# Strengths and weaknesses in the implementation of maternal and perinatal death reviews in Tanzania: perceptions, processes and practice.

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# **Abstract**

**Background** Tanzania introduced maternal and perinatal death reviews (MPDR) in 2006, yet there is scarce evidence on the extent and quality of implementation of the system.

**Objectives** To review the national policy documentation and to explore stakeholders' involvement in, and perspectives of, the role and practices of MPDR in district and regional hospitals, and to establish current capacity for achieving MPDR.

**Methods** We reviewed the national MPDR guidelines and conducted a qualitative study using semi-structured interviews. 32 informants in Mara Region were interviewed within health administration and hospitals, and five informants were included at the central level. Interviews were analysed for comparison of statements across health system level, hospital, profession, and MPDR experience.

**Results** The current MPDR system does not function adequately to either perform good quality reviews or fulfil the aspiration to capture every facility-based maternal and perinatal death. Informants at all levels express differing understandings of the purpose of MPDR. Hospital reviews fail to identify appropriate challenges and solutions at the facility level. Staff are committed to the process of maternal death review, with routine documentation and reporting, yet action and response is insufficient.

**Conclusion** The confusion between MPDR and maternal death surveillance and response results in a system geared towards data collection and surveillance, failing to explore challenges and solutions from within the remit of the hospital team. This reduces the accountability of the health workers and undermines opportunities to improve quality of care. We recommend initiatives to strengthen the quality of facility-level reviews in order to establish a culture of continuous quality of care improvement and a mechanism of accountability within facilities. Effective facility reviews are an important peer-learning process that should remain central to quality of care improvement strategies.

# **Background**

Maternal and perinatal mortality remain high in most sub-Saharan African countries. In 2010 the maternal mortality ratio (MMR) in Tanzania was 454 deaths per 100,000 live births and the perinatal mortality rate was 36 deaths per 1000 births (1). Half of all Tanzanian women deliver in health facilities and 5% deliver by caesarean section (1), while only 73% of hospitals currently provide comprehensive emergency obstetric care and just 39% of health centres are equipped for basic emergency obstetric care(2). Quality of maternal and newborn care remains poor, with delays in referral or treatment, stock-out of essential commodities, poor monitoring during labour, or absence of blood, (3-6), as well as widespread weaknesses in human resource provision (7).

As part of larger efforts to promote quality obstetric care in health facilities (8), the Tanzanian Government adopted a national system of facility-based maternal and perinatal death reviews (MPDR) in 2005, although maternal death reviews had been promoted and mandatory in certain facilities since 1984 (9). A National Guideline on MPDR was released in 2006 (10), describing the rationale behind MPDR, and the mechanism of implementation. This coincided with a growing recognition at the international level that an in-depth understanding of the circumstances contributing to maternal death is necessary to inform strategies to avert maternal death. A seminal text published by the WHO in 2004, called 'Beyond the Numbers' (11), documented a number of approaches to elucidate the factors underlying a maternal death or a near-miss case. The facility-based maternal death review, which informed the Tanzanian MPDR, identifies avoidable factors and opportunities for improvement through a confidential multidisciplinary team discussion with contributions from staff involved in the patient's care and a review of the patient documentation. It is an educational process for health professionals, and a mechanism for accountability, improved decision-making, and evidence-based action (11). At present, there is contradictory evidence for the success of facilitybased maternal death review in improving quality of care in Tanzania and similar settings, particularly when these are scaled up. (3, 4, 12-17)

Internationally, increasing attention is being paid to high-level accountability for maternal and newborn survival. The Commission on Information and Accountability for Women's and Children's Health (18), established in 2010, oversees global reporting and accountability on women's and children's health, and proposes actions to improve accountability at national level. Increasingly promoted internationally (19), there is mounting pressure on governments to expand existing MPDR systems to maternal death surveillance and response. Introduced in 2011, maternal death surveillance and response aims to count every maternal death and collect data for aggregate analysis and public health decision-making (20, 21). In Tanzania, a shift towards maternal death surveillance and response has been set in motion and the Government is keen to streamline the National MPDR Guidelines with the latest WHO Technical Guidance on maternal death surveillance and response (19).

Little is known about the performance of the existing MPDR system in Tanzania or the practical barriers to its implementation (3, 4, 16, 17, 22). The overall aim of this study is to explore the current implementation of MPDRs in Tanzania. In this study we critically review the 2006 guidelines; we specifically aim to understand the role and practices of MPDRs in district and regional hospitals and we seek to understand key stakeholders' involvement in, and perspectives of, the MPDR process.

# **Methods**

## Review of the National MPDR guidelines

We reviewed the 2006 National MPDR guidelines. We assessed the document against its own objectives, and compared it with facility-based maternal death reviews as described in 'Beyond the Numbers' (11), FIGO-Logic documentation (23), and the latest WHO Maternal Death Surveillance and Response Technical Guidance (19) as well as the evidence base from published literature on audit effectiveness (12, 24).

## In-depth qualitative study

We conducted semi-structured interviews with informants who were involved in MPDR at the central, zonal, regional, district, or facility level. The Mara region in the Lake Zone was selected because Evidence for Action Tanzania (25) (a programme supporting maternal and newborn survival through strengthening use of evidence, advocacy and accountability) has an agreement with the government to adopt this region as the focal area for their work. Out of eight hospitals in Mara, three were purposively chosen for the study: one regional referral hospital, one government district hospital and one faith-based district hospital.

Informants were purposively sampled at each hospital and at the corresponding district health administration, along with Mara Region, Lake Zone and national health administrations. All staff that were involved with MPDR were selected for interview. Involvement in MPDRs was based on *a priori* understanding of the MPDR Committee membership, as stipulated in the National Guidelines. Informants were midwives, hospital directors, medical officers, laboratory staff, pharmacists, matrons, nurses, reproductive and child health coordinators, district, region and zonal health administration. Data collection accommodated other interviews with additional staff who participated in MPDR, including experts at the zonal and national level.

Semi-structured interviews enabled a detailed exploration of informants' views and experiences of the MPDR system, using a flexible and responsive approach. Three interview guides were generated; one each for national level, decentralised administrative level, and for facility personnel, based on research questions drawn from a literature review of MPDR implementation in Tanzania and through reviewing the National Guidelines (Box 1). The interview guides focussed on the involvement of the informant in the MPDR system, and perceptions of its function, however they each differed slightly according to the roles and responsibilities defined in the National Guidelines at each level, for example; the facility level interview guide included questions about the discussion within the facility-based death review meetings; the decentralised administration level guide had questions about district-wide reporting and use of findings; while the national level guide asked about aggregate data analysis and response at the central level. Leadership, reporting, action, supervision and accountability were explicitly addressed at each level. Questions were open-ended, so as to minimise social desirability bias.

# **Box 1. Main research questions**

- 1. What are the aims and purpose of MPDRs?
- 2. Who are the actors engaged in the process?
- 3. How are MPDRs carried out?
- 4. What are the effects of MPDRs?
- 5. What are the factors that prevent or enable MPDRs?
- 6. What are factors that prevent/enable responsive action from MPDRs?

Fieldwork was conducted by three researchers (C. E. A, M. M. & I. L. L.) that were trained in qualitative interviews, in June 2013. Interviews took place privately, and interviewers were not staff employed by MOHSW or implementing partners. Each typically lasted 60 minutes and were audio-recorded (if informants gave consent), complemented by field notes and informal conversations that took place while in the wards and hospital grounds. Interviews were transcribed and translated into English (if performed in Swahili) and a quality control was carried out on the transcriptions. An adapted thematic approach (26) was employed to map the data on the basis of *a priori* topics (Box 1.) and recurring themes that arose through analysis, stratified by type of respondent and facility. Data were analysed independently by the three researchers, and written-up according to the main research questions, and themes that emerged through iterative readings and discussion between the researchers. Names of informants or places were removed from all quotes.

## **Results**

# **Review of the National MPDR Guidelines**

The guidelines stipulate that the MPDR system was adapted from facility-based death reviews described in 'Beyond the Numbers' (11). This approach is explicitly defined as a "qualitative, in-depth investigation of the causes of and circumstances surrounding maternal deaths which occur in health facilities". A qualitative approach implies that not every case is systematically investigated, as indepth analysis is privileged over a full description of all cases, and that the review is iterative rather than prescriptive, depending on the case particularities.

The guidelines instruct in the analytical approach of individual case reviews, but do so only very briefly (Box 2.) with no advice for formulating an action plan at any level, unlike the FIGO-Logic guidance(23) which details each step of the process and provides template tools to guide the analytical discussions and generate solutions and actions.

The guidelines elaborate much more extensively on hierarchical reporting structures, technical committees, and administrative management of data. An example action plan is included but only brief instructions describe potential contributory factors for discussion. The structured reporting forms (one for each case reviewed) are designed to collect mostly medical causes of death, and as such are less suitable to guide the team through an analytical discourse on the gaps in service provision, nor stimulate action-oriented dialogue in the forum.

# Box 2 Description of review meeting in the guidelines

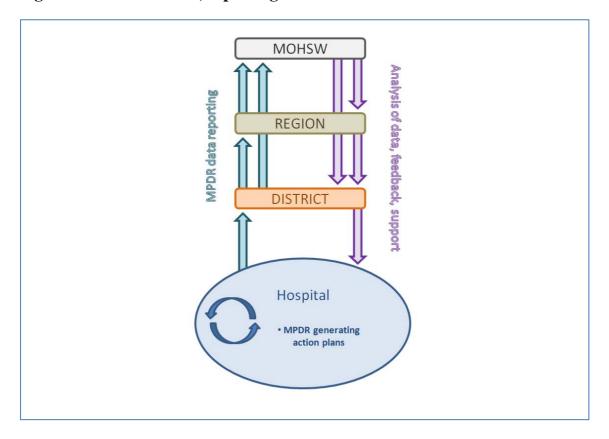
- The discussion should identify the gaps that might have led to death
- Analyse causes of the gaps then formulate appropriate action plan for implementation

The document describes the membership of technical committees at district, region and national level in great detail, and states the reporting commitments after the review (Figure 1). One copy of the completed form should remain at the facility and one copy sent to the district medical officer (DMO), who submits further copies on a monthly basis to the regional medical officer (RMO) and the Ministry of Health and Social Welfare (MOHSW). The DMO should provide feedback to the health facilities, the RMO should feedback to the districts, while the national technical committee should feedback to the regions and districts. The MOHSW presents annual reports to RMOs', DMOs', and regional nursing officers' meetings. The system of reporting is designed for establishing national levels of maternal and newborn mortality, to classify causes of death, and to plan action for death prevention, but the document does not elaborate on the various responsibilities at each administrative level or on the roles of the committees.

This is in contrast to the WHO Maternal Death Surveillance and Response Technical Guidance(19) that describes specific responsibilities at the district and national level. The district's main role is to report suspected and confirmed maternal deaths, triangulate and analyse maternal death review data, perform district-level reviews, and formulate responsive action at the community and district level. WHO states that the national level is responsible for country-wide data analysis, making priority recommendations based on aggregated data, and responding with direct action at the multi-sectoral level.

The guidelines state that the fundamental principles of confidentiality and anonymity apply; the information of discussion should not go outside of the committee room and that the process should be anonymous. However the name of the deceased and facility are included in the reporting form, while focusing on characteristics of the deceased, with little space allocated for detailing the problems and solutions identified.

Figure 1. Official review, reporting and feedback mechanism



## In-depth qualitative study

Data were collected from 37 informants who were all professionally involved in MPDR, including 20 hospital staff (six midwives, three directors, three medical officers, two laboratory staff, one obstetrics nurse, three pharmacists and two matrons), twelve district, regional and zonal level stakeholders (four reproductive and child health coordinators, one district laboratory technician, one district nursing officer, two DMOs, two health secretaries, two zonal MPDR medical officers), and five representatives from the MOHSW, professional bodies, non-government organisations, and national MPDR experts. We were unable to interview one expert and one member of MOHSW because of time constraints, and one administrative-level respondent because they refused to participate. Four of the main themes that emerged through analysis are detailed below.

# A. The practice of MPDR

MPDR is part of the medical school curriculum in Dar es Salaam and Mwanza (city hub in the Lake Zone), in the form of a weekly lecture and case review presentation, but they do not appear within midwifery or nursing education. Very few informants had ever seen the guidelines, yet most had experience reviewing maternal deaths. Perinatal deaths were rarely reviewed.

Many informants expressed a dedication to the process of reviewing the death and finding solutions to problems, besides MPDR being a required routine practice. Both national and decentralised administrative levels were engaged in the MPDR process. Facility providers expressed a solid commitment to the process of reviewing deaths, and were motivated to participate for educational purposes. MPDR is considered a tool to shift behaviours, "They become more responsible for those patients, [...] because they reviewed, remembered what happened last time" (zonal MPDR expert).

When scheduled audit meetings have to be postponed (due to workload, emergencies, or understaffing), it is not unusual for multiple maternal deaths to be reviewed in one sitting. This is considered arduous, draining and associated with a more uncomfortable dynamic. Deaths that have not been reviewed for months are not dismissed, they are eventually reviewed after long delays, illustrative of commitment to the process; "it may take one, two, three weeks... Now we have had two maternal deaths but we have not had a review ...but we are planning to meet" (midwife).

The meeting atmosphere was generally reported to be participatory, blame-free and "not for finger pointing" (midwife), "It is free, everyone can contribute" (hospital director), "the aim is to solve the problem not punishment" (midwife). Other informants noted that junior doctors, nurses and midwives sometimes felt unable to speak freely or criticise the conduct of more senior personnel, "Let me ask you, [say] a patient is brought in critical condition, the doctor has been called but has not come for eight hours and as a result you see a patient dies. Can you say boldly in front of a doctor you know, or you would rather keep your mouth shut?" (laboratory staff). Tension and worry around MPDR was an issue for some informants, who reported instances of blame; "people fear being blamed, fear that they will be considered unskilled" (midwife).

## B. The purpose of MPDRs

Interpretations of the purpose of MPDR varied between informants and included: to improve the quality of care (n=24); to understand the medical cause of death (n=10); to collect and report data on maternal deaths (n=7) and to blame or identify an individual who is at fault (n=4). Some informants expressed more than one interpretation of the purpose of MPDR, while others (n=7) did not articulate a clear response.

Only eight of the 20 facility informants (mostly senior staff) reported the purpose of the MPDR to be to improve quality of care while five additionally perceived MPDR as aiming to learn about the medical causes of death. There was specific emphasis from the hospital directors that the aim of MPDR is not to identify a person at fault, however two other hospital staff felt that MPDRs are intended to discover which individual was responsible for causing the death.

All but one of the 17 representatives at national, zone, regional and district level perceived MPDR as a tool for improving quality of care, and five added that an aim of MPDRs was collecting data on maternal deaths.

# C. The nature of challenges and solutions identified through MPDR

Significant emphasis was placed on contributory factors outside of the facility's control, while challenges and action plans focussed on changes within the community (Box 3). Deaths were for the most part attributed to the interrelating problems of inadequate family planning ("women give birth a lot" (midwife)), abortions, poverty, preference for delivering at home, late arrival at facilities, and delay in referral; "Most of the time that action is a blaming one, they say 'this patient delayed in the community', or something that is not correct" (national level). Lack of blood was commonly cited, and was considered to be beyond the control of the facility, dependent on individual donors and supply from the zonal blood bank in Mwanza. Thus action plans rarely included solutions within the facility to minimise risk of blood scarcity.

Challenges identified and solutions derived within the health providers' remit were rarely alluded to. Examples include creating checklists for emergency procedures in the labour ward, and providing

overnight accommodation for doctors on-call. Box 3 illustrates the challenges and solutions that one hospital concluded through a case review, emphasising factors outside of the hospital. The analysis and discussion of the case is weak; it does not identify appropriate causal determinants and it lacks a specific measurable action plan to be implemented at the hospital level.

# **Box 3. Example Case Review\***

The woman began bleeding at home from around 9am. Eventually, with family oriented delays, she was taken to a district facility where there were more delays, before she ended up being referred to the hospital. She was transported to the hospital without an intravenous line, lacking fluids. At the hospital the patient had her blood monitored and a blood group match was found. The doctor on duty tried to perform an emergency venous cutdown procedure (to give her blood/fluids) but was unable to, and the patient died.

#### Challenges identified

- 1) Dispensary staff involved in the patient's referral lacked skills to administer a cannula and so did not provide fluids which led to shock
- 2) Haemoglobin was not routinely checked in the reproductive and child health unit (antenatal clinic)
- 3) Community does not adhere to safe motherhood practices especially in responding to danger signs
- 4) Families lack safe motherhood knowledge to encourage care-seeking behaviours
- 5) There was a lack of blood at the hospital
- 6) Community lacks knowledge of danger signs so family did not react to danger signs
- 7) Lab and pharmacy did not come to the MPDR meeting even though they received the invitation
- 8) Reviews are not happening promptly enough after the death.

#### Solutions identified

- 1) The hospital surgeon should provide skills training to maternity staff at the hospital to perform an emergency venous cutdown
- 2) The reproductive and child health coordinator should go to the peripheral health centres and ensure that they are giving health education to women in community. Peripheral facilities must be reminded to check vital signs like blood pressure. They should be trained on haemoglobin and blood pressure monitoring.
- 3) Women in the community should have safe motherhood education, provided by nurses at health centers and the reproductive and child health coordinators, with supervision by the regional reproductive and child health coordinator.
- 4) Education on safe motherhood should be close to people in the community. Peripheral facility nurses should be given training. People in the community should be given education, and as this is the district medical officers' responsibility, the district medical officers need to be informed about those mothers who are dying.

\* extracted from minutes of the meeting, not the national forms documented by the hospital for internal circulation.

Sometimes maternal death audit meetings generated no recommendations at all; "they are supposed to make an action plan, but most of the time it is not happening" (national level NGO); or produce ineffective recommendations; "most of the time the action is a blaming one, they say 'this patient delayed in the community', or something that is not correct' (national level).

#### D. The mechanisms for reporting, feedback, and follow-up on responsive actions

## Reporting of MPDR data to higher levels

The MPDR forms are generally submitted per the guideline requirements (figure 2). A MOHSW informant told us that some regions report very irregularly and some forms reportedly arrived at the district and national level incomplete.

## Feedback from higher levels and follow-up of recommendations

There was no systematic mechanism at any level to follow-up on recommendations. This was noted by many respondents as a major barrier to effective MPDR (figure 2). Routine analysis and utilisation of MPDR data was not widely practiced at any level (figure 2). Some informants noted that a stronger mechanism for follow-up of actions would encourage evidence-based decision-making for management.

Contrary to instructions in the guidelines, feedback on previously reported MPDR data was rarely received from higher level administration (figure 2). One DMO sometimes received feedback from the regional medical officer. Several informants added that sharing positive developments arising from MPDRs is important and motivating.

#### National level

Despite MPDR data reaching the national level, the reporting forms have not been systematically analysed and the technical committee meetings were never held, reportedly due to insufficient human resources and funding. "The documentation is not taking place as supposed to be, and the analysis of this is not taking place, and the feedback is not there to the facilities" (national expert).

### District and regional level

District reproductive and child health coordinators (RCHC) are responsible for district-wide implementation of recommendations and tracking progress. Two of the districts had no mechanism for the coordinator to share MPDR information with administration or facility staff. However, one district hosted quarterly district-level MPDR meetings, where participants discussed recommendations from the last session with progress made against each action, and generated new 6-month strategies. This district also held monthly meetings as a forum for district-level feedback to council and community members.

## Facility level

Despite some concrete examples of changes made, there was no systematic way for monitoring implementation of MPDR actions at facility level.

## Community level

The district RCHC is responsible for implementation and tracking progress in community-based recommendations and action, with limited support from hospital staff, "Who goes to [help] the community? The hospital is here, we don't go out" (hospital director). Implementing actions at the peripheral facilities is infrequent, and reliant on scheduled supervision visits, incurring transport and logistical hurdles.

**MOHSW** Analysis of data, feedback, support pr 11 [1 MPDR data reporting REGION DISTRICT **District RCH** 11 Coordinator long of atlon 1L Hospital · Bias directed towards community, district, RCH coordinator · No mechanism for follow-up of recommendations · Expectation that opportunities for improvement lie outside of the hospital remit

Community & peripheral facilities

Figure 2. Review, reporting and feedback mechanism implementation

# **Discussion**

This study suggests that the MPDR system, introduced in Tanzania in 2006, has been established in Mara region, and most health providers and public health officers appear to be dedicated to the process. The process of reviewing the factors contributing to maternal deaths was felt by informants to be a useful way to understand and improve the quality of care in health facilities, and was generally perceived to be inclusive and blame-free. Despite the generally positive attitude at facility level, and commitment to the system at national level, the implementation of MPDR is dysfunctional and the system still faces a number of challenges, most of which may be related to a lack of clarity in its intended purpose. Perinatal deaths are rarely reviewed, in direct contract to the national guidelines. Whilst aiming at a qualitative investigation resulting in action at the facility level, the qualitative review process itself lacked detailed instructions, and facility teams were not trained or supported in the process by which the review could be used to inform decision-making and action within their facility. Nevertheless, reporting of data from facility to district, district to region, and region to central level is fairly well adhered to, yet leaving missed opportunities for creating and implementing feasible action plans at each stage and a tension in where accountability is seen to lie. The prominence of reporting directives and technical review committees in the guidelines suggests that the responsibility for addressing deficiencies in quality of care may lie outside the facility, even though no clear lines of accountability were made explicit. As a result, the utilisation of MPDR data for responsive action is weak at all levels, while reviews generate recommendations that do not necessarily address quality of care in facilities.

The ambiguity in the purpose of the MPDR system is problematic. For facility-based death reviews, not all deaths need to be counted, and responsibility for identifying and implementing remedial action largely lies with the review team, with support from heads of department and management (11). Where possible records are anonymised and discussions are kept confidential, although hospital personnel involved in the care of the woman are named (11, 23). Maternal death surveillance and response draws local data to the national level, where anonymous aggregate findings are utilised by decision-makers in assessing the magnitude of mortality, evaluating effectiveness of interventions, and prioritising needs (19), rather than encouraging direct action at the facility or decentralised administration levels. Although there is no objective tension between the two systems, the level at which responsibility is envisaged to lie differs substantially, and the types of action that ensue are likely to vary. Increasing accountability can generate better quality services when negotiations are targeted at the agents with the power and influence to support or implement change (27). Where accountability flows upward, the agency for systemic improvement lies with decision-makers outside of the facilities. The strength in facility-based MPDR lies in the continuous and systematic evaluation of care provision by peer groups, with direct agency to implement necessary changes. Macro-level pressures (18, 20) to implement maternal death surveillance and response over facility-based reviews has a potential to sabotage strategic facility-level quality of care improvements (21) and undermine its effectiveness as a system strengthening tool, through shifting accountability to the national level.

Maternal death reviews have had limited success in Tanzania and elsewhere in sub-Saharan Africa. Inadequate knowledge on its purpose, and poor generation and implementation of recommendations (13, 15, 16), attrition of staff (4), and inadequate identification of sub-standard care (3, 17) are major weaknesses that match our findings. Reviews that were undermined by problems of professional hierarchy have resulted in the identification of external and inaccurate problems and solutions (15) or abandonment of audit altogether (14). Although blame was not perceived to be a major problem in our study, it is plausible that the lack of anonymity (for the deceased and facility name) in the data that is required to be nationally reported, has contributed to the poorer quality dialogue during the case reviews. Workable solutions were found in two Tanzanian studies where MPDR was being implemented and coordinated by a dedicated external champion of the tool (3, 4). An external champion is often seen as the key to the success of maternal death reviews (12).

Our sample size was small, and the facilities and respondents were selected purposively thus the interpretations of the MPDR system reported here may not represent the general view of MPDR actors across Tanzania. The inclusion of several participants at every administrative level has enabled us to gather a spectrum of opinions and perspectives. Mara is not representative of Tanzania, being one of the most remote, impoverished, and low-performing regions, but is a setting that reflects many of the same challenges that are faced by health systems in other low-income countries. We did not have an opportunity to observe any MPDR meetings, and cannot definitely state the practices and dynamics of the review discussions. Transcription and translation may have affected data although steps were taken to limit this through a quality control carried out on a sample of the transcriptions. We feel, however, that the findings are highly relevant to the current macro context of maternal death surveillance and response and MPDR, at a time where many countries and institutions are exploring the opportunities presented by maternal death surveillance and response.

Should Tanzania wish to activate change in the MPDR system at the local level, evaluation, training and supervision is recommended to assess and capacity-build the skills of facility-level providers in performing quality reviews, for example establishing designated impartial MPDR coordinators (19),

and utilising the FIGO-LOGIC international guidance (23). The results of the QUARITE trial in Senegal and Mali demonstrate that adequate training and supervision by trained external facilitators contribute to better quality audit discussions and recommendations at the facility level (12). A revision of the extensive reporting requirements is recommended. De-identified case summaries (19), for example, emphasise confidentiality for the facility to enable better quality audit discussions and decisions, and better reflect the reduced data requirements at central level.

Many countries may be facing the same tension as Tanzania in trying to accommodate the needs of an existing system of maternal death reviews with the external demands of moving towards MDSR. If national-level accountability is pursued through MDSR, efforts should be made not to release health providers from reviewing deaths themselves and taking direct responsibility for the care in their facilities. It is unwise for providers to disengage, and facility-level reviews are an important iterative learning process that should remain the core of any effort to improve care in health facilities, whether through facility-based maternal death reviews or MDSR.

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**Ethical approval and consent** Free and informed consent was obtained from all participants in this study. The study protocol was approved by the Catholic University of Health and Allied Sciences and Bugando Medical Centre no. CREC/018/2013, Tanzania National Institute of Medical Research Ethical Review Board permit no. NIMR/HQ/R.8a/Vol.IX/1543 and the London School of Hygiene and Tropical Medicine Ethical Review Board.

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