside Zanzibar, and they could therefore not be reached

^cThis section was reproduced from the Advanced Life-saving Skills in Obstetrics' course syllabus, with permission from their legal board [33]

understanding among staff that FHR <120 or >160 bpm was an indication for caesarean section. Simultaneously, even for FHR <100 bpm, it was common to wait 30 min before deciding for caesarean section, which was often followed by delays in the decision-to-delivery interval [12]. Likewise, IMPAC is unclear on this matter [14]. Management in the non-reassuring zones was now specified and did not include operative delivery (Fig. 3a). For FHR < 100 bpm, we agreed on an interval of 5 min before re-check and, if FHR remaining <100 bpm, plan for expedite delivery (in the second stage of labour preferably by vacuum extraction). Concerning FHR >180 bpm, no evidence or international consensus was found for when to decide on caesarean section/vacuum extraction. Consensus was reached on a 1 h time frame (Fig. 3a).

B. Poor progress in first stage of active labour

For routine surveillance during active labour, IMPAC's recommendations for vaginal examination were found achievable (Additional file 2, page 1) [14]. Assessments of contractions half hourly was, however, structurally impossible; one birth attendant would have a full time job assessing contractions on three labouring women. We found no studies comparing different frequencies of monitoring contractions. When progress is normal, no oxytocin administered, and maternal and foetal conditions reassuring, consensus was reached on counting contraction every second hour. Evaluating foetal head descent was reduced from every two to every 4 h.

Management of poor progress in first stage of active labour is illustrated by WHO's alert and action lines (Fig. 3b). A similar diagram was successfully used in a previous Tanzanian study [25]. Before guidelines implementation, more than 20% of labouring women received oxytocin for augmentation, often on doubtful indication, and oxytocin was a predisposing factor for stillbirth [12]. To ensure safe administration of this potent drug in the resource constrained context, a restrictive regimen was agreed upon where oxytocin is saved for women crossing the action line with ruptured membranes for ≥ 1 h and <4 strong contractions in 10 min [39]. Danger of uterine hyperstimulation was stressed, and a restrictive dose recommended: 2.5 units in 500 ml Ringer's Lactate/Normal Saline at 10 drops per minute, infusion increased with 5 drops per minute every 30 min until 4–5 strong contractions per 10 min. By a '5 Ps mnemonic', elaborated from the Advanced Life-saving Skills in Obstetrics (ALSO) course [33], attention was drawn to alternative and less dangerous interventions to augment labour: i.e. artificial rupture of membranes, emptying bladder, exercise, oral intake, continuous support, and intravenous normal saline or Ringer's Lactate (Additional file 2, page 4) [14, 40].

When the action line is crossed, we found no clear evidence for when to decide in favour of caesarean

section. However, women often suffered from severe delays in management of poor progress in this facility [12]. Consensus was reached on three indications (Fig. 3b).

C. Hypertensive disorders

This part provides management guidance for hypertension and pre-eclampsia/eclampsia (Fig. 3c; Additional file 2, page 5). In accordance with the scope of the guidelines, recommendations on pre-labour management were not included. Diagnostic criteria for pre-eclampsia were based on RCOG guidelines, but for simplicity mild and moderate pre-eclampsia were merged, and biochemical/haematological impairment was excluded from the definition of severe pre-eclampsia (Additional file 2, page 5) [31]. Due to time and budget constraints, urine dipstick was excluded from routine assessments of labouring women and saved for women with hypertensive disorders or signs of urinary tract infection.

Management of hypertensive disorders was inspired by the LIVKAN treatment chart, which was found useful among birth attendants in Somali-land [34]. For simplicity, management of severe hypertension and severe pre-eclampsia/eclampsia were grouped together. Furthermore, for these severe cases an intensive treatment protocol was agreed upon aiming at delivery within 12 h of admission, versus 24 h in international guidelines [14, 31, 41]. This was because many women were admitted with severe hypertension of unknown duration (Fig. 3c) [12]. Medical treatment was restricted to the drugs available at the study site (magnesium sulphate as anticonvulsant and the antidote calcium gluconate; hydralazine for fast antihypertensive treatment). Concerning hydralazine, its associations with maternal hypotension, placental abruption, and adverse perinatal outcome were considered when deciding on a more conservative regimen than suggested by IMPAC [14, 42]: 5 mg every 20 min until systolic blood pressure < 160 mmHg (Additional file 2, page 5) [35].

Staff's perceptions and use

The questionnaire evaluation of the guidelines was responded to by 12/13 (92%) doctors and 23/26 (89%) nurse-midwives in permanent positions at the department, as well as by 49/61 (80%) intern doctors (Table 1).

The Likert scale evaluation is presented in Fig. 4. Among all staff, there was agreement that the PartoMa guidelines were achievable at the study site (mean score 4.22–4.65), and the graphics and colour codes for urgency appeared broadly accepted (mean scores 4.22–4.50 and 4.39–4.75, respectively). The majority stated that the guidelines helped to improve knowledge on labour management (mean score 4.32–4.78), and that they were providing better care to labouring women by using the guidelines (mean score 4.22–4.58). Staff would recommend the guidelines to colleagues (mean score 4.48–4.92). Particularly some

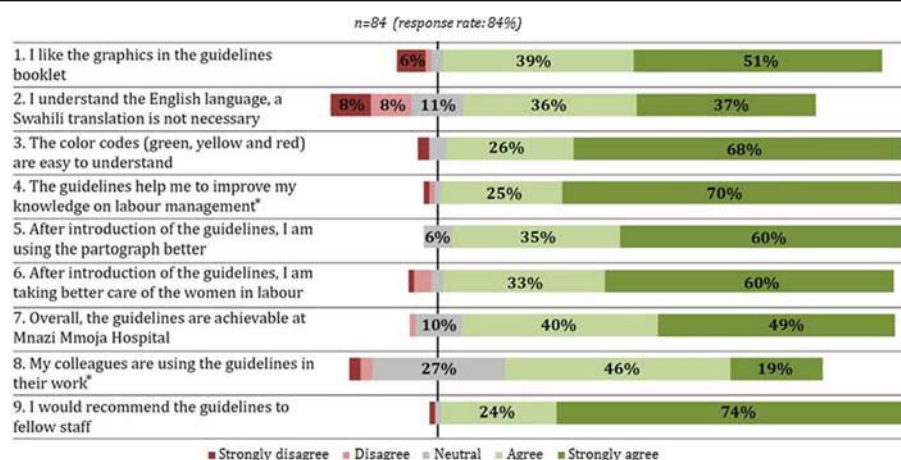


Fig. 4 Five-point Likert scale evaluation of health providers' perceptions and use of the PartoMa guidelines 12 months after implementation. The respondents included 12 medical doctors and 23 nurse midwives in permanent positions at the Department of Obstetrics, as well as 49 intern doctors who had conducted their six-weeks obstetric rotation during the past ten months. Nurse-midwives disagreed more often to question 2 (mean score 3.30), when compared to intern doctors (mean score 3.94) and doctors in permanent positions (mean score 4.50). Otherwise, no major differences were found between the groups. * Concerning questions 4 and 8, 1 (1%) and 2 (2%) health providers, respectively, did not respond

nurse-midwives indicated that the English language was a challenge in understanding the guidelines (mean score 3.30–4.50).

All cadres of staff found 'FHR and foetal distress' (Fig. 3a) to be one of the most useful pages. For nurse-midwives, the 'labour progress and poor progress' page was also a favourite (Fig. 3c), while doctors and intern doctors were particularly fond of 'hypertensive disorders' (Fig. 3b; Table 1).

Doctors, including interns, more often responded to use the guidelines on daily basis than nurse-midwives (54/61 (89%) and 17/23 (74%); Table 1). Similarly, when asked about colleagues' use, the mean Likert scale score indicated that some staff did not apply the guidelines on regular basis (3.67–4.05, Fig. 4).

In free text comments, some respondents described how there were no barriers for them to use the guidelines; in particular intern doctors emphasized how the PartoMa guidelines were their "friend in the pocket". Others referred to the high work load being a challenge for guidelines use. Many suggested that the combination of guidelines and seminars should continue beyond the study period, and that the intervention package would also be useful at other Zanzibarian facilities. Often, additional topics were suggested for inclusion in the guidelines; e.g. induction of labour and management of postpartum haemorrhage.

Discussion

We here presented a participatory approach to development of innovative, readily available, integrated guidelines

for intrapartum management, suited for birth attendants at the referral hospital of Zanzibar. As often reported from similar settings, intrapartum guidelines were not routinely used prior to the study, and quality of surveillance and decision-making was poor [12, 18, 23–25, 43, 44]. The development process revealed that international recommendations were often too time- and resource-consuming, as well as underspecified, too complex, and too long, leading to demoralized attitudes. Twelve months post-implementation, staff found that the PartoMa guidelines ensured achievable, acceptable, and applicable decision-support for timely surveillance, treatment, and triage; they felt that the guidelines help them to provide better care.

Interpretation

The guidelines development process was highly dependant on time, project funding, access to evidence, capacity to synthesize and apply evidence, skills in graphical design, and a robust coordination of partners; resources that can seldomly be spared at facilities like the study site. Likewise, review of Uganda's health sector guidelines concluded that low income countries face multiple barriers in conducting guidelines modification processes [18]. It is therefore warranted that the central development process of international evidence-based guidelines targeting low resource settings involve end users already in the initial phases.

During the initial steps of development, the PartoMa guidelines appeared to better match the reality that birth attendants experience. This may be associated with early involvement of end users and the study team's familiarity with the context. Furthermore, the initial

guidelines draft provided a new transparency in what was expected best practice at the study site. This enabled formulation of audit standards for the simultaneous baseline study on quality of care [12]. During the later steps of guidelines adjustments, feedback from criteria-based audit aided in further prioritising key contents of the guidelines. As commented elsewhere, production of contextually tailored guidelines for low income settings will be the first step for conducting comprehensive audits [45].

Non-realistic guidance may lead to either no use or unpredictable individual adaptations, and both scenarios may cause variable and risky performance [46]. More specifically, studies on clinical guidelines show that standards that are simple and easy to understand have a greater chance of implementation [47]. In the PartoMa study, the guidelines' restriction to eight pages, simplified wording, partograph-associated graphical presentations, and colour codes for urgency appeared to be key drivers for acceptance and use. It was challenging to dare modifying well-established evidence-based guidelines to reach simplicity and achievability. However, the diversity in the peer-reviewers' comprehensive comments, and the often limited scientific evidence base, eased the process [30].

Even when simplified and only taking up eight pages, PartoMa guidelines cover an integrated continuum of common care for women giving birth. First, recommended monitoring and treatment of the individual woman took into account that each birth attendant on average cared for 4–6 women simultaneously. Second, because severe obstetric complications are often preceded by delays in basic care, we found it crucial to integrate routine and emergency obstetric care [12]. Third, we emphasized partograph use as an integrated early warning tool to assess FHR, labour progress, and maternal condition throughout latent and active phase of labour, including the often forgotten second stage [32].

Guidelines development is an on-going process. While unnecessary updates and changes cause pointless confusion, it is crucial ethically to ensure updates in relation to emerging scientific evidence and changes in supplies, staff numbers, and knowledge level of staff. In addition, during the first implementation year, in alignment with suggestions from staff and observations of care, we have continuously incorporated minor adjustments in wording and graphical presentations to improve unambiguity and clinical relevance. A similar strategy has proven highly cost-effective in a high-income setting, where continual modifications of guidelines were conducted in response to practice variances [48]. Moreover, we plan for a future second edition, which include additional management recommendations as suggested by staff; e.g. induction of labour, trial of scar, management of postpartum bleeding, and neonatal resuscitation. Lastly, we hope to introduce a Swahili version.

Strengths and limitations

This pragmatic development process was designed to suit an obstetric department with severe resource and capacity constraints [12]. Through the in-depth peer-review process, we believe to have taken all reasonable precautions to verify the information contained in the PartoMa guidelines. Importantly, the guidelines were developed specifically to guide staff at the study site. If implemented in better resource settings, the recommendations might cause unintended effects, e.g. unnecessarily infrequent assessments. Notably, the group of birth attendants at the study site was dominated by rather inexperienced professionals. This was due to the immense responsibility given to intern doctors, and to a high turnover among doctors and nurse-midwives in permanent positions, which are typical challenges in East African settings.

The intervention design does not allow clear differentiation of staff's perceptions of the guidelines versus the seminars. However, 54% of the respondents in the 12-months evaluation had attended ≤ 1 seminar, and it seems unlikely that their perceptions were primarily based on the seminars. Moreover, in line with the call for achievable guidelines from similar settings, the major modifications here described seem crucial for acceptance and use [18, 23–25].

Restricting pilot-testing and 12-months evaluation to written questionnaires may have been too narrow to capture all dimensions.

Conclusions

This participatory, peer-reviewed guideline development process is a crucial example of bridging the gap between evidence-based international recommendations and local realities at resource limited health facilities. The PartoMa guidelines ensured a readily available, achievable, and acceptable decision-support for timely surveillance, treatment, and triage during labour. It is, however, unlikely that all resource limited facilities will have the means for such major development processes. It is warranted that future international guidelines targeted at low income countries take into account the realities of care-giving in such contexts; if easy usability is not ensured, simply producing evidence-based guidelines will not drive change. Preliminary findings regarding effects of the PartoMa guidelines on clinical practice and labour outcome are promising and will be presented in another paper. It will furthermore be relevant to investigate the PartoMa guidelines' feasibility in similar settings.

Additional files

Additional file 1: The 12-months evaluation questionnaire of satisfaction with and use of PartoMa guidelines. (PDF 351 kb)

Additional file 2: The PartoMa guidelines booklet. (PDF 1608 kb)

Additional file 3: A systematic literature search: Labour and delivery guidelines for African low-income settings. (PDF 401 kb)

Abbreviations

ARM: artificial rupture of membranes; BP: blood pressure; Bpm: beats per minute; CS: caesarean section; FHR: foetal heart rate; G: grams; IMPAC: WHO integrated guidelines for managing complications in pregnancy and childbirth; PV: vaginal examination; Temp: temperature; WHO: World Health Organization

Acknowledgements

The research team would like to thank the doctor in charge, Matthew Oswald Zacharia, and all skilled birth attendants at Mnazi Mmoja Hospital for their enthusiasm, time, and numerous input to the guidelines development process. Likewise, we are thankful to the seven external reviewers for their in-depth reviews and ideas: Barbara Kwast, Bjarke Lund Sørensen, Charles Ameh, Gaynor D. Maclean, Karen Odberg Pettersson, Rachel Macleod, and Tom Weber. Finally, thanks to Mohamed Mussa Ahmad, Mnazi Mmoja Hospital, for his kind help in collecting questionnaire evaluations, and Therese Østergaard Møller, Copenhagen University Library, for assisting with the systematic search strategy.

Funding

The PartoMa study is financed by grants from the Lundbeck, Laerdal and Augustinus foundations. The foundations have no role in the design, implementation, interpretation, and reporting.

Availability of data and materials

The evaluation questionnaire and datasets supporting the conclusions of this article are included within the article and its additional files. The PartoMa study, University of Copenhagen, remains the copyright holder of the PartoMa guidelines, which are presented in Fig. 3 and Additional file 2.

Authors' contributions

NM formulated the study design, drafted and graphically designed the initial guidelines version as well as later modifications, managed the data acquisition, analysed and interpreted data, and drafted the paper. NH participated substantially in acquisition, analysis, and interpretation of data, and in critically revising the PartoMa guidelines and paper draft. TM, JvR, and BBN contributed substantially to the study design, drafting and modifying of the PartoMa guidelines, analysis, and interpretation of data, and they critically revised the paper draft. ICB and BPT contributed substantially to the study design, analysis and interpretation of data, and revising of the paper draft. RSK participated substantially in the acquisition of data and in critically revising the paper draft. In addition, all authors have approved the final version to be published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Competing interests

The authors declare that they have no competing interests. Jos van Roosmalen is a Section Editor for BMC Pregnancy and Childbirth. Tarek Meguid is an Associate Editor for BMC Pregnancy and Childbirth.

Consent for publication

Not applicable.

Ethics approval and consent to participate

Ethical approval was attained from the Zanzibar Medical and Research Ethical Committee (ZAMREC/0001/JUNE/014, 7th October 2014) and Mnazi Mmoja Hospital, and the project is listed in ClinicalTrials.org (NCT02318420, 4th November 2014). All questionnaire respondents were informed of the study purpose, and they agreed to respond to the questionnaire voluntarily and anonymously.

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Received: 24 January 2017 Accepted: 26 May 2017

Published online: 07 June 2017

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A systematic literature search: Intrapartum guidelines for African hospitals

Summary:	By a systematic search in PubMed combining search terms related to clinical guidelines, intrapartum care, and low resource settings, with specific focus on Africa (1 st January 2000 – 6 th July 2016, English language), we identified 43 published studies on guidelines development/modification, use, or effectiveness. Four studies concerned development/modification of guidelines, and eight evaluated guidelines implementation (one study was included in both of these categories). The remaining 32 publications compared actual clinical practice with expected best quality of care as recommended by well-established international evidence-based guidelines. All of the latter 32 analyses concluded clinical practice to be alarmingly suboptimal when compared to international guidelines; 15 of these, representing 11 sub-Saharan African countries, specifically called for simpler and more achievable guidance. While international guidelines production for intrapartum care appears to have increased rapidly since 2000, published literature suggests that it has only in few instances been matched with reviews of local modifications, use, and impact at the targeted low resource facilities.		
Objective:	To quantify the number and summarize the content of published studies on intrapartum guidelines for low income settings, with specific focus on Africa.		
Eligibility criteria:	Topic:	Intrapartum clinical guidelines, defined as guidelines for the period from the onset of labour to the end of the third stage of labour.	
	Types:	All published studies, including reviews, concerning: 1. Development/modifications/adaptations of guidelines 2. Implementation of guidelines 3. Evaluation of guidelines use and effect, including perceptions among staff, knowledge/skills changes, and resulting changes in practice and outcome	
	Exclusion criteria: Articles solely reporting on drugs regimens or single procedures.		
	Settings: The main focus of the search was African low resource hospitals. However, when found by the search, relevant studies from comparable low resource settings in other parts of the world were included as well.		

Time interval: 1st January 2000 – 5th July 2016

Language: English

Database: Pubmed

Search strategy: **Main search:**

Search parts	Guidelines	Intrapartum	Low resource settings
Mesh terms	Practice Guidelines as Topic	Labour, obstetric Parturition	Poverty Developing countries Africa
Free text	Guideline(s) "Best practice(s)" Standard(s)[Title] Instruction(s)[Title]	Intrapartum Birth Childbirth Parturition	"Low income" Africa "Developing countries" "Developing country"

(((((((Instruction[Title]) OR Standard*[Title])) OR (Guidelines OR "Best practices" OR "Best practice")) OR "Practice Guidelines as Topic"[Mesh])) AND (((("Labor, Obstetric"[Mesh]) OR "Parturition"[Mesh])) OR (Parturition OR Intrapartum OR Birth OR Childbirth))) AND (((("Poverty"[Mesh]) OR "Developing Countries"[Mesh]) OR "Africa"[Mesh])) OR ("Low income" OR Africa OR "Developing countries" OR "Developing country"))*

Supplementary search:

A focused search was conducted on the World Health Organization's guidelines for managing complications in pregnancy and childbirth:

Search parts	World health organization	The IMPAC guidelines
Mesh terms	World Health Organization	
Free text	"World Health Organization" WHO	"managing complications in pregnancy and childbirth" "integrated management of pregnancy and childbirth" IMPAC

(((("World Health Organization"[Mesh]) OR "World Health Organization") OR WHO)) AND (((("managing complications in pregnancy and childbirth")) OR ("integrated management of pregnancy and childbirth")) OR IMPAC)

Study selection: The main broad search resulted in 405 titles. After a scan of abstracts and full text articles where relevant, 42 publications followed the eligibility criteria and were included. In the vast majority of excluded publications, the term guidelines or its synonyms was e.g. used in methodological sections or in debates/discussions without the eligibility criteria being met. In addition, some publications concerned antenatal or neonatal care, or child health, which lay outside the scope of this review.

The supplementary search resulted in 32 titles, of which one additional quality assurance study was included, resulting in a total of 43 included publications.

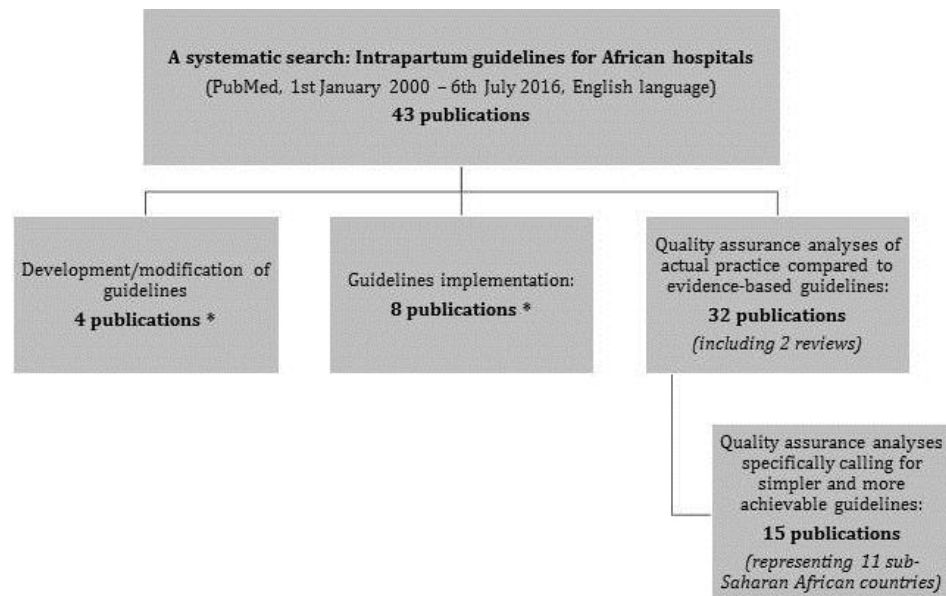


Figure S1 A systematic literature search of intrapartum guidelines for African hospitals; synthesis of the results. *One study is included in both categories.

Synthesis of results (Figure S1):

Four publications described the development or modification process of guidelines. In two of the publications, Kongnyuy et al. described participatory national approaches for development of standards for obstructed labour and women friendly intrahospital care in Malawi.^{1,2} They concluded that while international guidelines were traditionally based on expert consensus, it was beneficial to include the actual end users in the processes. As part of a package to improve emergency obstetric care in two rural districts of Mali, Otchere et al. briefly described that they in collaboration with hospital partners, the Ministry of Health, and others developed clinical protocols for the targeted facilities.³ Finally, Ameh et al. described the development process, including feedback from Nigerian birth attendants, of a severe pre-eclampsia/eclampsia monitoring and treatment sheet (the LIVKAN chart), which includes guidelines.⁴

Eight publications concerned evaluation of implemented guidelines. A study from a community hospital in Senegal implemented emergency obstetric guidelines by criterion-based audit and feedback and evaluated the effect on clinical practice.⁵ In two publications, the QUALMAT study team presented multicenter evaluation of a computer-assisted clinical decision support system for antenatal and delivery care in sub-Saharan Africa, which included guidelines.^{6,7} They explored both staff's

perceptions and the effect on maternal and perinatal outcome. A one-center study from India evaluated effects of the WHO Safe Birth Checklist, which included guidelines, on clinical practice.⁸ Two single-hospital studies from tertiary facilities in Tanzania and Pakistan evaluated the effect of locally developed guidelines for eclampsia and postpartum haemorrhage, respectively, on clinical practice and outcome.^{9,10} One study from Malawi evaluated national guidelines regarding the obstructed labour guidelines described above.¹¹ Finally, in the LIVKAN publication described above, birth attendants' immediate perceptions to the new chart was included.⁴ All publications concluded their guidelines to show promising effects.

The remaining 32 publications reported on quality assurance studies of intrapartum care compared to well-established international evidence-based guidelines.^{12–43} They presented findings from one or more low resource facilities, and quantitative, qualitative, and mixed methods approaches were applied. All studies concluded intrapartum care to be suboptimal when compared to evidence-based best practice. Of the studies, 15 (47%), representing 11 sub-Saharan African countries, specifically stressed the need for useful guidelines in their facilities.^{12–26} Others stressed the need for strengthening supplies, staff numbers, and training in order to follow established international guidelines. Two of the publications presented reviews of criterion-based audits concerning intrapartum care and reached similar conclusions.^{42,43}

Conclusion: Multiple quality assurance studies from low resource settings conclude intrapartum care to be suboptimal when compared to well-established recommendations of best practice, and the need for locally useful guidelines is repeatedly stressed. However, while international guidelines production for intrapartum care appears to have increased rapidly since 2000, it has not been acceptably matched with reviews of actual use and impact at the targeted low resource facilities.

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Paper III

Effect of locally-tailored labour management guidelines on intrahospital stillbirths and birth asphyxia at the referral hospital of Zanzibar: A quasi-experimental pre-post-study (The PartoMa study)

Maaløe N, Housseine N, Meguid T, Nielsen BB, Jensen AKG, Khamis RS, Mohamed AG, Ali MM, Said SM, van Roosmalen J, Bygbjerg IC. BJOG. 2018;125(2):235–45.

Supporting tables S1, S2, and S3 are included after the paper, as well as a corrigendum concerning a typing error.



Effect of locally tailored labour management guidelines on intrahospital stillbirths and birth asphyxia at the referral hospital of Zanzibar: a quasi-experimental pre-post study (The PartoMa study)

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Accepted 29 August 2017. Published Online 16 October 2017.



This paper includes Author Insights, a video abstract available at <https://vimeo.com/rcog/authorinsights14933>

Objective To evaluate effect of locally tailored labour management guidelines (PartoMa guidelines) on intrahospital stillbirths and birth asphyxia.

Design Quasi-experimental pre-post study investigating the causal pathway through changes in clinical practice.

Setting Tanzanian low-resource referral hospital, Mnazi Mmoja Hospital.

Population Facility deliveries during baseline (1 October 2014 until 31 January 2015) and the 9th to 12th intervention month (1 October 2014 until 31 January 2015).

Methods Birth outcome was extracted from all cases of labouring women during baseline ($n = 3690$) and intervention months ($n = 3087$). Background characteristics and quality of care were assessed in quasi-randomly selected subgroups ($n = 283$ and $n = 264$, respectively).

Main outcome measures Stillbirths and neonates with 5-minute Apgar score ≤ 5 .

Results Stillbirth rate fell from 59 to 39 per 1000 total births (RR 0.66, 95% CI 0.53–0.82), and subanalyses suggest that this

was primarily due to reduction in intrahospital stillbirths. Apgar scores between 1 and 5 fell from 52 to 28 per 1000 live births (RR 0.53, 95% CI 0.41–0.69). Median time from last fetal heart assessment till delivery (or fetal death diagnosis) fell from 120 minutes (IQR 60–240) to 74 minutes (IQR 30–130) (Mann–Whitney test for difference, $P < 0.01$). Oxytocin augmentation declined from 22% to 12% (RR 0.54, 95% CI 0.37–0.81) and timely use improved.

Conclusion Although low human resources and substandard care remain major challenges, PartoMa guidelines were associated with improvements in care, leading to reductions in stillbirths and birth asphyxia. Findings furthermore emphasise the central role of improved fetal surveillance and restricted intrapartum oxytocin use in safety at birth.

Keywords Birth asphyxia, guidelines, labour, partograph, PartoMa, Stillbirth, Tanzania.

Tweetable abstract #PartoMa guidelines aided in reducing stillbirths and birth asphyxia at a Tanzanian low-resource hospital

Plain Language Summary

PartoMa guidelines help birth attendants in Tanzania to save lives

Every year, 3 million babies die on the day of birth. The vast majority of these deaths occur in the poorest countries. If their mothers had received better care during birth, most babies would have survived.

At Mnazi Mmoja Hospital, an East African referral hospital, the PartoMa study shows that use of locally developed guidelines helps birth attendants to deliver better quality of care, which has led to improved survival at birth.

At the hospital studied, resources are scarce. Each birth attendant assists four to six birthing women simultaneously, and many have less than 1 year of professional experience. International guidelines are available, but they are often unachievable and seldom applied. The PartoMa guidelines were developed in close collaboration with the birth attendants and approved by seven international experts. The result is an 8-page pocket booklet providing locally achievable and simple decision support for care during birth.

Use of the PartoMa guidelines began in February 2015. As the staff group frequently changes, quarterly seminars are conducted where birth attendants are welcomed after working hours to learn about the guidelines. The guidelines have been positively received, and seminar attendance remains high.

Use of the PartoMa guidelines is associated with:

- A decrease by one-third in stillbirths (59 to 39 per 1000 total births)
- A nearly halving in the number of babies born in immediate poor medical condition (52 to 28 per 1000 live births)

The results presented here derive from a comparison of births before using the PartoMa guidelines and during the 9th–12th month of use. Such a ‘before-after’ study cannot exclude the possibility of other causes of better survival at birth. However, the improved survival is consistent with improved care during birth, which is in line with the PartoMa guidelines.

Please cite this paper as: Maaløe N, Housseine N, Meguid T, Nielsen BB, Jensen AKG, Khamis RS, Mohamed AG, Ali MM, Said SM, van Roosmalen J, Bygbjerg IC. Effect of locally tailored labour management guidelines on intrahospital stillbirths and birth asphyxia at the referral hospital of Zanzibar: a quasi-experimental pre-post study (The PartoMa study). *BJOG* 2018;125:235–245.

Introduction

Annually, 303 000 maternal deaths occur globally, with the majority occurring around the day of birth.¹ Likewise, 3 million babies die on the day of birth, as intrapartum stillbirths or early neonatal deaths.^{2,3} The majority of deaths occur in the poorest countries.^{1–3} Though the global proportion of facility births is increasing, it has not been matched with improvements in the quality of intra-facility labour care.^{4–6} This is a key priority in the post-2015 era.⁷ Even at the tertiary level, where birth attendants are expected to have received a certain level of training, reports from sub-Saharan Africa show ample room for improvement.^{8–12}

A central barrier for enhancing evidence-based care at resource-constrained hospitals is discrepancies between international recommendations and contextual realities: non-realistic guidance may cause either no use or unpredictable individual adaptations, both of which may lead to variable and risky performance.^{7,13–17} A literature gap exists on contextually tailored guidelines development, implementation, and use in low-resource settings.¹⁶ Furthermore, although several short training packages, which are often guideline-based, have been evaluated in low-income countries, their sustainability and long-term effect on quality of care is questionable.^{18–21} All in all, sustainable implementation of clinically effective guidelines is warranted to support birth attendants at resource-constrained hospitals in

providing quality care and ending avoidable intrapartum-related deaths and disabilities.^{7,22,23}

The low-resource referral hospital of Zanzibar is no exception to the challenge of delivering acceptable care during birth. Findings from our pre-intervention study suggested, however, that practice could potentially be improved by low-cost strengthening of intrapartum monitoring and decision-making, even without additional health providers and supplies.²⁴ Acknowledging contextual constraints, a participatory and internationally peer-reviewed guidelines development process was conducted to formulate partograph-associated, locally achievable, and easy-to-use clinical practice guidelines for common intrapartum care. This resulted in the PartoMa guidelines booklet, which was launched together with reoccurring quarterly seminars.¹⁶ We here present an analysis of the associated effect on rates of stillbirth and birth asphyxia, through behavioural changes in clinical practice.

Methods

Setting

At the governmental referral hospital of Zanzibar, Mnazi Mmoja Hospital, approximately 12 000 women deliver annually. Resources are scarce. Throughout the study, average ratio of birth attendants to labouring women was 1:4 at daytime and 1:6 during evenings and nights. Birth attendants include medical doctors and nurse-midwives in

permanent positions, as well as intern doctors. Staff turnover is massive: 40% of doctors and 25% of nurse-midwives in permanent positions during the first 6 months of the PartoMa intervention were no longer working at the department when finalising the 12th intervention month. Intern doctors stay 6 weeks only, but constitute more than 30% of birth attendants. In addition, more than 200 Tanzanian nurse-midwifery and medical students conduct their obstetric training at the department each year. At baseline, no intrapartum guidelines were routinely applied, but use of the World Health Organization (WHO) composite partograph was encouraged for all labouring women.²⁵ Approximately 50 maternal deaths occur annually (420 deaths per 100 000 live births). The facility-based neonatal death rate is unknown, but our baseline study revealed a stillbirth rate of 59 per 1000 total births, of which approximately half were alive at the time of admission.²⁴

Intervention

We here present a health system quality improvement project aimed at strengthening intrapartum surveillance and decision-making using the 8-page PartoMa pocket booklet. The internationally peer-reviewed guidelines were developed in close collaboration with staff to assure that they present integrated partograph-based decision-support for intrapartum management, including both routine and emergency care, and are achievable and easy to use when considering local resources. An elaborate description of the development process, content, and staff perceptions of the guidelines is presented elsewhere.¹⁶

The PartoMa guidelines were launched at the initial PartoMa seminars (27–28 January 2015). The seminars have been conducted quarterly ever since, in a communal room at the hospital and facilitated by hospital staff and members of the study team. Each seminar lasts 4 hours and commences after work. The guidelines implementation strategy focuses on motivation of individual providers to improve quality of care voluntarily: no per diems are paid, but free food and the guidelines booklet are provided. To assure that all staff have opportunity to participate, each seminar is conducted twice. The main part of the seminar is case-based training at five work stations, each lasting 30 minutes and including main topics of partograph-associated labour management, in accordance with PartoMa guidelines. During the study, an average of 74% of doctors and 62% of nurse-midwives from the obstetric division participated at each seminar round. Of the approximately 60 intern doctors at the hospital, 37% on average attended seminars, including nearly all currently working in obstetrics.

The PartoMa guidelines are available on posters and are often used during discussions at the departmental daily clinical meetings.

Study design

We conducted a quasi-experimental pre-post study comparing all women delivering at the study site during baseline (1 October 2014 until 31 January 2015) with the 9th to 12th intervention month (1 October 2014 until 31 January 2015). Donabedian's quality of medical care framework was applied, including evaluation of birth outcomes, process of care delivery, and structural setting and resources.²⁶

The study's primary outcome measures were stillbirths (fetal deaths ≥ 1000 g) and neonates with Apgar scores between 1 and 5. Six of the authors carefully went through all available case files from baseline and intervention months. Additional cases, where the case file was lost, were searched for by a twice-repeated review of the admission, delivery, and operation theatre registers. A reduction in stillbirths with intrauterine fetal death on admission would be outside the scope of the intervention. Therefore, a sub-analysis of fetal heart rate (FHR) on admission was conducted on all available case files of singleton stillbirths in the intervention months to approximate the proportion with positive FHR on admission (intra-hospital stillbirths). This was previously done for the baseline.²⁴ Notably, classification of fresh and macerated stillbirths was earlier found unreliable and therefore not applied.²⁴ Multiple pregnancies were excluded from the sub-analysis of FHR due to unclear recording (e.g. often only one FHR was registered). A 5-minute Apgar score between 1 and 5 was applied as an indicator of birth asphyxia with possibly serious adverse consequences.²⁷ However, the 5-minute Apgar score was not always available, and in such cases the 1- or 10-minute score was used instead.

Secondary outcomes included maternal deaths, and rates of caesarean sections and vacuum extractions. Due to substantial underreporting of very early neonatal deaths in all registers, and flaws in record-keeping between obstetric and neonatal units, neonatal deaths were not included.²⁴

To study comparability between baseline and intervention months and quality of care, quasi-randomly selected subgroups were identified from the baseline and intervention months. Due to time and budget constraints, it was not feasible to conduct these in-depth analyses on all women ($n = 6777$). To obtain a representative sample, every tenth delivery in the department's admission, delivery, and operation theatre registers was identified. Intensive efforts were made to retrieve the case files, which included all women delivering singletons with birthweight ≥ 2000 g. The 2000-g cutoff for the subgroup evaluation was chosen as it reflects a gestational age of 32–34 weeks, when survival is less dependent on lung maturation and advanced intensive neonatal care.²⁸ Very preterm gestations might influence decisions on intrapartum care, which our preselected audit criteria did not take into account. From subgroup

cases, all available background characteristics were extracted, and intrapartum practice was analysed against the preselected criteria: fetal surveillance, labour progress, and maternal vital signs, of which blood pressure and temperature were selected for analysis. These criteria were successfully applied for the baseline study and methodological details have been presented elsewhere.²⁴

Structural changes, which potentially could be contextual mediators or confounders to practice and outcome changes, were assessed quarterly during the study: availability of emergency obstetric and neonatal care signal functions, number of births, number of health care providers in each cadre of staff, and introduction of other interventions to improve maternal and perinatal health.

Sample size calculation

To avoid possible season variations, we wanted to compare the baseline with identical months of the intervention year (the 9th to 12th intervention month). We could not extend the baseline further back in time due to a long-lasting breakdown in the hospital storage system of case files. Power was calculated based on a two-sided comparison of two proportions, using the baseline intrahospital stillbirth rate (positive FHR on admission) of 28 per 1000 total

births in 3690 total deliveries and an expected 40% reduction by the intervention with a significance level of 5%.²⁴ Assuming that at least 3000 women would deliver in the four intervention months, this resulted in a power of 88%.

Statistical analyses

Data were entered into a structured entry form (EPI INFO 7 software, Centres for Disease Control and Prevention, Atlanta, GA, USA). Statistical analyses were performed in SAS ENTERPRISE GUIDE 6.1 (SAS Institute, Inc., Cary, NC, USA). Data on background characteristics for baseline and intervention months were compared using Fisher's exact test. Birth outcomes and quality of care were compared by relative risk (RR) with 95% confidence intervals (CI) for categorical variables and Mann-Whitney values for numeric variables.

Ethical considerations

The PartoMa study received ethical approval from Zanzibar Medical and Research Ethical Committee (ZAMREC/0001/JUNE/014). The project is registered with ClinicalTrials.org (NCT02318420). Birth attendants were highly engaged, but patients were not involved in the study design.

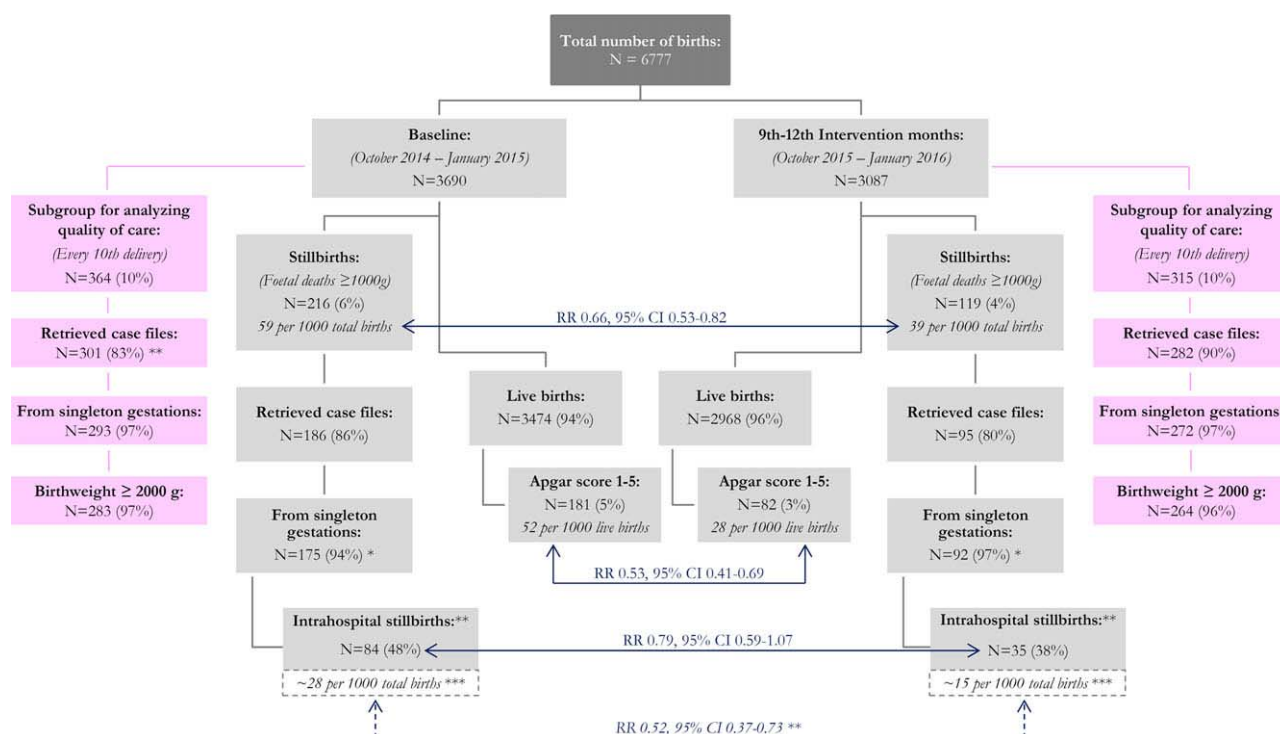


Figure 1. Participant flow for analysing birth outcome (grey colour) and for the subgroup comparisons of background characteristics and quality of care (pink colour). Percentages are based on the number immediately above. *Of the included singleton gestations at baseline and in intervention months, respectively 34 and 30 had a birthweight <2000 g. **Documented positive fetal heart rate during the admission. ***Based on extrapolation from an analysis of singleton stillbirths with retrievable case files [175/216 (81%) at baseline and 92/119 (77%) in the intervention months]: (59/1000)*0.48 and (39/1000)*0.38, respectively. CI, confidence interval; RR, relative risk.

Table 1. Background characteristics. Comparison of women quasi-randomly selected at baseline (October 2014–January 2015) and during the 9th to 12th intervention month of the PartoMa study (October 2015–January 2016)

	Baseline n (%)	9th to 12th Intervention month n (%)	P-value*
<i>Of all women in the subgroups</i>	(n = 283)	(n = 264)	
Age			
<20 years	28 (9.9)	26 (9.8)	0.26
20–29 years	142 (50.2)	148 (56.1)	
30–39 years	94 (33.2)	82 (31.1)	
≥40 years	16 (5.7)	7 (2.7)	
Information missing	3 (1.1)	1 (0.4)	
Parity on admission			
Para 0	123 (43.5)	107 (40.5)	0.38
Para 1–4	113 (39.9)	123 (46.6)	
Para ≥5	37 (13.1)	30 (11.4)	
Information missing	10 (3.5)	4 (1.5)	
Antenatal care			
≥4 visits	119 (42.0)	127 (48.1)	0.42
1–3 visits	125 (44.2)	115 (43.6)	
Not attended	0 (0.0)	1 (0.4)	
Information missing**	39 (13.8)	21 (8.0)	
HIV			
Negative	243 (85.9)	242 (91.7)	0.12
Positive	0 (0.0)	4 (1.5)	
Information missing**	40 (14.1)	18 (6.8)	
Severe hypertensive disorders			
Severe hypertension (BP ≥160/110)	16 (5.7)	17 (6.4)	0.72
<i>Of multiparous women in the subgroups</i>	(n = 150)	(n = 146)	
Previous obstetric history			
Previous death of child/children***	35 (23.3)	23 (15.0)	0.11
1 previous caesarean section	11 (7.3)	14 (9.2)	0.54
≥2 previous caesarean sections	10 (6.7)	8 (5.2)	0.81
<i>Of all women in the subgroups</i>	(n = 283)	(n = 264)	
Progress on admission			
Before active phase of labour****	77 (27.2)	83 (31.4)	0.56
First stage of active phase of labour	176 (62.2)	156 (59.1)	
Second stage of labour	27 (9.5)	23 (8.7)	
Information missing	3 (1.1)	2 (0.8)	
Referrals			
Referral from smaller health centre	14 (4.9)	10 (3.8)	0.54

BP, blood pressure.

*Fisher exact test.

**Significantly fewer women had missing information in the intervention months regarding number of antenatal care visits (RR 0.58, 95% CI 0.35–0.95) and HIV status (RR 0.48, 95% CI 0.28–0.82).

***Documentation was insufficient to differentiate perinatal deaths from deaths later in life.

****Cervical dilation <4 cm.

Results

At baseline, 3690 babies were delivered, 3087 in the intervention months. Of these, 364 (10%) from baseline and 315 (10%) from intervention months were identified for subgroup comparison of background characteristics and quality of care. It was possible to retrieve case files of 301/364 (83%) and 282/315 (90%), respectively, of which 283/

301 (94%) and 264/282 (94%) were singletons with birth-weight ≥ 2000 g (Figure 1).

Background characteristics

Within the subgroups, age and parity were approximately equally distributed. Approximately 15% of multiparous women in both periods had previously had one or more caesarean sections. Of multiparous women, 35/150 (23%)

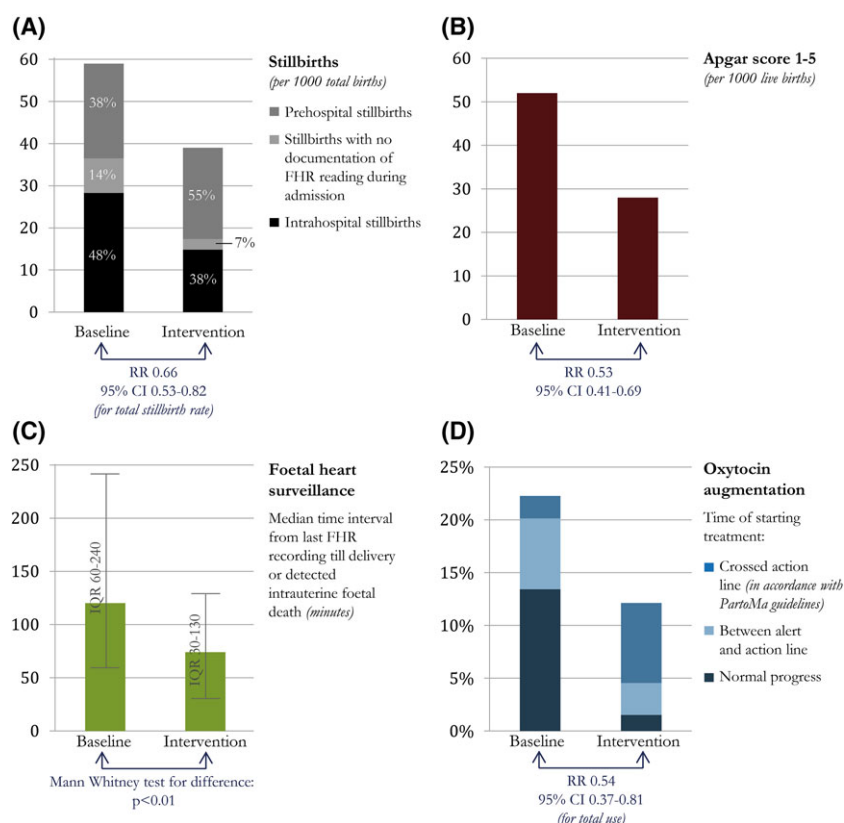


Figure 2. Key findings – comparison of baseline (October 2014–January 2015) and the 9th to 12th intervention month of the PartoMa study (October 2015–January 2016). (A) Stillbirths (fetal deaths ≥ 1000 g). The division into prehospital (no FHR on admission) and intrahospital (positive FHR during admission) stillbirths is based on extrapolation from an analysis of singleton stillbirths with retrievable case files [175/216 (81%) at baseline and 92/119 (77%) in intervention months]: $(59/1000) \times 0.48$ and $(39/1000) \times 0.38$, respectively. (B) Signs of birth asphyxia. (C) Quality of fetal heart surveillance, assessed in the quasi-randomly selected subgroups. (D) Quality of treatment with oxytocin augmentation in women not induced, assessed in the quasi-randomly selected subgroups. CI, confidence interval; FHR, fetal heart rate; IQR, interquartile range; RR, relative risk.

at baseline and 23/146 (16%) in intervention months had lost one or more children ($P = 0.11$). Labour progress on admission and rates of referrals were comparable between baseline and intervention months (Table 1).

Birth outcomes

At baseline, 216 stillbirths occurred in 3690 total births (59 per 1000 total births), compared with 119 in 3087 births in intervention months (39 per 1000 total births) (RR 0.66, 95% CI 0.53–0.82). The number of neonates with Apgar scores between 1 and 5 nearly halved: from 52 to 28 per 1000 live births (RR 0.53, 95% CI 0.41–0.69) (Figure 2, Table 2).

It was possible to retrieve case files of 175/216 (81%) singleton stillbirths at baseline and 92/119 (77%) in intervention months. Of these, 84/175 (48%) at baseline and 35/92 (38%) in intervention months had positive FHR during admission (RR 0.79, 95% CI 0.59–1.07) (Figure 1). Of the remaining stillbirths at baseline, in 67/175 (38%), intrauterine fetal death was clearly documented on admission, and

24/175 (14%) had no documentation of FHR readings during the admission and so could potentially also be intrapartum. In the intervention months, this was the case for 51/92 (55%) and 6/92 (7%), respectively. The proportion of intrahospital stillbirths among retrieved and the approximately 20% non-retrieved case files might differ, but, if assuming similar proportions, this would imply an almost halving of intrahospital stillbirths occurring after admission [$(59/1000) \times 0.48$] and $(39/1000) \times 0.38$, respectively], from 28 to 15 intrapartum stillbirths per 1000 total births (RR 0.52, 95% CI 0.37–0.73) (Figure 2A, Table 2).

Maternal deaths were largely unchanged, from 15 in 3474 live births to 16 in 2968 (RR 1.25, 95% CI 0.62–2.52) (mortality causes are listed in Table S1). The proportion of vacuum extractions increased from 10/3690 (0.3%) to 37/3087 (1.2%) (RR 4.42, 95% CI 2.20–8.88) and caesarean sections from 431/3690 (11.7%) to 489/3087 (15.8%) (RR 1.36, 95% CI 1.20–1.53) (Table 2).

Birth outcomes delineated to the subgroups are available as Table S2.

Table 2. Birth outcomes and quality of intrapartum care. Birth outcomes are evaluated for all women and their offspring during baseline (October 2014–January 2015) and the 9th to 12th intervention month of the PartoMa study (October 2015–January 2016). Quality of care is evaluated within the quasi-randomly selected subgroups.

Birth outcomes (evaluated on all women and offspring)	Baseline Rate (n/Total)	9th to 12th Intervention Month Rate (n/Total)	RR (95% CI)
Perinatal outcome			
Stillbirth rate per 1000 total births	59 (216/3690)	39 (119/3087)	0.66 (0.53–0.82)
Intra-hospital stillbirth rate per 1000 total births*	~28 (104/3690)	~15 (45/3087)	0.52 (0.37–0.73)
Apgar score ≤ 5 rate per 1000 live births	52 (181/3474)	28 (82/2968)	0.53 (0.41–0.68)
Maternal outcome			
Maternal deaths per total live births	– (15/3474)	– (16/2968)	1.25 (0.62–2.52)
Mode of delivery			
Vacuum extraction rate (%)	0.3 (10/3690)	1.2 (37/3087)	4.42 (2.20–8.88)
Caesarean section rate (%)	11.7 (431/3690)	15.8 (489/3087)	1.36 (1.20–1.53)
Process of intrapartum care delivery (evaluated on women and offspring included in the subgroups)			
Overall partograph use			
<i>Of women in first stage, active phase of labour</i>	(n = 239)	(n = 219)	
The partograph at least partially applied	213 (89.1%)	209 (95.4%)	1.07 (1.02–1.13)
<i>Of women with the partograph applied</i>	(n = 213)	(n = 209)	
First cervical dilation in active labour plotted correctly	192 (90.1%)	195 (93.3%)	1.04 (0.98–1.10)
Fetal surveillance			
<i>Of all women in the study</i>	(n = 283)	(n = 264)	
At least one FHR reading	233 (82.3%)	244 (92.4%)	1.12 (1.05–1.20)
<i>Of women with at least one FHR reading</i>	(n = 233)	(n = 244)	
< 90 minutes between any 2 FHR recordings	96 (41.2%)	121 (49.6%)	1.20 (0.99–1.47)
<i>Of women in active phase of labour and positive FHR</i>	(n = 269)	(n = 244)	
Time from last FHR till delivery calculated	235 (87.4%)	224 (91.8%)	1.05 (0.99–1.12)
Last FHR till delivery (minutes); median time [IQR]**	120 [60–240]	74 [30–130]	
Labour progress			
<i>Of women admitted before active labour</i>	(n = 77)	(n = 83)	
Cervical dilation assessed in active labour***	51 (66.2%)	52 (62.7%)	0.95 (0.75–1.19)
<i>Of women in first stage, active phase of labour</i>	(n = 239)	(n = 219)	
<5 hours between any 2 cervix recordings	191 (79.9%)	192 (87.7%)	1.10 (1.01–1.19)
<3 hours between any 2 contraction recordings	138 (57.7%)	141 (64.4%)	1.12 (0.96–1.29)
Alert line crossed	57 (23.8%)	78 (35.6%)	1.49 (1.12–1.99)
Action line crossed	25 (10.5%)	42 (19.2%)	1.83 (1.16–2.90)
<i>Of all women in the study</i>	(n = 283)	(n = 264)	
Oxytocin augmentation, total use****	63 (22.3%)	32 (12.1%)	0.54 (0.37–0.81)
Oxytocin augmentation, before action line	57 (20.1%)	12 (4.5%)	0.23 (0.12–0.41)
Oxytocin augmentation, after action line	6 (2.1%)	20 (7.6%)	3.57 (1.46–8.76)
Maternal vital signs			
<i>Of women in active phase of labour and positive FHR</i>	(n = 269)	(n = 244)	
BP recorded at least once during active labour	182 (67.7%)	161 (66.0%)	0.98 (0.86–1.10)
<i>Of all women in the study</i>	(n = 283)	(n = 264)	
≥ 1 temperature recording before delivery	165 (58.3%)	141 (53.4%)	0.92 (0.79–1.06)

BP, blood pressure; CI, confidence interval; FHR, fetal heart rate; min., minutes; RR, relative risk.

*RR based on extrapolation from an analysis of singleton stillbirths with retrievable case files [175/216 (81%) at baseline and 92/119 (77%) in the evaluation months]: (59/1000)*0.48 and (39/1000)*0.38, respectively.

**Time interval from last FHR recording till delivery or detected intrauterine fetal death. Mann–Whitney test for difference: $P < 0.01$.

***If vaginal examination was performed in latent phase ≤ 4 hours prior to delivery, this was registered as acceptable.

****Women receiving induction of labour are excluded from analyses of oxytocin augmentation.

Quality of care

In both subgroups, more than 90% of women reaching active labour and admitted before second stage had a

partograph started, and more than 90% of these had first cervical dilation appropriately plotted on the alert line (Table 2).

At baseline, 233/283 (82%) had at least one FHR recorded, versus 244/264 (92%) in intervention months (RR 1.12, 95% CI 1.05–1.20). The median time from last FHR recording until delivery (or until detected intrauterine fetal death) was 120 minutes at baseline (IQR 60–240 minutes) versus 74 minutes in intervention months (IQR 30–130 minutes) (Mann–Whitney test for difference, $P < 0.01$) (Figure 2C, Table 2).

Oxytocin use for labour augmentation when not induced, decreased significantly from 63/283 (21%) at baseline to 32/264 (12%) in intervention months (RR 0.54, 95% CI 0.37–0.81). More specifically, oxytocin use before crossing the action line fell (RR 0.23, 95% CI 0.12–0.41), whereas it increased after crossing the line (RR 3.57, 95% CI 1.46–8.76) (Figure 2C). Meanwhile, 25/239 (11%) of women crossed the action line in the first stage of active labour at baseline compared with 42/219 (19%) in intervention months (RR 1.83, 95% CI 1.16–2.90) (Figure 2D, Table 2).

Surveillance of blood pressure and temperature were unchanged (Table 2).

Structural mediators and confounders

There were no other obstetric or neonatal interventions introduced during the 12 intervention months. Only one birth attendant received additional formalised training externally, and no in-house training was organised in either neonatal resuscitation or postpartum haemorrhage. Daily clinical meetings supervised by a senior obstetrician were launched 7 months prior to the baseline – these were similar throughout the study period and were mainly attended by doctors. Although maternal death audits commenced in August 2015, presentations of findings were first initiated after the end of the 12th intervention month. Parameters to be measured and findings of the PartoMa study, including baseline data, were only presented after the 12th intervention month. During the study period, hardly any differences were observed in staff numbers, including foreign staff, continuous shortages of supplies, and available emergency obstetric and neonatal care signal functions (Table S3). However, there were 16% fewer deliveries in intervention months.

Discussion

Main findings

We found a risk reduction of 34% in stillbirths, corresponding to 20 prevented stillbirths per 1000 total births, and 47% with Apgar scores between 1 and 5, resulting in 24 fewer neonates with signs of birth asphyxia per 1000 live births. Consistently, and in line with PartoMa guidelines, FHR surveillance and timely oxytocin augmentation improved significantly. Considering contextual mediators

and confounders, and high satisfaction with guidelines¹⁶ and seminars, it is likely that the PartoMa intervention catalysed these behavioural changes. We have no knowledge about other studies evaluating effect of locally tailored intrapartum guidelines on perinatal outcome in low-resource settings.¹⁶

Strengths and limitations

This pragmatic and low-cost pre-post study was designed to suit limitations in data and budget, and the variables may inspire the development of realistic core outcomes for low-resource settings.²⁹ Although there are specific restrictions for each sub-analysis, multiple variables enabled exploration of the guidelines' pathway through practice to changes in birth outcome.^{26,30} To strengthen causality further, we undertook knowledge tests; however, these tests were anonymous in order not to expose participants, which made evaluation at individual level impossible.

Comparison of delivery modes between subgroups and total numbers (Tables 2 and S2) suggests subgroups to be representative of the entire population. Likewise, comparable background characteristics of women in baseline and intervention subgroups strengthens internal validity. Two baseline time points would have explored possible time-related changes, but this was hampered by breakdown of the hospital case file storage system.²⁴ The 16% reduction in total deliveries might have enabled more timely care. Although no other formalised training activities were conducted, discussions at daily clinical meetings might have influenced practice independently of PartoMa. Moreover, conducting a quality improvement project might have influenced practice independently of the intervention.³¹ However, the Hawthorne effect was minimised by avoiding systematic direct observations of care, and study parameters and results were not presented before finalising this study.

Intrahospital stillbirths would have been a more delineated primary outcome, but time of death in stillbirth cases could only be analysed in approximately 80% due to poor case file storage. The pre- versus intrahospital stillbirth proportions are therefore an extrapolation, and carry a risk of bias. However, the reduction in the intrahospital stillbirth proportion from 48% to 38% is an important indication of the likelihood that the overall stillbirth reduction is associated with improved intrapartum care. Notably, this is further supported by the simultaneous reduction in birth asphyxia.

A major strength was motivation to learn and improve among many birth attendants, e.g. as revealed by high seminar attendance. This is consistent with the focus of the PartoMa intervention on individuals' personal wish to improve. It may be explored further whether staff motivation was the pathway's starting point, or motivation was stimulated by PartoMa. Although it is unlikely that the

intervention would have been effective without motivation, in particular, nurse-midwives not applying guidelines¹⁶ were a challenge for team work and further improvement. Non-participants may, for example, have contributed to unchanged routine blood pressure and temperature surveillance, which are mainly monitored by nurse-midwives. Additional methodological considerations have been discussed previously.²⁴

Interpretation

The PartoMa study indicates that intrahospital stillbirths can be partially reduced by implementation of locally tailored guidelines, without increasing the alarmingly suboptimal staff numbers or introducing additional medical technology. Simultaneous reduction in birth asphyxia suggests that the babies survived in a reassuring medical condition. Although results from intervention months show that care is still far from following the PartoMa guidelines optimally, significant progress has occurred since baseline. This is in line with the particular high satisfaction among staff to parts of PartoMa guidelines.¹⁶ Intervals from last FHR recording till delivery were reduced significantly. Consistently, our baseline study revealed an increase of 20% in the odds of stillbirth for each 1-hour increase in FHR assessment interval.²⁴ Our baseline study furthermore identified inappropriate oxytocin augmentation as a predisposing factor for intrahospital stillbirths.²⁴ It appeared unrealistic to assure close monitoring of oxytocin augmentation if multiple women were treated simultaneously, and PartoMa guidelines therefore recommend reserving intrapartum oxytocin for women crossing the partograph action line.¹⁶ Consistently, overall oxytocin augmentation decreased significantly from 21% to 12% with reduced use prior to the action line and increased use when crossing the line. This also indicates improvement in partograph use for timely surveillance and management of labour progress.²⁵ Associated with reduction in oxytocin augmentation, there was an expected increase in women with slow labour progress. The subgroup evaluation indicated that the increase in caesarean sections was not caused by more cases of prolonged or obstructed labour.

While still suboptimal, a 1.2% rate of deliveries by vacuum extraction is an encouraging significant improvement.³² Recommendations for vacuum extraction were adapted and included in PartoMa guidelines,³³ and this might be associated with the increase.

The caesarean section rate increased from 12% to 16%. While an elaborate pre-post analysis of the indications for caesarean will require a detailed study, the subgroup evaluation did not raise concerns about an increase in unnecessary surgeries. Moreover, if timely performed, the increased rate may have aided in reducing perinatal risk.

Our results suggest that the PartoMa intervention was well tailored to the needs of staff, presenting a realistic aim for quality care. At baseline, multiple international and national evidence-based guidelines were available, but staff rarely applied these. As reported from comparable settings, informal sharing of knowledge and experience dominated decision-making.^{15,34} Reasons for translation of PartoMa guidelines to practice may be multifactorial and concern both guidelines content and implementation. The content was developed in close collaboration with staff to assure that the guidelines are contextually achievable and easy to use.¹⁶ Contrary to the passive strategy often used to disseminate guidelines,^{14,16} PartoMa guidelines were actively applied at daily meetings and taught at seminars. It is likely that this reoccurring low-dose training may have boosted guidelines use, particularly when considering the massive staff turnover. Conversely, an appropriate guidelines curriculum appears crucial for effective training.

Fourteen months post-implementation, a local voluntary steering group took over distribution of PartoMa guidelines and organising seminars. Guidelines are still requested, both by staff at the study site and from other hospitals, and many staff still attend seminars.

In addition to fetal surveillance and labour progress, PartoMa guidelines' recommendations for management of severe hypertensive disorders was highly appreciated among doctors,¹⁶ and we are currently studying associated changes in practice. The next steps may include assessing feasibility at comparable hospitals, optimising guidelines content and implementation further, developing a course to train facilitators, assessing guidelines users on key competencies, and discussing voluntary versus compulsory training. Although the evaluation here presented applies a narrow definition of quality care, the PartoMa intervention also focuses on respectful maternity care, which needs further evaluation, including engagement of labouring women. Finally, adding to the overall cost-effectiveness of stillbirth reduction,³⁵ it may be relevant to study the facility-based cost-effectiveness of PartoMa.

Conclusion

At the referral hospital of Zanzibar, the PartoMa study addresses the need for sustainable implementation of effective intrapartum guidelines. The locally tailored PartoMa guidelines were well accepted and sought by staff,¹⁶ and they were associated with improvements in practice, leading to significant reductions in stillbirths and birth asphyxia. While low human resources and substandard care remain major challenges, results emphasise the central roles of enhanced fetal surveillance and restricted intrapartum oxytocin use in improving survival – and indicate the effectiveness of the partograph when closely coupled with

management guidelines. Two years post-implementation, the PartoMa intervention is still running.

Disclosure of interests

None declared. Completed disclosure of interests form available to view online as supporting information.

Contribution to authorship

NM and ICB formulated the study design. NM managed the data acquisition, analysed and interpreted data, and drafted the paper. ICB contributed substantially to analyses and interpretation of data, and critically revised the paper draft. NH participated substantially in acquisition, analyses, and interpretation of data, and in critically revising the paper draft. JvR, TM and BBN contributed substantially to the study design, analyses and interpretation of data, and they critically revised the paper draft. RSK, AGM, MMA, and SMS participated substantially in acquisition of data, and contributed to the analyses and interpretation of data, and in revising the paper draft. AKGJ contributed substantially to the statistical part of the study design and analyses, data interpretation, and revising of the paper draft. In addition, all authors have approved the final version to be published and agree to be accountable for all aspects of the work.

Details of ethics approval

Ethical approval was attained from the Zanzibar Medical and Research Ethical Committee (ZAMREC/0001/JUNE/014, 7 October 2014) and Mnazi Mmoja Hospital, and the project is listed in ClinicalTrials.org (NCT02318420, 4 November 2014).

Funding

The PartoMa study is financed by grants from the Lundbeck (R164-2013-16038), Laerdal (40108) and Augustinus (14-1059) Foundations. The Foundations have no role in design, implementation, interpretation or reporting.

Acknowledgements

The research team is most grateful for the great enthusiasm and engagement with the PartoMa study within the group of birth attendants at Mnazi Mmoja Hospital. In particular, we would like to thank the following health providers for their help in multiple stages of this project: Naufal Kassim, Msafiri Marijani, Mathew Oswald Zacharia, Margaret Tayari, Tatu Fundi Salum, Kamilya Aly Omar, Sabra Salum Masoud, Lamlat Hassan Nondo, Sanura Abdalla, Dhuria Abdallah Ahmed, Fatma Mrisho Haji, Wahida Rashid Abdi, Mishi Juma Ali, Saida Abukabar, Ashura Amour Mwinyi, and Saada Juma Amour. Furthermore, we would like to thank Barbara Kwast, Britt Ingeborg Eide, Stine Marie Noe Nielsen, and Andrea Solnes Miltenburg for their useful input to the project design

and assistance in training facilitators and participants at the PartoMa seminars.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Causes of maternal deaths during baseline (October 2014–January 2015) and the 9th to 12th intervention month of the PartoMa study (October 2015–January 2016).

Table S2. Birth outcome for women and their offspring included in the quasi-randomly selected subgroup evaluations during baseline (October 2014–January 2015) and the 9th to 12th intervention month of the PartoMa study (October 2015–January 2016).

Table S3. Analysis of structural mediators and confounders during the PartoMa study (October 2014–January 2016). Assessed every 3 months during the study.

Video S1. Author insights. ■

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Corrigendum

In the following article,¹ there were errors in the abstract and in the text under the ‘study design’ section on page 237.

1. In the abstract section, the ‘Population’ section reads:

Population Facility deliveries during baseline (1 October 2014 until 31 January 2015) and the 9th to 12th intervention month (1 October 2014 until 31 January 2015).

The ‘Population’ section should read:

Population Facility deliveries during baseline (1 October 2014 until 31 January 2015) and the 9th to 12th intervention month (1 October 2015 until 31 January 2016).

2. On page 237, under ‘Study design’ section, the sentence reads:

We conducted a quasi-experimental pre-post study comparing all women delivering at the study site during baseline (1 October 2014 until 31 January 2015) with the 9th to 12th intervention month (1 October 2014 until 31 January 2015).

The sentence should read:

We conducted a quasi-experimental pre-post study comparing all women delivering at the study site during baseline (1 October 2014 until 31 January 2015) with the 9th to 12th intervention month (1 October 2015 until 31 January 2016).

Reference

- 1 Maaløe N, Housseine N, Meguid T, Nielsen BB, Jensen AKG, Khamis RS, Mohamed AG, Ali MM, Said SM, van Roosmalen J, Bygbjerg IC. Effect of locally tailored labour management guidelines on intrahospital stillbirths and birth asphyxia at the referral hospital of Zanzibar: a quasi-experimental pre-post study (The PartoMa study). *BJOG* 2018;125:235–45.

Table S1 Causes of maternal deaths during baseline (October 2014-January 2015) and the ninth till twelfth intervention month of the PartoMa study (October 2015-January 2016).

	Baseline	9 th -12 th Intervention Month
Total maternal deaths (N/total live births)*	15/3474	16/2968
Primary medical causes:		
<i>Direct:</i>		
Postpartum haemorrhage	3	5
Severe pre-eclampsia/eclampsia	0	5
Anaesthetic complications	2	1
Placental abruption	2**	1
Uterine rupture	0	1
Ectopic pregnancies	2	0
Unspecified shock post-caesarean section		1
Abortion	1	0
<i>Indirect:</i>		
Cardiac disease	2	0
Severe anaemia	1	0
AIDS	0	1
Brain tumour	0	1
Unknown medical cause	2	0

*RR 1.25, 95% CI 0.62-2.52

**1 of these had severe pre-eclampsia

Table S2 Birth outcome for women and their offspring included in the quasi-randomly selected subgroup evaluations during baseline (October 2014-January 2015) and the ninth till twelfth intervention month of the PartoMa study (October 2015-January 2016).

	Baseline	9 th -12 th Intervention Month	p-value*
	N (%)	N (%)	
<i>Of all women in the subgroups:</i>	<i>(n=283)</i>	<i>(n=264)</i>	
Mode of delivery			
Vaginal delivery	248 (87.6)	223 (84.5)	0.16
Caesarean section**	30 (10.6)	40 (15.2)	
Information missing	5 (1.8)	1 (0.4)	
Maternal outcome			
Maternal deaths	0 (0.0)	0 (0.0)	-
Post-partum haemorrhage	17 (6.0)	16 (6.1)	1.00
Intrapartum fever or infection	0 (0.0)	3 (1.1)	0.11
Episiotomy/spontaneous tears ***	92 (32.5)	92 (34.8)	0.59
<i>Of vaginal deliveries:</i>	<i>(n=248)</i>	<i>(n=222)</i>	
Prolonged admission. ≥ 1 day	6 (1.2)	7 (1.6)	0.78
<i>Of caesarean sections:</i>	<i>(n=30)</i>	<i>(n=39)</i>	
Prolonged admission. ≥ 5 days	2 (6.7)	1 (2.5)	0.58
<i>Of all babies in the study:</i>	<i>(n=283)</i>	<i>(n=264)</i>	
Perinatal outcome			
Apgar score 0	8 (2.8)	5 (1.9)	0.13
Apgar score 1-5	8 (2.8)	6 (2.3)	
Apgar score 6	10 (3.5)	2 (0.8)	
Apgar score 7-10	249 (88.0)	242 (91.7)	
Information missing	8 (2.8)	9 (3.4)	

* Fisher exact test

** Poor labour progress / obstruction was the most frequent indication in both periods (11/30 (37%) in baseline vs. 12/40 (30%) in evaluation months), followed by ≥2 previous CSs (10/30 (33%) vs. 12/40 (20%)), Failure of induction in severe pre-eclampsia/eclampsia (2/30 (7%) vs. 5/40 (13%)), breech presentation (1/30 (3%) vs. 3/40 (8%)), suspected foetal distress (2/30 (7%) vs. 2/40 (5%)) . In 3/30 (10%) and 8/40 (20%), CS was done due to more rare indications (e.g. impending rupture, failure of vacuum extraction, oblique lie), and in 1/30 (3%) and 2/40 (5%) indication was unclear.

*** Information was inadequate to differentiate between spontaneous perineal or vaginal tears and episiotomies.

RR, relative risk

Paper IV

Effect of locally-tailored clinical guidelines on intrapartum management of severe hypertensive disorders at Zanzibar's tertiary hospital (The PartoMa study)

Maaløe N, Andersen CB, Housseine N, Meguid T, Bygbjerg IC, van Roosmalen J. Int J Gynecol Obstet. 2019;144(1):27-36.

Supplementary material is available on the journal homepage.

CLINICAL ARTICLE

Obstetrics

WILEY



Effect of locally tailored clinical guidelines on intrapartum management of severe hypertensive disorders at Zanzibar's tertiary hospital (the PartoMa study)

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Funding Information

Lundbeck Foundation; Laerdal Foundation; Augustinus Foundation; University of Copenhagen

Abstract

Objective: To estimate the effect of locally tailored clinical guidelines on intrapartum care and perinatal outcomes among women with severe hypertensive disorders in pregnancy (sHDP).

Methods: A pre-post study at Zanzibar's low-resource Mnazi Mmoja Hospital was conducted. All labouring women with sHDP were included at baseline (October 2014 to January 2015) and at 9–12 months after implementation of the ongoing intervention (October 2015 to January 2016). Background characteristics, clinical practice, and delivery outcomes were assessed by criterion-based case file reviews.

Results: Overall, 188 of 2761 (6.8%) women had sHDP at baseline, and 196 of 2398 (8.2%) did so during the intervention months. The median time between last blood pressure recording and delivery decreased during the intervention compared with baseline ($P=0.015$). Among women with severe hypertension, antihypertensive treatment increased during the intervention compared with baseline (relative risk [RR] 1.37, 95% confidence interval [CI] 1.14–1.66). Among the neonates delivered (birth-weight ≥ 1000 g), stillbirths decreased (RR 0.56, 95% CI 0.35–0.90) and Apgar scores of seven or more increased during the intervention compared with baseline (RR 1.17, 95% CI 1.03–1.33).

Conclusion: Although health system strengthening remains crucial, locally tailored clinical guidelines seemed to help work-overloaded birth attendants at a low-resource hospital to improve care for women with sHDP.

ClinicalTrials.org: NCT02318420.

KEYWORDS

Birth asphyxia; Guidelines; Labor; PartoMa; Pre-eclampsia; Severe hypertensive disorders; Stillbirth; Tanzania

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1 | INTRODUCTION

Hypertensive disorders in pregnancy (HDP) cause one-tenth of maternal deaths in Africa.^{1,2} A previous facility-based survey in low- and middle-income countries found that the likelihood of maternal near-miss was eightfold and perinatal death threefold higher in a group of women with pre-eclampsia than in a reference group without HDP.² Although most cases are preventable, undiagnosed or suboptimally treated HDP is repeatedly reported in sub-Saharan Africa.^{3–10} This violates human rights and is a key priority for safe motherhood.^{11,12}

Hypertensive disorders in pregnancy can rapidly progress in severity, with increased risk of organ failure such as cerebral hemorrhage, coagulopathy, eclampsia, and pulmonary edema. Lifesaving treatment includes induction and/or oxytocin augmentation of labor while stabilizing blood pressure (BP) and supporting vital organ functions.^{13,14} In high-volume low-resource hospitals, urgent intrapartum diagnosis, surveillance, and management of such complex diseases are challenging and need realistic practical guidance.^{3,5–9,15,16}

In Tanzania, however, only one-third of maternity units have emergency obstetric care guidelines available, and only one-quarter have at least one birth attendant with adequate training in applying these.¹⁷ Even if available, guidelines are often not tailored to low-resource settings.^{9,15,16,18} Unachievable international guidelines limit implementation and may demoralize staff. Clinical guidelines tailored and disseminated to facilitate effective application in low-resource settings are required.^{15,17,18}

Zanzibar is a low-income, semiautonomous archipelago of the United Republic of Tanzania, with a facility delivery rate of 55%. In its tertiary Mnazi Mmoja Hospital, approximately 12 000 births are attended to annually. There were 59 stillbirths per 1000 births in 2014–2015, and 52 neonates per 1000 live births had an Apgar score of 1–5. Approximately half of the stillborn fetuses were alive on admission, and the quality of intrapartum care was widely unacceptable.³ This prompted, in collaboration with doctors and nurse-midwives, the development of locally achievable clinical guidelines for common intrapartum care. The resulting eight-page PartoMa pocket booklet has subsequently been implemented among doctors and nurse-midwives by quarterly seminars.¹⁸ In particular, doctors have reported finding the booklet's page on essential intrapartum management of HDP useful.¹⁸ The aim of the present study was therefore to estimate the effects of the PartoMa intervention of pocket guides and quarterly low-dose training on care and delivery outcomes among women with severe HDP (sHDP).

2 | MATERIALS AND METHODS

In a retrospective pre–post study, case files were reviewed for all women with sHDP (defined as systolic BP 160 mm Hg or higher and/or diastolic BP 110 mm Hg or higher and/or eclampsia pre-delivery) who attended Mnazi Mmoja Hospital before the PartoMa intervention (October 1, 2014, to January 31, 2015) and 9–12 months after implementation (October 1, 2015, to January 31, 2016). The PartoMa

study was approved by Mnazi Mmoja Hospital and Zanzibar Medical and Research Ethical Committee (ZAMREC/0001/JUNE/014), and registered with ClinicalTrials.org (NCT02318420). Patient identities were anonymized, and thus informed consent not required.

Throughout the study, each birth attendant (nurse-midwife or doctor) simultaneously cared for an average of 3–6 laboring women, and 30% were intern doctors conducting their initial 6-week rotation. Turnover was high among staff in permanent positions: 25% of nurse-midwives and 40% of doctors during the initial 6 months of the intervention were no longer working there after 1 year.¹⁹ As a result, most staff had limited experience with childbirth care. Only two had a master in midwifery and there were only two obstetricians. At baseline, clinical intrapartum guidelines were not routinely used. The WHO composite partograph was recommended for all deliveries.²⁰

The “PartoMa Pocket Guide” (File S1) was launched on January 27–28, 2015, at the first “PartoMa seminars”. These 3-hour seminars were conducted quarterly in order to establish use of the guidelines via case-based discussions. They were conducted outside working hours and without ‘per diems’ or other allowances. An average of 74% of doctors and 62% of nurse-midwives from the obstetric division attended each of five seminar rounds during the first intervention year. One page of the pocket guide (Fig. 1) and one of five seminar cases concerned intrapartum care for women with sHDP. Detailed descriptions of guidelines development and the seminars are presented elsewhere.^{18,19,21}

Quality of intrapartum care for women with sHDP was delineated to diagnosis, surveillance, and treatment, and based on pre-selected indicators (Fig. S1). In addition, maternal background characteristics, maternal mortality, neonatal Apgar score, and stillbirth were recorded, including the proportion of stillbirths with fetal heart rate (FHR) present on admission. The indicators were chosen to represent unambiguous audit criteria for low-resource settings that were sensitive in monitoring progress in care and could be retrieved from case files.

Structural changes at the study site that might potentially explain outcome changes (or lack of changes) after implementation of the PartoMa intervention were assessed quarterly and have been previously described.¹⁹ In brief, staff numbers, supply shortages, and available emergency obstetric and neonatal care signal functions were similar throughout the baseline and first intervention year, but there were 16% fewer deliveries during the ninth to 12th intervention months compared with baseline. Daily clinical meetings were introduced 7 months before baseline and continued similarly throughout the study. No other formalized in-house training or obstetric or early neonatal interventions were organized. Only one birth attendant received formalized training externally. The department started conducting maternal death audits in August 2015, but the audit findings were first presented for staff after the 12th intervention month.¹⁹

For the present study, the baseline period was limited to October 1, 2014, to January 31, 2015, because the hospital's case file storage system did not work properly before this period.¹⁹ The intervention period studied, October 1, 2015, to January 31, 2016 (the ninth to 12th intervention months), was previously used in the overall evaluation of PartoMa.¹⁹ For the assessment of sHDP, the calculated sample size for the intervention months was based on a two-sided comparison

High blood pressure (BP) & proteinuria

5

Version 1.2

Hypertension & pre-eclampsia/eclampsia

! THESE GUIDELINES ONLY INVOLVE TREATMENT DURING LABOUR AND DELIVERY

▲ SBP ≥ 160
and/or
DBP ≥ 110
▼ (mmHg)

SEVERE Hypertension / Pre-eclampsia:**Medication (SLOWLY):**

Anticonvulsant * & Antihypertensive **

Assess every 30 min. (use the specific observation sheets):

- Pulse, BP, RR, Temp, FHR, GCS

Symptoms of organ failure * or****Magnesium Sulphate toxicity *?**

Ask patient and assess lungs, urine output, urine dipstick, patellar reflexes

Strict fluid balance:

- Catheterize bladder (fluid intake & output, proteinuria)

- If urine output <30mL/hr.: IV Ringer's Lactate 1L in 8 hrs

Plan for delivery within 12 hrs. of admission (if at all possible, vaginal delivery is preferable)**Convulsions (eclampsia):****! Treat as eclampsia until other diagnosis is confirmed**

1. Shout for help
2. Airways and breathing
3. Position on left side and protect from injuries
4. Insert IV lines
5. Start Magnesium Sulphate SLOWLY *
6. Oxygen by mask / nasally

Additional management as for severe pre-eclampsia

▲ SBP 140-159
and/or
DBP 90-109
▼ (mmHg)

MILD-MODERATE Hypertension / Pre-eclampsia:

Ask & observe for symptoms of organ failure ***

Assess lungs, urine output, proteinuria, patellar reflexes

Reassess Pulse & BP every hr. FHR every 30 min.

! For pre-eclampsia and eclampsia, specific observation & treatment sheets must be used in combination with the partogram

▲ SBP 100-139
and/or
DBP 60-89
▼ (mmHg)

NORMAL

BP every 4 hrs.

(for other routine assessments, see page 1)

*** Anticonvulsant****Magnesium sulphate (50%):****Loading dose:**IV 4 g in 250 mL Normal Saline **SLOWLY** over 15 min.

IM 5 g + 1 mL 2% Lignocaine in each buttock

Maintenance dose:

IM 5g + 1mL 2% Lignocaine every 4 hrs, alternate buttocks

Check for toxicity and DO NOT repeat dose if:

RR < 16/min.

Urinary output < 30 ml/hr.

Patellar reflexes diminished or absent

Antidote:

IV Calcium Gluconate 1 gram (10mL in 10% solution) over 10 min.

Duration:

Continue maintenance dose for 24 hrs. after delivery or last convulsion, whichever occurs last

**** Antihypertensive****Hydralazine:**IV 5 mg **SLOWLY** over 10 min.

Repeat 5mg every 20 min. until SBP < 160 mmHg

! DBP should not fall below 90 mmHg**! Observe closely:** Hydralazine may cause maternal hypotension and fetal distress***** Diagnosing pre-eclampsia****Mild-moderate pre-eclampsia:**

Hypertension on two consecutive readings AND Proteinuria ≥ ++

SEVERE pre-eclampsia:

Pre-eclampsia AND

Severe hypertension OR

Symptoms of organ failure:

- Headache (persistent & severe)
- Blurred vision
- Upper abdominal pain (persistent)
- Decreased urine production (< 30 ml/hr)
- Breathlessness (pulmonary oedema)

Version 1.2

HIGH BLOOD PRESSURE (BP) & PROTEINURIA

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5

FIGURE 1 Intrapartum management of hypertensive disorders in pregnancy: page 7 of the PartoMa Pocket Guide version 1. A full overview of the PartoMa guidelines applied is available in File S1. Abbreviations: BP, blood pressure; CS, cesarean; FHR, fetal heart rate. Reproduced from [18].

of proportions. The proportion of women with sHDP treated with anti-hypertensives was used as a key indicator of care and was 86/184 (47%) at baseline. Post-implementation, an improvement of at least 50% in the number of women treated was expected. Thus, the sample size of approximately 180 women in each group resulted in 99.9% power at a 5% significance level.

A structured form in Excel (Microsoft, Redmond, WA, USA) was used to collate data, with statistical analyses performed in RStudio version 1.1.383 (RStudio, Boston, MA, USA). Background characteristics were compared by using Fisher exact test. Care and delivery outcomes were compared by using relative risk (RR) and 95% confidence intervals (CIs) for dichotomous indicators, and Mann-Whitney test for time intervals. A P value of less than 0.05 was considered statistically significant.

3 | RESULTS

According to the hospital registers, 3599 women gave birth at baseline and 3002 did so during the four intervention months studied, but case files of 3609 and 3067 women were retrieved from the respective study periods. Of these, 2761 (76.5%) and 2398 (78.2%) women, respectively, had at least one BP measurement, or had eclampsia documented without a BP recording, of whom 188 (6.8%) and 196 (8.2%) fulfilled the criteria for sHDP and were included in the baseline and intervention groups. An additional 848 (23.5%) and 669 (21.8%) of the

women retrieved from the study periods had no BP recorded during the whole admission period (RR 0.93, 95% CI 0.85–1.01), respectively, which could lead to an underestimation of sHDP (Fig. 2).

The background characteristics of women with sHDP were comparable between the baseline and intervention groups: approximately 40% were nulliparous; 75% had completed 34 weeks (birthweight ≥ 2000 g) of pregnancy; more than 80% had attended prenatal care at least once and 40% had at least four prenatal visits. Among the multiparous women, 30% had previously lost one or more children (documentation was inadequate to distinguish perinatal deaths from deaths later in life). Labor progress on admission was similarly comparable between the two groups: 50% were admitted before active labor and 2% in the second stage. Fifteen percent were referred from lower level facilities. On admission, 9% were diagnosed with intrauterine fetal death (Table S1). Among the 188 women at baseline, 184 (97.9%) had severe hypertension (systolic BP ≥ 160 mm Hg and/or diastolic BP ≥ 110 mm Hg) and 70 (37.2%) had a systolic BP of 180 mm Hg or higher. These proportions were comparable with the intervention group: 193 (98.5%) and 85 (43.4%). The incidence of proteinuria (dipstick measurement $\geq 2+$) was slightly higher during the intervention months, which might be due to fewer women in this group lacking a urine test (Table S1).

The routine BP assessments of all laboring women did not improve between the two periods (RR 0.93, 95% CI 0.85–1.01) (Fig. 2). Among women with sHDP, diagnosis was more frequent

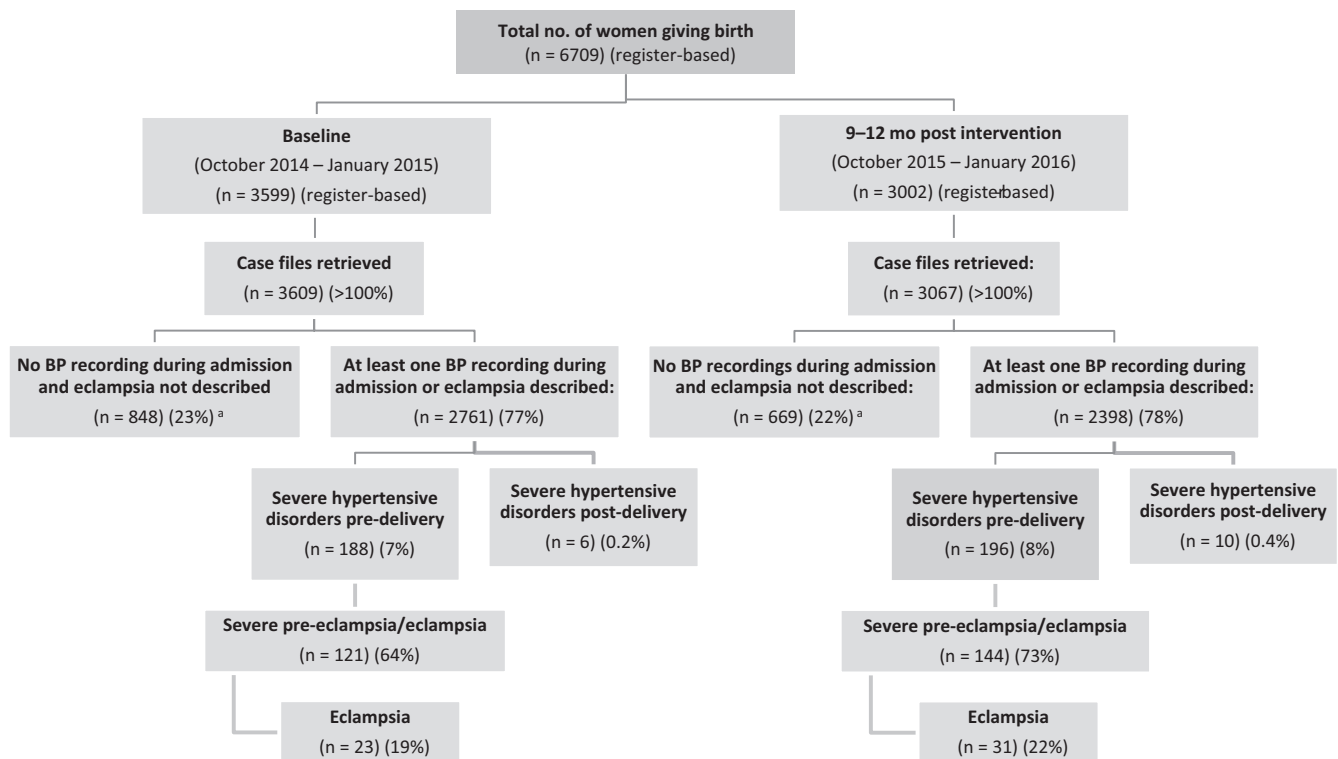


FIGURE 2 Flow chart showing women included in the study. The inclusion criteria were severe hypertension (systolic blood pressure [BP] ≥ 160 mm Hg and/or diastolic BP ≥ 110 mm Hg) and/or eclampsia. A subgroup of women with severe pre-eclampsia/eclampsia were defined as having at least one recording of severe hypertension and a proteinuria measurement of at least 2+, and/or eclampsia recorded before or during admission. Abbreviations: BP, blood pressure; RR, relative risk; CI, confidence interval. ^aAmong all women in labor, routine BP assessments did not improve (RR 0.93, 95% CI 0.85–1.01).

on admission in the intervention months (110 [56.1%]), compared with the baseline group (82 [43.6%]) (RR 1.29, 95% CI 1.05–1.58). Among the women not diagnosed on admission, only one had mild-to-moderate HDP diagnosed prior to severe disease. There was a tendency toward a decrease in women remaining undiagnosed despite recorded inclusion criteria (RR 0.72, 95% CI 0.51–1.00) (Fig. 3, Table 1). More women had proteinuria tested in the intervention group (177 [90.3%]) than in the baseline group (156 [83.0%]) (RR 1.09, 95% CI 1.01–1.18) (Table S1).

Among women with vaginal delivery and at least one recorded BP pre-delivery, the median time between last BP and delivery was 162 minutes (interquartile range [IQR], 80–328 minutes; $n=126$) at baseline versus 129 minutes (IQR, 60–245 minutes; $n=130$) during the intervention months (Mann-Whitney test, $P=0.015$). The proportion of women with at least one recorded BP post-delivery improved from 126 (67.0%) at baseline to 151 (77.0%) during the intervention months (RR 1.15, 95% CI 1.01–1.30). Among 140 women at baseline and 164 during intervention months with at least one documented FHR, the median time between the last FHR and delivery (or identified intrauterine fetal death) decreased from 150 minutes (IQR, 60–296 minutes) to 90 minutes (IQR 35–180 minutes) (Mann-Whitney test, $P=0.001$) (Fig. 3, Table 1).

Among the women with severe hypertension (184 at baseline and 193 during the intervention months), initiation of antihypertensive treatment increased, from 86 (46.7%) women at baseline to 124 (64.2%) during the intervention months (RR 1.37, 95% CI 1.14–1.66). In both periods, 90% of women with severe pre-eclampsia/eclampsia had magnesium sulfate treatment initiated. Among the 110 women at baseline and 127 during the intervention months with magnesium sulfate initiated, 20 (18.2%) compared with 44 (34.6%), respectively, had patellar reflexes and respiratory rate recorded at least once for surveillance of toxicity (RR 1.91, 95% CI 1.20–3.03) (Fig. 3, Table 2). The median duration of labor from diagnosing sHDP to delivery was approximately 7 hours in both groups (IQR, 161–790 minutes and 225–745 minutes, respectively; Mann-Whitney test, $P=0.356$) (Table 2).

Among all deliveries (203 at baseline and 206 in the intervention months), the mode of delivery was comparable; 58 (28.6%) were delivered by cesarean at baseline compared with 63 (30.6%) during the intervention months. Among 65 (34.6%) women at baseline and 66 (33.7%) during the intervention months, there were no records in their medical file after the day of delivery; although it seems unlikely, it is unknown whether these women had been discharged.

Birthweight was 1000 g or more for 201 (99.0%) neonates at baseline and 196 (95.1%) during the intervention months. Of these, the incidence of stillbirth decreased from 42 (20.9%) at baseline to 23 (11.7%) during intervention months (RR 0.56, 95% CI 0.35–0.90), and the incidence of an Apgar score of seven or higher increased from 130 (64.7%) to 148 (75.5%), respectively (RR 1.17, 95% CI 1.03–1.33) (Table 3).

One woman at baseline and five during the intervention months died (RR 4.80, 95% CI 0.57–40.67). The woman at baseline died from obstetric hemorrhage. In the intervention group, one woman died from obstetric hemorrhage, and one had been referred from elsewhere and died on admission. The other three women experienced severe organ

dysfunction postpartum in the study hospital; one patient had pulmonary edema and hypoxia, one had eclampsia and cerebral edema, and one had eclampsia and renal failure.

4 | DISCUSSION

The present findings show that, although care remained substandard, several improvements had occurred during the ninth to 12th intervention months, such as progress in surveillance, a 37% increase in antihypertensive treatment, and a 44% reduction in risk of stillbirth. Taken together with previous studies,^{3,18,19} the findings suggest that the PartoMa intervention was an important determinant of improvements. This indicates how effective locally tailored clinical guidelines and associated quarterly, low-dose training can be in a weak health-care system with critical shortages in human resources.

The study has both strengths and limitations. The low-cost, pre-post approach had applicable process and outcome indicators. The comparable background characteristics of women between baseline and the intervention months strengthened its internal validity. Two baseline periods would have enabled potential time-related changes to be examined, but the hospital's poor case file storage prevented this approach. There were few contextual confounders identified, but the 16% fewer deliveries in the intervention months might have allowed better care.¹⁹ Birth attendants were not paid to attend the seminars. Therefore, the high attendance after working hours appeared to indicate staff motivation to improve care, which was a mediator of improvements.¹⁹ Through retrieving all available case files from the months studied and reviewing them manually, the number of women in labor identified was 2% higher than if hospital registers alone had been used. This close approximation in a low-resource hospital was a strength. The present findings are further strengthened by triangulation with similar results of the other PartoMa studies, emphasizing low inter-observer bias and unambiguity of indicators.^{3,18,19} Although the effect of the PartoMa intervention was explored in terms of care and birth outcomes, the available case file data did not enable analyzing the frequency of organ failure and neonatal mortality, the in-depth quality of monitoring and treatment, and whether the birth attendants' interactions with the women were respectful. Furthermore, data from case file reviews might be biased owing to under- or over-recording.³

The current study shows that the previously reported overall reduction in stillbirths from 59 to 39 per 1000 total births between baseline and the ninth to 12th intervention months¹⁹ was also true within the sHDP subgroup; stillbirths reduced from 20.9% to 11.7%. Although not reaching statistical significance, the results suggest that the reduction predominantly occurred among intra-hospital stillbirths. Whereas a decrease in over-use of oxytocin augmentation seemed to be a major contributor among non-sHDP women,¹⁹ it did not explain the present reduction in stillbirths observed among sHDP women. Taken together with our previous evaluation,¹⁹ the improvements observed seem to relate to the three pages of the

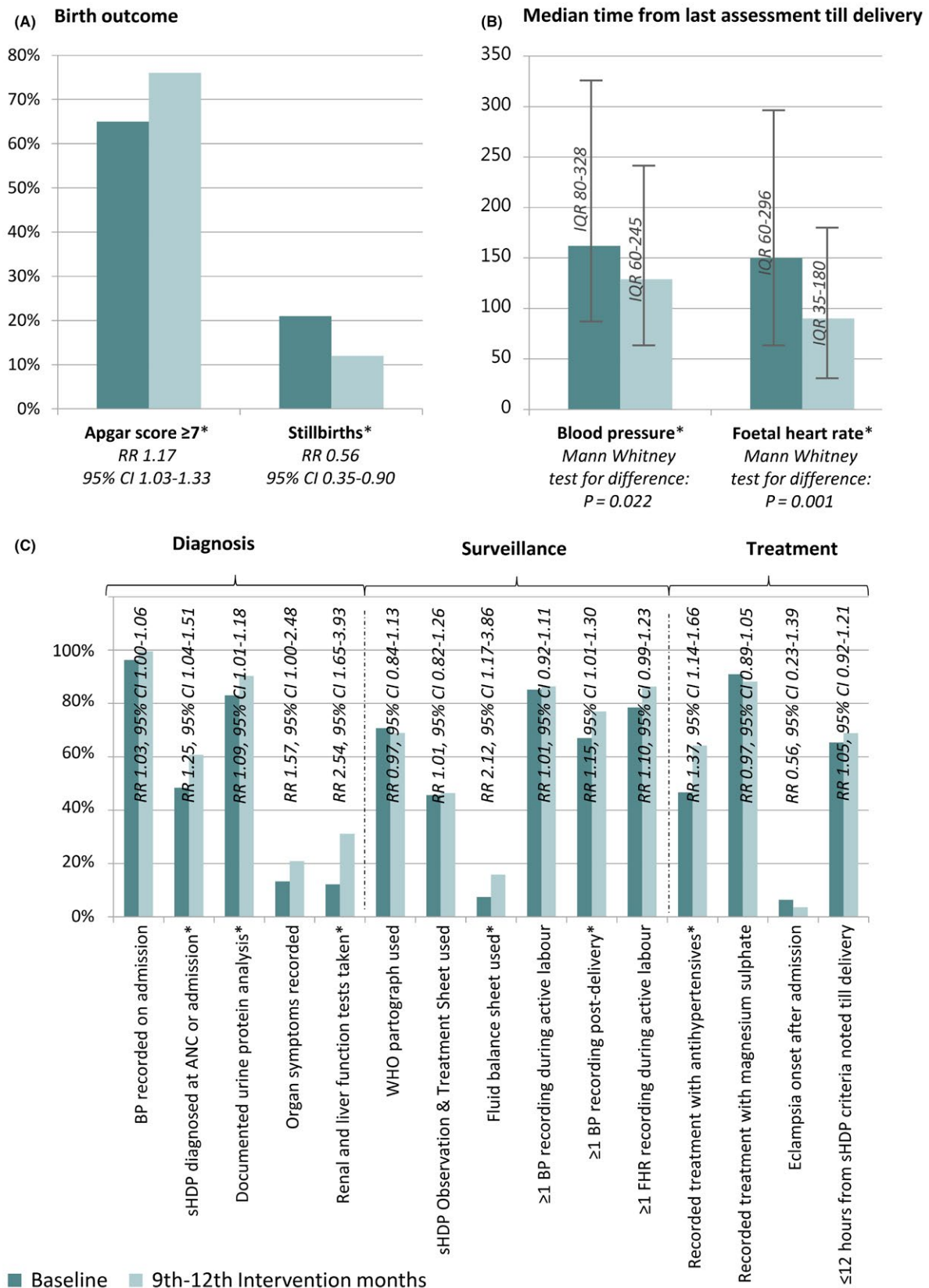


FIGURE 3 Comparison of key findings at baseline (October 2014–January 2015) and at 9–12 months of the PartoMa study (October 2015–January 2016). (A) Stillbirths (defined as fetal death with weight ≥ 1000 g) and newborns with an Apgar score of 7 or higher. (B) Median time between last recorded fetal heart rate (FHR) or blood pressure (BP) measurement and delivery. (C) Additional quality indicators of diagnosis, surveillance, and treatment of women with severe hypertensive disorders during pregnancy (sHDP). Abbreviations: CI, confidence interval; IQR, interquartile range; RR, relative risk. Asterisk indicates significant difference.

TABLE 1 Univariable analysis of the diagnosis and surveillance of women with severe hypertensive disorders during childbirth, comparison of relative risk of outcomes during the ninth to 12th months of the intervention (October 1, 2015, to January 31, 2016) compared with during the baseline period (October 1, 2014, to January 31, 2015).^a

Characteristic	At baseline (n=188)	At 9–12 intervention months (n=196)	P value	RR (95% CI)
Time of diagnosis severe hypertensive disorder				
Prenatal care visit	9 (4.8)	9 (4.6)		0.96 (0.39–2.36)
During admission assessment	82 (43.6)	110 (56.1)		1.29 (1.05–1.58)
After admission assessment	38 (20.2)	33 (16.8)		0.83 (0.55–1.27)
Undiagnosed	59 (31.4)	44 (22.4)		0.72 (0.51–1.00)
Physical examination recorded on diagnosis				
Minimum: headache, epigastric pain, vision	25 (13.3)	41 (20.9)		1.57 (1.00–2.48)
Blood count: taken: renal and liver function tests as minimum	23 (12.2)	61 (31.1)		2.54 (1.65–3.93)
Documentation sheets at least partially applied ^b				
Women in first stage of labor	161	155		
Partograph	114 (70.8)	107 (69.0)		0.97 (0.84–1.13)
All study women	188	196		
Specific observation and treatment sheet for HDP	86 (45.7)	91 (46.4)		1.01 (0.82–1.26)
Fluid balance sheet	14 (7.4)	31 (15.8)		2.12 (1.17–3.86)
Blood pressure				
BP recorded on admission	181 (96.3)	195 (99.5)		1.03 (1.00–1.06)
Women with known start of active phase of labor	149	140		
BP recorded at least once during active phase of labor	127 (85.2)	121 (86.4)		1.01 (0.92–1.11)
All study women	188	196		
BP at least once between delivery and discharge ^c	126 (67.0)	151 (77.0)		1.15 (1.01–1.30)
Women with vaginal delivery and ≥ 1 BP recording during admission	126	130		
Time from last BP till delivery, min	162 (80–328)	129 (60–245)	0.022 ^d	
Fetal heart rate				
Women in active phase of labor, no IUFD	144	131		
FHR at least once during active phase of labor	113 (78.5)	113 (86.3)		1.10 (0.99–1.23)
Women with recorded FHR	140	164		
Time from last FHR till delivery, min	150 (60–296)	90 (35–180)	0.001 ^d	
Labor progression				
Women in active phase of labor	165	156		
<5 h between any two cervical assessments ^d	103 (62.4)	112 (71.8)		1.15 (0.99–1.34)

Abbreviations: BP, blood pressure; CI, confidence interval; FHR, fetal heart rate; HDP, hypertensive disorders in pregnancy; IUFD, intrauterine fetal death; relative risk.

^aValues are given as number (percentage), absolute number, or median (interquartile range), unless indicated otherwise.

^bThe documentation sheets included a partograph sheet (at least the first cervical dilatation in active labor plotted correctly on the alert line), a specific sheet for HDP (at least one recorded observation and treatment, and fluid balance sheet (at least one recording of input and output).

^cOverall, 70/188 (37%) at baseline and 82/196 (42%) during the intervention had at least one BP recording every 24 h during the first 2 days postpartum (RR 1.12, 95% CI 0.88–1.44).

^dBy Mann-Whitney test for difference. This include the interval between the last recording of cervical dilatation and delivery.

PartoMa pocket guide that were highest rated among birth attendants (FHR, labor progress, and intrapartum HDP).¹⁸ Furthermore, this is consistent with challenges identified in the baseline case-control study of stillbirth.³ It seems that the PartoMa intervention's integrated recommendations and training in routine and emergency intrapartum care have helped to trigger quality improvements. Qualitative implementation research is warranted to further identify

organizational and individual aspects associated with the changes, and with lack of changes.²²

Two other criterion-based audits from East African referral hospitals also included locally tailored guidelines and similarly proved effective in strengthening care for women with HDP. However, their interventions were narrowly targeted at pre-eclampsia/eclampsia and included additional structural changes.^{6,8} To our knowledge, no

TABLE 2 Univariable analysis of the treatment of women with severe hypertensive disorders during childbirth, comparison of relative risk of outcomes during the ninth to 12th months of the intervention (October 1, 2015, to January 31, 2016) compared with during the baseline period (October 1, 2014, to January 31, 2015).^a

Characteristic	At baseline (n=188)	At 9–12 intervention months (n=196)	P value	RR (95% CI)
Antihypertensive treatment				
All women with severe hypertension ^b	184	193		
Hydralazine or nifedipine administered	86 (46.7)	124 (64.2)		1.37 (1.14–1.66)
Anticonvulsant treatment				
Women with urine protein ≥ 2 or eclampsia ^c	121	144		
MgSO ₄ treatment initiated	110 (90.9)	127 (88.2)		0.97 (0.89–1.05)
Women receiving MgSO ₄	110	127		
Patellar reflexes and respiratory rate at least once	20 (18.2)	44 (34.6)		1.91 (1.20–3.03)
Labor progression				
All women with the required date and time recorded:	173	189		
Time from inclusion criteria recorded till delivery, min	390 (161–790)	457 (225–745)	0.356 ^d	
All study women	188	196		
Partograph action line crossed (prolonged first stage)	22 (11.7)	22 (11.2)		0.96 (0.55–1.67)
Induction of labor ^e	48 (25.5)	75 (38.3)		1.50 (1.11–2.03)
Oxytocin for augmentation in active phase of labor ^f	45 (23.9)	36 (18.4)		0.77 (0.52–1.13)

Abbreviations: CI, confidence interval; MgSO₄, magnesium sulfate; RR, relative risk.

^aValues are given as absolute number, number (percentage), or median (interquartile range), unless indicated otherwise.

^bDiagnostic criteria for severe hypertension applied: systolic BP ≥ 160 mm Hg and/or diastolic BP ≥ 110 mm Hg.

^cDiagnostic criteria for severe pre-eclampsia/eclampsia applied: severe hypertension on at least one reading and urine protein ≥ 2 , or eclampsia/convulsions described (owing to poor data quality, women without severe hypertension or eclampsia, but fulfilling the WHO criteria of severe pre-eclampsia due to symptoms of organ failure could not be identified). For an additional 28/188 (15%) women at baseline and 12/193 (6%) during the intervention, urine dipstick was not performed.

^dMann-Whitney test for difference.

^eOne woman was induced by balloon catheter; all others were induced by misoprostol with or without subsequent oxytocin.

^fWomen were excluded if induced. For 11/45 (24%) and 7/36 (19%), respectively, membranes were still intact when starting oxytocin augmentation (RR 0.80, 95% CI 0.34–1.84).

other studies of broader guidelines have been shown to be effective in strengthening care and perinatal survival for women with HDP in low-income countries.

Nevertheless, the five maternal deaths in the ninth to 12th intervention months reflect the unacceptable quality of care throughout the study. Moreover, the 7%–8% prevalence of severe hypertensive disorders, with 85% of affected women admitted directly from home and only one diagnosed with mild-moderate disease prior to this, might in itself indicate missed opportunities for early detection and treatment, both prenatally and intrapartum. Data from another Tanzanian tertiary hospital reported an incidence of eclampsia of 6%,⁶ whereas a facility-based survey of mild-severe HDP in multiple low- and middle-income countries found an overall prevalence of only 2.7%.² The high prevalence of sHDP in the present study may also be associated with a high predisposition in the target population, which further emphasizes the need to strengthen early detection and management: 19% of Zanzibari women aged 25–44 years are affected by hypertension,²³ with the risk of gestational aggravation and superimposed pre-eclampsia.^{2,24}

In quality improvement processes, the potential effects, and adverse effects, of more or less broad focal points must be carefully

considered. As part of the internationally formulated obstetric care signal functions, maximizing magnesium sulfate coverage has been repeatedly emphasized.²⁵ At the study hospital, it was administered to 90% of women with severe pre-eclampsia/eclampsia during both baseline and intervention months. Although evidence suggests that severe hypertension is a similarly important contributor to maternal mortality in sHDP,¹⁴ antihypertensives are not included in the signal functions, and this omission might have contributed to more than half of the women with sHDP at baseline not receiving antihypertensive treatment. A similar mismatch in pre-eclampsia/eclampsia treatment was reported in Ghana, where health providers described how clinical guidelines were adhered to more closely if they were given more attention and if local adjustments were made.⁹ A second version of the brief and simple PartoMa pocket guide was launched in 2018, with the focal point broadened further by including additional essential intrapartum and postpartum care, and PartoMa seminars have now been conducted for nearly 4 years.²¹

It remains crucial to address the human resources crisis and substandard clinical competencies among staff, as well as unacceptable shortages in supplies and space. Nevertheless, in the meantime, locally tailored clinical guidelines and associated reoccurring, in-house

TABLE 3 Birth outcomes among women with severe hypertensive disorders, comparison of relative risk of outcomes during the ninth to 12th months of the intervention (October 1, 2015, to January 31, 2016) compared with during the baseline period (October 1, 2014, to January 31, 2015).^a

Outcome	Baseline	At 9–12 intervention months	RR (95% CI)
Maternal outcomes	188	196	
Maternal death	1 (0.5)	5 (2.6)	4.80 (0.57–40.67)
Day of discharge postpartum ^b			
Delivery day	65 (34.6)	66 (33.7)	0.97 (0.74–1.29)
1–2 d postpartum	35 (18.6)	64 (32.7)	1.75 (1.22–2.51)
≥3 d postpartum	88 (46.8)	67 (34.2)	0.73 (0.57–0.93)
Neonatal outcomes	203	206	
Mode of delivery			
Spontaneous vaginal	133 (65.5)	130 (63.1)	0.96 (0.83–1.11)
Vaginal breech	10 (4.9)	6 (2.9)	0.59 (0.22–1.60)
Vacuum extraction	0	4 (1.9)	
Cesarean	58 (28.6)	63 (30.6)	1.07 (0.79–1.44)
Unknown	2 (1.0)	3 (1.5)	1.48 (0.25–8.75)
Neonatal outcomes for those with birthweight ≥1000 g ^c	201	196	
Apgar score			
≥7	130 (64.7)	148 (75.5)	1.17 (1.03–1.33)
6	5 (2.5)	7 (3.6)	1.44 (0.46–4.45)
1–5	19 (9.5)	12 (6.1)	0.65 (0.32–1.30)
0 (stillbirths)	42 (20.9)	23 (11.7)	0.56 (0.35–0.90)
Information missing	5 (3.0)	6 (2.9)	1.23 (0.38–3.97)
Stillbirths, time of death			
Pre-hospital (fetal death diagnosed on admission)	18 (9.0)	14 (7.1)	0.80 (0.41–1.56)
Intra-hospital (positive FHR on admission)	18 (9.0)	9 (4.6)	0.51 (0.24–1.11)
Time unknown (no documented FHR during admission)	6 (3.0)	0	

Abbreviations: CI, confidence interval; FHR, fetal heart rate; RR, relative risk.

^aValues are given as absolute number or number (percentage), unless indicated otherwise.

^bThe last recording in the file was treated as the last day of stay.

^cOf all neonates, 2/203 (1%) at baseline and 10/206 (4.9%) during the intervention had birthweight <1000 g approximate pregnancy duration <28 wk. At the study hospital, stillbirths at <28 weeks are classified as late spontaneous abortions. Although there might be a risk of mis-categorizing stillbirths affected by severe intrauterine growth restriction, those stillbirths were excluded from the perinatal outcome data.

training, which takes account of the current resource constraints, are warranted in assisting work-overloaded birth attendants in improving care. Achievable guidance is a basic right for birth attendants holding the lives of others in their hands.

AUTHOR CONTRIBUTIONS

NM contributed to the design of the study, data collection and analysis, data interpretation, and writing the manuscript. CBA contributed to the design of the study, data collection and analysis, and revising the manuscript. NH contributed to data collection and analysis, and revising the manuscript. TM contributed to data interpretation and revising the manuscript. ICB and JvR contributed to the design of the study and revising the manuscript. All authors approved the final manuscript and agreed to be accountable for all aspects of the work.

ACKNOWLEDGMENTS

The PartoMa study is financed by grants from the Lundbeck Foundation (R164-2013-16038), the Laerdal Foundation (40108), the Augustinus Foundation (14-1059), and University of Copenhagen. The funding bodies have no role in the design, implementation, interpretation, or reporting of the study.

CONFLICTS OF INTEREST

The authors have no conflicts of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

File S1. PartoMa Pocket Guide version 1 applied in the present study.

Figure S1. Indicators analyzed to assess intrapartum quality of care and birth outcomes among women with severe hypertensive disorders of pregnancy (SHDP). The indicators are unambiguous research criteria that are sensitive in monitoring care progress at the low-resource study site and can be retrieved from the case files. They do not represent acceptable quality of care. The following documentation sheets (asterisk) were used: a partograph sheet (at least the first cervical dilatation in active labor plotted correctly on the alert line), a specific sheet for HDP (at least one recorded observation), and a fluid balance sheet (minimum of one recording of input and output). Severe hypertension (double asterisk) was defined as systolic blood pressure (BP) 160 mm Hg or higher and/or diastolic BP 110 mm Hg or higher. Severe pre-eclampsia (triple asterisk) was defined as severe hypertension on at least one reading and proteinuria of at least 2+, or recorded eclampsia/convulsions before or during admission. Abbreviations: FHR, fetal heart rate; IUFD, intrauterine fetal death.

Table S1. Background characteristics of women included at baseline and at 9–12 mo of the PartoMa intervention.

Paper V

Clinical Guidelines for Maternal Health versus Clinical Realities in Low-Resource Settings: Closing the Gap

Maaløe N, Meguid T, Housseine N, Nielsen KK, Bygbjerg IC, van Roosmalen J. Submitted to WHO Bulletin, June 2018.

International Guidelines for Maternal Health versus Clinical Realities in Low-Resource Settings: Closing the Gap

Submitted to the Bulletin of the World Health Organization in June 2018.

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Perspective

To end the epidemic of preventable lost lives at birth, the global toolkit of clinical guidelines for low-resource settings is expanding rapidly. However, fundamental gaps are repeatedly found between internationally-derived clinical guidelines and realistic best practices in busy low-resourced maternity units. Such discrepancies minimize use, demoralize health workers, and drain resources.¹⁻³ It raises the question of whose view counts, regarding implementation and aspiration.⁴

At the maternity unit in Zanzibar's tertiary hospital, adherence to internationally-derived clinical guidelines is often impossible. As common in high-volume, low-resource hospitals, one birth attendant typically cares for 3-6 labouring women simultaneously. This makes it impossible, for instance, to spend 10 minutes half-hourly with each woman counting foetal heart rate and contractions.⁵ Hence, clear guidance that assists in prioritizing the multiple tasks is warranted. Therefore, a 'PartoMa Pocket Guide©' on best possible locally-achievable maternity care was co-created with the birth attendants. As encouraged by the World Health Organization (WHO),⁶ it was based on adaptations and modifications of international guidelines, and externally peer-reviewed by a panel of specialists. In addition to everyday use, the guidelines were practiced at quarterly in-house, case-based 'PartoMa seminars'. Of all birth attendants, 60-70% participated each time, after working hours and without per diems. The PartoMa guide and related training appeared associated with significant improvements in knowledge, skills and clinical practice, resulting in fewer stillbirths and asphyxiated newborns.⁷ Three years later, demand for the PartoMa intervention remains high among Zanzibari birth attendants. Unfortunately, there are alarmingly few examples of such effective clinical guidelines development and implementation in low-resource settings, both within and beyond obstetrics.^{1,2,8}

To achieve local usefulness of the PartoMa guide, reductions were made in international guidelines' frequencies of assessments, information load, inconsistency and ambiguity. It was highly time- and resource-demanding, and not a realistic process to be performed in many low-resource settings.^{1,2} Large-scale maternal health guidelines targeting low-resource settings have typically relied heavily on top-down development by experts without involvement of target users, followed by inflexible waterfall implementation.^{2,3,8,9} The WHO's 'Managing Complications in Pregnancy and Childbirth' (MCPC) is an example.⁵ It has informed multiple training and intervention programs, including eHealth solutions. Yet, a systematic literature search revealed hardly any published evaluations of its use and effects since initial publication in 2000.¹ Similarly, the absence of target users was described as a key contributor to ineffective Ugandan national guidelines.²

We call for the development of international, regional, and national clinical guidelines that are better attuned to input from targeted low-resource settings – thus paving the way for facility-level adaptations, or even adoptions. Inspired by Pronovost et al.'s model targeting large-scale guidelines development in high-income countries, three central interactive steps are proposed, after which implementation, evaluation, and iterative adaptation are conducted at each target facility:¹⁰

The first step concerns summarizing evidence and identification of interventions with largest benefits and lowest barriers to use. Obvious barriers in low-resource settings may be finances, health system organization, human resources, equipment, disease burden, (epi-)genetic diversity, and culture.^{1,8} Evidence must, however, be understood more broadly to include research evidence as well as clinical experience, labouring women's preferences, and locally-derived data. Therefore, the second step concerns identifying less predicted barriers, gains, and losses by field visits and stakeholders' meetings. This includes aligning guidance with attendant-to-labouring-women ratio and professional competencies, assessing risks of contradictory recommendations or a counterproductive guidelines overload, integrating and aligning routine and emergency management within the continuum of care, and 'walking the process' of providers and labouring women. The third step concerns developing realistic performance measures based on the guidelines, which is crucial for evaluating the guidelines' effects and side-effects, and in setting realistic core outcomes.

Take labour augmentation with oxytocin in busy, low-resource maternity units for example. Blind intravenous titration during labour may cause uterine hyperstimulation with risk of foetal death, uterine rupture, and bleeding after birth,

and oxytocin is therefore classified as one of 12 medications bearing heightened risk of significant harm. At the same time, its use is suggested crucial to reduce the similarly harmful epidemic of caesarean sections due to poor labour progress. Cautious oxytocin augmentation is thus warranted, but may be hampered in busy, low-resource maternity units by lack of one-to-one care and electronic drip count devices. Last year's second edition of MCPC recommends that oxytocin augmentation may be started when cervical dilatation is less than 1 cm per hour. If followed, it would, however, cause a judicious overuse among many women with uncomplicated variations in labour progress – as is reported from Nigeria and Uganda with oxytocin augmentation rates of 28%-40%.^{11,12} MCPC's guidance is contradicted by both WHO's 2014 recommendations on 'augmentation of labour' and 2018 recommendations on 'intrapartum care for a positive childbirth', both of which endorse an undefined interval of watchful waiting before starting oxytocin. Yet, considering the alarming work load typically carried by the too few birth attendants in busy low-resource maternity units, and the limited access to knowledge and skills acquisition, is it fair that they are left alone to judge how long an undefined interval may last?

It appears that the label of 'evidence-based best practices' requires evidence generated through experimental study designs, often conducted in non-comparable high-resource settings while controlling for the contextual factors that are crucial to understanding the translation of evidence to clinical practice. However, when comparing multiple international so-called 'high-quality evidence-based clinical guidelines' in the field of maternal health, major areas of inconsistency and disagreement are disclosed.⁸ This emphasizes the limitations and ambiguity in experimental studies and the strong influence of values, culture and professional tradition even in what is considered high-quality international guidelines production.¹³ Moreover, translating evidence into recommendations inevitably requires judgments about the balance between benefits and risks.⁹ Therefore, it is mind-boggling that there still appears to be limited room for the evidence of low-resource realities in international evidence-based guidelines production targeting low-resource health systems.

The three-step, pragmatic, large-scale guidelines development that we propose may be criticized for unprofessionally promoting non-best-practice solutions, inefficiently 'reinventing the wheel', or failing to meet global standards.³ We do acknowledge ethical dilemmas in producing achievable and acceptable guidance for unacceptable realities, with the human resource crisis at its centre. However, in line with the Paris Declaration and Accra Agenda for aid effectiveness, this redirection enables health workers at resource-constrained facilities to enhance control and influence how problems and solutions are outlined at the global level.⁴ Overworked birth attendants demand access to professional development, staff support, and supervision, for which realistic clinical guidelines are fundamental.¹⁴ Such aspirations for respectful work conditions are crucial for providing best possible safe and respectful childbirth care (Sustainable Development Goals 3.1, 3.2, 3c, 5.1, 8.8) – and it is an opportunity for determining a minimal acceptable ratio of attendants-to-labouring-women.

In the era of personalized medicine in high-income countries, time is overdue for co-created, resource-stratified international clinical guidelines for low-income countries – with embedded feedback loops to facilitate rapid experiential learning throughout development and implementation.³ WHO does emphasize the relevance of 'conditional recommendations' when interventions are suitable for some locations only, and the Lancet Maternal Health Series call for context-appropriate implementation strategies with guidelines that are formulated in ways that facilitate understanding and use.^{5,6,8} Yet, developing the second version of the 'PartoMa Pocket Guide©' in 2018 emphasizes that a crucial gap remains for international maternal health guidelines to be easily adaptable to realities at facilities carrying the highest burden of adverse outcomes.¹⁵ With the art of the possible, we can co-create decision-support that assists health workers in saving lives in facilities with highest burden of death and disabilities, rather than the blockage, which the desire for perfectionism may cause. Within and beyond maternal health, realistic clinical guidelines and associated training are conditional for translating evidence into practice, pivotal in strengthening health systems' accountability, and a basic, fundamental right for health workers with the lives of others in their hands.

Acknowledgements

Members of the PartoMa Steering Group at Mnazi Mmoja Referral Hospital, Zanzibar, are Alawiya Abubakar Ahmed, Dhuria Abdallah Ahmed, Fatma Mrisho Haji, Lamlat Hassan Nondo, Maryam Ahmed, Natasha Housseine, Naufal Kassim, Mubina Rajhy, Rashid Saleh Khamis, Saada Juma Amour, Salma Abdi Mahmud, and Zuhura Abdallah Balozi. We are grateful to the members for their support to this commentary. We extend a special thanks to the 40 Zanzibari birth attendants who recently pilot-tested and gave anonymous feedback to version 2 of the 'PartoMa Pocket Guide' (launched in April 2018), to the 12 external reviewers for their multiple rounds of thorough feedback, and to the Zanzibar Ministry of Health and the United Nations Population Fund (UNFPA) for taking over the continuation of the PartoMa project in Zanzibar. For more information, please visit the PartoMa homepage (www.publichealth.ku.dk/partoma).

Authors' contribution

All authors have contributed with their clinical and research experiences in raising the arguments presented here. NM has drafted the commentary and TM, NH, KKN, JvR and ICB have all critically reviewed the manuscript and approved the final version. The final draft is approved by the PartoMa Steering Group at Mnazi Mmoja Referral Hospital, Zanzibar.

Declaration of interests

None to declare.

Funding

The PartoMa study is supported by grants from The Lundbeck Foundation (R164-2013-16038), The Laerdal Foundation (40108), and The Augustinus Foundation (14-1059). The study's results and conclusions, and the opinions presented here, are those of the authors and the PartoMa Steering Group at Mnazi Mmoja Referral Hospital, and independent from the funding sources.

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Letter I

Re: Cervical dilatation over time is a poor predictor of severe adverse birth outcomes: a diagnostic accuracy study

Maaløe N, Meguid T, Kwast B, van Roosmalen J. BJOG.2018;125:1341-1342.

they observed, but it is of note that only 5 of 14 were considered to have a 'probable' relation to latex. It is also clear that the severity of the reactions observed was variable, with at least one-third of a lesser severity to those we included in our study; it is uncertain how many would meet the internationally accepted definition of anaphylaxis that we used.

Our findings are consistent with previous research; a previous registry study on anaphylaxis in pregnancy in Texas showed no reactions as a result of exposure to latex;³ and a recent national audit of all National Health Service hospitals in the UK found that there were no anaphylactic reactions as a result of latex.⁵

The lack of latex-induced anaphylaxis in our study and in the recent national audit in the UK may be explained by an increase in latex-free environments and a decline in the use of latex gloves in the work place.^{5,6} However, we did not specifically collect information on whether latex gloves were used during the hospital stay of women included in our study. We can only speculate as to whether clinical practice accounts for some of the observed differences.

Disclosures of interest

None. ■

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Accepted 21 May 2018.

DOI: 10.1111/1471-0528.15302

Re: Cervical dilatation over time is a poor predictor of severe adverse birth outcomes: a diagnostic accuracy study

Sir,

We thank the World Health Organization (WHO) team, Souza et al.,¹ for crucial findings on variations in uncomplicated labour progress and the danger of the alert line as an indication for interventions. We are furthermore concerned with disturbingly high rates of oxytocin augmentation in the low-resource hospitals – 40% of nulliparous and 28% of multiparous low-risk women.²

Souza et al. refer to Lavender et al.'s *Cochrane Review* and conclude that experimental comparisons failed to demonstrate the effect of partographs in improving birth outcomes. We acknowledge ample room for improving partograph use in low-resource settings, but find it premature to conclude its ineffectiveness. While Souza et al. exclusively focus on cervical dilatation, the partograph includes multiple vital parameters of the condition of mother and baby and labour progress, reviewed at a glance. Moreover, the partograph's full potential will only be explored if it is combined with unambiguous and achievable guidelines on what to do with the assessments—and we do see potential. It is mystifying that Lavender et al. neglected WHO's Asian multicentre trial of 35 484 deliveries, which showed the effect of partograph use if coupled with such guidelines.³

International practice guidelines on for instance slow labour progress in busy low-resource hospitals remain, however, largely unachievable, contradictory, and vague.⁴ WHO's 2017 edition of *Managing Complications in Pregnancy and Childbirth* (MCPC) contradicts both WHO's 2014 and 2018 guidelines: prolonged active first stage is defined by crossing the alert line. If there are weak contractions at this point, and cephalopelvic disproportion is excluded, the MCPC recommends that inadequate uterine activity is diagnosed and oxytocin is started. Diagnosing cephalopelvic disproportion, especially in nulliparae, usually requires oxytocin augmentation, and the majority of women crossing the alert line would most likely fulfil MCPC's criteria for oxytocin. Hence, nearly half of all women in Souza et al.'s study would be augmented, which would inevitably cause dangerous titration in low-resource facilities without one-to-one care, no controlled infusion devices, and delays in surveillance and treatment.

In collaboration with birth attendants at Zanzibar's referral hospital, we co-created locally tailored and internationally peer-reviewed *PartoMa Pocket*

Guidelines[©] on best possible safe and respectful childbirth care (<http://public.health.ku.dk/partoma/>). Concerning oxytocin augmentation, we detected injudicious use at baseline, and substandard surveillance of drip count, contractions and foetal heart rate. We therefore recommended saving oxytocin for women crossing the action line with ruptured membranes for ≥ 1 hour. Between the alert and action lines, attention was drawn to less dangerous labour enhancement. PartoMa was associated with statistically significant reductions in stillbirths and asphyxiated neonates. Overall, oxytocin augmentation declined likewise significantly – it fell before crossing the action line and increased after crossing it.⁴ Our findings are similar to the results of the Asian multicentre trial³ and to findings from a study of 20 227 Norwegian women.⁵

Souza et al. recommend that averaged labour curves should not be used in decision-making for individual women and propose the development of individualised algorithms by decision-analysis models and machine learning.^{1,2} That prospect, however, seems distant for many low-resource hospitals. Meanwhile, we urgently recommend that partograph use is not abandoned, but re-encouraged – not using the alert line as an intervention starting point, but with associated unambiguous and achievable guidelines, including a restricted action-line-based augmentation regimen. ■

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Accepted 6 May 2018.

DOI: 10.1111/1471-0528.15323

Authors' reply

Sir,

We believe that the global phenomenon of growing and unnecessary medicalisation of labour and childbirth (as shown by increasing rates of caesarean section and augmentation of labour) can be harmful to women and babies, particularly in low-resource settings. The consequences of deploying unnecessary labour interventions go beyond individual women and babies; it affects the stability and sustainability of maternity care in the health systems of low-income countries. Addressing this situation is a priority for improving maternal and newborn health and ensuring that women and babies achieve their full potential.

Although the determinants of this phenomenon are complex and multifactorial, low thresholds for diagnosing

slow labour progression and triggering the use of interventions are contributory factors to unnecessary interventions. In this context, we carried out a study to assess the accuracy of the alert line and other variables included in the World Health Organization (WHO) partograph in the identification of women at risk of developing severe adverse birth outcomes. Our findings showed that labour is an extremely variable event, and the assessment of cervical dilatation over time is a poor predictor of severe adverse birth outcomes. Other candidate maternal and fetal monitoring parameters in the partograph had a similarly disappointing performance. We concluded that the validity of an alert line based on the 'one-centimetre per hour' rule should be re-evaluated. In future, we expect that technology will be sufficiently advanced and precision medicine will have a greater reach than today, allowing individualised labour assessment and care to benefit a substantial proportion of the population.

We read with interest the letter of Prof. Jos van Roosmalen and colleagues.¹ We were happy to see that their findings and solutions also call for a re-evaluation of the current partograph alert line and that their locally tailored guidelines for labour management tend to align with the 2018 WHO recommendations intrapartum care for a positive childbirth experience.² It is important to clarify, however, that our paper does not call for abandoning the use of the partograph, but for revising it to conform to a more realistic reference for labour progress assessment.³ The new WHO recommendations, prepared following standard and rigorous process, and informed by the best available body of evidence, conclude in the same direction. The new WHO recommendations acknowledge that a paper-based labour monitoring tool will continue to be relevant for the foreseeable future and that the alert line could be applied in peripheral health centres as a triaging tool where the capacity or facilities to augment labour or perform a caesarean section are

unavailable. It should be noted that the new recommendations supersede previous WHO recommendations. Previous documents (such as those mentioned by Prof. Jos van Roosmalen and colleagues) will be updated and harmonised to reflect the new recommendations. WHO and partners are currently working to revise the design of the partograph to support implementation of the new recommendations at country level and will continue to advance research and guidance on this subject to ensure that woman-centred intrapartum care becomes a reality for all countries. ■

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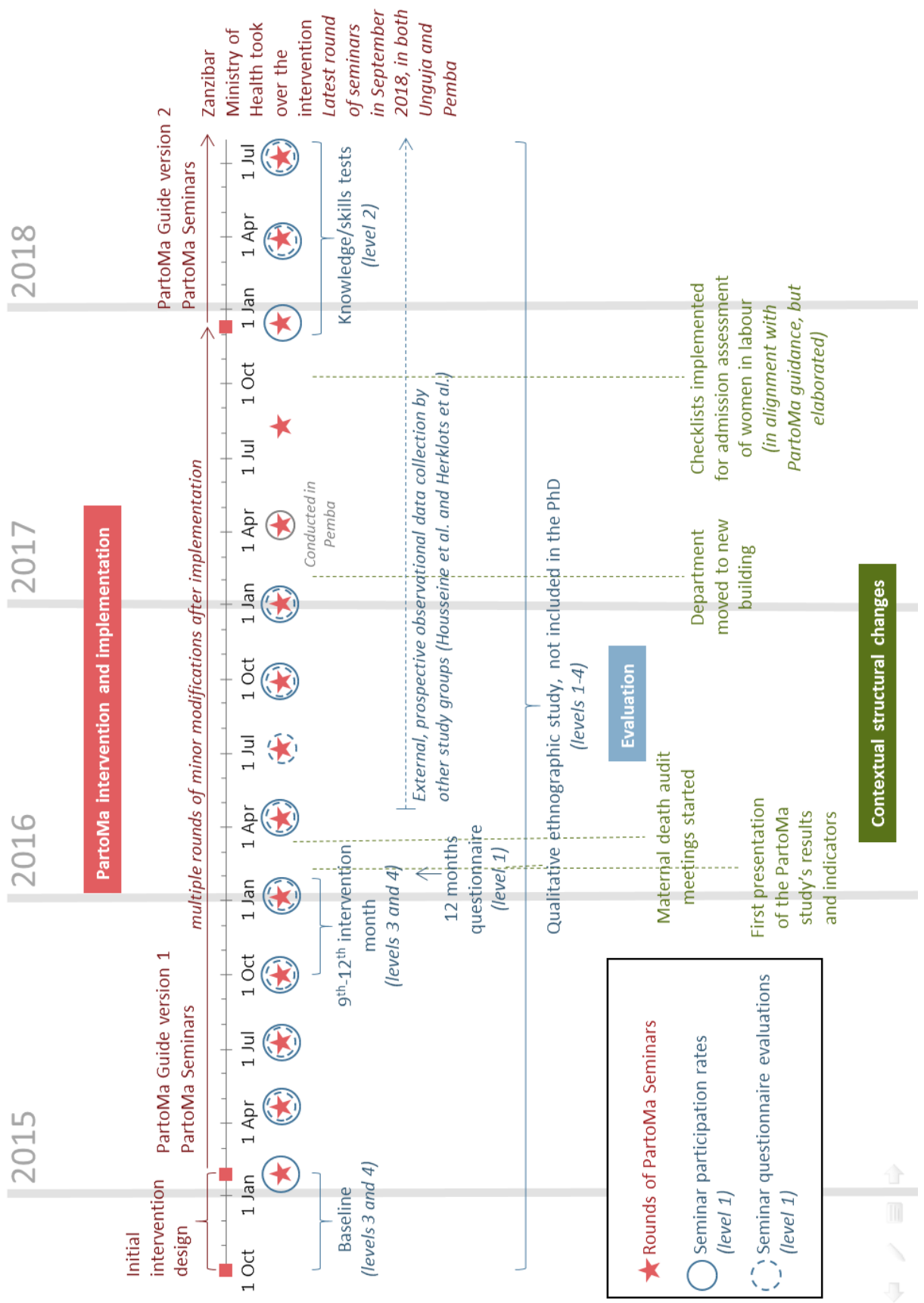
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Accepted 6 June 2018.

DOI: 10.1111/1471-0528.15322

Timeline

Timeline for the PartoMa study, including intervention development and implementation, evaluation methods, and major contextual changes, which might have influenced or been associated with the study.



Additional information for Kirkpatrick level 1: Perceptions

The seminar evaluation questionnaire is included. The 12-months evaluation questionnaire of the pocket guide was embedded in Paper II and is available on the journal homepage.

Additional information for Kirkpatrick level 2: Learning

The following additional information is included:

- The knowledge and partograph skills test
- Supplementary Table S1: Comparison of overall knowledge and partograph skills test-scores before and after the first seminar included in the study period.
- Supplementary Table S2: Comparison of knowledge and partograph skills test-scores for the 24 participants completing both the first seminar pre- and post-test and the second seminar pre- and post-test.
- Supplementary Table S3: Comparison of test-scores before and after the first seminar included in the study period, divided into the three parts of the test

This is an anonymous knowledge test, which will only be checked by research investigators. It will be used for improving the PartoMa training. Thank you very much for participating.

Hili ni jaribio bila majina, ambalo litaangaliwa na wachunguzi tu. Litatumika kwa kuendeleza Partoma. Ahsante kwa kushiriki

Please circle the correct answer (*Tafadhali zungushia duara jibu sahihi*).

I. Your employment (*Aina ya ajira*):

- Intern doctor • Doctor (registrar) • Nurse-midwife
- Clinical Officer • Assistant Medical Officer (AMO)
- Other employment? (*Kazi nyengine?*) _____

II. Work place / hospital, you may circle more than one affiliation (*Sehemu ya kazi / hospitali, piga duara sehemu ambayo unafanya kazi*):

- Mnazi Mmoja Hospital • Mwembeladu Hospital
- Kivunge Hospital • Makunduchi Hospital
- Al-Rahma Hospital • Global Hospital

Other affiliation? (*Uhusiano mwengine*) _____

III. Have you previously attended a PartoMa seminar? (*Umewahi kuhudhuria semina yoyote ya PartoMa?*)

- Yes • No

IV. Have you been using the PartoMa guidelines in your work? (*Unatumia miongozo ya Partoma katika kazi zako*)

- Every day when I am working in the maternity ward
(*Siku zote niwapo kazini katika wodi ya maternity*)
- At least once a week (*kwa uchache mara 1 katika wiki*)
- Less than once a week (*chini ya mara 1 lwa wiki*)
- Never (*sijawahi kutumia*)

V. How many years of experience do you have with childbirth care? (*Unamiaka mingapi ya uzoefu katika kazi ya ukunga*)

- Less than 1 year (*chini ya mwaka moja*) • 1-5 years (*mwaka 1-5*)
- 6-10 years (*miaka 6-10*) • More than 10 years (*zaidi ya miaka 10*)

How old are you? (*Una umri gani*)

- 20–30 yrs (*miaka 20-30*) • 31–40 yrs (*miaka 31-40*)
- 41–50 yrs (*miaka 41-50*) • Above 50 yrs (*zaidi ya miaka 50*)

Please circle the correct answer. There is only one correct answer for each question.

(Tafadhali zungushia jibu sahihi. Kuna jibu moja tu sahihi kwa kila suala)

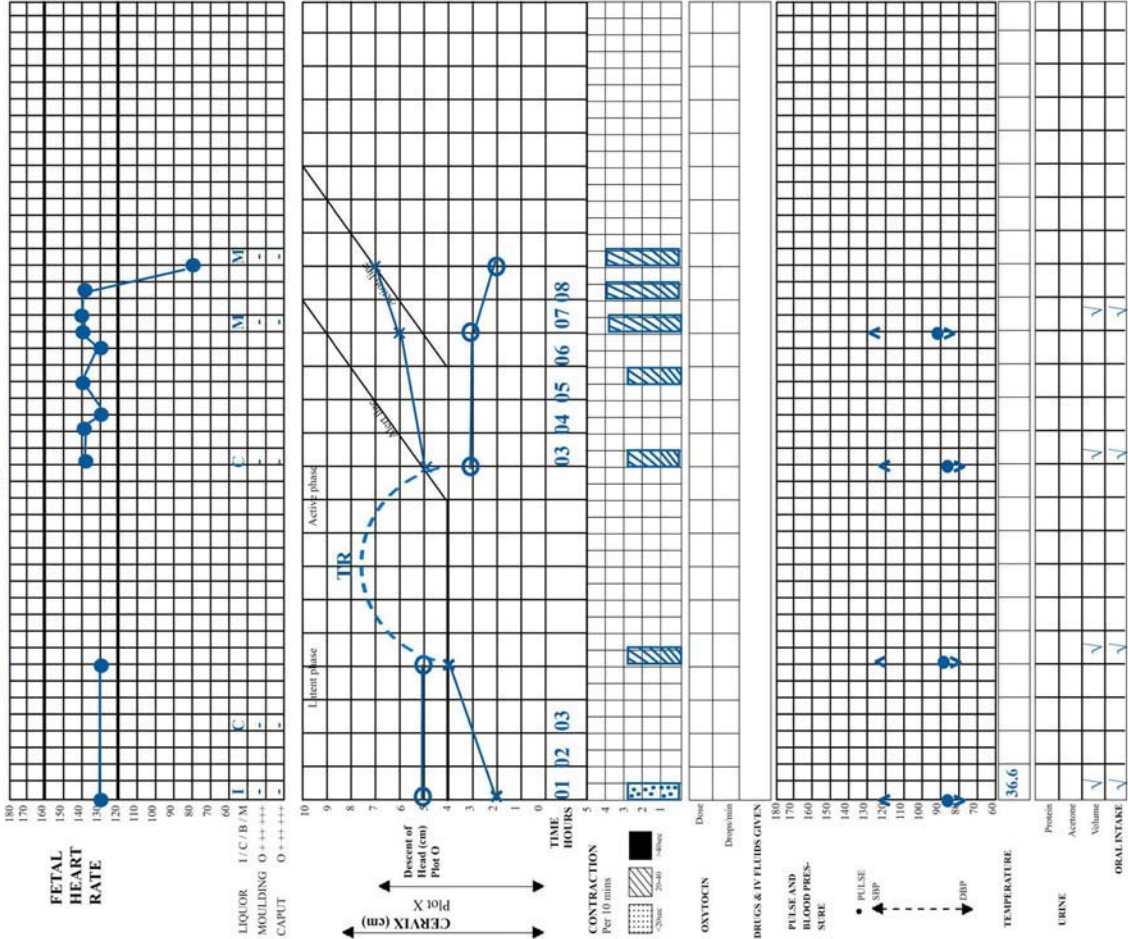
1. When fetal heart rate is 108 beats per minute, you should decide on:
(Mapigo yam toto yakiwa 108 kwa dakika. Uamue hivi:)
 - a. Emergency caesarean section, or vacuum extraction if fully dilated
(Upasuaji wa uzazi wa dharura, au kumvuta kwa vacuu kama njia imemaliza kufunguka)
 - b. Put woman on left side and monitor FHR closely every 15 minutes
(Muweke mzazi kwa upande wa kushoto na chunguza kwa ukaribu kila baada ya dakika 15)
 - c. Start Oxytocin augmentation
(Anzisha oxytocin)
2. If a woman with severe headache has blood pressure of 165/115 mmHg and protein in the urine (+2), what should be given:
(Kama mama anaumwa sana na kichwa BP 165/115 mmHg and "protein" kwenye mkojo +2, mama apewe nini?)
 - a. Broad spectrum antibiotics (such as Ampicillin and Gentamicin) and IV Oxytocin
(Antibiotics (kama Ampicillin na Gentamicin) na kuchoma oxytocin)
 - b. Magnesium sulphate and antihypertensive (such as Hydralazine or Nifedipine)
(Magnesium sulphate na dawa za kupunguza presha (kama hydralazine au nifedipine))
 - c. Magnesium sulphate only
(Magnesium sulphate tu)
3. When maternal temperature is 38.8 ° during labour, what immediate treatment should always be started (if not allergic):
(Kama ujoto wa mama ni 38.8 °C, dawa gani aanzishiwe (kama hazitomdhuru))
 - a. Broad spectrum antibiotics, such as Ampicillin and Gentamicin
(Antibiotics kama Ampicillin na Gentamicin)
 - b. Corticosteroids, such as Bethamethasone or Dexamethasone
(Corticosteroids, kama Bethamethasone au Dexamethasone)
 - c. Magnesium sulphate
(Magnesium sulphate)
4. If a woman has a fully dilated cervix with the fetal head below ischial spine, regular painful contractions and fetal heart rate 80 bpm (beats per minute), what do you do:
(Kama njia imemaliza kufunguka, na kichwa cha mtoto chini ya "ischial spine", na mapigo yam toto ni 80 kwa dakika, unatakiwa ufanyeje?)
 - a. Vacuum extraction
(Kutoa mtoto kwa vacuuum)
 - b. IV Oxytocin
(Choma oxytocin kwenye mshipa wa damu kwa kuzaa kwa haraka)
 - c. Emergency caesarean section
(Upasuaji wa kutoa mtoto kwa dharura)

Please circle the correct answer (Tafadhali zungushia jibu sahihi)

There is only one correct answer for each question. *(Kuna jibu moja tu sahihi kwa kila suala)*

5. When a woman bleeds more than 500 ml after birth and delivery of placenta, which of these is the most important immediate care while calling for help:
(Kama mama akitoka damu Zaidi ya 500ml baada ya kujifungua na kutoa zalio, kitu gani muhimu Zaidi afanyiwe)
 - a. Start oxygen treatment through nasal catheter
(Anzisha oxygen kwenye mrija wa pua)
 - b. Stop bleeding by continual uterine massage or bimanual compression
(Katisha utokwaji wa damu kwa kusugua fuko la uzazi kwa uendelevu)
 - c. Stop bleeding quickly by Misoprostol per rectum
(Katisha utokwaji damu haraka kwa misoprostol katika njia ya nyuma)
6. When a newborn is not breathing, what is the most important management, which should be started within one minute of birth:
(Kama mtoto hapumui, ni nini cha muhimu aanzishiwe katika dakika ya mwanzo baada ya kuzaliwa)
 - a. Suction mouth and nose
(Futa mdomo na pua)
 - b. Cardiac massage
(Sugua moyo)
 - c. Bag-mask ventilation
(Msaidie hewa kwa bag-mask)
7. When giving Oxytocin for labour augmentation, what is the danger:
(Lipi kati ya haya ni hatari unapotoa oxytocin kwa kuanzisha uchungu)
 - a. Placental abruption with risk of fetal death
(Uharibifu wa upandaji wa kuta za uzazi kusababisha vifo)
 - b. Severely high maternal blood pressure with risk of cerebral bleeding
(Kuongezeka kwa msukumo wa damu wa mama na kuvuja dama kwa ubongo)
 - c. Hyperstimulation with risk of fetal distress and uterine rupture
(Msisimko mkubwa pamoja na kumnyima mtoto hewa na kuchanika kwa fuko la uzazi)

Sabra: 27 years, Gravida 1, para 0



Please circle the correct answer (Tafadhali zungushia jubi sahihi)

There is only one correct answer for each question. (Kuna jibu moja tu sahihi kwa kila suala)

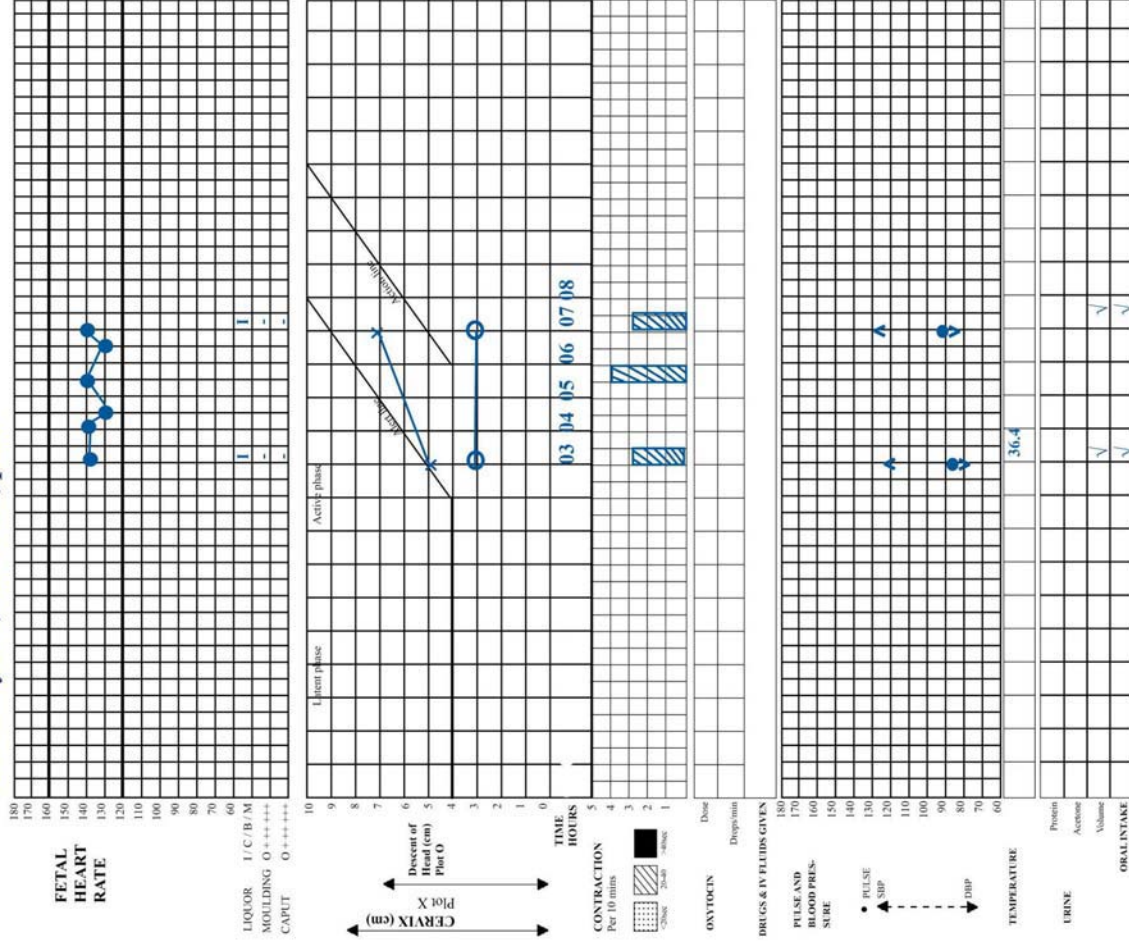
What is the problem? (Tatizo ni lipi)

1. Poor progress with obstruction
(Muendeleo mbaya na "obstruction")
2. Poor progress with fetal distress
(Muendeleo mbaya na kuchoka kwa mtoto)
3. Poor progress with maternal bleeding
(Muendeleo mbaya na mama kupoteza damu)
4. Poor progress with severe hypertension
(Muendeleo mbaya na presha kuwa kubwa sana)
5. Poor progress with signs of infection
(Muendeleo mbaya na dalili za maambukizi)

Actions to be taken? (Nini kifanyike)

- a. Labour augmentation by oxytocin
(Uchungu ukolezwe kwa oxytocin)
- b. Emergency caesarean section
(Upasuaji wa dharura wa kutoa mtoto)
- c. Start Magnesium Sulphate treatment
(Anzisha Magnesium sulphate)
- d. Close monitoring for 60 minutes, caesarean section if no improvement
(Uangalizi wa karibu kwa dakika 60, upasuaji wa kutoa mtoto kama hakuna mafanikio)
- e. Vacuum extraction
(Kutoa mtoto kwa vacuum)

Aziza: 22 years, Gravida 2, para 1



Please circle the correct answer (Tafadhali zungushia jubi sahihi)

There is only one correct answer for each question. (Kuna jibu moja tu sahihi kwa kila suala)

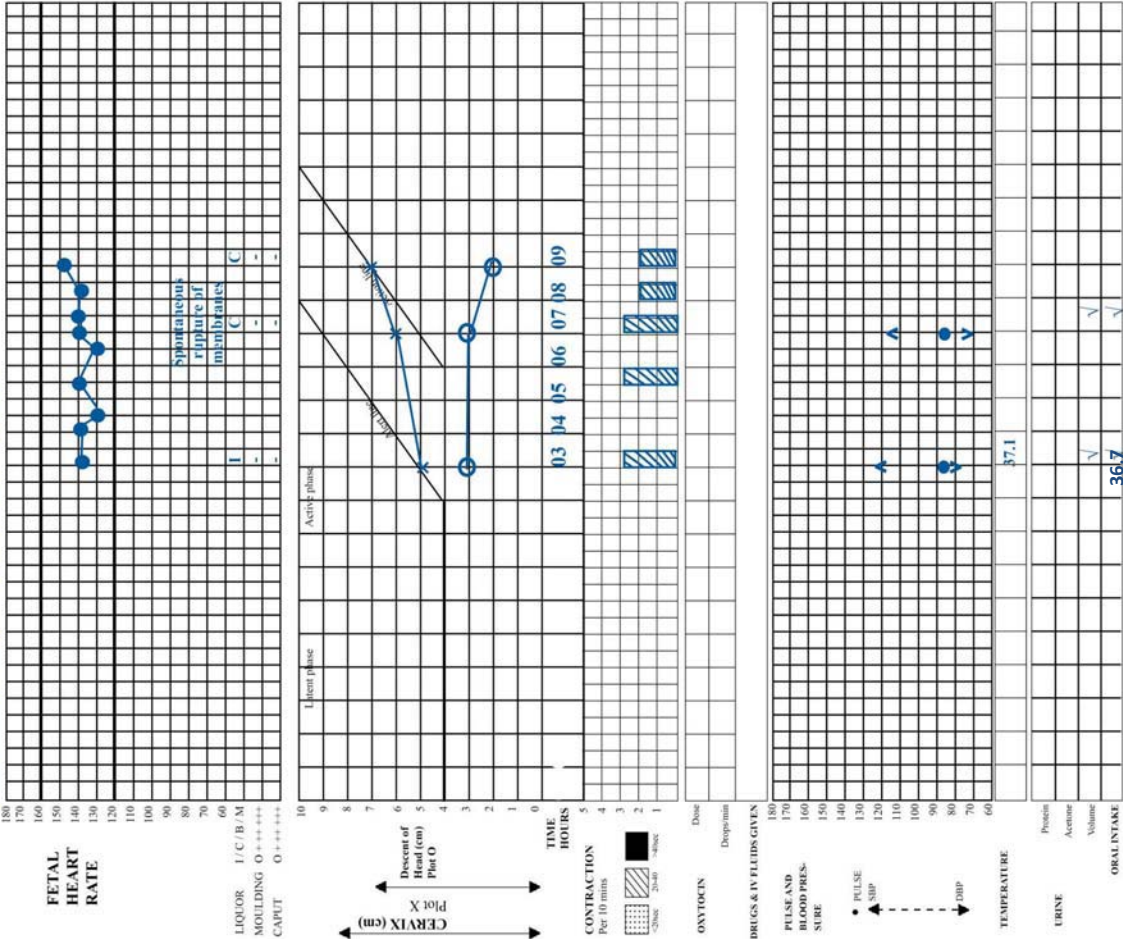
What is the problem? (*Tatizo ni lipi*)

1. Signs of maternal bleeding
(*Dalii za mama kumwagika damu*)
2. Poor progress due to poor power of contractions
(*Muendelo mbaya kwasababu ya uchungu dhafu*)
3. Poor progress due to obstruction
(*Muendelo mbaya kwasababu ya “obstruction”*)
4. Fetal distress
(*Kuchoka kwa mtoto*)
5. Pre-eclampsia/edampsia
(*Kifafta cha mimba*)

Actions to be taken? (Hatua gani zichukuliwe)

- Labour augmentation by oxytocin
(*Kuendeleza uchungu kwa oxytocin*)
- Caesarean section
(*Upasuaji wa kutoa mitoto*)
- Start broad-spectrum antibiotics
(*Anzisha antibiotics*)
- Artificial rupture of membranes (ARM)
(*Kuvunjwa kwa chupa*)
- Close monitoring for 30 minutes, caesarean section if no improvement
(*Kitazamwa kwa ukaribu kwa dakika 30, upasuaji wa kutoa mitoto kama hakuna maendeleo*)

Catherine: 32 years, Gravida 2, para 0



Please circle the correct answer (Tafadhali zungushia jubi sahihi)

There is only one correct answer for each question. (Kuna jibu moja tu sahihi kwa kila suala)

What is the problem? (Tatizo ni lipi)

- Poor progress due to poor power of contractions
(Muendeleo mbaya kwasababu ya uchungu dhafu)
- Poor progress due to obstruction
(Muendeleo mbaya kwasababu ya "obstruction")
- Fetal distress
(Kuchoka kwa mtoto)
- Pre-eclampsia/eclampsia
(Kijafa cha mimba)
- Signs of maternal infection
(Dalili za maambukizi kwa mama)

Actions to be taken? (Hatua gani zichukuliwe)

- Artificial rupture of membranes (ARM)
(Kupasuliwa kwa chupa)
- Labour augmentation by oxytocin
(Kuendeleza uchungu kwa oxytocin)
- Caesarean section
(Upasuaji wa kutoa mtoto)
- Vacuum extraction
(kutia mtoto kwa vacuum)
- Close monitoring for 30 minutes, caesarean section if no improvement
(Uangalizi wa karibu kwa dakika 30, upasuahi kwa kutoa mtoto kama hakuna maendeleo)

Case: Asma

Please fill in the following information in the partogram below

(Tafadhali jaza ya fuatayo katika parto hapa chini)

Asma is admitted on the 5th May 2015 at 4.00 in the morning:

- FHR 130

BP 120/80

Fetal head 4/5

• 3 contractions per 10 minutes, 35 seconds each

• P 85

• Temperature 36.8

• Intact membranes

• Cervix 5 cm

• Just emptied bladder spontaneously

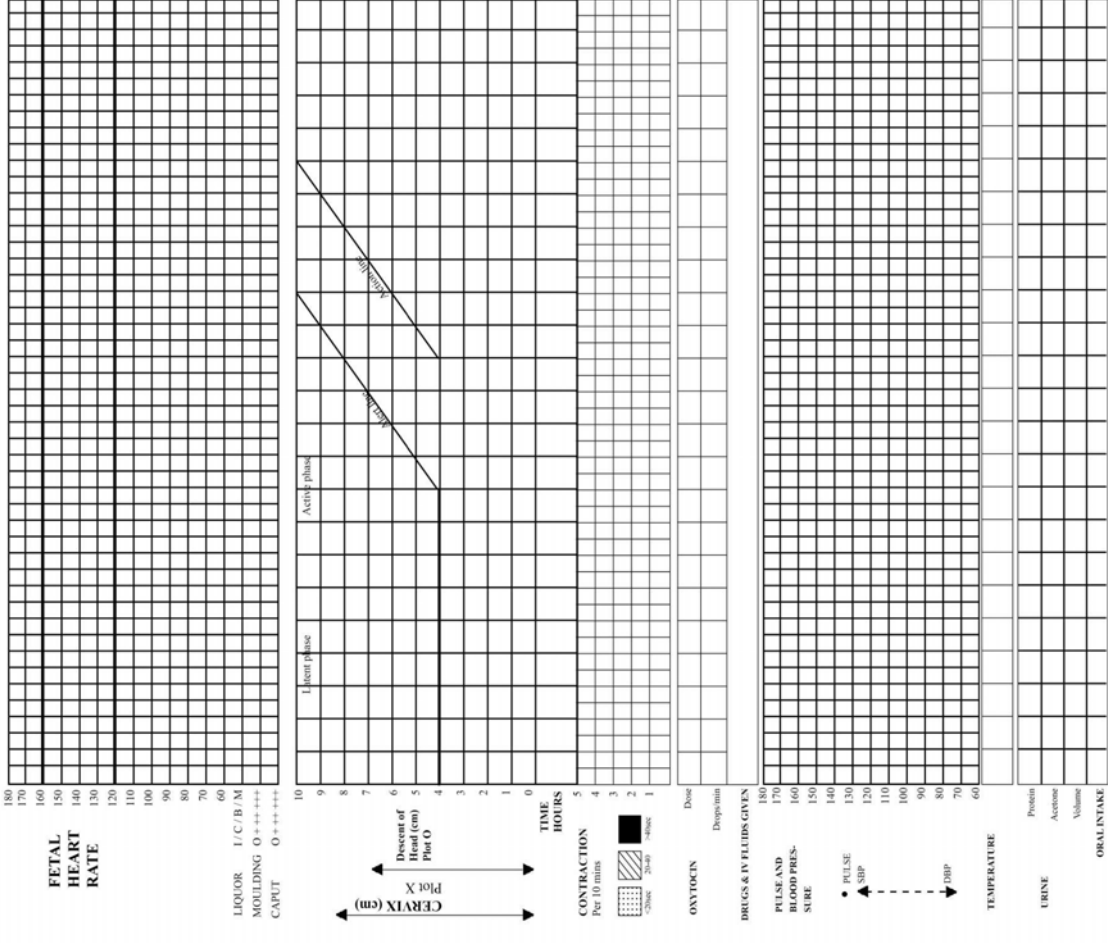


Table S1 Comparison of overall knowledge and partograph skills test-scores before and after the first seminar included in the study period. The overall test-score is calculated based on all three parts of the test (text based questions, partograph interpretation, and partograph recording). The score ranges from 0-15 with 0 being the lowest and 15 the highest. P-values have been calculated using a paired sampled t-test.

	First seminar pre-test	First seminar post-test	First seminar pre- vs. post-test (p-value)
All participants (n=143)* Mean score n (SD)	10.4 (2.2)	12.6 (2.0)	<0.001
Medical doctors (n=17) Mean score n (SD)	11.4 (2.6)	13.6 (1.1)	0.001
Nurse-midwives (n=66) Mean score n (SD)	10.0 (2.5)	12.0 (2.2)	<0.001
Intern doctors (n=15) Mean score n (SD)	10.5 (1.3)	12.7 (1.8)	<0.001
Last year medical students (n=45) Mean score n (SD)	10.5 (1.8)	13.0 (1.6)	<0.001
Less than 1 year experience with childbirth care (n=80) Mean score n (SD)	10.5 (1.9)	13.1 (1.5)	<0.001
1-5 years experience with childbirth care (n=34) Mean score n (SD)	10.1 (2.4)	11.7 (2.7)	<0.001
More than 5 years experience with childbirth care (n=19) Mean score n (SD)	11.9 (1.9)	12.7 (1.5)	0.134
Have attended a seminar before this knowledge study (n=36) Mean score n (SD)	11.6 (1.8)	13.0 (1.7)	0.001
Have not attended a seminar before this knowledge study (n=106) Mean score n (SD)	10.0 (2.2)	12.4 (2.1)	<0.001
Used PartoMa Guidelines every day or at least once a week before the study (n=92) Mean score n (SD)	10.5 (2.0)	12.4 (1.9)	<0.001
Used PartoMa Guidelines never or less than once a week before the study (n=50) Mean score n (SD)	10.3 (2.4)	12.9 (2.2)	<0.001

**143 of the 166 participants with a first seminar pre- and post-test have completed all three parts of the tests required to calculate an overall test-score, and are included in the analysis. 23 participants had not filled out the partograph at the pre- and/or post-test and an overall score could therefore not be calculated.*

Table S2 Comparison of knowledge and partograph skills test-scores of the 24 participants completing both the first seminar pre- and post-test and the second seminar pre- and post-test.

	First seminar pre-test	First seminar post-test	Second seminar pre-test	Second seminar post-test	First seminar pre- vs. post-test (p-value)*	First seminar pre-test vs. second seminar pre-test (p-value)*	First seminar post-test vs. second seminar pre-test (p-value)*	Second seminar pre- vs. post-test (p-value)*
All participants (n=24) Mean score n (SD)	10.9 (1.9)	13.0 (1.8)	12.2 (2.1)	13.6 (1.4)	<0.001	0.006	0.090	<0.001
Medical doctors (n=2) Mean score n (SD)	11.6 (1.4)	13.3 (1.0)	14.9 (0.1)	15.0 (0.0)	0.500	0.205	0.228	0.500
Nurse-midwives (n=10) Mean score n (SD)	11.8 (1.6)	12.7 (1.6)	11.5 (1.9)	13.2 (1.2)	0.215	0.579	0.166	0.005
Intern doctors (n=2) Mean score n (SD)	9.9 (2.1)	13.5 (0.1)	12.6 (1.1)	14.3 (0.7)	0.236	0.161	0.421	0.416
Final year medical students (n=10) Mean score n (SD)	10.1 (1.9)	13.1 (2.3)	12.4 (2.4)	13.6 (1.7)	<0.001	0.001	0.220	0.041
Have attended a seminar before the study (n=8) Mean score n (SD)	12.0 (1.3)	12.6 (1.6)	11.8 (1.1)	13.4 (0.9)	0.447	0.741	0.395	0.015
Have not attended a seminar before the study (n=16) Mean score n (SD)	10.4 (2.0)	13.2 (1.8)	12.5 (2.5)	13.7 (1.6)	<0.001	0.001	0.157	0.006

*p-values have been calculated using a paired sampled t-test

**The overall test-score is calculated based on the three parts of the test (text based questions, partograph interpretation and partograph recording). The score ranges from 0-15 with 0 being the lowest and 15 the highest.

Table S3 Comparison of test-scores before and after the first seminar included in the study period, divided into the three parts of the test (text based questions, partograph interpretation, and partograph recording). The total test-score ranges from 0-15 with 0 being the lowest and 15 the highest. P-values have been calculated using a paired sampled t-test.

Test scores	First seminar pre-test	First seminar post-test	First seminar pre- vs. post test (p-value)*
Simple multiple choice (score: 0-7) (n=166)			
Mean score n (SD)	4.7 (1.3)	6.0 (1.1)	<0.001
Partograph interpretation (score: 0-6) (n=166)			
Mean score n (SD)	3.7 (1.5)	4.6 (1.4)	<0.001
Partograph recording (score: 0-2) (n=143)			
Mean score n (SD)	1.6 (0.4)	1.8 (0.3)	<0.001

*p-values have been calculated using a paired sampled t-test

The Safe Motherhood Series

This thesis is part of the International Safe Motherhood and Reproductive Health working party's 'Safe Motherhood Series'



The Dutch Working Party 'International Safe Motherhood and Reproductive Health' aims to contribute to improvement of the reproductive health status of women around the globe, in particular by collaborating with local health workers (<http://www.safemotherhood.nl>). The Working Party is part of both the Dutch Society of Obstetrics and Gynaecology (NVOG) and the Dutch Society for International Health and Tropical Medicine (NVTG). The activities that are undertaken under the umbrella of the Working Party can be grouped into four pillars: education, patient care, research and advocacy.

Research activities are undertaken by (medical) students, Medical Doctors International Health and Tropical Medicine and many others. Some research activities develop into PhD-trajectories. PhD-candidates all over the world, Dutch and non-Dutch, work on finding locally acceptable and achievable ways to improve the quality of maternal health services, supervised by different members of the Working Party. Professor Jos van Roosmalen initiated the Safe Motherhood Series, which started in 1995.

The Safe Motherhood Series

- Safe motherhood: The role of oral (methyl)ergometrin in the prevention of postpartum haemorrhage (Akosua N.J.A. de Groot), Nijmegen, 1995
- Safe motherhood: Perinatal assessment in rural Tanzania (Gijs E.L. Walraven), Nijmegen, 1995
- Safe motherhood: Confidential enquiries into Maternal Deaths in the Netherlands, 1983-1992 (Nico W.E. Schuitemaker), Leiden, 1998
- Safe motherhood: Confidential enquiries into Maternal Deaths in Surinam (Ashok S. Mungra), Leiden, 1999
- Safe motherhood: Reproductive health matters in rural Ghana (Diederike W. Geelhoed), Leiden, 2003
- Safe Motherhood: Vaginal birth after caesarean section in Zimbabwe and The Netherlands (Wilbert A. Spaans), Amsterdam AMC, 2004
- Safe Motherhood and Health systems research: Health care seeking behaviour and utilisation of health services in Kalabo District (Jelle Stekelenburg), VU University Medical Centre, Amsterdam, 2004
- Safe Motherhood. Enhancing survival of mothers and their newborns in Tanzania (Godfrey Mbaruku), Karolinska Institute, Stockholm, Sweden, 2005
- Safe Motherhood. Beyond the numbers: confidential enquiries into maternal deaths in Accra-Ghana (Afisah Yakubu Zakariah, Accra, Ghana), Vrije Universiteit Brussel, Belgie, 2008
- Safe Motherhood. Severe maternal morbidity in the Netherlands: the LEMMoN study (Joost Zwart), Leiden University Medical Centre, the Netherlands, 2009
- Safe Motherhood. Obstetric audit in Namibia and the Netherlands (Jeroen van Dillen), VU University Medical Centre, Amsterdam, the Netherlands, 2009
- Safe Motherhood. Confidential enquiries into maternal deaths in the Netherlands 1993-2005 (Joke Schutte), VU University Medical Centre, Amsterdam, the Netherlands, 2010
- Delay in Safe Motherhood (Luc van Lonkhuijzen), University Medical Centre Groningen, the Netherlands, 2011
- Safe Motherhood: Medical Mirrors: Maternal care in a Malawian district (Thomas van den Akker), VU University Medical Centre, Amsterdam, the Netherlands, 2012

- Safe Motherhood: Leading change in the maternal health care system in Tanzania: application of operations research (Angelo Nyamtema, Ifakara, Tanzania), VU University Medical Center, Amsterdam, the Netherlands, 2012
- Safe Motherhood: Health professionals and maternal health in Malawi: mortality and morbidity at district level (Jogchum Beltman), VU University Medical Center, Amsterdam, the Netherlands, 2013
- Safe Motherhood: Obstetric emergencies in primary midwifery care in the Netherlands (Marrit Smit), Leiden University Medical Center, the Netherlands, 2014
- Safe Motherhood: Improving maternal outcome in rural Tanzania using obstetric simulation based training (Ellen Nelissen), VU University Amsterdam, the Netherlands, 2014
- Safe Motherhood: The aberrant third stage of labour (Giel van Stralen), Leiden University Medical Center, the Netherlands, 2015
- Safe Motherhood: Terugvinden van waardigheid, community-based sociotherapie in Rwanda, Oost-Congo en Liberia (Cora Bakker), VU University Amsterdam, the Netherlands, 2016
- Safe Motherhood: Severe acute maternal morbidity, risk factors in the Netherlands and validation of the WHO Maternal Near-Miss Tool (Tom Witteveen), Leiden University Medical Center, the Netherlands, 2016
- Safe Motherhood: Getting the job done, providing lifelong HIV-treatment in settings with limited human resources for health: innovative approaches (Marielle Bemelmans), VU University Amsterdam, the Netherlands, 2016
- Safe Motherhood: Identifying needs for optimizing the health work force in Ethiopia (Tegbar Yigzaw Sindekia), VU University Amsterdam, the Netherlands, 2017
- Safe Motherhood: Improving frontline health workers' performance in low resource settings; the case of Ethiopia (Firew Ayalew Desta), VU University Amsterdam, the Netherlands, 2017
- Safe Motherhood: Increasing access to anaesthesia in Ethiopia: task shifting (Sharon J.N. Kibwana), VU University Amsterdam, the Netherlands, 2017
- Safe Motherhood: Assisting Birth Attendants in Providing Acceptable Care under Unacceptable Clinical Realities - The PartoMa Intervention Study at Zanzibar's Tertiary Hospital (Nanna Maaløe), University of Copenhagen, Denmark, 2018