Improving quality and equity of maternal health services in Malawi:
Why is the Standards Based Management - Recognition for Reproductive Health
intervention not achieving its desired outcomes?

Clearly state the problem to be addressed, demand by key stakeholders to address the problem and to identify key barriers to successful implementation
This project addresses a key concern of the Malawian Ministry of Health (MOH), namely the persistence of a high maternal mortality ratio (MMR) of 675/100,000 live births despite a facility birth rate of 73%.[1] With the goal of reducing MMR to 155/100,000, the MOH wants to understand how the implementation of its quality improvement initiatives, specifically the Standards Based Management - Recognition for Reproductive Health initiative, can be improved.

In 2000, the Government of Malawi adopted the facility-birth strategy and implemented a number of evidence-based interventions aimed at providing high quality, facility-based maternal health care. As a result, both antenatal coverage and proportion of facility births have increased.[1][1] The persistently high MMR despite high rates of facility births suggests women in Malawi may not be receiving essential high quality emergency obstetric care (EmOC). The most common reasons for maternal deaths in Malawi are haemorrhage, sepsis and hypertensive disorders, all of which require EmOC. Ameh et al.[4] found met need for EmOC is only 24%. C-section rates of 4.9% are well-below the 15% recommended by the WHO.[1] Moreover, district maternal death audits indicate that the majority of deaths due to haemorrhage and sepsis take place in facilities. [5]

In its attempt to meet its MDG-5 target the Government of Malawi focused on three key areas in its reproductive health strategy: 1) Increasing number of health facilities designed to provide basic and comprehensive EmOC services[6]; 2) Increasing the quantity and quality of human resources by expanding the number of cadres trained and authorized to perform EmOC signal functions[6] and 3) Adopting the Standards-Based Management and Recognition for Reproductive Health **(**SBM-R (RH) initiative for improving of quality of care. SBM-R (RH) sets evidence-based performance standards for facility readiness and clinical care. The facility readiness dimensions include human, physical and material resources, labs, blood banks and management systems. Clinical care includes standards for three components: counselling, client assessment and clinical management and procedures, separate for each service area (antenatal care, labour and childbirth, postnatal care and family planning). Health-care managers and providers are expected to assess and address gaps between actual and desired performance at their facility.[7]

By 2010, the total number of health facilities increased to meet the UN minimum coverage levels for population size.[4] The total number of health care workers rose by 53%, and capacity of health training institutions was strengthened.[8] There are now 37 nurses and midwives per 100,000 population compared with 29 per 100,000 population in 2004.[8]

However, despite these initiatives, availability of signal EmOC functions remains limited. In 2010 only 2% of facilities designed to provide Basic EmOC and 47% designed to provide comprehensive EmOC were actually providing the care. Significant personnel vacancies remain, with just 57% of district-level nurse/midwife technician and 39% of registered nurse posts being filled.[9] An evaluation of the SBM-R (RH) initiative showed that the initiative had no impact on quality of any component of labour and delivery, although it did improve the quality of family planning and postnatal care.[10] Furthermore, inequities persist in women's access to high quality maternal health care. Women in the lowest wealth quintile are less likely to deliver in a facility than women in the highest wealth quintile: 65% compared to 90%. Women in urban areas are twice as likely as women in rural areas to have had a C-section (8% and 4% respectively).[1]

Given the three quality improvement initiatives implemented by the MOH identified above-infrastructure development, availability of human resources and the SBM-R (RH) initiative - are evidence-based and have demonstrated success in a number of other countries,[7] questions are raised regarding their implementation within the Malawian context. A number of studies have investigated relevant aspects of these initiatives but to-date there has been no comprehensive exploration of the implementation process. Lobis et al.,[11] for example, found ineffective use of the various cadres trained to provide EmOC, but the study did not explore the specific reasons for their ineffective use. Similarly, Rawlings et al.[10] suggested inexperienced providers and high staff turnover as one possible reason for the sub-optimal performance of the SBM-R (RH), but were unable to confirm this assertion with detailed data. This implementation study will provide a detailed understanding of how evidence-based quality improvement interventions are being operationalised on the ground and avenues to overcome current obstacles within the Malawian context, thereby providing the MOH with knowledge of how to enhance their effective implementation. As such the project responds directly to the current call and the wider recognition that 'one of the greatest challenges facing the global health community is how to take proven interventions and implement them in the 'real world'.[12]

Clearly spell out the proposed research including brief description of proposed research questions, conceptual or theoretical framework, study design and methods
With the intention to support Malawi 2011 - 2016 Health Sector Strategic Plan's aim to strengthen and systematically improve the quality of its reproductive health care services, the proposed research aims to map, understand and address the factors that diminish the effectiveness of specifically the SBM-R (RH) initiative in improving the quality of maternal health care. The research will investigate the following:

Research questions
1. What is the current quality of maternal health care provided in Malawi health centres and hospitals?
2. What is the program theory underlying the SBM-R (RH) initiative? What are the assumptions embedded in the theory?
3. What are the contextual factors operating within the Malawian health care system and wider social setting that moderate the impact of the SBM-R (RH) initiative on quality improvements it is rolled out at the facility level?
4. How does the SBM-R (RH) program theory relate to the real life factors that moderate the implementation of the SBM-R (RH) intervention? What areas of misalignment are evident?
5. How can these factors and forces be manoeuvred to improve implementation of the SBM-R (RH) initiative?
6. How can SBM-R (RH) deliver quality improvements that benefit women currently least likely to receive high quality maternal health care?

Study objectives
With the overall aim to contribute to the evidence-base of innovative maternal and neonatal health quality improvement strategies in Malawi and elsewhere, the specific objectives of the study are to:
1. Develop a program theory of the SBM-R (RH) initiative and identify both explicit and implicit assumptions embedded within it.
2. Identify the gaps between the SBM-R (RH) program and the ground reality across the range of contexts that characterize the Malawian healthcare landscape.
3. Co-produce and test potential solutions to improve the effective implementation of the SBM-R (RH) initiative to enhance quality of care provided in the health centers.
4. Provide the MOH on-going, contextually relevant information that will support the process of re-iterative refinement needed for successful adaptation of the SBM-R (RH) for RH intervention.

Theoretical framework
The SBM-R (RH) is an adaptation of the widely known Plan-Do-Study-Act cycle of quality improvement.[7] Falling into the category of the 'standardization' type of quality improvement

methodology, it is considered the most useful for developing countries where health services lack basic standardization.[7] However, despite positive experiences elsewhere,[7] the evidence-base of its effectiveness, particularly when scaled up in the context of the Malawian health care landscape is limited; most existing evidence consists of evaluations of pilots.[10] The current study responds to calls for a more systematic approach to investigating the mechanisms through which such quality improvement initiatives do (or do not) work.[13] Our theoretical framework is informed by Bickman[14] and Peters et al..[12] These approaches take as their starting point the need to explicitly articulate the program theory of the interventions; that is "a plausible and sensible model of how a program is supposed to work" (pg. 5).[14] This approach involves identifying embedded assumptions of the program theory and then exploring their alignment with ground realities, before going on to facilitate the creation of context-specific strategies to overcome any misalignments. Implementation research is an emerging science that enables this approach by investigating, using multiple research methods, the many social, behavioral, economic, and management factors that may impede effective implementation of interventions when scaled up.[12]

Study design and methods
The study will consist of two phases: Phase 1 will aim to understand the current obstacles and enablers shaping the implementation of the SBM-R (RH) initiative and Phase 2 will identify and test potential solutions to increase the effectiveness of the implementation of the SBM-R (RH) initiative.

Phase 1 (Year 1-2)
This phase will address study objectives one and two. Using both quantitative and qualitative research methods, data will be collected in four modules over a 24-month period.

1. Module 1: To develop the SBM-R (RH) program theory, data will be collected using document review and in-depth interviews with at least 20 national and district level policymakers and program managers.

2. Module 2: To assess quality of care we will map both (i) facility readiness to deliver care and (ii) healthcare provider adherence to standardised criteria of care. Facility readiness will be assessed in terms of physical (e.g. whether the design of the labour room respects women's privacy) and instrumental (e.g. numbers of staff on duty, staff mix, availability of essential drugs and supplies) infrastructure using the MOH Malawi Integrated Performance Standards for Reproductive Health checklists. Health-care provider adherence to clinical performance standards during service delivery will be assessed using the same checklists. Three service areas will be assessed: antenatal, labour and childbirth, and postnatal care, both for normal and complicated cases. The data will be collected from districts Rumphi, Nkhotakota and Phalombe, in each region of the country where the SBM-R (RH) initiative has been implemented. These two districts represent the range of facility birth rates (39% and 90% respectively). The unit of analysis will be a 'patient-provider interaction' and an estimated sample size of 770 patient-provider interactions will be needed each for labour/delivery and postnatal interactions. This sample size (1540 interactions) will be collected from 10 health centers and two hospitals randomly selected.

3) Module 3: To map the ground reality of quality of care as experienced by both providers and patients, an institutional ethnography will be conducted. Institutional ethnography is increasingly recognised as a powerful tool within implementation research in general, and quality of care studies, in particular.[15] The goal of this approach is to find out "how things actually work" (p. 352).[16] It draws on providers' descriptions of their daily activities, together with observation, to develop a rich picture of the larger network of relations and processes that organize and govern the social environment of a health center and the health system generally. This method will provide an in-depth understanding of how patient care is embedded in the socio-cultural, political and economic context of Malawi and produce a detailed account of contextual factors that support or hamper desired outcomes.[12] Specifically, data will be collected using in-depth interviews with all healthcare providers, 20 exit interviews with mothers, their husbands and

other family members, observations of 25 provider-patient interactions and of 20 deliveries per facility.[17] Using the 'near-miss' approach,[18] 20 women will be identified who experienced birth complications and a 'critical incident analysis'[19] will be conducted to understand their experiences of the care received (prior to arrival, in the initial facility and referrals if any).

4. Module 4: With the aim to understand women and men's experiences of maternal health care usage, specifically the issues they face in navigating the health system, communicating with providers, and their satisfaction with the care they received, 20-in-depth interviews with mothers and 20 husbands will be conducted. Ten focus group discussions will also be conducted with community members. In addition, five case studies of maternal deaths will be conducted.

Data collection Trained medical anthropologists will collect data for modules 1, 3 and 4 and clinical experts for module 2.

Data analysis: Data from module 2 will be analysed using Stata. To obtain quantitative measure of the current quality of care, indicators such as 'proportions of interactions that meet at least 80% of the established criteria' will be calculated. Data from modules 1, 3 and 4 will be analyzed using a social constructivist, interpretative approach.[20] It will be coded and broad themes identified. We will develop a program theory of the SBM-R (RH) initiative, identify both explicit and implicit assumptions embedded within it and the gaps between the theory and the ground reality.

Phase 2

Based on findings from Phase 1, the team will identify potential solutions to improve the effective implementation of the SBM-R (RH) quality of care initiative. We will draw upon Graham's knowledge-to-action process.[21] Through four knowledge production workshops, the team will identify and devise interventions to address some of the specific challenges in the implementation of SBM-R (RH) identified in phase 1. Two types of potential solutions are envisaged: specific interventions that require higher level policy response from the MOH and smaller changes that can be implemented at the facility level. The latter will be implemented and tested using randomized controlled or quasi-experimental methods.

Describe what the proposed research would achieve and how this achievement will be measured
The proposed research will have several outcomes. First, it will provide empirical evidence of the effectiveness of the SBM-R (RH) initiative in improving the quality of maternity care in facilities, measured by the proportion of patient-provider interactions that meet 80% of quality of care indicators. Second, the research will identify the structural, health system, personnel, professional, and community level facilitators and barriers for quality improvement that emerge when such complex initiatives are scaled up. Third, this evidence will constitute the basis for production and testing of new solutions for the effective implementation of the SBM-R (RH) initiative that will not only make it more effective, but also equitable. Fourth, the research will provide theoretical advances in the development of the science of Implementation Research. Finally, the project will promote knowledge and skills transfer between Canada, Malawi and Kenya, thereby supporting a key objective of Canada's Maternal and Child Health Initiative: 'to deliver a visible, durable impact on the mothers and children of the world, including reducing social inequalities'.

Discuss the gender equality and equity considerations of the proposed implementation research
Gender equality and class equity will be key themes weaving throughout the research process. All data will be collected and analyzed using gender and equity lens. We will seek to understand how gender values interact with class to shape the design and delivery of the SBM-R (RH) initiative and women's experience of the quality of care they receive. How do dominant societal-level gender values influence the allocation of resources for maternal health services and the design and delivery of maternal health services? Our selected study sites are rural districts which will allow us to understand and address obstacles to quality improvement in more

remote/under-served areas. The team PIs, EC and ZM, have extensive experience researching gender and class inequities.

Provide details of the research team including the position and qualifications of the principal investigator and other team members as well as a quick overview of the teams track record in research
Research Team: The research team will include:
1) Dr. Ellen Mbweza Chirwa, MSc. PhD, Nursing (African PI). Dr Chirwa's areas of expertise include sexual and reproductive health, with a focus on relational power and HIV-prevention. She will provide conceptual guidance and ensuring data quality, analysis and report writing meet standards of excellence.
 2) Dr. Zubia Mumtaz, PhD (Public Health Medicine) (Canadian co-PI). A physician, she specializes in women's access to reproductive health services and gender and class inequities in reproductive health policy, design and delivery of services. Dr. Mumtaz will provide conceptual guidance, and will ensure the research, data analysis and manuscript development meets standards of excellence.
3) Fannie Kachale (Policymaker co-PI), Director, Reproductive Health Program, Ministry of Health Malawi. Mrs Kachale has led the SBM-R (RH) initiative. She will liaise between the MOH and the research team and ensure relevance and application of the research.
4) Dr. Joachim Osur (co-I), MBChB, MPH, PhD has extensive experience leading reproductive health programs in East and South Africa. As AMREF's MNCH technical lead he will provide insights in the practical application of research findings.
5) Dr. Sarah Salway (co-I), PhD is Senior Research Fellow in the School of Health & Related Research at the University of Sheffield. She has been PI on numerous grants focused on development and implementation of effective solutions to inequitable service access and outcomes. Dr. Salway will provide conceptual guidance on Implementation research, knowledge translation approaches and contribute to manuscript development.
6) Madalitso R Tolani, Programming Monitoring and Evaluation Officer, AMREF Malawi. Mr Tolani will be the research manager overseeing the project.
7) Dr. Duncan Saunders, PhD has more than 30 years of health systems research experience in Africa. Dr Saunders will provide conceptual guidance, build local research capacity and contribute to manuscript development.

Provide an overview of the engagement of trainees, if any, in this research project
The research will enhance research capacity in the emerging field of quality of care and implementation research in Malawi and Canada. We anticipate at least 3 graduate and post-graduate students (1 from Malawi, Kenya and Canada each) will generate a thesis or post-doctoral work from this research.

Budget

Line item	Unit	Unit cost	Duration	Cost (C$)
Personnel				
Ellen Chirwa	15%	23,431 per year	54 months	105,441
Zubia Mumtaz	15%	0 per year	54 months	0
Fannie Kachale	10%	15,620 per year	54 months	70,294
Joachim Osur	5%	7810 per year	54 months	35,147
Madalitso Tolani	5%	2905 per year	54 months	17,574
Sarah Salway	5%		54 months	38,000
Duncan Saunders	5%	0	54 months	0.00

Consultant	Hired if needed	0	0	0
Equipment				
Laptops	5	2000		10,000
AtlasTi software	1	2500		2500
Travel				
International travel	6	5000		30000
Travel to Field site (x1 per year)	5	5000		25,000
Training	3	17,000/year	1 year	51,000
Field Research			54 months	500,000
Indirect costs	1	13%	54 months	115,044
Total				1,000,000

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