

PATIENT SAFETY

Triggers, bundles, protocols, and checklists—what every maternal care provider needs to know

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The rise in maternal morbidity and mortality has resulted in national and international attention at optimally organizing systems and teams for pregnancy care. Given that maternal morbidity and mortality can occur unpredictably in any obstetric setting, specialists in general obstetrics and gynecology along with other primary maternal care providers should be integrally involved in efforts to improve the safety of obstetric care delivery. Quality improvement initiatives remain vital to meeting this goal. The evidence-based utilization of triggers, bundles, protocols, and checklists can aid in timely diagnosis and treatment to prevent or limit the severity of morbidity as well as facilitate interdisciplinary, patient-centered care. The purpose of this document is to summarize the pertinent elements from this forum to assist primary maternal care providers in their utilization and implementation of these safety tools.

Key words: obstetric quality, patient safety, quality improvement

The United States is one of the few developed countries in the world with an *increasing* maternal mortality rate.¹ Equally disconcerting is that its rate of 17 maternal deaths per 100,000 live births is ranked 60th in the world.² While the maternal mortality rate

is alarming, the number of deaths is dwarfed by the number of women who experience severe maternal morbidities, and these complications have increased >75% from 1998 through 1999 and 2008 through 2009, affecting approximately 2-4 women per 1000 live births.³⁻⁵ Furthermore, marked disparities remain in maternal health outcomes for those of racial/ethnic minority and/or low socioeconomic status.^{2,5} The causes of the rise in maternal morbidity and mortality are multifactorial and likely include the increasing maternal age, body mass index, and prevalence of comorbid medical conditions, along with the increasing cesarean delivery rate.⁶

Multifaceted and collaborative approaches to optimizing maternal health in the United States have been advancing, exemplified by initiatives such as state-level perinatal quality collaboratives.⁷⁻⁹ These collaboratives have prioritized core obstetric safety programs that are focused on postpartum hemorrhage, severe hypertension, and venous thromboembolism.^{10,11} Recently, national attention has been

directed to the development and implementation of regionalized systems of maternal care to facilitate provision of services in risk-appropriate settings.¹² This regionalization of obstetric care may result in improved outcomes for women known prior to delivery to be at risk for severe morbidities (eg, maternal heart disease or placenta accreta).¹³⁻¹⁵ Yet, even if such regionalization were to be widely enacted, most women in the United States would continue to be delivered in lower-acuity birthing centers and hospitals by primary maternal care providers (obstetricians, family medicine physicians, and midwives) and not in specialized, tertiary-care centers by maternal-fetal medicine subspecialists. Hemorrhage, acute severe hypertension, venous thromboembolism, sepsis, and cardiovascular collapse (eg, secondary to amniotic fluid embolism) are examples of the complications that can occur unexpectedly in patients considered to be low risk.

Therefore, because maternal morbidity and mortality can occur unpredictably in any obstetric setting, primary maternal care providers should be integrally involved in efforts to improve the safety of obstetric care delivery. Quality improvement initiatives remain vital to meeting this goal. While the science behind quality improvement is rapidly evolving, there are several core tools that have been demonstrated to improve the quality and safety of care. Triggers, bundles, protocols, and checklists are examples of tools that: (1) are evidence-based and can facilitate measurable improvements in quality of care, (2) aid timely diagnosis and treatment to prevent or limit the severity of morbidity, and (3) are customizable for local implementation. These tools also have

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the potential to facilitate interdisciplinary, patient-centered care and to contribute to a culture of safety. It is important to note, however, that the implementation of many of these tools in obstetrics is still in its early stages. Thus, recommendations for implementation are often based on data from other specialties, expert opinion, or clinical consensus, although the body of direct evidence in obstetrics supporting utilization continues to grow.

While the primary benefit of the adoption of this set of tools would be to improve patient outcomes, there are several appealing secondary benefits as well. The implementation of quality improvement initiatives has been associated with decreased costs related to professional liability litigation and adverse outcomes. For example, data from a national health care system with >200 hospitals documented a decrease in malpractice claims from 14-6 per 10,000 births after the institution of a quality improvement program.¹⁶ Payers, specialty societies, and national policymakers also have placed an emphasis on quality and patient safety through their endorsement of publically reportable metrics, reimbursement through pay-for-performance mechanisms, and mandating of continuing physician education through maintenance of certification.^{10,17-19} The purpose of this document is to summarize the definition, purpose, and supporting evidence, as well as provide examples of triggers, bundles, protocols, and checklists to assist primary maternal care providers in their utilization and implementation of these safety tools.

Triggers

Definition and purpose

Triggers can be used prospectively or retrospectively. Prospectively, a “trigger” is used to identify an event or condition that mandates further action by the health care team.^{16,20} This action is designed to facilitate timely intervention and reduce practice variation to improve efficiency and safety. While “notify MD if” orders are commonplace, triggers not only notify the maternal care provider, but also require further action by the

entire health care team. Retrospectively, a “trigger tool” is a list of predefined occurrences likely to indicate an action or potential adverse event and are generally used for retrospective internal quality monitoring and improvement.²¹

Examples

Examples of prospective triggers include patient agitation, new onset of difficulty of movement, or specific thresholds for abnormal vital signs.²² While utilized for >20 years in the nonobstetric population, early warning systems for abnormal vital signs have been less commonly utilized in obstetrics.²³

Effective early warning systems include an expectation for surveillance, defined criteria for abnormalities, and a protocol for direct provider assessment after an abnormality is detected. An early warning system can serve as both a diagnostic *and* communication tool, highlighting an increased risk for compromise prior to clinical decompensation, so that care can be escalated to limit the severity of morbidity.²⁴ Thus, triggers can help to identify patients at risk of decompensation and prevent morbidity by facilitating the escalation of care. Recently, several early warning systems have been either created specifically for pregnancy or adapted for use in the obstetric context and are termed “maternal” or “modified” obstetric early warning systems.²³⁻²⁶ While a comprehensive review of modified obstetric early warning systems is beyond the scope of this discussion, it is notable that

this type of early warning system has been broadly implemented by the United Kingdom’s National Health Service.²⁵

In the United States, the National Partnership for Maternal Safety was formed in response to the rising maternal mortality rate and evidence demonstrating the contribution to this rate of delays in recognition and treatment of hemorrhage and hypertension as well as prevention of thromboembolism. This collaborative initiative included the American Congress of Obstetricians and Gynecologists (ACOG); Society for Maternal-Fetal Medicine; American Academy of Family Physicians; American College of Nurse-Midwives; and Association of Women’s Health, Obstetric and Neonatal Nurses, among others. It has proposed an early warning system—maternal early warning criteria (MEWC)—that incorporates aspects of the United Kingdom’s early warning system. In the MEWC system, any one abnormal value should trigger a response by the health care team, including bedside assessment by a clinician (Figure 1).²⁴ This system, ideally incorporated into the electronic medical record, provides a practical tool to facilitate timely recognition of and response to acute maternal illness and may serve as a framework for quality improvement on obstetric units. Figure 2 graphically depicts one health system’s individual early warning system along with a guide to assist physicians in the initial evaluation and management of abnormal vital signs.

FIGURE 1
Maternal early warning criteria

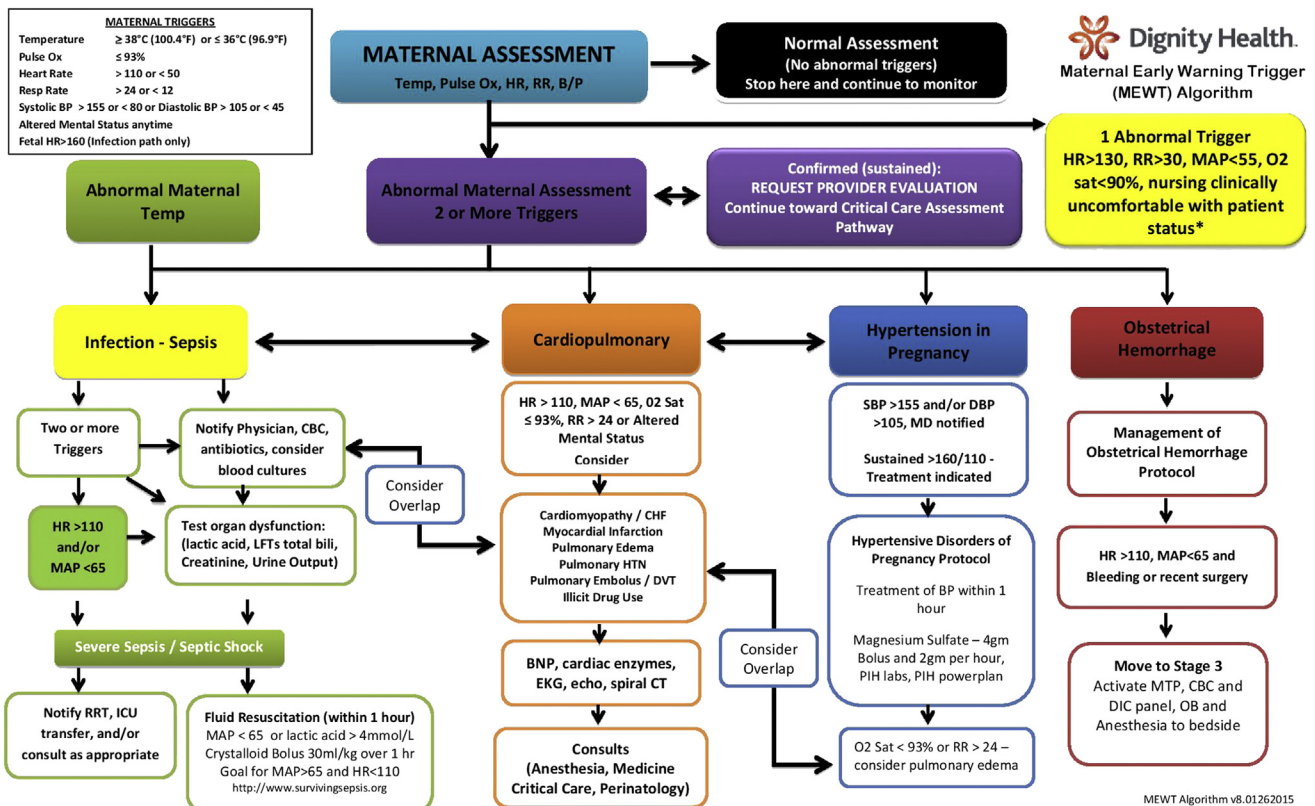
Systolic BP (mm Hg)	<90 or >160
Diastolic BP (mm Hg)	>100
Heart rate (beats per min)	<50 or >120
Respiratory rate (breaths per min)	<10 or >30
Oxygen saturation on room air, at sea level, %	<95
Oliguria, mL/hr for ≥2 hours	<35
Maternal agitation, confusion, or unresponsiveness; Patient with preeclampsia reporting a non-remitting headache or shortness of breath	

Early warning system proposed by National Partnership for Maternal Safety.

BP, blood pressure.

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FIGURE 2
Escalation due to early warning system



Example of individual health system's early warning system with protocol for initial evaluation (L.E. Shields, MD, written communication, May 14, 2015).

O₂, oxygen; bili, bilirubin; bnp, b-type natriuretic peptide; BP, blood pressure; CT, computed tomography; DBP, diastolic blood pressure; DIC, disseminated intravascular coagulation; echo, echocardiogram; ekg, electrocardiogram; HR, heart rate; ICU, intensive care unit; LFTs, liver function tests; MAP, mean arterial pressure; MTP, massive transfusion protocol; PIH, pregnancy-induced hypertension; pulse ox, pulse oximetry; RR, respiratory rate; RRT, rapid response team; SBP, systolic blood pressure; Temp, temperature.

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Since only 10-20% of errors are reported through the traditional ad-hoc chart and outcome review, a more effective method to accurately identify adverse events is needed.^{16,20} Retrospective obstetric trigger tools, such as the Adverse Outcome Index (AOI) illustrated in the Table or an algorithm for severe maternal morbidity during delivery hospitalizations, can assist clinicians and administrators in analyzing rates of complications, guiding further in-depth review, and monitoring the impact of quality improvement programs.^{6,27,28}

Supporting evidence

Outside of obstetrics, early warning systems have demonstrated an ability to identify pediatric patients who are more likely to need intensive care unit (ICU)

admission from the emergency department and to lessen the chance of readmission after colorectal surgery.^{29,30} In a systematic review of 13 unique early warning system models, the predictive capability, as quantified by the area under the receiver-operating characteristic curve, for cardiac arrest models ranged from 0.74-0.86 and for death ranged from 0.88-0.93, suggesting high predictive values for both.³¹ In the obstetrical literature, while validation studies are underway for the MEWC, the use of other modified obstetric early warning systems has been associated with improvement in mortality rates in maternal ICUs, and also improvement in the recording of vital signs in the clinical setting of maternal bacteremia.^{26,32} The utilization of trigger tools such as the AOI to improve system policies also has

been associated with a reduction in the occurrence of adverse events.^{16,27,28}

Bundles

Definition and purpose

The Institute for Healthcare Improvement (IHI) defines bundles as small sets of evidence-based, independent interventions that when implemented together in an all-or-none fashion result in significantly improved outcomes compared to when they are implemented individually.¹⁶ The power of the bundle is the synergistic effect of each evidence-based component, so that the summative increase in quality of care is greater than would be realized with individual interventions. The Safe Motherhood Initiative from ACOG District II uses the term, "bundle" to signify a collection of materials (eg, checklists,

protocols, educational materials) that is targeted toward a particular morbidity such as hemorrhage or severe hypertension in a multifaceted and comprehensive approach.³³

Examples

The IHI has advanced several perinatal bundles including those for the use of oxytocin in labor induction and augmentation and for operative vaginal deliveries with vacuum. In its labor induction bundle, the IHI recommends that there is clear delineation of the following 4 elements: (1) the approach to assessment of gestational age, (2) the standard recognition and management of fetal heart rate tracings, (3) the performance of pelvic assessment, and (4) the recognition and appropriate management of tachysystole.¹⁶

The Council on Patient Safety in Women's Health Care, a larger umbrella initiative over the National Partnership for Maternal Safety, has developed a 4-phase bundle concerned with obstetric hemorrhage: (1) readiness, (2) recognition and prevention, (3) response, and (4) reporting/systems learning.³⁴ The Safe Motherhood Initiative proposed a hypertension bundle that details the differential diagnosis of hypertension in pregnancy; defines triggers to prompt further evaluation and treatment; and provides algorithms for common antihypertensive medication administration, checklists for eclampsia management, and educational material for providers regarding quality improvement.³³

Supporting evidence

In an evidence report for the Agency for Healthcare Research and Quality, an expert panel recommended that the IHI 5-item bundle regarding the approach to central line-associated bloodstream infections should have a high level of support for universal adoption given the sustained and cost-effective reduction of central line-associated bloodstream infections from 7.7-1.6 per 1000 per catheter day after implementation.³⁵ Similarly, for those undergoing emergency laparotomy, a surgical bundle that includes early antibiotics, goal-directed

fluid therapy, and reduction of the time to surgery has been associated with a reduction in mortality from 15.6-9.6%.³⁶ In obstetrics, neither the IHI perinatal bundle nor the one proposed by the Greater New York Hospital Association's Perinatal Safety Committee on fetal monitoring have specifically demonstrated improved maternal safety.^{16,37} However, given that each component of these bundles has been shown to correlate with improved outcomes independently, it stands to reason that this series of individual clinical steps grouped together could also be associated with improved care, though evaluation after implementation is necessary.³⁷ Certain aspects of these bundles, such as checklists on management of hypertension or hemorrhage, were based, in part, on the approaches that in some studies have demonstrated to improve maternal morbidity and mortality.³⁸ Furthermore, early data after implementation of the Council on Patient Safety in Women's Health Care's maternal hypertension bundle are associated with a reduction in severe maternal morbidity.³⁹

Protocols and Checklists

Definition and purpose

Protocols and checklists serve to augment memory and limit the chance of human error.^{40,41} Such tools are particularly useful in highly stressful environments such as labor and delivery units. By improving communication and standardizing responses, these tools allow for necessary clinical variation in practices, while reducing unnecessary clinical variation that can lead to medical errors. Protocols and checklists help to remind clinicians of details that form baseline expectations of actions even when the care pathway is complex. Protocols are precise and rigid plans of action for a specific problem or clinical scenario, while checklists are informational aids that ensure consistency and completeness.

Examples

ACOG, the IHI, and others have focused on common clinical presentations in which protocols and checklists can lead

TABLE
Adverse Outcome Index indicators²⁸

Indicator
Blood transfusion
Maternal death
Maternal ICU admission
Maternal return to operating room or labor and delivery
Uterine rupture
Third- or fourth-degree laceration
Apgar score <7 at 5 min
Fetal traumatic birth injury
Intrapartum or neonatal death >2500 g
Unexpected admission to neonatal ICU >2500 g and for >24 h

Example of retrospective trigger tool for quality assessment.

ICU, Intensive care unit.

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to improved quality of care.^{16,40} One example is a protocol for the diagnosis and management of severe hypertension in pregnancy, with the specific goal that an intravenous antihypertensive agent be administered in a timely fashion after identification of a severe blood pressure elevation (systolic blood pressure >160 mm Hg or diastolic blood pressure >110 mm Hg).⁴² Another example is a postpartum hemorrhage protocol that includes early blood product transfusion and escalation of care (an example of a published protocol is illustrated in Figure 3).⁴³⁻⁴⁶ A formalized delineation of steps for the management of a shoulder dystocia represents another example.⁴⁷ A fourth example is the use of a checklist prior to the performance of an operative vaginal delivery to ensure that a team time-out is performed, the bladder is drained, and fetal position and station are confirmed.⁴⁸ Finally, the success surgical time-outs prior to surgery to verify laterality and preoperative antibiotic prophylaxis at cesarean delivery represent examples of improvements in clinical care due to standardization of actions through the implementation of protocols and checklists.⁴⁹⁻⁵⁰

FIGURE 3
Postpartum hemorrhage protocol

No observable abnormal bleeding, but maternal pulse rate >115bpm or systolic pressure < 95mmHg may indicate postpartum hemorrhage			
<input type="checkbox"/> Contact obstetric resident [redacted], an anesthesia resident [redacted], and mentor nurse [redacted] to examine the patient and discuss the following: <input type="checkbox"/> Need to enact postpartum hemorrhage protocol (below) <input type="checkbox"/> Need for type and screen <input type="checkbox"/> Need for additional uterotonics (Methergine, Hemabate, and Cytotec) <input type="checkbox"/> Need to move patient to L&D prep/room/recovery room (for postpartum patients only) <input type="checkbox"/> If the physician decides not to enact the pph protocol, he/she must document why there is a low suspected probability of a hemorrhage and list alternate etiologies <input type="checkbox"/> Notify attending			
Abnormal Blood Loss: between 500-1,500cc for vaginal or 1,000-1,500cc for cesarean delivery and continued bleeding			
Primary nurse actions	Secondary nurse actions	Obstetric service actions	Anesthesia service actions
<input type="checkbox"/> Call Obstetric Resident [redacted] to assess the patient <input type="checkbox"/> Call Anesthesia Resident [redacted] to assess the patient <input type="checkbox"/> Alert Team Lead [redacted] to get uterotonics in the room and secure additional nursing resource <input type="checkbox"/> Type and Screen if not already complete <input type="checkbox"/> Initiate NPO status until resolution of hemorrhage <input type="checkbox"/> Complete pph flow sheet q 15 minutes <input type="checkbox"/> Stay with the patient until bleeding is resolved, regardless of transfer	<input type="checkbox"/> Serve as primary clinical contact for other providers <input type="checkbox"/> Retrieve Methergine, Hemabate, and Cytotec from Omnicell and have available in patient's room <input type="checkbox"/> Begin weighing chux and pads <input type="checkbox"/> Check with primary nurse q 30 minutes to evaluate situation	<input type="checkbox"/> Resident accountable for notifying attending of the situation and reviewing plan of care with primary nurse <input type="checkbox"/> Call in attending to lead medical/surgical interventions	<input type="checkbox"/> Resident accountable for notifying attending of the situation and reviewing plan of care with primary nurse
Severe Blood Loss: Between 1,500-2,000cc and continued bleeding			
Primary nurse actions	Secondary nurse actions	Obstetric service actions	Anesthesia service actions
Call/page immediate responders: <input type="checkbox"/> Obstetric resident [redacted] and attending (page) <input type="checkbox"/> Anesthesia Resident [redacted] <input type="checkbox"/> Call Team Lead and secure additional nursing resource [redacted] <input type="checkbox"/> Complete pph flow sheet q 5 minutes <input type="checkbox"/> Record temp q 30 minutes	Notify following services (ensure emergent nature of situation is communicated) <input type="checkbox"/> Interventional Radiology [redacted] during day or page [redacted] after hours) for physician to physician communication and possible transfer <input type="checkbox"/> Page Gynecologic Oncology attending on call for physician to physician communication <input type="checkbox"/> Blood Bank [redacted] <input type="checkbox"/> Unit Attending [redacted] <input type="checkbox"/> Call OR Clinical Coordinator [redacted] and Gyne OR [redacted] to arrange for instruments or OR use <input type="checkbox"/> Order labs (PT/PTT, H&H, Fibrinogen- Superstat) <input type="checkbox"/> Type and cross-match 8u PRBC <input type="checkbox"/> Arrange for baby to be transferred <input type="checkbox"/> Ask charge nurse to call manager or HOA if additional resources needed	<input type="checkbox"/> Attending present to lead medical/surgical interventions	<input type="checkbox"/> Resident to call attending [redacted] <input type="checkbox"/> Attending to lead fluid resuscitation, line placement, and monitoring
Critical Blood Loss: >2,000cc and continued bleeding			
Primary nurse actions	Secondary nurse actions	Obstetric service actions	Anesthesia service actions
<input type="checkbox"/> Call/page immediate responders (if not already notified) <input type="checkbox"/> Complete pph flow sheet q 5 minutes <input type="checkbox"/> Record temp q 30 minutes	<input type="checkbox"/> Call in Gynecologic Oncology team Call/page additional resources for intervention or transfer <input type="checkbox"/> Interventional Radiology [redacted] <input type="checkbox"/> Blood Bank [redacted] <input type="checkbox"/> L&D OR [redacted] <input type="checkbox"/> Inform Bed Assignment [redacted] or HOA of need for ICU bed (pager [redacted])	<input type="checkbox"/> Attending present to lead medical/surgical interventions	<input type="checkbox"/> Attending present to lead medical/surgical interventions <input type="checkbox"/> Consider Oneg blood transfusion if SC not available <input type="checkbox"/> Activate critical blood loss protocol [redacted]

Example of individual institution's postpartum hemorrhage protocol.

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Supporting evidence

Multidisciplinary surgical checklists have been demonstrated to be associated with an absolute decrease in both surgical complications and mortality. Similar checklists exist to reduce the incidence of adverse drug events, venous thromboembolism, and surgical-site infections, among other morbidities.⁵¹ In obstetrics, the use of a postpartum hemorrhage protocol has been associated with more rapid use of pharmaceutical and procedural interventions and an increase in the days between ICU admissions at the institution.⁴⁴ Finally, investigators have demonstrated reduced maternal morbidity with checklists regarding oxytocin administration, postpartum hemorrhage management, and hypertension treatment.^{38,52,53}

Implementation

While the need for a consistent approach to evaluation and treatment in acute situations is well established, there remain significant barriers to implementation of these patient safety tools.⁴¹ Five such potential barriers are the potential to decrease individualization of care, to be less suited to the local environment, to have limited uptake, to encourage overdiagnosis, and to require the performance of periodic reassessments of impact. The first potential barrier to implementation is that some providers mistakenly believe that protocols and safety tools diminish clinical care by compromising individualization and physician autonomy. The aforementioned core quality tools assist in reducing variability and improving

reliability of action, particularly in stressful situations during which human and system-level errors are more likely to occur. Importantly, these tools are not intended to preclude physician judgment or the ability to individualize care. Rather, they are meant to allow health care providers to avoid distractions and enhance patient care by providing an evidence-based foundation upon which their attention, judgment, and individualization can be directed. Thus, these tools can serve to augment, rather than detract, from high-quality, patient-centered care.

A second barrier to widespread implementation is that triggers, bundles, protocols, and checklists may need to be individualized for each institution's model of care, local patient population,

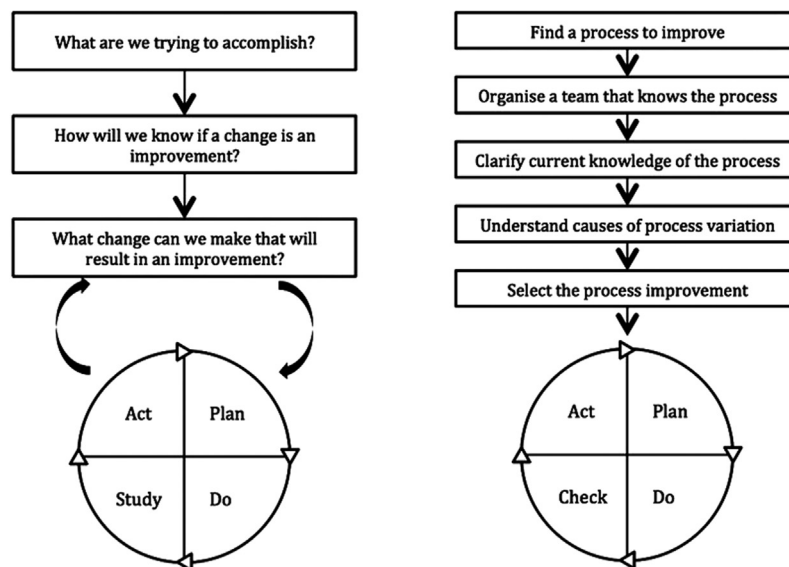
and institutional organizational structure and functions, and should include multidisciplinary team input.⁵⁴ Given that different institutional protocols for postpartum hemorrhage, for example, may vary based on availability of in-house anesthesia, interventional radiology, and gynecologic surgical backup, it is important that each institution develop a protocol that is appropriate to its resources and with the expectation that the approach to care is shared among relevant stakeholders. Multidisciplinary simulations can serve to increase familiarity with such protocols, clarify roles and responsibilities, identify obstacles to efficient care, provide opportunities for practice of rare events, and foster a culture of team-based collaborative care.^{16,20,21} TeamSTEPPS and other systems designed to improve communication and teamwork may also be beneficial by improving team awareness and optimizing resource utilization, fostering healthy communication and heightened team awareness, and resolving conflicts and clarifying roles.⁵⁵

Another significant barrier toward widespread implementation is low compliance. Obstetrical units that utilize bundles have reported only a 10-20% compliance rate.¹⁶ Universal implementation is important since discretionary use limits overall utility. The IHI defines compliance as all-or-none (an institution does not get “partial credit” for completing 3 of the 4 parameters in the induction bundle, for example) and recommends a goal of >95% compliance.¹⁶ Yet, it is likely that improvements in safety can be achieved by building a system designed for reliability, regardless of whether optimal compliance is achieved.¹⁶

Widespread utilization of triggers, bundles, protocols, and checklists may result in overdiagnosis, overtreatment, and thus an increased utilization of limited health care resources. It is important to keep in mind that preventing morbidity and mortality, the goal of these quality improvement tools, is paramount and if that goal can be achieved, justifies these resources. Additionally, early aggressive

FIGURE 4
Plan-do-study-act cycle⁵⁹

The Model for Improvement; FOCUS.



Michael J Taylor et al. *BMJ Qual Saf* doi:10.1136/bmjqs-2013-001862

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Plan-do-study-act cycle for rapid-cycle continuous quality improvement.

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interventions can often prevent downstream adverse outcomes that are significantly more costly. For example, adoption of a postpartum hemorrhage protocol increased the number of days between maternal ICU admissions.⁴⁴ Costs are also reduced as fewer liability claims are made due to increased safety and improved outcomes.⁵⁵ Furthermore, ongoing assessment and refinement of quality tools will improve sensitivity and utility, thus potentially decreasing costs.

A final potential barrier is the need to periodically examine, reassess, and incorporate the results of these patient safety improvements to ongoing care. Retrospective triggers tools, such as the AOI illustrated in the [Table](#), allow for hospitals and obstetricians to analyze medical records for the occurrence of predefined events to prompt further investigation into the cause and response by the health care team.^{27,28} Similar to root cause analysis processes after “never events,” trigger tools allow for individual institutions

to perform ongoing quality monitoring and improvement. Ideally, institutions can sample charts to identify the clinical events listed on a trigger tool. For identified cases, the patient record, hospital course and documentation, and ultimate outcome can be reviewed to provide feedback to the treating team and further refine institutional processes.

Demonstrating Impact

Triggers, bundles, protocols, and checklists should be living tools that are evaluated and modified based on ongoing feedback after their implementation and in the context of evolving care standards and processes. The ideal early warning system is one that does not overwhelm the system due to resource overutilization, lead to burnout, or result in desensitization due to a low positive predictive value. Conversely, an effective early warning system will reliably identify those patients in need of further evaluation and possible escalation of care.

Rapid-cycle continuous quality improvement “identifies, implements, and measures changes” over a series of weeks and months rather than years.⁵⁶ Using this method, bundles, protocols, and checklists can be studied and refined using the iterative 4-stage plan-do-study-act cycle (Figure 4).⁵⁷ Analyses can be conducted using statistical process control charts to demonstrate significant change over time and to accelerate the rate of improvement. The IHI also offers an improvement tracker on its World Wide Web site to allow easy visualization of changes in quality metrics over time. The use of these visual graphs can serve as powerful evidence of improvement to patients, physicians, and administrators.⁵⁸

Conclusion

The rise in maternal morbidity and mortality has resulted in national and international attention at optimally organizing systems and teams for pregnancy care. Primary maternal care providers, as core members of these systems and teams, should play a crucial leadership role in these efforts. Thus, at a time of increasing national focus on both quality and safety of medical care, it is important that primary maternal care providers participate in the implementation of quality improvement tools such as triggers, bundles, protocols, and checklists. Given the growing evidence in obstetrics and in other fields of medicine that such quality improvement tools improve health outcomes, it is likely that adoption of these tools by hospitals and health care policy organizations will continue to rise. By embracing their adoption, primary maternal care providers can improve the quality of care provided to individuals and improve the safety of the health care system overall. ■

REFERENCES

1. WHO, UNICEF, UNFPA TWB and the UNPD. Trends in maternal mortality: 1990 to 2013; 2014.
2. Creanga AA, Berg CJ, Syverson C, Seed K, Bruce FC, Callaghan WM. Pregnancy-related mortality in the United States, 2006-2010. *Obstet Gynecol* 2015;125:5-12.
3. Callaghan WM, Grobman WA, Kilpatrick SJ, Main EK, D'Alton M. Facility-based identification of women with severe maternal morbidity: It is time to start. *Obstet Gynecol* 2014;123:978-81.
4. Grobman WA, Bailit JL, Rice MM, et al. Frequency of and factors associated with severe maternal morbidity. *Obstet Gynecol* 2014;123:804-10.
5. Grobman WA, Bailit JL, Rice MM, et al. Racial and ethnic disparities in maternal morbidity and obstetric care. *Obstet Gynecol* 2015;125:1460-7.
6. Callaghan WM, Creanga AA, Kuklina EV. Severe maternal morbidity among delivery and postpartum hospitalizations in the United States. *Obstet Gynecol* 2012;120:1029-36.
7. New York State Perinatal Quality Collaborative. Available at: http://www.albany.edu/sph/cphce/mch_nyspqc.shtml. Accessed May 8, 2015.
8. Ohio Perinatal Quality Collaborative. Available at: <https://www.opqc.net/>. Accessed May 8, 2015.
9. California Perinatal Quality Care Collaborative. Available at: <https://www.cpqcc.org/>. Accessed May 8, 2015.
10. American College of Obstetricians and Gynecologists. Quality and safety in women's health care, 2nd ed. Washington (DC): ACOG; 2000.
11. Council on Patient Safety in Women's Health Care. Available at: <http://www.safehealthcareforeverywoman.org/>. Accessed May 2, 2015.
12. American College of Obstetricians and Gynecologists. Levels of maternal care. Obstetric care consensus no. 2. *Obstet Gynecol* 2015;125:502-15.
13. Wright JD, Herzog TJ, Shah M, et al. Regionalization of care for obstetric hemorrhage and its effect on maternal mortality. *Obstet Gynecol* 2010;115:1194-200.
14. Olive EC, Roberts CL, Algert CS, Morris JM. Placenta previa: maternal morbidity and place of birth. *Aust N Z J Obstet Gynaecol* 2005;45:499-504.
15. Mhyre JM, Shilkrot A, Kuklina EV, et al. Massive blood transfusion during hospitalization for delivery in New York State, 1998-2007. *Obstet Gynecol* 2013;122:1288-94.
16. Institute for Healthcare Improvement. How-to guide: prevent obstetrical adverse events. Cambridge (MA): Institute for Healthcare Improvement; 2012.
17. Centers for Medicare and Medicaid Services. Quality measures and performance standards. Available at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Quality_Measures_Standards.html. Accessed April 20, 2015.
18. ACOG. Maintenance of certification: part 3—cognitive expertise test. Available at: <http://www.acog.org/About-ACOG/ACOG-Departments/District-Newsletters/District-VIII/December-2012/Maintenance-of-Certification>. Accessed April 20, 2015.
19. Bisognano M, Cherouy PH, Gullo S. Applying a science-based method to improve perinatal care. *Obstet Gynecol* 2014;124:810-4.
20. Griffin FA, Resar RK. IHI global trigger tool for measuring adverse events. 2nd ed. IHI innovation series white paper. Cambridge (MA): Institute for Healthcare Improvement; 2009.
21. Institute for Healthcare Improvement. Perinatal chart review tool. Available at: http://app.ih.org/extranetng/content/fdb3913c-db0f-481f-9553-1ee7ed523088/affa65b0-e571-4033-89b9-f7e2deb05068/PerinatalTriggerTool_New_Feb_2010.pdf. Accessed April 20, 2015.
22. American Congress of Obstetricians and Gynecologists. Preparing for clinical emergencies in obstetrics and gynecology. *Obstet Gynecol* 2014;123:722-5.
23. Edwards SE, Grobman WA, Lappen JR, et al. Modified early obstetric warning systems (MEOWS): diagnostic performance for severe sepsis in women with chorioamnionitis. *Am J Obstet Gynaecol* 2015;212:536.e1-8.
24. Mhyre JM, D'Oria R, Hameed AB, et al. The maternal early warning criteria: a proposal from the National Partnership for Maternal Safety. *Obstet Gynecol* 2014;124:782-6.
25. Singh S, McGlennan A, England A, Simons R. A validation study of the CEMACH recommended modified early obstetric warning system (MEOWS). *Anaesthesia* 2012;67:12-8.
26. Carle C, Alexander P, Columb M, Johal J. Design and internal validation of an obstetric early warning score: secondary analysis of the Intensive Care National Audit and Research Center Case Mix Program database. *Anaesthesia* 2013;68:354-67.
27. Mann S, Pratt S, Gluck P, et al. Assessing quality in obstetrical care: development of standardized measures. *Jt Comm J Qual Patient Saf* 2006;32:497-505.
28. Pettker CM, Thung SF, Norwitz ER, et al. Impact of a comprehensive patient safety series on obstetric adverse events. *Am J Obstet Gynecol* 2009;200:492.e1-8.
29. Seiger N, Maconochie I, Oostenbrink R, Moll HA. Validity of different pediatric early warning scores in the emergency department. *Pediatrics* 2013;132:e841-50.
30. Li LT, Mills WL, Gutierrez AM, Herman LI, Berger DH, Naik AD. A patient-centered early warning system to prevent readmission after colorectal surgery: a national consensus using the Delphi method. *J Am Coll Surg* 2013;216:210-6.e6.
31. Smith MEB, Chiovaro JC, O'Neil M, et al. Early warning system scores for clinical deterioration in hospitalized patients: a systematic review. *Ann Am Thorac Soc* 2014;11:1454-65.
32. Maguire PJ, O'Higgins AC, Power KA, Daly N, McKeating A, Turner MJ. Maternal bacteremia and the Irish maternity early warning system. *Int J Gynaecol Obstet* 2015;129:142-5.
33. ACOG. Safe motherhood initiative bundles. Available at: <http://www.acog.org/About-ACOG/>

ACOG-Districts/District-II/Safe-Motherhood-Initiative-Bundles. Accessed April 20, 2015.

34. Council on Patient Safety. Patient safety bundle: obstetric hemorrhage. Available at: <http://www.safehealthcareforeverywoman.org/get-hemorrhage-bundle.php> April 20, 2015.

35. Making health care safer II: an updated critical analysis of the evidence for patient safety practices. Available at: <http://www.ahrq.gov/research/findings/evidence-based-reports/services/quality/ptsafetyII-full.pdf>. Accessed April 20, 2015.

36. Huddart S, Peden CJ, Swart M, et al. Use of a pathway quality improvement care bundle to reduce mortality after emergency laparotomy. *Br J Surg* 2014;102:57-66.

37. Minkoff H, Berkowitz R. Fetal monitoring bundle. *Obstet Gynecol* 2009;114:1332-5.

38. Clark SL, Christmas JT, Frye DR, Meyers JA, Perlin JB. Maternal mortality in the United States: predictability and the impact of protocols of fatal postcesarean pulmonary embolism and hypertension-related intracranial hemorrhage. *Am J Obstet Gynecol* 2014;211:32.e1-9.

39. Shields LE, Kilpatrick S, Melsop K, Peterson N. Timely assessment and treatment of preeclampsia reduces maternal morbidity. *Am J Obstet Gynecol* 2015;212:S69.

40. American College of Obstetricians and Gynecologists. Standardization of practice to improve outcomes. *Obstet Gynecol* 2012;119:1081-2.

41. Gawande A. The checklist manifesto: how to get things right. New York (NY): Metropolitan Books; 2009.

42. Clark SL. Strategies for reducing maternal mortality. *Semin Perinatol* 2012;36:42-7.

43. Lappen JR, Seidman D, Burke C, Goetz K, Grobman WA. Changes in care associated with the introduction of a postpartum hemorrhage patient safety program. *Am J Perinatol* 2013;30:833-8.

44. Einerson BD, Miller ES, Grobman WA. Does a postpartum hemorrhage (PPH) patient safety program result in sustained changes in management and outcomes? *Am J Obstet Gynecol* 2015;212:140-4.e1.

45. Shields LE, Smalarz K, Reffige L, Mugg S, Burdumy TJ, Propst M. Comprehensive maternal hemorrhage protocols improve patient safety and reduce utilization of blood products. *Am J Obstet Gynecol* 2011;205:368.e1-8.

46. Shields LE, Wiesner S, Fulton J, Pelletreau B. Comprehensive maternal hemorrhage protocols reduce the use of blood products and improve patient safety. *Am J Obstet Gynecol* 2015;212:272-80.

47. Grobman WA, Miller D, Burke C, Hornbogen A, Tam K, Costello R. Outcomes associated with introduction of a shoulder dystocia protocol. *Am J Obstet Gynecol* 2011;205:513-7.

48. American College of Obstetricians and Gynecologists. Operative vaginal delivery. No 17. 2000.

49. De Vries EN, Prins HA, Crolla RMPH, et al. Effect of a comprehensive surgical safety system on patient outcomes. *N Engl J Med* 2010;363:1928-37.

50. American Congress of Obstetricians and Gynecologists. Patient safety in the surgical environment. *Obstet Gynecol* 2010;116:786-90.

51. Health Research and Educational Trust. Checklists to improved patient safety. Chicago

(IL): Health Research and Educational Trust. 2015. Available at: <http://www.hpoe.org/checklists-improve-patient-safety>. Accessed May 31, 2015.

52. Clark S, Belfort M, Saade G, et al. Implementation of a conservative checklist-based protocol for oxytocin administration: maternal and newborn outcomes. *Am J Obstet Gynecol* 2007;197:480.e1-5.

53. Clark SL, Meyers JA, Frye DK, Perlin JA. Patient safety in obstetrics—the Hospital Corporation of America experience. *Am J Obstet Gynecol* 2011;204:283-7.

54. American Congress of Obstetricians and Gynecologists. Clinical guidelines and standardization of practice to improve outcomes. *Obstet Gynecol* 2015;125:1027-9.

55. TeamSTEPPS. Available at: <http://teamstepps.ahrq.gov/>. Accessed April 20, 2015.

56. Robert Wood Johnson Foundation. Quality/equality glossary. Available at: <http://www.rwjf.org/en/library/research/2013/04/quality-equality-glossary.html>. Accessed April 20, 2015.

57. Institute for Healthcare Improvement. Plan-do-study-act (PDSA) worksheet. Available at: <http://www.ihl.org/resources/Pages/Tools/PlanDoStudyActWorksheet.aspx>. Accessed April 20, 2015.

58. Institute for Healthcare Improvement. Improvement tracker. Available at: <http://app.ihl.org/workspace/tracker/>. Accessed April 20, 2015.

59. Taylor MJ, McNicholas C, Nicolay C, Darzi A, Bell D, Reed JE. Systematic review of the application of the plan-do-study-act method to improve quality in healthcare. *BMJ Qual Saf* 2014;23:290-8.