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Issue Brief 6

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Introduction

Maternal mortality continues to be a public health crisis, with 20 percent to 60 percent of deaths considered preventable after thorough case review.^{1,2} The World Health Organization defines maternal mortality as a death while pregnant or within 42 days of termination of pregnancy.³ The Centers for Disease Control and Prevention defines maternal mortality as a death while pregnant or within 1 year of the end of pregnancy from any cause related to or aggravated by pregnancy.^{4,5}

While the global maternal mortality ratio has decreased by 38 percent in the last two decades (2000-2017), from 342 deaths to 211 deaths per 100,000 live births,⁶ the United States is an exception among high-resource countries. In the United States, maternal mortality has continued to increase, from 7.2 deaths per 100,000 live births in 1987 to 17.3 deaths per 100,000 live births in 2017,⁵ with about 700 birthing people dying every year from pregnancy-related causes.⁷

One-third of maternal deaths occur during pregnancy, one-third during childbirth and up to a week postpartum, and one-third after a week to a year postpartum.⁴ The top causes of maternal death include hemorrhage, hypertensive disorders in pregnancy, sepsis, and cardiovascular conditions.¹ The exploration of the contribution of delayed or missed diagnosis to maternal mortality is a nascent area of study.

Maternal mortality is thought of as the "tip of the iceberg," as severe maternal morbidity has similar root causes, is much more common, and has a substantial impact on patients, families, and the healthcare system. Severe maternal morbidity (SMM) is defined as an unintended outcome of birth that results in significant short-term or long-term consequences.⁸ For every maternal death, 70 women are estimated to suffer from a severe complication.⁹ Birthing people who have a blood transfusion, sepsis, or pulmonary edema are more likely to have maternal morbidity.^{8,10}

Similar to maternal mortality, multidisciplinary review shows that maternal morbidity is associated with a high rate of preventability.¹¹ While no consensus has been reached on what extent maternal mortality and SMM are attributable to diagnostic error, emerging evidence suggests it is imperative to focus on diagnostic safety in obstetrics to prevent and mitigate diagnostic errors.^{2,12}

This issue brief discusses what is known about the contribution of diagnostic error to maternal morbidity and mortality, explains the rationale for improvement methods, and outlines the research agenda needed to make progress in this emerging area of diagnostic safety. The brief focuses on the maternal events that occur during childbirth and up to a week postpartum, with maternal hemorrhage as a primary example due to its prevalence, high rate of preventability, and interprofessional effort needed for diagnosis and treatment.

The Contribution of Diagnostic Error to Maternal Mortality and Severe Maternal Morbidity

Delays in recognition of risk factors and escalation of care are known to be associated with preventable maternal morbidity and mortality.¹³ These include delays in assessing clinical warning signs, providing accurate diagnoses, implementing optimal treatment, and coordinating care with multidisciplinary teams.^{1,13,14} For example, for deaths related to maternal hemorrhage, recognition of hemorrhage could be improved through awareness of risk factors, accurate assessment of blood loss, and identification of early signs of hypovolemia.¹⁵

The sidebar presents a composite case (combined elements from multiple cases with identifying features, including all personal identifiers, removed to ensure patient confidentiality). The case has been adapted from the Obstetric Hemorrhage Quality Improvement Initiative of the California Maternal Quality Care Collaborative. The case demonstrates how deficiencies in multiple dimensions of the diagnostic process can lead to the escalation of a low-risk pregnancy and birth to an emergent situation and preventable death.

Figure 1 shows the key gaps in the diagnostic process and opportunities for improvement. The diagram is an adaptation of the multidisciplinary Safer Dx framework for measuring, monitoring, and improving diagnostic error.¹⁶ The boxes on the left of the diagram are in alphabetical order and note the diagnostic process dimensions within the Safer Dx Framework. The dimensions link to the Quality Improvement Opportunities and Learning Points noted with superscript letters (e.g., a, b) in the Maternal Hemorrhage Case.

The Safer Dx framework adapts the structure-process-outcome framework¹⁶ to describe the foundations of safe and timely diagnosis:

- 1. Structure: characteristics of care providers, their tools and resources, and the physical/organizational setting;
- 2. Process: both interpersonal and technical aspects of activities that constitute healthcare; and
- 3. Outcome: change in the patient's health status or behavior.

The Safer Dx framework emphasizes system-level learning and improvement as a continuous feedback loop. Measurement and learning from diagnostic error (and circumstances without diagnostic error) must include all aspects of the diagnostic process that may evolve over time and should not be limited to what occurs during a single patient encounter. As AHRQ states, "Diagnostic performance is the outcome of these processes within a complex, adaptive sociotechnical system. Safe diagnosis (as opposed to missed, delayed, or wrong) is an intermediate outcome compared with more distal patient and healthcare delivery outcomes."¹⁷

The most common types of preventable events after a patient has accessed care in the hospital system for childbirth are related to:

- Inadequate diagnosis or delay in recognition of acuity,
- Inappropriate or inadequate treatment, and
- Inadequate documentation (poor charting or failure to chart) of risk factors.²

Cognitive biases, such as confirmation bias and implicit biases, can also affect a provider's diagnostic accuracy. Communication breakdowns can occur between patients and providers and within the healthcare team in an often-fragmented healthcare system.^{18,19} A number of different approaches can address these known process vulnerabilities, including:

- Implementing hospitalwide safety bundles;
- Addressing implicit bias, structural racism, and social determinants of health; and
- Using healthcare simulation, a unique tool for assessing and addressing gaps in care.

Case Discussion: Maternal Hemorrhage²⁰

Composite Case Example: A healthy 24-year-old presented at 39 weeks gestation and gave birth vaginally to an 8-pound, 6-ounce infant after 10 hours in labor.

After placental delivery, the patient had an episode of uterine atony (inability of the uterus to contract) that firmed with massage and described feeling "tired and thirsty" to the healthcare team.^a The nurses called the physician 30 minutes later to report a heart rate of 105^b and more bleeding,^c for which methylergonovine (a medication to help promote uterine contraction) was ordered.^d

Sixty minutes after the initial call, the physician performed a dilation and curettage (D&C), with removal of minimal tissue from within the uterus, thus excluding retained placental tissue as the cause of increased bleeding. The patient received more methylergonovine.^e

Forty-five minutes later, a second D&C was performed, again with minimal return of placental tissue. Estimated blood loss at this point was >2,000 mL.^c Delays in blood transfusion occurred due to the inability to find proper tubing for the rapid infuser.^f Arrival of an anesthesiologist was delayed due to another emergency.^g

Vital signs became markedly abnormal, with a pulse of 144 beats per minute and blood pressure 80/30 mm Hg. The patient received 2 units of red blood cells but a massive transfusion protocol was not activated due to the lack of an organized standard approach.^h The patient had a cardiac arrest from severe blood loss and died 3 hours later despite intensive resuscitative efforts.

Figure 1. Using the Safer Dx Framework 16 as a Model for Improvement of Diagnostic Error and Contributions to Maternal Mortality and Severe Maternal Morbidity With Hemorrhage as a Case Example



Rationale for Improvement Tools

A number of different approaches can be used to address delays in recognition and escalation of obstetric emergencies. Several approaches that have demonstrated benefit in other aspects of perinatal care are described below.

Implementing Hospitalwide Safety Bundles

Maternal safety bundles²¹ are "a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices —generally three to five —that, when performed collectively and reliably, have been proven to improve patient outcomes."²² Although bundles may vary in exact composition, they include a selection of existing guidelines and evidence-based recommendations in formats that promote adoption for consistency of practice.

For example, the National Partnership for Maternal Safety Consensus Bundle on Obstetric Hemorrhage includes 13 key elements spanning the types of equipment, checklists, personnel, and processes associated with improved assessment, diagnosis, and response to maternal hemorrhage.²³ Participation in a quality improvement collaborative with adoption of this safety bundle²³ led to a 21 percent reduction in severe maternal hemorrhage morbidity.²⁴

Bundles can be customized to fit each institution's needs and culture, which requires local resources and revision of existing protocols, aiding organizations toward their journey to high reliability.²⁵ Designation of bundle implementation as a key quality/safety priority is essential, with commensurate resources and incorporation of frontline input.^{26,27} Successful implementation requires commitment and investment from leadership and stakeholders, including education and training to implement these practices.

Addressing Implicit Bias, Structural Barriers, and Social Determinants of Health

Severe maternal morbidity and mortality disproportionately affect birthing people of color, especially Black women, with Black women twice as likely to experience a severe complication²⁸ and three to four times more likely to die than non-Hispanic White women.⁵ How implicit bias affects diagnosis and adequate treatment needs to be better recognized. For example, although missing early signs of hypovolemia has been identified as a contributing factor to delayed recognition, understanding how implicit bias plays a role when underrecognition occurs is needed to inform targeted approaches to address this important diagnostic error.

Potential interventions to reduce disparate outcomes include training providers on cultural humility and implicit bias, identifying and dismantling structural barriers to accessing care, providing additional support in navigating healthcare systems, and incorporating community-based education and support for families.^{29,30} Many of these remain to be evaluated, suggesting much work still remains to ensure that the individuals caring for birthing people and the structures in which they are cared for are promoting racial and social equity for all.

Healthcare Simulation To Characterize, Design, and Change Processes

Healthcare simulation, a technique that creates a situation to allow people to experience a representation of a real event,³¹ has been applied to improve the outcome of a variety of obstetric emergencies, including shoulder dystocia,³² maternal cardiac arrest,³³ and maternal hemorrhage.²³ Simulation has also been used as a tool for health professional education and training.³⁴ It is ideal for use in clinical settings, giving the multidisciplinary teams needed to respond to obstetric emergencies an opportunity to practice teamwork, communication, and skills to address obstetric process issues.^{35–37}

Simulation can also be used to identify, understand, and address diagnostic error.^{38–41} Additional research could explore how simulation can also serve as a means of mitigating both cognitive factors such as bias and misdiagnosis/misinterpretation, as well as system errors (latent safety threats), to support reduction in diagnostic error,^{19,39,42} specifically in maternal care.

For example, in the Maternal Hemorrhage Case above, simulation could explore the causes of systemic issues (e.g., latent safety threats such as having the proper tubing for blood transfusion available in all rooms) and cognitive errors¹⁹ (e.g., related to implementing additional treatment options when those tried were ineffective). Simulation can be a useful modality for addressing diagnostic error in maternal health by facilitating implementation of new equipment or processes,⁴³ including safety bundle components such as standardized stage-based treatment for hemorrhage or implementation of a massive transfusion protocol.

Some barriers exist to using simulation to improve quality, including the cultural shift needed to effectively use simulation as an improvement strategy, cost of equipment and staff time, recruitment and training of skilled facilitators/debriefers, and challenge of measuring its direct impact on improvement.⁴³ Balancing the potential benefits and drawbacks of simulation is key for maximizing the potential of this technique.

Research Agenda

Overall, more research is needed to reduce maternal morbidity and mortality,⁴⁴ including the contribution of diagnostic error to the care and treatment of birthing people. Through a 2014 cooperative agreement, Alliance for Innovation in Maternity Care, the Health Resources and Services Administration and the American College of Obstetricians and Gynecologists have advocated for solutions to maternal morbidity and mortality. They propose the "4 R's":

- Readiness (institution's resources, protocols, and procedures),
- Recognition and Prevention (assessment, measurement, and management),
- Response (treatment), and
- *Reporting and Systems Learning* (communication, debrief, and review).²³

In 2021, they included a fifth domain, *Respectful Care* (patients' right to be informed, educated, and supported), as it is critical for delivering safe, patient-centered, high-quality care.⁴⁵

The domains of the "5 R's" were used as an outline for a proposed research agenda (Table 1), building on existing work related to maternal hemorrhage during childbirth and through the immediate postpartum period as a primary example. This approach and agenda can be applied to other causes of maternal morbidity and mortality, such as sepsis and hypertensive disorders in pregnancy.

It is imperative to include a diagnostic safety lens to improvement efforts targeting maternal health. It will be crucial to understand, define, and measure diagnostic error and performance within this field to further optimize care.¹⁷ This agenda presents an opportunity to integrate ongoing diagnostic safety efforts and approaches into maternal health initiatives.

Table 1. Proposed Research Agenda To Understand and Improve the Contribution of				
Diagnostic Safety to Maternal Morbidity and Mortality				

	Research Gap	Justification	Proposed Research*
Readiness	Education and Training Modalities	It is unclear which training models or modalities have the greatest impact on increased quality and safety.	Evaluate trainings and training modalities associated with improved diagnostic safety in [maternal hemorrhage], such as simulation. ^{43,46}
		It is unclear which combination of trainings increase quality and safety.	Evaluate combinations of trainings and their effects on improving [maternal hemorrhage] quality and safety. ⁴⁷
		Deliberate practice to maintain skills is imperative to quality perinatal care	Explore the frequency of experiential trainings, including simulation, required to maintain skills.
Recognition and Prevention	Factors Contributing to Diagnostic Error	There is limited understanding of contribution of diagnostic error to diagnosis or escalation of care.	Determine incidence of diagnostic error in [maternal hemorrhage] recognition. ¹²
		Identification of risk factors is important to increase diagnostic accuracy.	Determine demographic and clinical factors associated with diagnostic delay during [maternal hemorrhage]. ¹⁵
		Cognitive and system errors are major contributing factors to diagnostic error.	Identify provider factors, including bias, that contribute to diagnostic error, including missed or delayed diagnosis. ¹⁹
		System errors are major contributing factors to diagnostic error.	Identify institutional factors that contribute to diagnostic error, including policies and cultural factors. ⁴⁸
	Assessments	Standardizing methods for determining risk will improve recognition and escalation efforts.	Identify the most sensitive markers for [maternal hemorrhage], e.g., quantitative blood loss, early warning signs.
			Develop and validate risk assessments that promote reliable and safe diagnostic practices.

Continued

	Research Gap	Justification	Proposed Research*
Response	Cognitive Errors	Significant evidence exists to suggest that providers may be affected by underlying cognitive errors.	Determine impact of various cognitive errors (e.g., implicit bias, anchoring, confirmation, knowledge synthesis) on diagnostic error in maternal hemorrhage care.
	Information Technology	Efficient health information technology can improve patient safety.	Evaluate how health information technology, such as electronic health records, contributes to diagnostic errors.
			Identify solutions based on health information technology that are associated with improved diagnostic safety.
	Treatment	Standardizing treatment can reduce cognitive error.	Build on existing best practices to include benchmarks for treatment, including medication administration of [maternal hemorrhage].
		Reviewing timeliness of interventions can provide more direct guidance for treatment.	Evaluate evidence of improvement in care if specific treatment is implemented in a specific timeframe.
	Teamwork	Objective triggers for automatic assembly of healthcare team are key to effective treatment.	Explore teamwork factors associated with prompt response to [maternal hemorrhage].
			Explore which factors promote real-time quantification and discussion of blood loss.
			Evaluate the impact of experiential learning, such as simulation, on teamwork culture and relationships.
	Data Collection	A need exists for standardized documentation and reporting of events.	Collect standardized institution-based reports of [maternal hemorrhage].
Learning		Iterative processes of review and refining of quality and safety measures are needed.	Identify diagnostic safety issues through case review using the Safer Dx framework. ^{16,17}
		Reviewing trends at a national/State level can affect care at the institutional level.	Synthesize learning from State/national repositories.
Reporting and Systems		Learning from when events go well (Safety- II) is crucial to improving systems. ⁴⁹	Collect and synthesize attributes of [maternal hemorrhage] where a diagnostic safety event did not occur.
			Apply lessons learned from trends and improvements in morbidity and mortality due to various comorbidities outside of pregnancy to obstetrics.
	Insurance Reimbursement	Extended care may affect diagnostic safety specifically during the postpartum period.	Explore the impact of bundled payment of postpartum coverage on diagnostic safety events. ¹⁰

Continued

Research Gap		Justification	Proposed Research*
Respectful Care	Patient Communication	Patients and their families deserve to be informed throughout their care.	Evaluate best way to engage patients and families in preventing diagnostic safety events.
			Evaluate best way to disclose diagnostic safety events to patients and families.
			Evaluate best ways to engage patients and families in diagnostic safety event mitigation and reporting.

* The proposed research agenda can be applied to understand and improve the contribution of diagnostic safety to various causes of maternal morbidity and mortality. It builds on existing works (completed or in progress) to identify notable gaps that should be prioritized for advocacy and funding.

Conclusions and Next Steps

Maternal morbidity and mortality continue to be major public health concerns. With a high-rate of preventability, changes in healthcare systems can reduce the prevalence of these cases. Although, many factors that contribute to diagnostic error in maternal health are unknown, there are feasible solutions, including simulation to both determine the causes of and reduce diagnostic error in maternal health. Awareness and foundational knowledge of diagnostic safety frameworks are required to support this shift in maternal health. More research is needed to identify related factors that contribute to diagnostic error and to determine solutions.

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