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Evidence Based Labor and Delivery Management



Vincenzo Berghella
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CHAPTER 3

Quality and Safety in Labor and Delivery

Christian Pettker, Krista Mehlhaff

INTRODUCTION

"Healthy mom, healthy baby." These simple words have been uttered to countless pregnant women in framing the goals for obstetric care and managing labor. The unique challenge in intrapartum care is managing the expectations for a good outcome when unexpected challenges arise that obstruct achieving optimum results. The system that we work in to achieve that goal is complicated, complex, dynamic and difficult to study. Medicine has followed the lead of other complex and complicated industries such as aviation, manufacturing and defense in adopting methods for reducing error and harm. Childbirth accounts for 4 million hospital admissions annually and is the second leading reason for hospitalization just behind cardiovascular disease in the United States.[1] Despite the significance of obstetrics, patient safety initiatives in obstetrics have lagged those in other specialties such as anesthesia, surgery and critical care. Becoming a "high-reliability organization"—an organization that consistently eliminates and mitigates adverse events despite carrying out intrinsically complex and hazardous work—should be the goal of all hospitals, particularly those providing obstetric care. This is a complicated task and takes a department-wide commitment to improving patient outcomes for all stakeholders, from administration to bedside providers.

The Institute of Medicine recognizes that patient safety, the prevention of error and harm, is "indistinguishable from the delivery of quality healthcare". While this is true from a healthcare delivery system's perspective, it is important to distinguish the nuanced differences. Quality is the achievement of the best possible outcomes and experiences across multiple domains (health outcomes, patient satisfaction, access, equity, etc.). Safety, on the other hand, is the prevention of inadvertent and unanticipated adverse outcomes. It is important to highlight this difference. Quality work aims to achieve maximal positive results, while safety focuses aim to minimize or mitigate the negative outcomes. These differences should be known to administrators and obstetric providers alike as they demand different approaches and monitoring methods. Safety and quality initiatives often have different implementation strategies and are measured and valued differently as well. This chapter will review the key concepts of quality and safety in obstetrics and will discuss the science of measuring outcomes in patient safety and quality. Further, the challenges of teamwork and communication in the administration of intrapartum care will be outlined. Finally, the importance of simulation training will be supported by demonstrating how it has been shown to be a valuable component of a comprehensive safety program.

QUALITY AND SAFETY IN LABOR AND DELIVERY

The Institute of Medicine describes quality as "the degree to which health services for individuals and populations increases the likelihood of desired health outcomes and are consistent with current professional knowledge".

The foundations for modern quality improvement began in the 1920s with the work of Walter Shewhart, WE Deming and Joseph Juran. In the setting of increased industrialization and standardization, they developed scientifically based tools and methods to streamline production processes. They minimized opportunities for human error, used data and understood variation to drive decision-making and built a culture of improvement whereby frontline workers and management are

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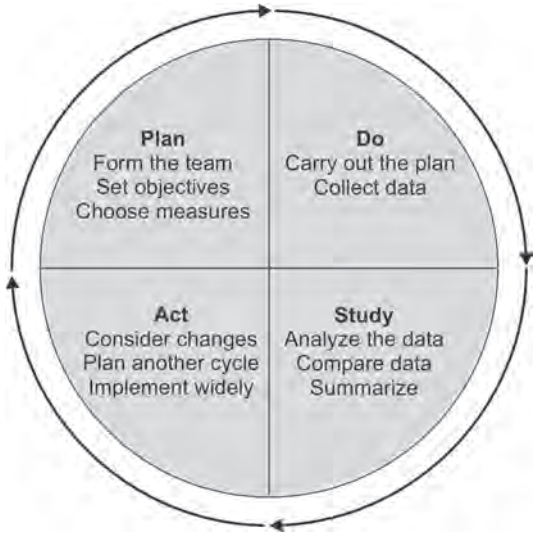

Fig. 3.1: Plan–do–study–act cycle.
Source: Pettker CM, Grobman WA. Obstetric safety and quality. Obstet Gynecol. 2015;126(1):196-206.

committed to improving work practices. Their work to simplify complex high-risk systems by reducing variability drove most current improvements in manufacturing. One tool for evaluation and improving quality in the workplace is the Plan–Do–Study–Act cycle (Fig. 3.1). This is a quasi-experimental but commonly used approach that allows for the investigation of change in less controlled, real-world settings. In this approach, stakeholders begin by forming a team, setting aims and objectives and determining how and what to measure. They then proceed through an iterative process of instituting changes into the system, learning from each cycle and correcting as needed for the next cycle of improvement. The process continues over and over until an agreed-upon endpoint, at which time the focus turns to sustainment. The burden of preventable errors and mistakes in obstetrics is not well characterized at this time. The practice of obstetrics is prone to human error. In practice, our patients are healthier and in the paradigm of supporting normal and physiologic processes (rather than illnesses), errors are less likely to lead to harm and adverse events. Adverse events are generally defined as outcomes attributable to medical management that are not due to the underlying course of the disease, that cause harm or burden to the patient. Adverse events likely complicate 1–4% of patients on an obstetric unit with up to two thirds of those considered preventable.[2]

SAFETY PROGRAM(S)/MEASURING PATIENT SAFETY

Safety is defined as the prevention of inadvertent adverse outcomes. A system with a strong patient safety culture works to prevent errors and harm from reaching the patient, learns from the errors that occur and is built on a culture that prioritizes safety and encompasses the entire healthcare team, from those at the front door to those in the administrative suites.[3] Patient safety initiatives have been shown to improve patient outcomes in several fields of medicine including anesthesia, surgery and critical care.[4–6] A current challenge to patient safety initiatives is that data collection and evidence measures are part of a young and growing field. The science of quality and safety, and specifically, adaptation of statistical and experimental models from manufacturing and industry, is not ingrained in medical or nursing education nor is it well known within the traditional scholarship domains of academic departments and journal publications. Quality and safety metrics are largely in the domain of regulatory and oversight agencies, informed by experts in the field. This is particularly true in obstetrics, where metrics such as the low-risk (nulliparous, term, singleton, vertex) cesarean rate and early elective delivery rate are overseen by the Joint Commission and the National Quality Form, counseled by advisors from nursing and physician groups.

Components of a Patient Safety Program

When planning the implementation of a quality and safety program, institutions should begin with a commitment from all levels of personnel to establish a culture of safety and to work at attaining the level of a high-reliability organization.[7] There is no single framework for a successful patient safety program; a program should be built according to the resources and needs of individual hospitals and the patients that they serve. Several systematic patient safety strategies in obstetrics have demonstrated significant reductions in adverse events.[8] A comprehensive patient safety program can also improve the perception of safety and improve the safety climate, which typically enhances the workforce culture by providing a foundation for teamwork and collaboration.[9] Examples of some of the components of a comprehensive patient safety program are unit or service-line audit, safety culture assessment, implementation of protocols and guidelines, implementation of a perinatal

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safety nurse, anonymous event reporting system, patient safety committee and implementation of standardized electronic fetal monitoring education. As it is important for the maintenance of a patient safety program, we will discuss teamwork training and simulation education in the final sections of this chapter.

Unit or Service-line Audit

Bringing in a fresh set of eyes allows for a nonjudgmental and impartial review of the service to highlight specific safety gaps or areas for quality improvement. An independent review of a service, with the goal of assessing organizational risk and patient safety issues and ending in a framework for improvement, can be a rallying point to unify administrators and care providers for change.

Safety Culture Assessment

Evaluating the current state of safety based on staff perception can be important both as an intervention tool—to let staff know that this is an important organizational priority—as well as an evaluation tool to determine how the staff views the safety and quality of the environment they are working in. The Safety Attitude Questionnaire (SAQ) is a tool adapted from the aviation field and used for the assessment of healthcare employee perception of teamwork and safety and has been correlated with actual clinical outcomes.[10] The Hospital Survey on Patient Safety Culture from the Agency for Healthcare Research and Quality is a more ubiquitous survey and is used by many hospitals and health systems to assess safety culture (https://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/index.html). The advantage of this tool is that it provides open-access benchmarking to compare to other institutions.

Standardized Protocols, Guidelines, Policies and Bundles

These clinical tools provide a common foundation for physicians and nurses to use in delivery of care for patients and hospital practices.[11] For example, by standardizing protocols and guidelines, 20 Ohio maternity hospitals were able to decrease the nonmedically indicated early-term birth induction rate from 25% to less than 5%.[10] The use of a bundle in the approach to postpartum hemorrhage has been shown to reduce hemorrhage and improve blood product utilization.[12] The Agency for Healthcare Research and Quality (AHRQ) and the US Department of Health and Human Services (DHHS) have developed a National Guideline Clearinghouse (www.guideline.gov) to assist healthcare teams in implementing and disseminating clinical practice guidelines, though largely protocols and guidelines are shared among institutions and adapted locally. The Council on Patient Safety in Women's Health Care (http://safehealthcareforeverywoman.org) is an organization with representation from most professional societies in women's healthcare in the United States (such as American College of Obstetricians and Gynecologists [ACOG] and Society for Maternal-Fetal Medicine [SMFM]) that has developed a series of bundles (including ones for postpartum hemorrhage, hypertension and venous thromboembolism) that are based on best evidence and interdisciplinary consensus. The Society for Maternal-Fetal Medicine has a wealth of published resources (clinical guidelines, consult series and checklists) that can offer templates for designing policies as well (https://www.smfm.org/publications). The Practical Obstetric Multi-Professional Training Program (PROMPT; http://www.promptmaternity.org/) and Managing Medical and Obstetric Emergencies and Trauma (mMOET; http://www.alsg.org/uk/MOET) programs, both based in the United Kingdom, offer interdisciplinary training curriculums that address coordinated and structured responses to emergencies seen in by obstetric providers.

Checklists

Checklists can simplify complex systems and organize the approach to a task. Checklists are a stepwise guide to evidence-based and best practice strategies. They attempt to improve the function of a team by creating a universal set of standards and goals. Among the areas that checklists may have an impact on are oxytocin use, acute clinical emergencies and labor management.[12–15] The use of checklists is prioritized by ACOG and guidance has been published on how to create and implement checklists in obstetrics.[10,16,17]

Perinatal Patient Safety Nurse

Perinatal patient safety nurse is an advanced perinatal nurse with significant experience in clinical and administrative systems who is dedicated to evaluating and maintaining the culture of safety on labor and delivery and can help organize efforts.[18]

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Safety Reporting Structure

A computerized tool for anonymous event reporting allows any member of the hospital staff to anonymously report medication errors, device-related events, falls or other events that in the opinion of a staff member may have caused harm to a patient or visitor. Effective reporting systems can be characterized by five following qualities: (1) an environment that supports easy reporting; (2) a portal that protects privacy; (3) reporting is performed by a broad range of personnel; (4) feedback is given through summaries and results are disseminated in a timely manner; (5) each report goes through a structured process of review, classification and resolution by key departments or committees.[19]

Obstetric Patient Safety Committee

A multidisciplinary team of obstetricians, anesthesiologists, pediatricians and nurses should review event reports and adverse events and set priorities for policy development and overall strategic safety planning. Such an approach has been shown to support and foster a change in organizational culture and to address actual and potential errors.[20,21] An effective model for a safety committee is one that blends the roles of operations and case reviews, with a good system for formulating action plans and accountability to change.

Electronic Fetal Monitoring Training

Fetal heart rate monitoring is subject to significant interobserver variability. Even the newest definitions that include a three-tier classification system have shown moderate to poor interobserver agreement, suggesting challenges in a truly objective approach.[22,23] Randomized control trials from the 1970s, 1980s and 1990s were conducted comparing intermittent auscultation and continuous fetal monitoring in labor.[24] During this era of obstetric practice, different interpretation criteria were utilized. Therefore, it is difficult to extrapolate those results into current practice guidelines. Those studies showed a 50% improvement in neonatal seizures and no difference in overall perinatal mortality or cerebral palsy (*see* Chapters 11 and 12). It is important to highlight that these trials were underpowered to detect differences in those outcomes, given the rare occurrence of perinatal deaths and cerebral palsy as a result of an intrapartum hypoxia or acidosis. It is important to note that these trials did reveal that continuous fetal monitoring was associated with a 63% increase in cesarean delivery and a 15% increase in operative vaginal deliveries.[24] Poor interpretation of fetal monitoring because of limited knowledge or outdated education on the subject may result in unnecessary intrapartum interventions that can confer additional risks to mother and baby. Given this, there is value in an institutional education program that includes dissemination and review of National Institute of Child Health and Human Development or Federation of Gynecology and Obstetrics guidelines (https://www.figo.org/news/available-view-figo-intrapartum-fetal-monitoring-guidelines-0015088),[25-27] review of tracings, allocation of study guides and voluntary review sessions within an obstetric department.[8] This training can culminate in one of two credentialing examinations run by nonprofit groups: the Fetal Monitoring Credentialing program offered by the Perinatal Quality Foundation (http://fmc.perinatalquality.org/) and another by the National Certification Corporation (www.nccnet.org). The Perinatal Quality Foundation examination uses a script concordance theory testing model to test both knowledge and judgment and further can be applied for maintenance of certification for the American Board of Obstetrics and Gynecology.[28]

Laborist

This is a title for the position that has been created to describe a hospitalist in an obstetric setting. This system of delivering intrapartum care may provide consistent hospital coverage in the labor unit and decrease physician fatigue and burnout. Critics of this model express that it may decrease continuity of care; it also certainly provides challenges for patients who expect a special relationship with the provider who attends the delivery. It is attractive from a safety perspective to have a provider immediately available and physically present on the labor floor for emergencies. Moreover, it creates a group of obstetricians who focus their practice on inpatient obstetrics. Evidence has shown mixed outcomes. A full-time laborist presence has been shown to decrease cesarean rate by 23–27% in one study.[29] Other studies have not reported the same decreases in cesarean section rates or composite maternal morbidity.[30]

Measuring Patient Safety and Quality

The benefits of a comprehensive patient safety and quality program are multifactorial including improved staff satisfaction and improved safety culture.[9] However, the

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most important variables in the measure of the success of any program that should be targeted are actual patient outcomes. These outcomes are difficult to quantify objectively because the confounding variables that can affect them, particularly in obstetrics, are difficult to isolate. Useful measures are those that are meaningful, measurable, reliable, actionable and modifiable. Metrics are usually divided into three groups according to the structure proposed by Donabedian: structural measures, process measures and outcome measures.[31]

1. **Structure measures:** These measures quantify infrastructural or organizational elements such as staffing ratios, equipment quality or numbers or safety survey results.[32,33]
2. **Process measures:** These track adherence to policies or practices, such as rate of antibiotic prophylaxis use before surgery or frequency of antenatal steroid use before preterm deliveries.[32,33]
3. **Outcome measures:** These metrics quantify the results of patient experiences and are most familiar to healthcare workers and patients. These would include adverse outcome rates and cesarean rates.[5]

Analysis of safety and quality improvement data can be performed using traditional statistical methods (such as t-tests and chi-square tests) or methods specific to quality improvement. For example, process control charts, which show changes in data points over time, can be used to demonstrate a change in frequency of outcomes and improvement in outlier data over time. The SQUIRE publication guidelines help authors, editors and reviewers report quality improvement work coherently and to the standards of expert consensus.[34] A summary of these important tools is beyond the scope of a chapter such as this, though it is important to anyone embarking on a safety project to have familiarity with them.

The pursuit of the optimal set of safety and quality measures in obstetrics is an active area of research though. The search is less about finding the best or optimal measures but more for finding the most meaningful, fair and measurable metrics that can drive performance improvement and care quality. Two publications from the APEX study (Maternal-Fetal Medicine Units network) as well as a study by Howell et al. looked at some of the major quality metrics and found weak relationships of performance on hospital structural and process measures with actual outcomes measures. This disappointing evidence has demonstrated that outcomes measures depend as much on patient-level factors (such as case-mix or individual patient risk) and other unexplained factors as on the way care is delivered.[32,35,36] This is not to say that a hospital or obstetric unit cannot identify important quality or safety metrics for improvement; rather, it is more difficult to compare hospitals on performance because of these factors.

Regulatory bodies, such as The Joint Commission and the Centers for Medicare and Medicaid Services are increasingly adding their weight to what should be and will be required for tracking by hospitals. Specifically, The Joint Commission tracks The Perinatal Care Core Measure Set, which includes five metrics: (1) nonmedically indicated deliveries at less than 39 weeks; (2) primary cesarean rates in low-risk women; (3) use of antenatal steroids before preterm birth; (4) newborn nosocomial bloodstream infections and (5) rates of exclusive breastfeeding at discharge.[33] The National Quality Foundation has endorsed, in addition to those five, additional quality measures for obstetrics: appropriate use of prophylactic antibiotics before cesarean section, appropriate use of thromboprophylaxis at the time of a cesarean, episiotomy rate, birth trauma rate and birth of infants weighing less than 1,500 g at sites with appropriate levels of care.[37]

TEAM TRAINING AND COMMUNICATION

Surgeon and world-renowned author Atul Gawande is known for saying, "Medicine is a team sport without the benefit of a coach." The Joint Commission root-cause analyses have demonstrated that communication failures account for approximately 60% of sentinel events, 51% of reportable maternal events and 68% of reportable perinatal deaths.[38] It is important to note that healthcare team members vary drastically in background and experience. We are all trained to deliver care well but we are not taught in training how to communicate across disciplines and understand one another's roles in patient care. Many medical training programs have identified this problem and improved education is being implemented in this area to address this issue at the training level.[39] While that gives us hope for the next generation, hospital units should be aware of communication strategies and work to improve cohesion and create a team that works seamlessly. A team training program, based on crew resource management (CRM) programs initiated and tested by the airline and defense industries, has been shown to enhance communication.[40] Similar interventions

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have helped improve teamwork and other qualitative outcomes, though not necessarily clinical outcomes, in obstetrics and medicine.[41–45] Definitions and descriptions of communication tools that can improve interaction between team members are listed below.

Crew Resource Management

Here workers are trained to develop habits of teams such as sharing a clear and valued vision, developing trust and confidence in each other, understanding leadership and following and adoption of clear communication tools. Team STEPPS (https://www.ahrq.gov/teamstepps/index.html) is a CRM program supported by the AHRQ that provides support and tools for team training by addressing four main competencies: leadership, situation monitoring, mutual support and communication.

Team Huddles

These are small meetings of nurses and providers at the bedside or at common care areas to discuss the current status of one or more patients. This is an opportunity to get all caregivers on the same page and discuss concerns and plans for patient care. These can be arranged as regularly occurring meetings or as spontaneous gatherings to bring people together.

Debriefings

Small meetings after an adverse or emergency event to discuss team performance and identify system issues are called debriefings. This is also an opportunity to identify and support the "second victim" in critical high-intensity events such as an adverse maternal or neonatal outcome.

Situation, Background, Assessment, Recommendation (SBAR)

This is a framework for communication between members of the healthcare team about a patient's condition. The SBAR is an easy-to-remember, concrete mechanism useful for framing any conversation, especially critical ones that require a clinician's immediate attention and action.[46]

Two-challenge Rule

A quick conflict resolution technique by which a team member may question an action two times, and if a sufficient answer is not provided, may halt that action.[47]

Concerned, Uncomfortable, Scared Words

These are trigger words that can be used by teammates to relay level of discomfort with a clinical situation with regards to safety.

Chain of Command

A well-established hierarchy helps to answer questions or mediate and resolve conflict as it arises on labor and delivery. The most functional chains of command use nursing–provider dyads at each level to emphasize interdisciplinary resolution.

SIMULATION IN OBSTETRICS

Simulation allows the practice of both skills and team collaboration of high-intensity and low-frequency events that occur on labor and delivery. As with any acquired skill, it takes practice to maintain top-notch performance and since these events are rare, the practice must be simulated. Simulation is an effective tool to learn and maintain skills required in obstetrics, a field that is dominated by the normal and routine with rare punctuations of emergencies. Simulation is thus an essential component of a patient safety program for labor and delivery, as the field is characterized by long periods of routine activities interrupted by infrequent but high-stakes events such as shoulder dystocia, hemorrhage and eclampsia. Simulation involves technologies that are used to imitate real-life medical tasks (surgery, shoulder dystocia, etc.). Medical simulation can be low fidelity involving only basic models, such as using a pelvic floor model for the practice of episiotomy repair or an actor and doll for a delivery. Simulations can also be high fidelity involving virtual reality robots and complex medical scenarios in close recreation to an actual emergency event. Improvements in material retention and comfort with procedures have been shown when obstetric residents participate in a simulation program.[39] Simulation programs can help reinforce teamwork and communication skills as well as identify system issues that impair optimal patient care. Related to the latter, simulations can be used to prepare new unit designs or constructions or to test before the implementation of a new electronic health record.

Strong simulations programs should involve three basic components. First, the didactic portion ensures a solid foundation in the knowledge about the subject matter. Next, the simulation portion allows participants to have practical hands-on experience. Adult learners often retain

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knowledge better by doing rather than by sitting in a lecture. The final component is the debriefing portion. This is likely the most critical component for discussing communication and systems issues and solidifying the knowledge that has been received. Simulations can take place in the hospital, outpatient setting or in a simulation facility. With respect to this, the perfect is the enemy of the good. Attempts to design an ideal simulation situation or facility should not forestall, executing a simulation program and often low-fidelity in situ simulations can provide the best impact. Video recording of simulations helps participants see the scenario played out in an unbiased manner, allowing self-reflection and open discussion. On-site, in situ simulations allow for better identification of system issues on units as they are testing situations in their actual settings.

Shoulder dystocia has been one of the best-studied simulation programs in obstetrics and has shown the greatest benefits of education skill retention and has been shown to improve patient outcomes. Studies have shown that simulation scenarios in shoulder dystocia improved resident performance in the management of shoulder dystocia, including the timeliness of interventions, the performance of maneuvers and overall technical performance. Notably, shoulder dystocia training has also been shown to improve clinical outcomes. Crofts and colleagues showed that mandatory multidisciplinary training on shoulder dystocia management resulted in more effective management with improved neonatal outcomes. No cases of brachial plexus injury were reported in over 17,000 vaginal deliveries compared with a pretraining rate of 1.9%.[48] Szymanski et al. described the key factors in successful roll-out of a shoulder dystocia program. They listed the following as key components of success: involvement of physician and nursing leadership from each academic medical center; administrative and logistic support from the insurer; development of consensus on components of training, scenarios and evaluation tools; conduct of gap and barrier analysis; financial support from insurer to close necessary gaps and mitigate barriers; and agreement to create dashboards and track performance regarding simulation training and clinical and financial outcomes.[49]

The ACOG and SMFM have dedicated resources to obstetric simulation development and improvement. Both bodies have working groups to address simulation application and have tools to assist programs to implement simulation programs at their institutions. The list of current recommended obstetric scenarios by ACOG is shoulder dystocia, eclampsia, postpartum hemorrhage, vaginal breech, fourth-degree laceration repair and operative vaginal delivery,[50] and by SMFM is invasive fetal needle diagnostics, invasive fetal therapy, cardiopulmonary arrest, thyroid storm, diabetic ketoacidosis and critical care obstetrics.[50]

CONCLUSION

A foundation of understanding of the principles and science of patient safety and quality is important for all healthcare providers. The science is young and evolving and the pursuit of optimal outcome measures is still a moving target. It is important to continue to study and improve our knowledge in this field to continue to improve the care provided and ultimately make our hospitals safer places to heal and improve outcomes for patients. Engaging in the processes discussed in this chapter can evolve a unit into a high-reliability organization, where safety is a paramount end, teams are valued over the individual, effective and transparent communication is constantly reinforced and the unexpected becomes expected.[7]

KEY POINTS

- Medical error is commonplace in obstetric care.
- Labor and delivery units should implement components of a comprehensive patient safety program in line with their needs and gaps, with a goal of becoming high-reliability organizations.
- Continued promotion of quality improvement research and education is critical for advancing the care of our patients and field.
- Focusing on the support of the performance and improvement of teams and communication are leading methods to reduce errors and variability.
- Simulation training is important for improving not only skills and education but also team building and communication and has been shown to improve obstetric outcomes.

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Evidence Based
Labor and Delivery Management

Labor and delivery are for us magical moments, when a new life comes into being, but they require a lot of careful management, as complications can occur. Our aims were many. First, to make an easy-to-read book to guide management in labor and delivery by any practitioner there, such as midwives, nurses, physicians, trainees, and others. Second, to guide management based on the best evidence, which usually comes from randomized controlled trials (RCTs) and from meta-analyses of RCTs. You will see that most of our references are indeed RCTs and meta-analyses. We have tried to summarize the highest quality literature in the labor ward practice because following that we can get the most desirable clinical outcomes and when this will not happen nobody would blame us because we have not done the best. Third, to provide the easy guidance not only in the written text, but also visually, and we are extremely grateful to Amanda Roman for the wonderful artwork, done by a maternal-fetal medicine professor who lives and breathes these issues like all four of us. More graphic materials (videos, tables, and figures) have not been included in the printed version, but are available in the online version of the book. Fourth, to focus on preventive issues. For example, a cesarean delivery can be done is so many ways, but attention to doing the dozens of technical steps right can avoid so much morbidity and mortality for this common operation. Fifth and ultimate goal, to improve the health of women going through labor and of their babies.



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