Summary
Legal challenges encountered in establishing and implementing a MDSR system represent a significant barrier to patients, families, health workers and facilities due to the lack of an enabling legal framework and minimal confidentiality and anonymity. The poor management of these issues can result in fear of punitive measures and liability, poor transparency and quality of data. Very little information and research exists in this area, and further investigation and documentation of practical experiences is needed.

Purpose
The purpose of this factsheet is to identify legal issues faced by women, families, health professionals and facilities implementing MDSR systems and to present recommendations based on literature, MDSR workshops reports and country experiences, to overcome legal barriers in MDSR systems.

The Issue
- The laws and customs of a particular country can have a significant impact on MDSRs by helping or hindering access to information, the involvement of health care professionals, the conduct of the investigation and the way findings are used (WHO, 2004).
- The majority of research and literature highlights the importance of creating an enabling environment to the MDSR system, although minimal information exists on how this is achieved in practice.
- The system is affected by numerous legal issues including confidentiality, ethical considerations and liability.
- The absence of legal protection may make health professionals less likely to report deaths, participate in reviews or provide information to investigators (WHO, 2004).
- Given the localised nature of MDRs it is often difficult to ensure complete confidentiality or anonymity (Hussein, 2012).

However, identifying the key challenges and further investigations of case studies and examples of successful MDSR systems are key to overcoming these challenges.

Identifying the challenges
Lack of legal framework
The presence of a legal framework is a driving force behind MDSR systems.

It is critical to mitigating legal challenges on numerous levels including for the patient, family, health professional and facility (Pearson, 2009).

Key elements of a legal framework for MDSRs
- National interest group and government ownership and commitment
- Developing guidelines
- Budget and financial support
- An MDSR system is part of the maternal and reproductive health programme

The identification, notification, quantification, determination of causes and avoidability and response to provide essential information to stimulate and guide actions to prevent future maternal deaths and improve the measurement of maternal mortality (Danel, 2011).

- MDSR systems stress delivery of real-time, systematic and frequent monitoring of maternal mortality levels, trends and causes of maternal death in communities and facilities
- MDSR highlights the need to respond and provide action to every maternal death

Many countries have laws covering some or all of the legal issues related to maternal death reviews, however, these laws may even vary by region within a country (WHO, 2004).

Confidentiality and ethical considerations
Issues of confidentiality and privacy are a significant legal issue in terms of protection of women, families, health workers and review committees, including discussions and findings from the review process (Berg, 2011).

The lack of autonomy, privacy, anonymity and immunity of patients, families, health professionals and review committees can threaten the environment for an MDSR system.
- Autonomy – women and families are not fully informed of the purpose of the investigation and participation is not outlined as voluntary
- Privacy – privacy of the woman, her family and health workers is not respected or maintained (WHO, 2004)
- Anonymity – details of the women, health care workers and facility are available, risking attribution of events to individuals (Hussein, 2007)
- Immunity – protection for committee members, witnesses and others providing information is not provided and concerns of liability and litigation are prevalent
- Access to information – lack of access to and availability of sensitive and confidential medical materials (e.g. medical records, family and staff interviews) will have a significant impact on the understanding of events leading up to the death (Berg, 2011)

Malawi Confidentiality and anonymity in MDRs highlighted as major problems encountered by staff (Kongnyuy, 2009)

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Fear of liability and punitive measures
Many studies report concerns of liability, judgment, repercussions, blame and punitive measures for health professionals as a significant challenge to implementing and sustaining MDSR systems (Hutchinson, 2010; Kongnyuy, 2008; Konmgnyuy, 2009; Kalter, 2011; Gao, 2009).

- These concerns were reported as a result of a lack of a legal framework to offer protection from punitive measures to health workers and committee members (Pearson, 2009; Hutchinson, 2010).
- A lack of a legal framework can lead to misconceptions and fears regarding possible punitive measures and the perception that audits are judgments on the actions of professional medical staff (Pearson, 2009; Gao, 2009).
- For example, in Malawi despite that ‘no name, no blame’ was emphasised, complete anonymity was difficult to achieve and an atmosphere of repercussions (blame) among providers continued (Kongnyuy, 2008; 2009).

Poor transparency and quality of data
- Underreporting and misreporting by health workers is likely to occur as a result of legal concerns including an overall lack of legal protection and fears of liability and punishment (Bacci, 2007; Kalter, 2011).
- During MDRs, health professionals can react defensively, justifying actions and inactions, shifting the blame (e.g. blame death on the time taken to seek care) or even covering-up deaths or errors (Kongnyuy, 2009; Bacci, 2007; Gao, 2009).

Example of poor transparency and quality of data
A study evaluating the maternal death review process in China found that the forms and process did not provide anonymity for the deceased woman, health workers or hospitals and as a result underreporting and misreporting of cause of deaths were observed as health workers were afraid of punitive measures both from management and from the patient’s family (Gao, 2009).

Recommendations to prevent and overcome legal challenges

Legal situational analysis
- Review and understand the legal barriers and lobby for changes, if needed, in order to facilitate implementation and expansion of the MDSR systems.
- A supportive health policy framework that encourages the on-going investigation of all maternal deaths can facilitate the implementation process (WHO, 2004).

Encourage and support legal reforms
- Recognise reproductive health rights (World Bank, 2011).
- Make maternal deaths a notifiable event, ensuring that all deaths of women during pregnancy, delivery and postpartum period are reported in a timely manner at the facility and community levels (World Bank, 2011; Danel, 2011).
- Introduce MDSR systems as part of reproductive and maternal health policies.

Establish MDSR guidelines and a legal framework
- Ensure legal protection for health professionals including immunity and anonymity for review committees are outlined in guidelines (CDC, 2001; World Bank, 2011).
- Establish understanding that reports, proceedings and findings of the review committee cannot be used (discovered or admitted into evidence) in litigation.
- National strategy or health policy should prioritise introducing MDSR systems into the maternal health care system in order to improve the quality of obstetric and neonatal services throughout the country (Hutchinson, 2010).
- Ensure that guidelines reflect a shared responsibility of maternal deaths with an emphasis on improving quality of care as opposed to placing blame on health staff.

South Africa
Confidential enquiry system of recording and analysis maternal deaths in operation since 1 October 1997.
- Established confidential inquiry system – National Committee on Confidential Enquiries into Maternal Deaths (NCCEMD).
- Routine data collection, analysis, publication of key findings and recommendations (DOH, 2012; South Africa Every Death Counts Writing Group, 2008).

An MDSR system should be incorporated as part of routine supervision and monitoring of maternal health outcomes, reflected in national policy (World Bank, 2011).
- Capacity building to set up MDSR guidelines, database and a legal framework.
- Use technical assistance from international organisations to improve knowledge and skills on establishing and implementing MDSR systems.

Establish rules on confidentiality
- Ensure reporting mechanisms and forms are standardised and confidential (for the patient, family, health professional and facility), not just from ‘outsider’ access but also from reviewers (Gao, 2009).
- Women and families should be informed of the purpose of the investigation and that participation is voluntary.
- The family and health workers must be assured that as much as possible, privacy will be maintained (WHO, 2004).
- All individuals with access to any identifiable information should sign a confidentiality agreement, stating that they will not disclose any identifiable information.
- Anonymity of women, health care workers and facility reduces the risk of attribution of events to individuals (Hussein, 2007).
- Standardised, anonymous, tools should be developed for the MDSR at the national level as well as a protocol for the facility level.
- Data collection forms, case summaries, review meetings and any reports or dissemination of results should not contain personal identification (WHO BTN, 2004).
- Consent forms (or disclosure statements) should be administered prior to interviewing family members (World Bank, 2011).
- Review all available information on each case and synthesise into case summaries for the committee, removing identifiers from records, and assign a ‘case number’ (CDC, 2001).
- Aggregate findings from MDSRs and remove identifiable information. Use findings to identify and respond to consistent trends.

India
Introduction of the ‘Maternal and Perinatal Death Inquiry and Response’ (MAPEDIR) a verbal autopsy tool aims to understand and tackle maternal mortality at family, community, health services and policy-making levels. Ways to overcome legal issues:
- Motherhood is a top priority of the country’s National Rural Health Mission.
- Confidential, non-threatening environment provided to describe and analyse factors leading to adverse maternal outcomes.
- Informed consent and confidentiality highlighted and ensured.
- Confidentiality ensured when sharing findings, leads to openness in reporting, trust and a more complete picture.
• Identifying information should be not be shared by electronic means (World Bank, 2011).
• All committee members and staff should sign a confidentiality agreement before receiving any information on cases (CDC, 2001).
• After committee meetings, all notes with identifying information collected for the purposes of the audit should be destroyed (World Bank, 2011).
• Ensure access to medical records and other sensitive and confidential information of events leading up to the deaths (Berg, 2011).

Establish a culture of non-blaming

• The principal of ‘no name, no blame’ within MDSR, amongst health staff, management and reviewers, should be established, supported and reiterated (Lewis, 2003; WHO, 2004).
• Educate health professionals, that the MDSR system seeks to identify improvements in the health care delivery system (at all levels) and use results for learning in order to improve quality of maternal care and not to provide the basis for litigation or punitive action (Lewis, 2003).
• Establish immunity and legal protection for committee members, witness and others providing information from personal liability based on activities during the review process (Berg, 2011).
• Engage stakeholders within the planning and set-up process and educate on the ‘no-blame’ process and atmosphere.
• Hospital management should value and integrate the process, through providing leadership and human or financial resources (Hutchinson, 2010).
• Surveillance and monitoring of implementation and processes to prevent misuse of MDSRs findings (e.g. confidentiality rules respected and punitive measures not introduced).
• Multi-professional approach taken to ensure every member of the team understands the MDSR process, feels involved and valued (Hutchinson, 2010).
• Communicate the change in accountability efforts and perspective from identification of individual responsible and blame to making a difference and contributing to improvements (Hussein, 2012).
• Promote forums for sharing experiences of health workers and facilities, such as workshops and exchange visits (Kongnyuy, 2008).

Malaysia and Sri Lanka

Both countries have had successes in improving maternal and newborn health outcomes and have implemented formal MDR and confidential inquiry systems.

- MDR processes were outlined as ‘no blame’
- Everyone involved was clear that the purpose of was to learn from each death and to prevent similar deaths in the future (World Bank, 2003).

Conclusion

Legal concerns have been identified by patients, health professionals, review committees and facilities as a key challenge to establishing an MDSR system.

Further investigation and documentation of practical experiences in creating an enabling legal environment for MDSRs is needed to ensure that successful strategies are shared and replicated in other settings.

References


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