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Maternal/Fetal Risks: Using Claims Analysis to Improve Outcomes

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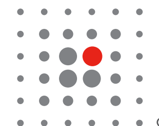

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TABLE OF CONTENTS

What You'll Learn From This Report 1
Introduction 2
A Fresh Approach to Claims Data 3
Obstetrics-Related Liability Claims at a Glance 4
- *Leading Causes of Claims* 4
- *Top Risk Management Issues* 5
- *Most Prevalent Injuries* 6
- *Top Patient Risk Factors* 7
- *Claims by Delivery Method* 7

Process Vulnerabilities During the Maternal/Fetal Episode of Care 8
- *Key Obstetrical Allegations* 8
  - Management of Pregnancy 8
  - Management of Labor 8
  - Choice of Delivery Method 9
  - Performance of Delivery 9

The High Costs of OB Risk 10
Issues Unique to OB Claims 11
From Conception to Delivery: Fresh Perspectives on Patient Safety 12
- *Management of Pregnancy: Risks & Recommendations* 13
  - General Guidelines for Genetic Testing 13
  - Risk Management Recommendations Relative to Pregnancy 14
- *Management of Labor: Risks & Recommendations* 14
  - Case Study 15
  - Risk Management Recommendations Relative to Labor 15
- *Performance of Delivery* 16
  - Case Study 17
  - Risk Management Recommendations Relative to Delivery 18

Teams, Training, and Communication 20
- *Human Factors Analysis* 21
- *Where Communication Is Breaking Down* 21

Patient Engagement and Meaningful Communication 22
Patient Attitudes and Cultural Trends Impacting OB Risk 23
Final Recommendations for Managing Risk and Improving Patient Safety 24
ECRI Institute Data 25
Conclusion 26

WHAT YOU'LL LEARN FROM THIS REPORT:

- The specific areas of greatest vulnerability during the maternal/fetal episode of care — when and where risk is the highest, why, and for whom.
- What can be done to reduce risk during management of pregnancy, management of labor, and performance of delivery — including new processes, practices, attitudes, training, and improved communication.
- How risk factors (comorbidities) like obesity, diabetes, and hypertension among pregnant women are influencing and increasing poor outcomes.
- What the results of maternal/fetal risk look like in terms of injuries and deaths.
- How roles in obstetrical practice (e.g., physicians, CNMs, nurses) are related to risk.
- What stories (case studies) are dominating the claims data.
- The complex nuances of obstetric-related claims and the issues unique to OB risk.

This report is dedicated to Mary Ellen Filbey, Senior Risk Specialist, our dear colleague and friend, who passed away in October 2018.

Mary Ellen dedicated her professional life to improving patient safety. Her experience as an obstetrical nurse made her particularly passionate about enhancing the safety of some of the most vulnerable patients—mothers and babies. During the course of her long career at Coverys, Mary Ellen authored numerous articles, resources, and materials in the area of perinatal safety. Many of the materials that are cited in this paper were developed by her.

To her colleagues, Mary Ellen was a "sensei" in the area of perinatal safety. She was always willing to answer a call, offer a recommendation, or send along a resource to a colleague or client in need. She was a mentor to many and a friend to all. Her dedication and gentle spirit continue to inspire us.

It is our hope that Mary Ellen's voice is heard in the pages of this report. Most of all, we hope it motivates readers to make their own facilities safer—especially for the patients that she was so passionate about.

INTRODUCTION

Each year in the United States, there are nearly 4 million births,[1] and every birth has a story. This special report is the story of what can go wrong — the real data about maternal/fetal risk, why poor outcomes related to childbirth trigger malpractice claims, and what can be done to improve outcomes and reduce liability.

Managing risk in the delivery of obstetrical care requires constant vigilance. Everything from a delayed ultrasound, to a misread fetal monitoring strip, to an ill-advised delivery method can put mother and/or baby in danger. When everything goes well — which it does in the vast majority of births — the outcome is joyful, beautiful, and full of celebration. But when something goes wrong, it may result in infant death or permanent injury. It is no wonder that more than 50% of Ob-Gyns in the U.S. report being burned out[2] and that litigation stress has been linked to depression and even suicide among providers.[3]

For Coverys, obstetric-related events are the fifth largest category of medical professional liability claims and the fourth highest category of indemnity payments. To help improve the management of pregnancy, labor, and delivery, and to improve patient safety (while also reducing claim frequency), physicians and healthcare providers need data-driven insights to provide a fresh perspective on new ways of thinking about the everyday activities of providing care to pregnant and laboring mothers.

This report looks at some of the causes of obstetric-related claims based on an analysis of 472 OB closed medical professional liability claims at Coverys across a five-year period (2013-2017).* We offer data, insights, and recommendations in hopes that when presented with this information, healthcare professionals will be motivated to investigate and implement new processes, practices, and systems to reduce overall mother/baby injuries and their severity.

**Unless otherwise indicated.*

This report is intended to provide general guidelines for risk management. It is not intended and should not be construed as legal or medical advice.

A FRESH APPROACH TO CLAIMS DATA

At Coverys, we refer to claims data as "signal intelligence." Our conclusions from analysis of the data are not absolute findings. Rather, they are hypotheses: signals from the past about where vulnerabilities existed and may still be at play.

Typically, a fully investigated liability claim will contain valuable information, such as:

- Allegations
- Patient health and demographic information
- Injury severity
- Physician specialty
- Risk management issues
- Location of the alleged error (e.g., office/clinic, ED/urgent care, lab/testing)
- Costs
- Expert reviews and opinions

Analysis of these key elements supports a fresh approach that incorporates claims data into the risk management process. Coverys uses this information to create evidence-based recommendations to mitigate future risks in the delivery of care.

Coverys uses claims data as "signal intelligence" to uncover the root causes of claims.

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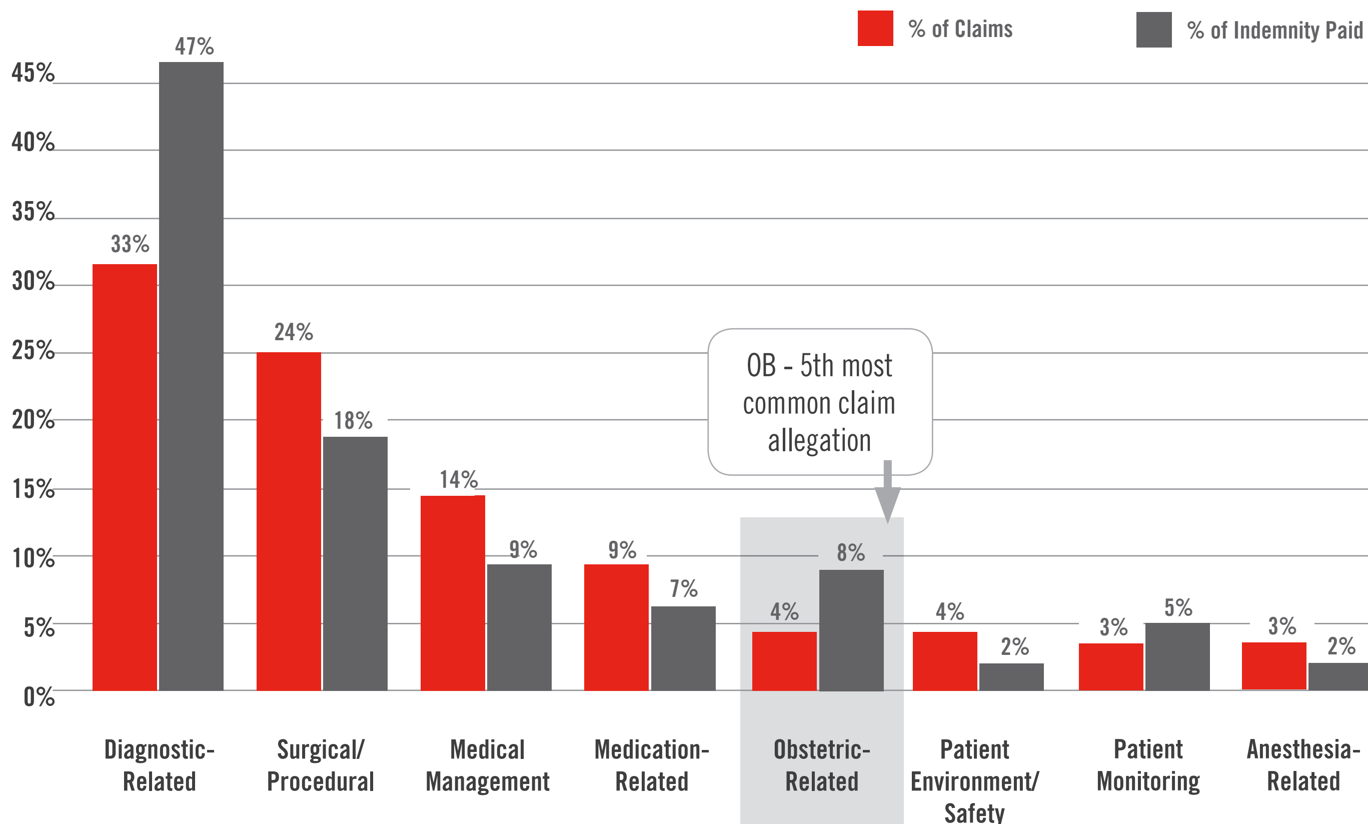
Leading Causes of Claims

Obstetric-related claims are the fifth largest category of medical professional liability claims and the fourth highest category of indemnity payments, accounting for 4% of claims and 8% of indemnity paid.



N = 10,618 closed claims between 2013-2017

40% of OB claims involve allegations related to management of labor.

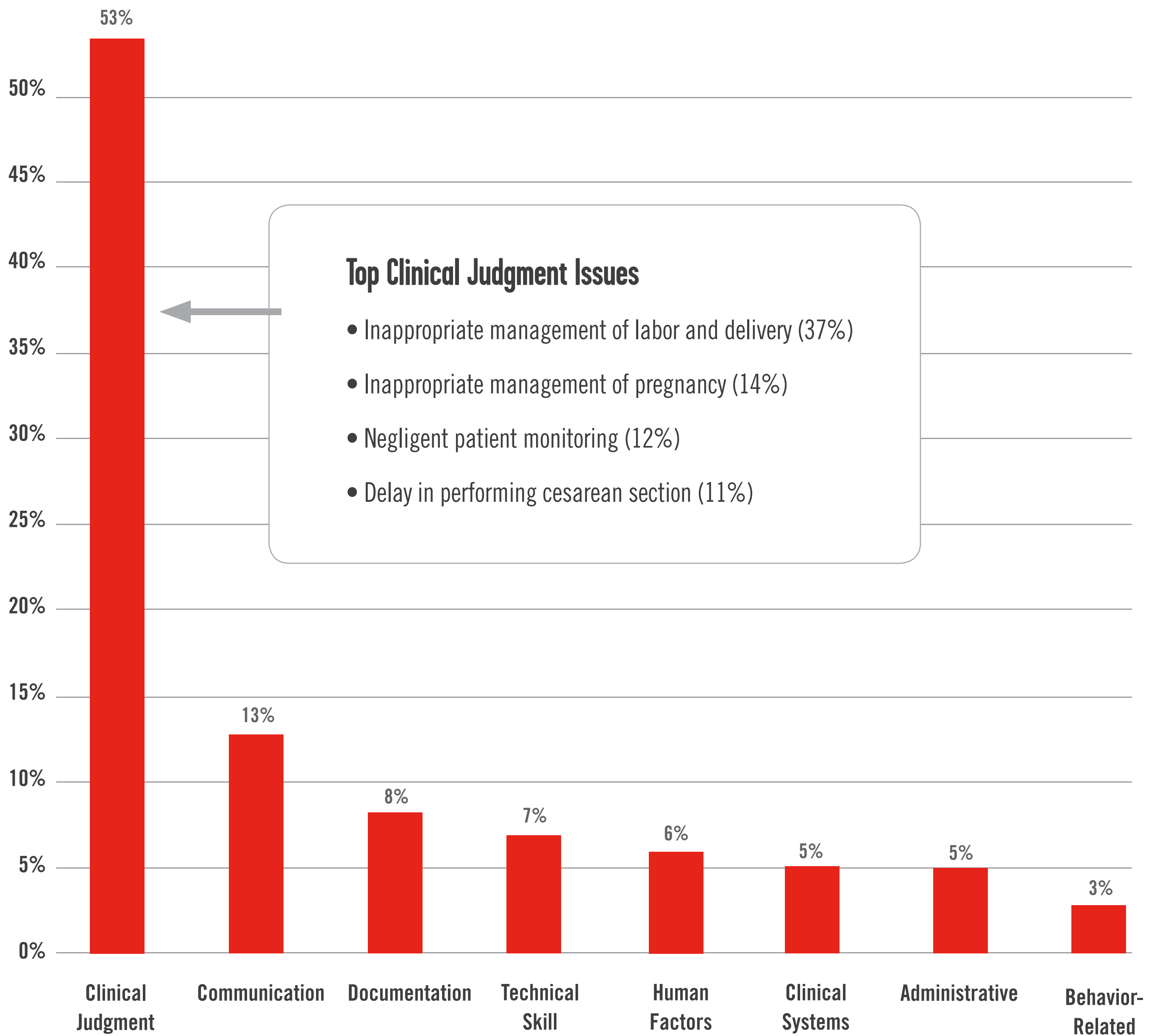
80% of OB claims are high-severity* and 24% resulted in death of the baby, mother, or both.

52% of OB claims involve vaginal deliveries (7% higher than claims involving cesarean sections).

**High-severity injury includes National Association of Insurance Commisioners (NAIC) injury codes = 6,7,8,9*

Top Risk Management Issues

Clinical judgment was cited as a factor in over 50% of OB-related claims. These issues were reflected in all phases of the perinatal process.



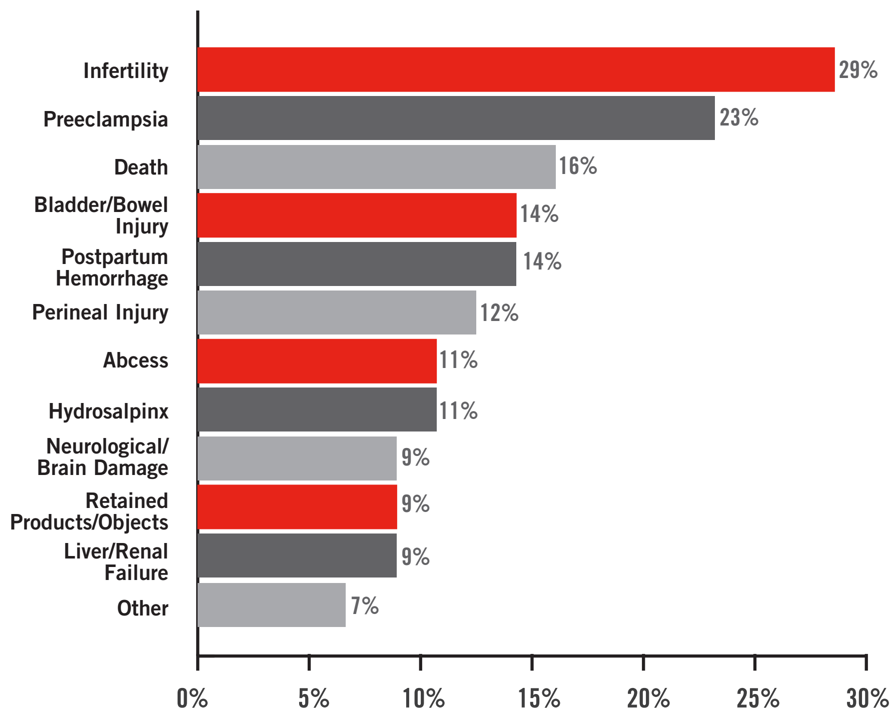
N = 486 claims with an OB-related allegation and a risk management issue identified
Claims may have more than one issue

Most Prevalent Injuries

Maternal

Obstetric claims that include complications or injuries to mothers are fairly rare and injury type varies.*

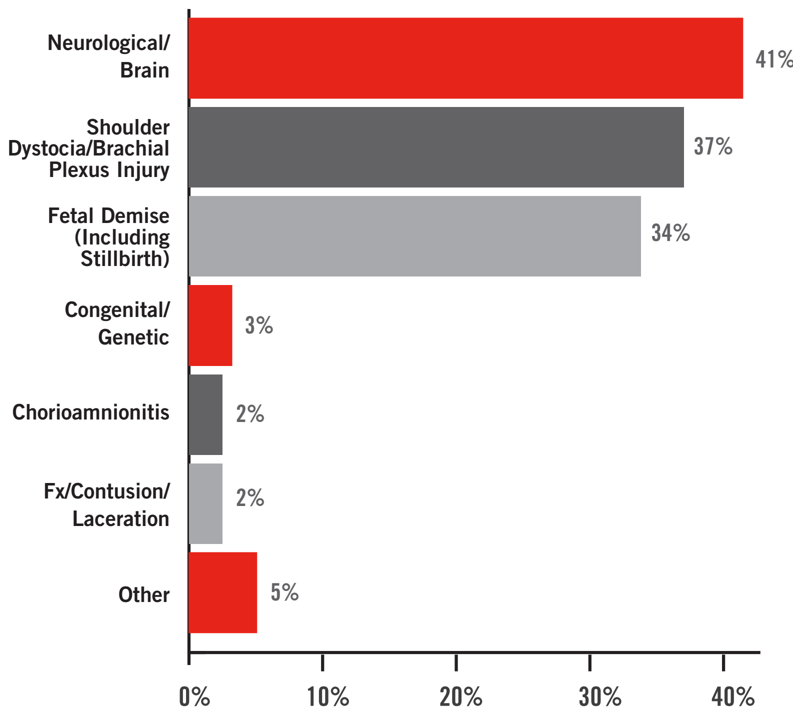
N=56 closed claims between 2013 and 2017 with an OB-related allegation and a maternal injury



Fetal

Obstetric claims that include injuries to babies are concentrated in three large categories.*

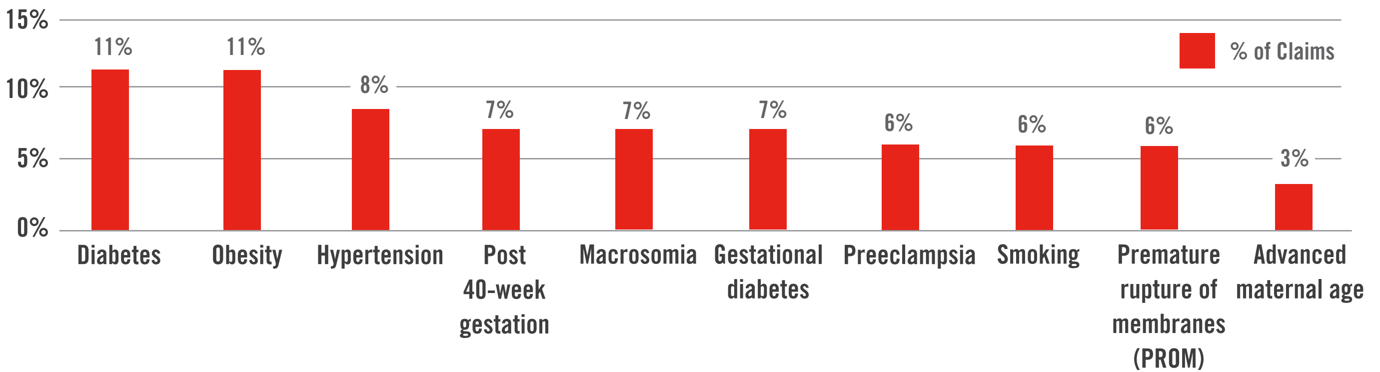
N=432 closed claims between 2013 and 2017 with an OB-related allegation and a fetal injury



* *Many cases involve multiple injuries to a single patient.*

Top Patient Risk Factors

Fifty-eight percent of OB-related claims involved patients with at least one known risk factor (or comorbidity). The most common were diabetes and obesity, two conditions significantly on the rise in the United States.[4]

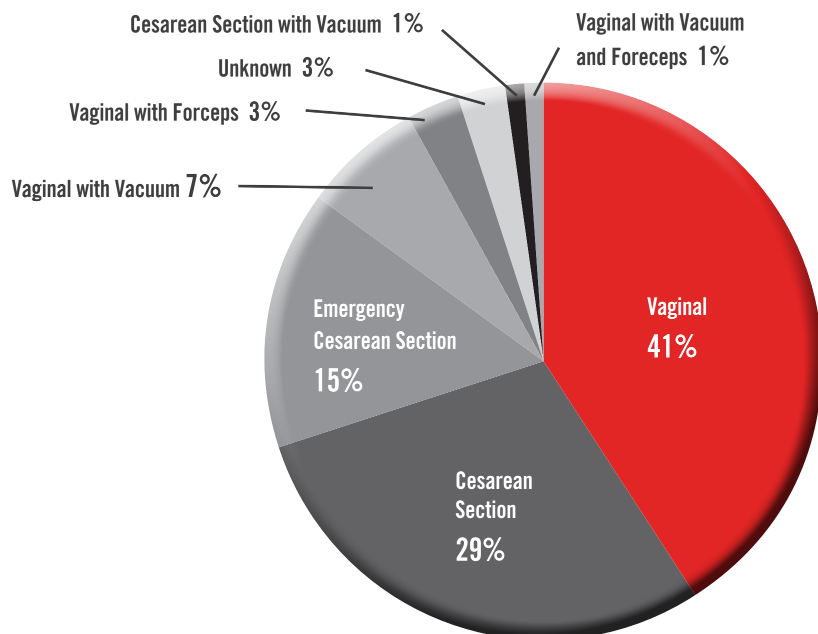


N = 472 closed claims between 2013-2017 with an OB-related allegation
Claims may have more than one risk factor

Claims by Delivery Method

Vaginal births resulted in more claims than cesarean sections (52% vs. 45%) and more than three times as many claims as emergency cesarean sections (52% vs. 15%).

N = 472 closed claims between 2013-2017 with an OB-related allegation



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PROCESS VULNERABILITIES DURING THE MATERNAL/FETAL EPISODE OF CARE

Shepherding mother and baby through a healthy pregnancy, labor, and delivery is a complex process that requires vigilance and collaboration among providers. Each phase of the process exposes vulnerable patients to unique patient safety risks. According to Coverys' data, the risks are highest during the management of labor. However, they could be significant at every stage of the process.

Key Obstetrical Allegations

Management of Pregnancy	*Risks include failure to:*
24% of claims **16%** of indemnity paid	• Conduct a thorough and relevant history and physical to uncover maternal and fetal risk factors that may contribute to complications throughout pregnancy (e.g., diabetes, genetic conditions, structural malformations). • Screen patients for presence of preexisting or emerging conditions that may contribute to maternal/fetal complications (e.g., diabetes, preeclampsia, macrosomia). • Appropriately manage or refer patients with comorbidities (e.g., obesity, diabetes, or hypertension) that contribute to maternal/fetal complications. • Effectively communicate with the patient about her expectations for labor and delivery, anticipated and unexpected complications that may arise, and how to prepare for possible changes to the delivery plan. • Communicate and document clinical information, risk factors, and informed consent/refusal (see tips below).

Tips from ACOG on Documenting Refusal of Recommended Treatment[5]

When a pregnant patient refuses recommended medical treatment, the provider should document the refusal in the medical record. Documentation should include the following components:

- That the need for the treatment has been explained to the patient.
- That the risks, benefits, and alternatives to treatment have been discussed with the patient.
- That the consequences of refusing the treatment have been discussed with the patient, as well as the impact of such refusal to her fetus.
- That the patient has refused to consent to the treatment.
- The reasons stated by the patient for the refusal.

Management of Labor	*Risks include failure to:*
40% of claims **49%** of indemnity paid	• Recognize and act on nonreassuring fetal heart tracings. • Abandon attempts at vaginal birth or a trial of labor after cesarean section (TOLAC) in favor of cesarean section. • Manage induction and augmentation of labor in response to clinical findings. • Monitor mother/fetus during administration of high-risk medications (e.g., oxytocin and magnesium sulfate). • Recognize and act on obstetric emergencies. • Provide deep vein thrombosis (DVT) and pulmonary embolism (PE) prophylaxis. • Communicate and document clinical information, risk factors, and informed consent/refusal.

Choice of Delivery Method

5% of claims
15% of indemnity paid

Risks include failure to:

- Screen patients for presence of preexisting conditions and risk factors that contribute to maternal/fetal complications; (e.g., obesity, preeclampsia, diabetes).
- Perform diagnostic testing when high-risk factors are identified prenatally (e.g., maternal diabetes which may result in large-for-gestational-age infants, history of shoulder dystocia, history of cephalopelvic disproportion).
- Document or communicate clinical information and risk factors, and the provider's plan for delivery (e.g. Will the patient be induced? Will there be a scheduled cesarean? Will a cesarean be performed if certain factors materialize during labor?).
- Identify contraindications to a spontaneous vaginal delivery (e.g., placenta previa, active genital herpes simplex virus/lesions, untreated HIV infection).
- Develop formal criteria of eligibility for a patient to undergo a trial of labor after a previous cesarean section (TOLAC).
- Recognize maternal or fetal complications as they occur so as not to delay the performance of an emergency cesarean section.
- Educate the OB team on the potential maternal/fetal complications related to various birth modalities (e.g., vaginal, TOLAC, operative, water birth).
- Evaluate the risks and benefits of the elective birth modality for multiple gestations (e.g., twins, triplets).
- Identify fetal malpresentation and develop evidence-based guidelines for the safe elective delivery of such presentations (e.g., frank breech, transverse lie, face presentations).

Performance of Delivery

31% of claims
20% of indemnity paid

Risks include failure to:

- Have collaborative agreements in place between certified nurse midwives (CNM) and physicians with obstetrical privileges (e.g., nonreassuring FHTs, operative deliveries, when to consult).
- Establish criteria for when a family medicine provider is to obtain a specialty consult from an Ob-Gyn or maternal/fetal medicine provider.
- Provide education and measure competencies in the use of operative vaginal delivery devices. The Institute for Healthcare Improvement (IHI) has established a vacuum bundle and guidelines to assist providers when this delivery modality is indicated (e.g., vacuum or forceps assisted by OB providers).[6]
- Prepare for potential complications with the use of operative devices (e.g., scalp lacerations, retinal hemorrhage, intracranial hemorrhage, maternal trauma).
- Require the immediate availability of the surgical team, anesthesia providers, and the ability to perform an emergency cesarean section for an active laboring TOLAC patient in the event of a uterine rupture.
- Document the interventions and maneuvers used to free shoulder dystocia during delivery (e.g., maternal positioning, delivery of posterior arm, episiotomy, which shoulder was impacted, and pain management).
- Define clinical competencies and protocols relative to the appropriate use, administration, dosing, and monitoring of induction agents (e.g., Pitocin).

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80% **of claims involve injuries with the highest clinical severity.**

77% **of fellows of the American College of Obstetricians and Gynecologists report they have been sued.**

THE HIGH COSTS OF OB RISK

For the vast majority of mothers and babies, pregnancy and birth go normally, naturally, and without complication. When adverse birth events do occur, they can be unpredictable and can happen even in the absence of practitioner negligence. As such, it's important that we acknowledge the sharp and sometimes long-lasting emotions that practitioners experience in the face and the wake of these outcomes as well as the incredible work performed safely and thoughtfully each day by obstetrical practitioners.

When something goes wrong in the practice of obstetrics, the results are often permanent, significant, grave, or even fatal. And that's why it's imperative that we identify and evaluate the risks that precede such outcomes and explore ways to proactively mitigate risk, improve patient safety, and reduce chances that adverse outcomes will occur.

The costs of OB risk are high. Among those cases where a claim is triggered, 80% involve injuries with the highest clinical severity: significant permanent (e.g., neonatal brachial plexus injury or maternal loss of fertility), major permanent (e.g., neonatal blindness or hearing impairment, maternal organ injury), grave (e.g., neonatal neurological/brain damage, hypoxic ischemic encephalopathy, or cerebral palsy), or death (of mother, baby, or both).

The financial costs can be astronomical. Infants born with permanent injuries often require extensive 24/7 medical care plans as they age which can cost a family millions of dollars in life care services. The hardships and economics of caring for a child in this way can force families to pursue litigation, even when they don't place specific blame on providers or facilities for negligence. There are, of course, major costs to physicians and insurance companies related to OB claims as 77.3% of fellows of the American College of Obstetricians and Gynecologists report they have been sued.[7]

"For the practicing obstetrician, the potential for bad outcomes following a patient's labor and delivery not only affects financial issues — medical malpractice premiums, the costs to the system of excessive testing, etc. — but colors his or her entire approach to patient care. Where one would want to devote all attention to providing optimal medical care and emotional support, there is all too often concern about that patient as a potential litigant if the outcome of a delivery is not perfect."

– Henry M. Lerner, MD, Ob-Gyn, Newton Wellesley Obstetrics & Gynecology, Newton, MA
(Dr. Lerner has reviewed hundreds of OB claims and has served as an expert witness on Coverys claims.)

Emotional Support for Providers

Being named as a defendant in a medical malpractice lawsuit, while not uncommon for an Ob-Gyn, can be one of life's most stressful events. Negative emotions such as guilt, self-doubt, shame, and fear can impact the physicians' personal lives, the lives of their families, their relationships with patients and their medical practices, and can last for many years. When litigation is completely unexpected, it can be traumatic and result in shock, numbness, hyperarousal, sleeplessness, and tension. While these negative emotions are normal, ACOG suggests that rapid intervention to emotionally support providers involved in litigation may be helpful.[8] To address these sobering truths, Coverys Risk Management provides policyholders with access to licensed and trained professionals for emotional support services (for individuals, groups, and hospitals).

To learn more, Coverys policyholders can contact a Risk Management Consultant at 800.225.6168, option 9.

ISSUES UNIQUE TO OB CLAIMS

- **Emotional Component.** Obstetrics involves caring for the tiniest, most vulnerable patients, and it's a specialty with uncontrollable and hidden emotional components. Families may often sue even when they don't "fault" anyone, and this can blindside practitioners. Similarly, verdicts and settlements involving fetal injury, in particular, are difficult. As a society, we feel driven to support grieving and struggling families — judges, juries, and insurance companies are impacted by these feelings too. Attempting to separate concepts like blame and guilt from legal and financial outcomes is a complex challenge.

Obstetrics involves caring for the tiniest, most vulnerable patients and it's a specialty with uncontrollable and unseeable emotional components.

- **Patient Wishes.** Obstetricians and obstetrical providers are required to adhere to evidence-based principles in situations that are often guided by patient wishes. Patient wishes may be influenced by folklore or input from nonmedical professionals and may be unrealistic or unsafe. It is important to provide the patient with accurate evidence-based data and recommendations while recognizing her right to direct her care. This can create a conundrum for an obstetrical provider as he or she grapples with knowing when and how to encourage sound medical practice over a woman's own desire for a specific birth plan.

- **Two Patients.** Unlike other healthcare providers, obstetrical providers have a duty to provide medical care to two patients at the same time. Fortunately, this duty is discharged without conflict or complication in most instances. However, when things do not go as planned, difficult decisions may have to be made that put the interests of one patient in direct conflict with the interests of the other.

- **Labor/Delivery Expectations.** Aside from obstetrics, there are few medical specialties that have an "experiential" component that can significantly change the style and safety of the delivery of care. Pregnant women often have a strong vision for the pregnancy and labor/delivery experience they are seeking. Unlike knee surgery, where a patient's primary focus is choosing a talented surgeon who is most likely to provide an optimal outcome, pregnant women are looking for far more. For example, they may have preconceived ideas about how and where they will labor and for how long, what method of delivery will be used, and even details about what they'll wear, what kind of music will be playing, and whether there will be dim lights, a water tub, or more. The focus must always be to achieve an optimal outcome — not create the ideal "birthing experience."

A mother wishes to deliver her second child at home, despite the fact that her first delivery was a cesarean section due to a large baby and pushing for three hours. The provider for her first delivery does not feel the patient is a candidate for a trial of labor after cesarean (TOLAC) due to her history of large babies and gestational diabetes, and is also against the idea of a home birth due to the previous cesarean section. The patient seeks prenatal care and a home birth option with an independent certified nurse midwife (CNM).

While in labor and attended by the CNM, the patient again pushed for three hours with minimal descent of the fetal head. The CNM requested transfer via ambulance to a hospital 15 minutes away. Once the patient arrived to the ED, she was emergently transferred to the birthing unit. Initial attempts to find fetal heart tones were unsuccessful. An emergency cesarean section was performed; however, the infant was unable to be resuscitated. Cause of fetal demise was determined to be prolonged hypoxia of the fetus due to prolonged cord compression and undue fetal stress during contractions.

FROM CONCEPTION TO DELIVERY: FRESH PERSPECTIVES ON PATIENT SAFETY IN OBSTETRICAL MEDICINE

As we examine the maternal/fetal episode of care — from early pregnancy management all the way through to delivery — we discover not just compelling data, but stories and trends. Predictable vulnerabilities seen in actual claims can help pinpoint actions and interventions that can improve outcomes for mothers and babies alike. Providers and organizations who use the insights in this report can be a powerful force for improvement.

Management of Pregnancy: Risks & Recommendations

There is good news: today's obstetricians have more tools at their disposal to detect earlier than ever before potential risk to the fetus at any stage of pregnancy. But there are still too many cases in which physicians have ample notice and evidence of risk during pregnancy and don't heed or recognize the warnings. Of particular concern is a reticence to actually term mothers "high risk" and treat them as such. The extra testing, care, and vigilance that come with high-risk treatment can and do keep mothers and babies safer. Whether a patient is diabetic, obese, hypertensive, or has experienced complications in previous pregnancies and deliveries, such risk factors cannot be ignored. Of the OB-related claims studied for this report, 24% alleged an issue with the management of pregnancy, and those claims made up 16% of indemnity paid. During pregnancy, a failure to communicate clearly and thoroughly with patients can emanate from the understandable realities of busy medical practices, short appointments, and introverted patients. Such a failure can ultimately be linked to a great number of risks. Pregnancy is also a vital time to consider indicated diagnostics, like genetic testing, that might reveal conditions or risks better known early than late in the pregnancy (see guidelines below).

General Guidelines for Genetic Testing[9]

- Genetic testing should be discussed as early as possible in pregnancy, ideally at the first obstetric visit, so that first-trimester options are available.
- All pregnant women should be offered prenatal assessment for aneuploidy by screening or diagnostic testing, regardless of maternal age or other risk factors.
- Prenatal genetic testing cannot identify all abnormalities or problems in a fetus, and any testing should be focused on the individual patient's risks, reproductive goals, and preferences.

The Best Source of Information

What is best source of information to predict and plan for a healthy pregnancy and birth? The patient herself. She is a wealth of insight about her general health, her previous pregnancies and births, and her family history. But she is also sometimes singularly focused, unwilling to compromise, or too optimistic in the face of risk. The obligation of obstetrical providers to balance these challenges and to communicate their way to the best possible outcomes is sometimes difficult to navigate.

Risk Management Recommendations Relative to Pregnancy:

- **Set expectations.** During the initial prenatal visit and at regular intervals thereafter, discuss with the patient what to expect during each stage of pregnancy — including what is "normal" and what is "abnormal" and when to seek medical help. Provide the patient with various methods to communicate with the provider, including email, patient portals, phone numbers, etc.
- **Listen to the patient.** The patient is in the best position to know when "something doesn't feel right." Be sure to document patient concerns using her own words, all findings on physical examination, and the thought process/rationale behind each intervention that is taken.
- **Identify patients with high-risk factors** (e.g. obese, diabetic, advanced maternal age, etc.). Discuss risks with the patient and document identified risks and your discussion in the medical record.
- **Refer high-risk patients when appropriate.** Develop a referral and consultation policy that includes specific criteria for a provider to consider when deciding whether to obtain a consult from a specialist and when to transfer care to a specialist (such as requiring a maternal fetal medicine (MFM) specialist to manage the patient with cardiomyopathy or bleeding abnormalities).
- **Follow up on routine and non-routine testing.** Develop policies and procedures regarding test tracking, communication, and follow-up on abnormal findings. This would include: ensuring that tests are ordered, performed, returned, documented, and the results are discussed with the patient and relayed to other providers. In the event of abnormal findings, document the findings, treatment plan, and your discussion with the patient.
- **Contact patients to reschedule if they miss or cancel an appointment.** Document this action in the medical record.

Management of Labor: Risks & Recommendations

Labor can be a lengthy and sometimes uneventful process for hours at a time —it's important to recognize warning signs when they begin to emerge.

The single largest cause of obstetrical claims is alleged negligence during the management of labor — accounting for 40% of claims and 49% of indemnity paid. Communication among team members becomes particularly crucial at this point. Clinical training or lack thereof begins to show itself in how effectively electronic fetal monitoring (EFM) strips are read and responded to, how appropriately practitioners prioritize safety against what is routine practice, and what is requested by the patient or her family.

During the management of labor, patients and practitioners can find themselves at odds and a patient's strong preference for a "natural" (i.e., vaginal and non-induced) delivery can result in allowing a woman to labor too long. Once patients have reached the second stage of labor (i.e., when the patient's cervix is 10 cm/fully dilated until physical delivery of the infant), a tendency or willingness to wait can be a potential blind spot for some practitioners. As for training and experience, we have seen claims involving nurses who are new to labor and delivery who have not been fully trained to read EFMs or to recognize that difficult situations can become exponentially worse with each passing minute. Labor can be a lengthy and sometimes uneventful process for hours at a time. From a human factors perspective, that can lead to complacency, a lack of urgency, or reduced situational awareness. Yet, when warning signs begin to emerge, it's imperative that they be immediately recognized and potentially acted upon.

Due to mild preeclampsia and post-dates, a 27-year-old patient was admitted to the labor and delivery unit for induction with Pitocin under the care of a family practitioner. The family practitioner notified the attending on-call OB that the patient was being admitted for induction, but did not communicate additional history or information. It was 6 p.m. The initial fetal heartrate showed tachycardia 160-170s, but it resolved with rest. During the evening, the L&D charge nurse requested an informal analysis of the fetal monitoring strip by an on-call OB at the nurse's station. The OB did not have the benefit of the patient's history or clinical course up until that point, but did look at 10 minutes of monitoring strip and described it as category 2, which required continued monitoring but no immediate intervention. During the ensuing eight hours, there were questions about the effectiveness of the fetal scalp electrode and the EFM strips showed significant changes, but the OB provider, who had left the hospital around 10 p.m., was not paged by the nurses or family practitioner until 1:45 a.m. This was after the family practitioner was aware of intrauterine resuscitation measures of oxygen, position changes, and fluids being implemented by nurses in response to late decelerations. There was scant amniotic fluid when the membranes were artificially ruptured, and the patient exhibited elevated blood pressure and protein in her urine. An emergency cesarean section was begun while the OB was en route to the hospital, at which time a fetal heartrate was not detected by EFM. The infant was stillborn, and autopsy revealed severe chorioamnionitis and severe acute funisitis. The patient's family was at her bedside throughout labor and delivery, and indicated having asked multiple times during the evening and night for an OB provider to evaluate the patient. The chart was silent as to these requests.

"To recognize and deal with our highest areas of vulnerability, we must make certain that all clinicians stay sharp in their ability to interpret fetal heart rate monitor strips, everyone on an obstetrical unit practices drills dealing with obstetrical emergencies, facilities are available to handle such emergencies when they arise, and that physicians, midwives, and nurses learn how to work together as well-coordinated, high-performance teams."

– Henry M. Lerner, MD, Ob-Gyn Newton Wellesley Obstetrics & Gynecology, Newton, MA (Dr. Lerner has reviewed hundreds of OB claims and has served as an expert witness on Coverys claims.)

Risk Management Recommendations Relative to Labor:

- **Require fetal heart rate (FHR) interpretation training.** Require all obstetric providers and staff to undergo training on the interpretation of FHR patterns prior to caring for obstetric patients and at regular intervals thereafter to show evidence of initial competency and maintenance of competency over time.
- **Speak the same language.** Providers and staff should use the same nomenclature when describing EFM patterns. The terminology that is used should align with the guidelines developed at the 2008 National Institute of Child Health and Human Development Workshop.[10] This nomenclature should be used consistently throughout all medical record entries and communications regarding the patient.
- **Develop fetal monitoring policies.** Develop evidence-based policies and procedures regarding fetal monitoring during labor that clearly delineate when each type of monitoring is to be used based upon the patient's condition and stage of labor, how often FHR should be evaluated and documented, and when the physician should be notified of FHR patterns.
- **Keep the physician in the loop.** Protocols allow the application of specific interventions to be applied by a nurse if a patient meets predefined criteria outlined in the protocol. The existence of a protocol does not, however, eliminate the need to communicate with the provider regarding the condition of the patient. Intervention taken on behalf of a patient, especially when the condition of the patient is concerning, should be communicated to the attending provider as soon as possible.

Risk Management Recommendations Relative to Labor (continued):

- **Develop a chain of command policy.** Develop a formal chain of command policy for providers and staff in the obstetric department. Empower all team members regardless of hierarchy to speak up in the event of a patient safety issue. Ensure that all team members know how to invoke the chain of command.

Midwife-attended Births

The reliance upon midwives is on the rise — 8.3% of U.S. births are attended by midwives.[11] Our data indicates that 17% of OB claims were for cases where a midwife was involved, and those cases resulted in 25% of indemnity paid.

Midwives have a reputation for building patient trust and confidence that can lay the groundwork for good outcomes. Yet for all the ways that midwives are strong at building relationships with patients, Coverys' claims data shows they may not be as adept at building relationships or inviting collaboration with obstetricians. Knowing when to bring in an OB for a consult and when to refer a patient to the OB are areas where a focused risk management program could help improve outcomes. A well-timed handoff or collaboration can avert an adverse event. This can also impact the OB as they may end up named in a lawsuit as a result of being called in too late.

Performance of Delivery

How a child enters the world can impact how healthy (s)he and the mother will be following delivery. Our data indicates that the majority of OB claims — 52% — involve vaginal births; this correlates with the majority of US births (68%) being accomplished by vaginal delivery.[12] One might imagine that surgical deliveries, particularly those done emergently, would carry the highest risk of harm, and yet vaginal births resulted in more claims than cesarean sections (52% vs. 45%) and more than three times as many claims as emergency cesarean sections (52% vs. 15%). And injuries related to delivery — like brachial plexus injury for infants and perineal injury for moms — are prevalent, 22% and 13% respectively.

Cultural issues come into play during delivery with populations of patients who are reluctant to agree to cesarean sections, and some outright refusing cesarean sections even if the baby is showing signs of potential harm or injury while in utero. And then there are hospitals that insist, "We don't perform VBACs," and

whose staff are not trained to address the risks associated with vaginal deliveries with a history of previous cesarean. It's often just a matter of time before a laboring mother comes through their emergency department doors, ready to deliver, having a history of cesarean section, and insisting on a vaginal delivery.

Ultimately, communication is key when it comes to delivery — from choosing the best method for the patient by working with the patient to performing it safely as an integrated team. OB claims allege that the delivery method of choice was the cause of a bad outcome in 5% of the claims. And with staff shift changes, the ability to pass on information and communicate effectively as a labor and delivery team is critical and should be a focus of initial training and competencies as well as annual education.

A 26-year-old patient was admitted to labor and delivery with spontaneous labor at 39 weeks. Her history was significant for oligohydramnios and a positive beta strep culture. After artificial rupture of membranes, her contractions continued in an irregular pattern so Pitocin was initiated and an epidural was given. Reevaluation of the patient six hours after admission raised the question of a facial presentation but bedside ultrasound was non-confirmatory. EFM strips were reassuring, baseline in the 150s with adequate variability and few decelerations. Cesarean section was discussed with the patient, and the physician elected to reevaluate in one to two hours. Approximately three hours later, the patient was fully dilated and facial presentation was confirmed by vaginal exam.

For the next two hours, as the patient pushed, fetal heartrate was recorded as 170-180s with accelerations at times correlating with contractions and variable decelerations not always correlating with contractions. During this time, a maternal heartrate of 173 was recorded on the monitoring strip, which the nurses discredited as being related to the automatic BP cuff "picking up fetal HR." During the final hours of labor, changes in fetal HR monitoring were documented as artifact. The physician and nurses believed the tracing was fetal throughout labor and did not suspect that maternal heartrate was being recorded. The baby was ultimately born in facial presentation with meconium stained amniotic fluid. The infant was hypotonic, floppy, and without spontaneous respirations. Apgars were 2/5/6. The infant had significant facial edema and bruising, required intubation, developed seizures on day one of life, and ultimately was diagnosed with cerebral palsy.

Several allegations related to inadequate monitoring were made against the nurses and hospital, including: lack of training regarding the recognition of signal ambiguity in EFM, failure to confirm maternal heart rate via methods other than the EFM, failure to evaluate and test placenta and cord blood, and failure to perform neurological imaging in a timely fashion.

Ensure policies, procedures, guidelines, and/or protocols for documenting the evaluation of fetal status are consistent with ACOG recommendations.

Risk Management Recommendations Relative to Delivery:

- **Engineer your OB department to be a model for collaborative teamwork.** Failure to function as a cohesive team is at the root of many poor outcomes for mothers and babies alike. Make teamwork a crucial focus.
- **Ensure maternal/fetal safety is properly prioritized with the requested birth plan.** Obstetricians are challenged every day to balance a women's right to guide her own medical care with the practitioner's responsibility to ensure she understands the risks that might be related to her choices. Practice, through role play, how to communicate effectively and persuasively in intense circumstances, such as being influenced by the patient and/or significant other's at-risk delivery choice (e.g., an elective breech vaginal delivery).
- **Informed consent — patients should understand and agree to potential consequences/risks and alternatives that may impact delivery outcomes.** Throughout pregnancy and labor, there are countless moments when patients are asked to make informed decisions about their care. It's important to communicate clearly with patients and ensure they understand procedures, alternatives, and potential risks. Such discussions should be reflected in the medical record.
- **Adhere to current evidence-based practice and recognized professional standards.** Ensure that the medical and nursing staff collaboratively develop written policies, procedures, guidelines, and/or protocols and orientation materials regarding emergency cesarean sections that are consistent with professional organization's guidelines and recommendations (such as ACOG). Use a common terminology with respect to the type of cesarean section (e.g., scheduled, unscheduled, urgent, emergency cesarean section). Ensure that the medical staff has reviewed and approved the policies. Likewise, ensure policies, procedures, guidelines, and/or protocols for documenting the evaluation of fetal status are consistent with ACOG recommendations.
- **Develop OB RN-specific job descriptions that define education, training, and competencies.** Ensure the job descriptions include:
    - A requirement to complete an OB competency-based orientation
    - Electronic fetal monitoring (EFM) education
    - An ongoing and annual review of competencies
    - High-risk clinical education, including simulation drills (e.g., hemorrhage, preeclampsia, shoulder dystocia, vaginal birth after cesarean sections [VBACs], instrumented deliveries, induction/augmentation of labor, and epidurals)
- **Ensure staff are trained and competent in the key elements of monitoring and documenting for VBAC patients undergoing a TOLAC.** In addition to training, conduct regular VBAC simulation drills to keep monitoring skills current and, importantly, in sync with each other. Include the following as required elements of documentation:
    - Executed consent form and a detailed entry in the medical record by the delivering provider that reflects the informed consent discussion
    - The decision and incision times, in the event of an emergency cesarean section
    - Date and time of each patient evaluation and/or assessment

Regularly conducted drills and simulations are recommended by ACOG as an effective way to improve patient outcomes in emergency situations.[13]

- Description of uterine activity
- Assessment and interpretation of EFM and/or auscultation of fetal heart tones (FHT)
- FHR and maternal contractions in the first stage of labor (monitored and documented every 15 minutes)
- FHR during the second stage of labor (monitored and documented every five minutes)
- Availability of the delivering physician (who has cesarean section privileges), the anesthesia provider, the OR team, and a provider certified in neonatal resuscitation during the course of the patient's labor
- Description of findings on vaginal exam, if performed, including progress since last exam
- Delivery plan, including significant interventions

- **Prepare and practice for the unexpected shoulder dystocia.** Ensure that your facility's policies, procedures, guidelines, and/or protocols for delivery address the assessment, recognition, and consideration of shoulder dystocia risk factors, as well as documentation requirements. Ensure that the following patient risk factors are routinely addressed:
  - Maternal diabetes
  - Maternal weight gain, obesity, or short stature
  - Fetal macrosomia or prior history of macrosomic infants
  - Gestational age > 40 weeks
  - Multiparity
  - Results of clinical pelvimetry
  - Results of ultrasounds and/or glucose screens
  - Previous shoulder dystocia

- **Regularly conducted drills and simulations are recommended by ACOG as an effective way to improve patient outcomes in emergency situations.**[13] Shoulder dystocia drills and simulations can be particularly helpful in identifying and correcting systems issues that contribute to clinical error. In addition, by practicing as a group, the care team can refine standardized responses.
- **Be prepared for operative vaginal deliveries.** Develop a policy, procedures, guidelines, and orientation and training programs pertaining to vacuum and forceps deliveries (operative vaginal delivery), ensuring that they are consistent with the latest evidence-based guidelines and recommendations. Also address documentation requirements, including informed consent for such deliveries.
- **Make sure your approach to induction is based on current best practices.** Have the medical and nursing staffs collaboratively review and revise induction policies, procedures, guidelines, and/or protocols to ensure that they are consistent with current standards, guidelines, and recommendations of applicable professional organizations (e.g., ACOG, AWHONN).

58.5%

of women of reproductive age are either overweight or obese; therefore every perinatal service should have policies and practices in place to manage this patient population. [14]

- **Be cognizant of greater risks of unanticipated outcomes in maternal obesity. Overweight and obese women are at increased risk for:**
  - Gestational diabetes
  - Hypertension
  - Preeclampsia
  - Preterm birth
  - Cesarean delivery
  - Operative and post-operative complications, including:
    - Prolonged operating times
    - Increased rates of excessive blood loss
    - Wound infection
    - Endometritis
    - Difficulties with anesthesia management

ACOG has published an Obesity Toolkit which you can access at https://www.acog.org/About-ACOG/ACOG-Departments/Toolkits-for-Health-Care-Providers/Obesity-Toolkit.

- **Complications for the fetus related to maternal obesity include:**
  - Increased risks of congenital anomalies
  - Growth abnormalities
  - Miscarriage[15]
- **Conduct an examination of the placenta and cord.** Include a brief description of a gross examination of the placenta and cord vessels, as a well as the length of the umbilical cord, in the medical record. Encourage delivering physicians to complete a standard checklist on all placentas sent to pathology.

  A checklist may include:
  - Length of cord
  - Diameter of cord
  - Cord insertion
  - Number of vessels
  - True knot in cord
  - Color of fetal surface
  - Insertion of membranes

TEAMS, TRAINING, AND COMMUNICATION

Obstetrics is arguably one of the most sensitive areas of medicine when it comes to keeping staff practiced and current on identified risk. Ongoing training is crucial. The goal is to build and sustain a culture of high reliability — an environment in which it is agreed that every voice will be heard, where standard protocols will be adhered to, pathways followed, and risk factors consistently identified and acted upon. Proactive organizations have hard-wired refresher training into their daily operations; when there's down time, they are running shoulder dystocia drills and the like. They're examining EFM strips and challenging one another to make the right calls based on the patterns they're seeing.

Tools to Help Improve Outcomes

Keeping your clinical skills and knowledge of best practices up to date can be a challenge. Many healthcare providers rely on online courses and tools to help. Coverys offers its policyholders complimentary specialty-specific clinical and risk management CME courses at no additional charge through Med-IQ,® a Coverys company and industry leader in continuing medical education. Insureds can contact Coverys Risk Management for more information at 800.225.6168, option 9. Non-insureds can also take advantage of these tools — visit Med-IQ.com for more information.

Human Factors Analysis

"The most common root causes of sentinel events are human factors, leadership, and communication. And I argue that leadership and communication are also human factors."

— Ronald Wyatt, MD, Medical Director, Office of Quality and Patient Safety at The Joint Commission

There is much to be gained by following the deliberate, thoughtful, and ongoing use of what is known as aviation-based training or human factors analysis. Developed by James Reason, PhD, human factors analysis is commonly used in high-risk industries like aviation, healthcare, nuclear power generation, and financial services. It provides a systematic way to help predict and prevent the breakdown of complex systems based on human factors like group think, normalization of deviance, and poor supervision.[16] Dr. Reason has argued that there are two ways to think about errors that happen in places like a hospital's labor and delivery ward. We can either think about errors with a person approach, whereby people are blamed for errors and then trained to avoid them in the future, or we can think about errors from a systems approach, whereby we know humans are fallible and errors are expected, so it's up to the organization to address issues that can lead to human error.

Given the complexity of the maternal/fetal episode of care — management of pregnancy, management of labor, and performance of delivery — and the degree to which OB clinicians are already at such high risk for burnout, depression, and even suicide, it's our strong recommendation that obstetrics teams adopt a systems-based training philosophy to reduce risk to patients and providers alike.

Where Communication Is Breaking Down

Clear and timely communication among and between all members of the obstetrics team is crucial, even more so than effective communication between doctor and patient. Of the OB claims in which communication was identified as a risk management issue, doctor-to-doctor and doctor-to-nurse interactions presented the highest risks.

N = 60 OB-related claims in which communication was a risk management issue
Claims may have more than one issue

Category of Communication	% of claims
MD to/from MD	28%
MD to/from RN	28%
MD to/from Midlevel Provider	17%
MD to/from Patient	10%

PATIENT ENGAGEMENT AND MEANINGFUL COMMUNICATION

We can't overestimate the importance of having an open, trusting, two-way dialogue with your patients. When clinician and patient aren't on the same page about needs and wants, when the clinician is missing key information about the patient's medical history or current symptoms, or when information shared by the patient with one member of the team (a nurse, for example) is not promptly and appropriately relayed to other team members, much can go wrong.

An engaged patient is a more compliant patient, a healthier patient, and a calmer patient. Engaging patients is also a crucial way to significantly increase the chances of an uneventful labor and delivery, reduce risk to mother and baby, and avoid litigation.

Engaging patients in a meaningful way starts with a purposeful decision to do so. What might it look like if every time you met with your patient — whether she's coming to your office for a check-up or you're going to her bedside to check on the progress of her labor — you mentally asked yourself:

- How can I encourage her to tell me what she's feeling (in her body and in her mind) right now so I can best serve her?
- How can I listen more actively even if I'm in a hurry?
- How can I make her feel safe and willing to listen closely and open-mindedly to information I need to share that could be confusing, overwhelming, or unwelcome news?
- What is the shared goal we're working together to accomplish, and how can these next several minutes help improve the odds that we get there together safely?

An engaged patient is a more compliant patient, a healthier patient, and a calmer patient. Engaging your patients from the diagnosis of their pregnancy all the way through to a successful delivery isn't just about "customer satisfaction." Engaging patients is also a crucial way to significantly increase the chances of an uneventful labor and delivery, reduce risk to mother and baby, and avoid litigation.

PATIENT ATTITUDES AND CULTURAL TRENDS IMPACTING OB RISK

While every patient and every pregnancy presents unique issues, challenges, and opportunities, there are several overlapping trends that impact entire populations of patients. Being aware of these can help prepare you for the possibilities that await you in the exam room, the hospital room, and the delivery room. Below are just a few of the trends we're seeing in Coverys' claims:

- Increased expectations that labor and delivery will involve a preplanned and ideal customer "experience" and that clinicians can and will adjust standards of care or hospital protocols to give patients what they are seeking.
- Increased expectations that delivery modalities (e.g., vaginal, cesarean section, VBAC) are simply a matter of choice and preference on the part of the patient, rather than a collaborative decision arrived upon only after careful consideration of all risk factors.
- Religious and/or cultural beliefs that make some women reluctant to undergo medically indicated procedures even when necessary to save the life of mother or baby. For example, in some cultural/religious communities it is believed that undergoing a cesarean section will limit the number of children a woman can have or cause death. In other cultures, it is believed that epidural anesthesia can cause chronic lower back pain or paralysis.[17,18]
- Educational divides that impact patients and practitioners alike regarding the perceived safety of vaginal vs. cesarean section deliveries. Some patients and practitioners believe, sometimes inexplicably, that one method is safer than the other (in all cases and with all patients) and will use the data to support their preference.

FINAL RECOMMENDATIONS FOR MANAGING RISK AND IMPROVING PATIENT SAFETY

Throughout this publication, we have provided data-driven recommendations for reducing risk and improving outcomes related to the full maternal/fetal episode of care, step by step. Following is a final list of recommendations that apply broadly to the phenomena of maternal/fetal risk in U.S. healthcare — regardless of where you practice or how you practice obstetrical medicine. As you and your colleagues approach each new day with an eye toward improving patient care and reducing risk, we strongly encourage you to consider these general principles:

Constantly innovate and organize when it comes to processes, checklists, and protocols.

- Simulate regularly to improve successful realities. Best-in-class hospitals have eliminated "down time" on labor-and-delivery floors and in emergency departments by making themselves busy with practice. When patient volume is low and workload is slow, the very best teams are running drills for shoulder dystocia or other common (and not-so-common) complications.
- Honestly examine the dynamics of team relationships, communication impasses, turf wars, and politics. Don't wait until giving a deposition or court testimony to get honest about difficult relationships, unwritten chain-of-command struggles, internal politics, or unnecessary pecking orders among OBs, family medicine, CNMs, and nursing.
- Engage the patient more meaningfully, at every step and during every interaction. Include her in all key decisions, re-engineer your patient assessment process to address cultural biases and expectations, and "check in" with her about everything from her health history, to her current symptoms, to hunches and hopes.
- Given today's comorbidities, high-risk pregnancies must be addressed and treated as such. Nearly a third of pregnant women are obese, and diabetes and hypertension during pregnancy are also on a rapid incline. These comorbidities make for complex and sometimes dangerous pregnancies, labors, and deliveries. It's important to document why the patient is considered to be high-risk and how you are monitoring and treating the risk factor(s) throughout the pregnancy.
- Make training and re-training your second most important job, behind caring for patients. Train, re-train, and re-train again. Whether it's ensuring that nurses newly transferred to L&D get the very best training on reading EFMs, learning new techniques for delivery complications (e.g., shoulder dystocia maneuvers), or improving the speed and clarity of communication across your team during critical moments, training is everything. Be generous with your training budget to reduce risks and costs later.
- Develop a bias toward decisiveness, but be open to reconsideration as situations evolve. The malpractice stories in obstetrics have many trends, including a "wait and see" one that can lead to tragedy.

ECRI INSTITUTE DATA

ECRI Institute data indicates that Coverys claims data is indeed a reflection of the larger landscape.

In order to better understand current obstetrical risk, Coverys partnered with the ECRI Institute to examine a related set of data — perinatal "event reports."

ERCI Institute PSO is a nonprofit patient safety organization (PSO), a special classification available to companies under the Patient Safety and Quality Improvement Act of 2005. ECRI Institute PSO currently collects and safeguards events reported by its more than 5,000 members, most of whom are hospitals and health systems.

Between 2015 and 2017, almost 30,000 perinatal events were reported to the ECRI Institute. These reports can provide critical information about where and how today's obstetrical risks are occurring. About half of these events involved the mother exclusively, while 37% involved the baby. While these events may not result in a malpractice claim, more than 5,000 resulted in some level of harm to the mother, the fetus, or both patients. Some 518 events resulted in permanent injury or death.

OVERVIEW OF ECRI INSTITUTE OBSTETRICAL REPORTS BY SEVERITY

Severity Scale* for Events Causing Harm	Event Count	
TEMPORARY HARM Required treatment or intervention (no hospitalization)	4,019	
TEMPORARY HARM Required initial or prolonged hospitalization	479	
PERMANENT HARM	65	High-Severity Injuries
NEAR-DEATH EVENT Required ICU care or other intervention necessary to sustain life	193	
DEATH	260	
TOTAL REPORTS Of events that contributed to or resulted in harm	5,106	

** Based on Agency for Healthcare Research & Development Harmscale*

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CONCLUSION

In the coming year, there will be approximately 4 million births in the United States. They will be preceded by pregnancies during which meaningful patient engagement is of utmost importance.

Obstetrical providers who attend to these births will do outstanding work and deliver healthy infants in the vast majority of cases. But the devastating outcomes — those involving serious, permanent injury or death — will continue to haunt providers, no matter how rare those occasions. Those events may be reduced by taking a close look at the data about maternal/fetal risk, then making changes to improve outcomes and reduce liability.

Among our own insured providers at Coverys, obstetric-related events are the fifth largest category of medical professional liability claims and the fourth highest category of indemnity payments. On a national scale, 77% of Ob-Gyns have already been named in at least one malpractice lawsuit.[19] To help improve the management of pregnancy, labor, and delivery, and to improve patient safety (while also reducing claim frequency), practitioners must look to the data to guide them. They must heed the signals, understand the trends, and rise to the challenge of implementing new practices, new processes, and new mindsets. The safety of pregnant and laboring mothers, as well as their infants, is at stake — there is perhaps no greater motivation to improve than this sobering reality.

As you review the statistics, insights, stories, and recommendations presented in this report, it is our sincere hope that you'll regard them not just as a dose of insight, but also a dose of optimism for the future. There is much to learn, and much to be done, and much to celebrate when we collectively rise to the challenge of continually improving care for mothers and babies.

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Case studies and other patient examples shared in this publication are derived from actual liability claims, with identifying details removed or altered to protect the anonymity of patients, families, practitioners, and healthcare organizations.

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