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Risk Management-Obstetrics and Gynecology Perspective

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Abstract: The Obstetrics and Gynecology physician's likelihood to experience medical malpractice claims are higher than in other medical specialties. We will review the basic principles of health care risk management, the role of the risk manager, and the importance of health care risk management in risk mitigation for obstetrics and gynecology physicians. Attention is focused on medical record documentation, disclosure of adverse events, second victim programs, grievance management techniques, alternative dispute resolution concepts, regulatory inquiries including state licensure investigations, product failures, and electronic media strategies. Concluding, health care risk management may be used as a claim avoidance tool and provider protective vehicle for physicians.
Key words: risk management, medical malpractice claim, disclosure, obstetrics, safety, regulatory

Introduction

Clinical adverse events, unintended harm, occur daily in health care systems.[1] These events cause physical and psychological harm to patients, but adverse events also affect the patient's families, medical staff, the community, and the organization. Often, patients and their families want the same things: (1) a truthful, factual explanation, (2) emotional first aid, (3) accountability, (4) apologies, and (5) preventive measures.[2]

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Following Basic Principles of Health Care Risk Management is Beneficial to Organizations

Health care risk management exists to identify risks, mitigate them, and protect insured providers and the associated infrastructure. According to "Crossing the Quality Chasm: A New Health System for the 21st Century", the following 6 core principles serve as the framework for health care risk management; safe, effective, patient-centered,

timely, efficient, and equitable.[3] The engagement of health care risk management as an integral part of health care delivery reduces state and federal reporting failures and lack of organization processes and mitigates malpractice risks. Failure to engage in health care risk management results in physicians, other providers, and the organization's exposure to avoidable risks and heightens the likelihood of medical malpractice claims.[4] This is especially important in clinically high-risk departments like obstetrics and gynecology.

Utilizing a Health Care Risk Manager Can Help to Protect Physicians and Other Providers and Organizations

Indeed, 4% of obstetric patients have reported adverse events and data reports two-thirds of obstetric complications are considered preventable.[5] Definition of terms is shown in Table 1. As it is rare for a medical malpractice claim to occur absent an identified adverse event, prudent physicians and organizations should engage health care risk managers

TABLE 1. Definition of Terms

Term	Definition
Adverse event	An undesirable medical event that was not caused by underlying disease but resulted in either of the following: harm to the patient, prolonged hospital stays, required life-saving intervention, or assisted in the patient's death
Alternation dispute resolution program	A facilitated conversation often takes place between the provider and patient with a neutral third-party present, which allows for a mutually agreeable resolution
Claim	Demand for financial compensation or additional incentives
Disclosure	Providing individuals with facts or information that is relevant to their care
Grievances	A formal or informal written or verbal complaint by a "grieving party", regarding the patient's care when the complaint is not resolved at the time of the complaint by staff present. It also includes any formal or informal written complaints of patient abuse or neglect and/or issues related to the hospital's compliance with the CMS Hospital Conditions of Participation ("CoPs"), or a Medicare beneficiary billing complaint related to rights and limitations provided by 42 CFR §489[6]
Licensure board	An individual who is all of the following: Licensed or certified by the State of Pennsylvania to provide professional services. Employed by or authorized to provide professional services in a medical facility
Mediation	Process where dissatisfied parties meet with a neutral person to facilitate a resolution of their differences. It may or may not include financial compensation. It is intended to control legal costs, privacy, and relationships. Mediation may or may not be legally binding nor is it guaranteed to resolve the differences
Negligence	The act of providing care in an irresponsible way results in injury or harm to the patient.
Preventable adverse event	An undesirable medical event that could have been avoided
Regulatory bodies	The establishment of requirements that provides safe health care, protects patients from health care risks and creates a safe working environment for providers

early and often. The American Congress of Obstetricians and Gynecologists reports at least 73% of obstetrics and gynecology physicians will be sued for medical malpractice.[7] Data reports that obstetrics and gynecology physicians are the fifth most likely to be sued in 29 specialties and have the largest malpractice claim payouts.[8]

In 2020, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic highlighted old problems and introduced new ones.[9] As it relates to old problems, the clinical risks remained and the associated adverse events occurred with regularity. Notably, since family members were restricted from hospitals during that time, it remains to be seen whether the absence of those patient champions resulted in an increase in adverse events and medical malpractice claims. As it relates to new problems, the pandemic punctuated the health disparities that exist based on income and race.[10] From a patient perspective, the following were amplified, access issues, underlying health disparities, and access or lack thereof to vaccines. From an industry perspective, workforce shortages, supply chain barriers, and provider fears were noted. And the entire world was united by chaos and uncertainty. The field of obstetrics and gynecology was no different.

Like other physicians, obstetrics and gynecologic physicians and patients were faced with physical and social distancing requirements impacting labor assistance support during childbirth, visitation and vendor restrictions, telemedicine consultation, video recordings, and academic training limitations. One could argue that the impact on obstetrics and gynecology was more acute given the traditional involvement of support persons in labor and delivery. Also, there were cancellations of routine testing and elective procedures, fear of intrauterine SARS-CoV-2 transmission, and controversy regarding coronavirus disease vaccination during pregnancy to name a few. Furthermore, pregnancy was classified as a comorbidity for SARS-CoV-2 disease, which increased the risk of maternal and fetal death by 70% and increased the risk of perinatal complications, and heightened patient and provider anxiety.[10] These stressors have impacted the patient risk for adverse events making the health care risk management perspective imperative for physicians.

Regarding the current state, health care risk management provides needed support to organizations, physicians, patients, and families by filling the gaps that are not filled by other health care professionals because their professional training gives them a unique perspective. When presented with an adverse event, health care risk managers launch an investigation that when done correctly, incorporates empathy. The health care risk managers also emphasize the importance of communication and early resolution and offer suggestions for improvements. In some ways, one of the biggest benefits of engaging health care risk managers is their ability to do what members of the clinical team cannot do; pause and evaluate the event without being concerned about the personalities of the clinical staff. This often leads to better results for organizations, physicians, patients, and families.

By way of professional background, health care risk managers are typically experienced clinical providers, often nurses, attorneys, or other administrators. Health care risk management duties include adverse event review and investigation, data analysis, communication, and collaboration with other disciplines, brainstorming of practical practice changes, and risk mitigation. Indeed, health care risk management offers a confidential way of reporting adverse events to limit legal risks and provide real-time support for clinical questions. Once a monetary,

regulatory, or service-based claim has been asserted, the health care risk management deploys to mitigate the professional, financial, public, or regulatory vulnerabilities of the physicians and/or the institutions in question. Health care risk managers answer medical/legal inquiries of physicians, nurses, and administrators regarding emergent patient care issues and loss control. They participate in supporting all legal discovery proceedings, which may include attending depositions and/or trials.

Importance of Risk Management in Promoting Patient Safety in Obstetrics and Gynecology

Because obstetrics and gynecology simultaneously involve 2 patients, a birthing person and a baby, the risks are inherently multiplied. Most deliveries are routine and without incident. And yet, in the blink of an eye, things can change for either patient. It is this potential for risk and the realized risks that have been observed and noted over time that emphasize the importance of risk management in promoting patient safety in obstetrics and gynecology.

Adverse events involving unanticipated outcomes, errors of omission and commission, and communication failures including patient family complaints are fundamental to patient safety systems and should be reported to the risk management program.[11] Table 2 shows Obstetrical and Gynecologic Adverse Events and Near Misses that should be reported by physicians or other providers. Reports of near misses add value by preventing future adverse events by determining process improvement opportunities.[12] This is imperative, as serious preventable adverse events complicate 15% of all hospitalizations.[5] Figure 1 shows the risk management adverse event cycle, for the steps associated after the occurrence of an adverse event that contributed to the harm.[13,14] Physicians should respond promptly to questions as open communication builds trust and confidence.

TABLE 2. Obstetrical and Gynecologic Adverse Events and Near Misses

Examples
Abortion complications
Abnormal vital signs:
Fever > 101.5 °F
Respiratory rate <8 or > 36
Heart rate <40 or > 140
Blood pressure changes <80 or > 200 systolic or 110 diastolic
Air embolism including umbilical embolism
Bleeding disorders
Bleeding, *c* section > and vaginal delivery >
Bleeding requiring blood transfusion
Burn
Communicable diseases
Contaminated gas or substance
Death or disability associated with equipment
Equipment failures resulting in lost sperm or eggs
Failure to identify or treat hyperbilirubinemia
Fetal and or maternal death
General anesthesia required
Hysterectomy after delivery
Hospital-acquired infections
Impersonating a health care worker
Implantation of the wrong sperm or wrong egg
Infant abduction
Infant discharged to the wrong person
Instrumented delivery
Miss management of fetal remains
New onset difficulty breathing
Nonreassuring fetal heart rhythm
Ophthalmia neonatorum treatment
Oxytocic agents
Pseudocyesis
Retained foreign body
Sepsis
Serious adverse drug reaction
Significant neurological deficits
Shoulder dystocia
Suicide or attempted suicide
Suspected abuse (drug, spousal, and child)
Terbutaline use
Third and fourth-degree laceration
Unanticipated transfer to a special care unit
Unanticipated specialty medical consultation
Wrong patient and wrong procedure

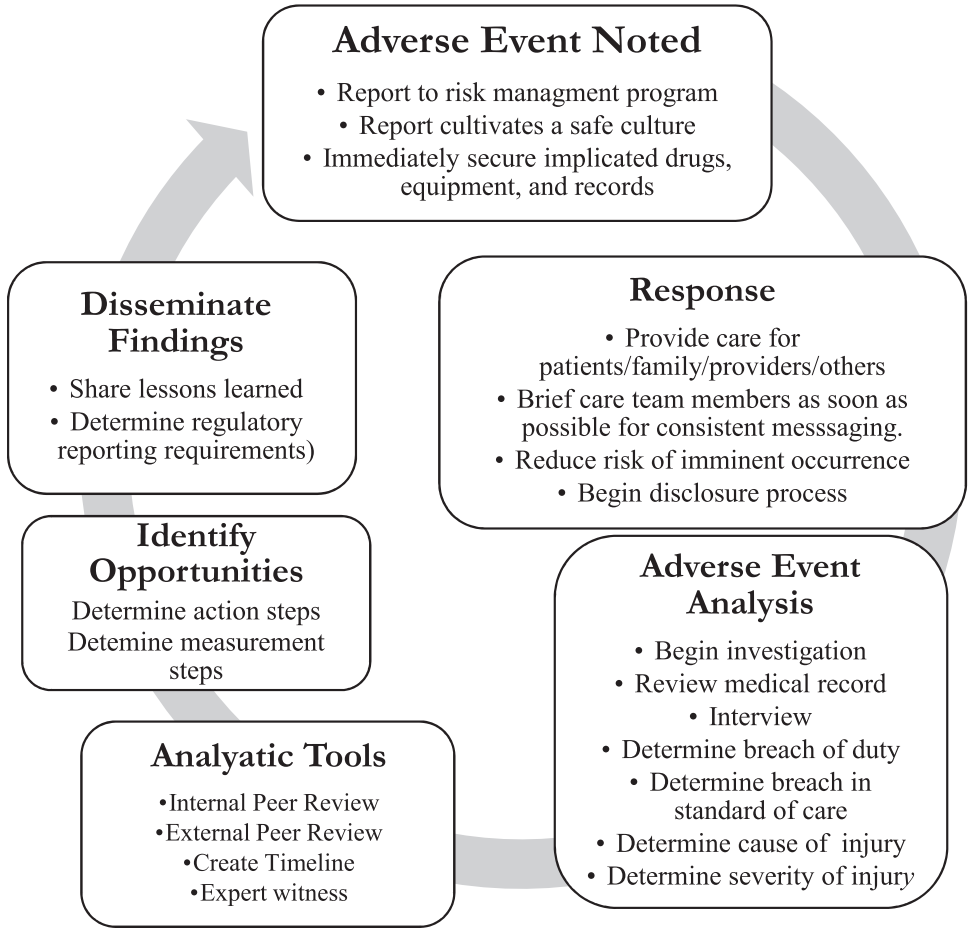

FIGURE 1. Risk management adverse event cycle.

Appropriate Medical Record Documentation is a Key Risk Management Step

In many ways, appropriate documentation in the medical record is a key step in implementing a health care risk management plan. It is important to remember that the medical record is primarily designed to do 2 things. First, it is designed to memorialize the clinical care of the patient. Second, it is designed to create a communication tool for the care team. Medical records are utilized when evaluating a patient's medical care as they provide data for education, research, quality assessment, peer review, and insurer review. Good documentation limits liability and serves as a valuable defense against medical malpractice claims. Because of this, documentation should be clear, concise, contemporaneous, honest, accurate, readable, timely, and fact-based. Any information that would affect the patient's health and recovery, should also be entered into the medical chart.[15] This includes refusal of care to treat such as infections in utero, medically necessary cesarean delivery, failure to attend scheduled medical appointments, and failure to comply with medical instructions. It is prudent to

refrain from noting any criticism or disagreements among providers in the record. Correct any inaccurate entries in the medical record without erasing or obliterating the error as this reduces the risk of allegations of fraud or abuse. It is advisable to follow federal and state mandates related to medical records retention rules.[16] Confidentiality of medical records including office records is a legal and ethical obligation, breaches may be subject to disciplinary action. Medical record release of information requests and subpoenas must be accompanied by a signed authorization from the patient or their legal representative. A subpoena from the coroner or courts does not require signed authorization but government investigators have no authority to review or receive copies of patient information without judicial authorization, these cases are best referred to risk management. There may be heightened confidentiality protections such as human immunodeficiency virus, mental health, and drug and alcohol records release. The health care risk managers, or the health information management department, may assist in appropriate releases of medical information. That said, even with prudent medical record documentation, patient safety, and legal risks loom because adverse events occur. That is why having an effective health care risk management plan that incorporates a trained health care risk manager is so important.

A key question in health care risk management is how and where to document the adverse events that occur.[17] As a threshold matter, adverse event reports should be factual and descriptive. Conjecture and criticism should be avoided. Secondly, having an electronic means of capturing these adverse events is beneficial. Many reporting and claims management tools are electronic and found online. Third, prudent organizations and physicians should seek guidance if they do not have a repository for capturing adverse event reports. They should refer to the health care systems or medical malpractice insurers to determine the correct risk management reporting tool. The completion of an adverse event report should not be referenced as a document in the medical record. If the clinical staff memorializes the adverse event report in the medical record, they have just made it that much easier for an attorney who desires to create a case against them to review it.

Disclosing Adverse Events is Often Legally Mandated and Always Beneficial From a Risk Management Perspective

Adverse event disclosure is identified as the ethical imperative to communicate with patients and families after harmful events occurred.[18] A complication occurs from any cause; whether it is a mistake, system failure, or human error, disclosure creates the patient's right to know. Although the transparency of adverse events contrasts with long-established risk management strategies, the literature supports that adverse event disclosure does not increase a physician's medical malpractice liability exposure.[2,19] Most health care organizations have disclosure policies that support the disclosure of harm, caused by errors. Hesitancy to disclose may be experienced by physicians because of inexperience with communication, the uncertainty of the outcome, the fear of negative repercussions, or concern for a medical malpractice lawsuit. Because of the fears these factors create, it is often useful to engage health care risk managers to assist with facilitating the conversation to ensure that the disclosure is clear, concise, compassionate, and appropriately documented. Disclosure key points are shown in Table 3.

TABLE 3. Disclosure Key Points

Examples
Display empathy
Allow expression of emotions
Acknowledge the expression of emotions
Validate feelings by stating their response is understandable
Be honest
Discuss the facts regarding the adverse events
Provide direct answers to the patient's questions and avoid medical jargon
Be comfortable stating "I do not know the answer to the question but I will keep you updated as I learn more"
Show sincerity in patient's questions and concerns
Be aware that nonverbal expressions are an important part of the communication process
Check for the patient's understanding of the information throughout the conversation
Be authenticate
Follow-up with patient and family
Check for understanding
Do not avoid patient or family

Second Victim Program is an Essential Part of a Comprehensive Risk Management Programs

Organizations should understand that the physicians involved in adverse events are often distressed emotionally. Accordingly, having a program to assist them with how to process these emotions is prudent, from a risk management perspective. Coined by Wu,[20] the term "second victim" is used to describe how physicians are affected by adverse events. Indeed, "second victim" programs address a physician's need for support after being involved in an unanticipated adverse event or medical error. The most common events that result in the "second victim" experience are fetal or neonatal losses and maternal death. Approximately 700 women and more than 1 million fetus deaths occur annually in the United States because of pregnancy or delivery complications.[21] As a result, obstetrics and gynecology physicians are at higher risk of becoming the "second victim".

With the goal of helping physicians manage the "second victim" phenomenon, the patient safety literature suggests obstetrics and gynecology departments should consider resources and support systems to help physicians deal with the self-blame, self-doubt in their profession, and lower professional self-efficacy that often follows these events.[20] One study further suggested physicians who experienced the second victim have worse qualities of general health and vitality.[22] To help eliminate these outcomes, awareness of the second victim experience should be encouraged, as education and peer support may contribute to decreased turnover and a better understanding of triggering events.

Efficient and Effective Grievance Management Techniques Are Essential for Those Who Wish to Avoid as Many Medical Malpractice Claims as Possible

Health care delivery is complicated, and the patients and their families often do not understand the process. Indeed, it is ripe for conflict. And it should come as no surprise that complaints and grievances arise, even those most physicians comply with the Hippocratic oath and strive to provide dignity and respect to their patients and families. If organizations lack an avenue for addressing these matters, their exposure to litigation increases as does their physician's exposure to licensure risk. Indeed, unheard, disregarded, disrespected, and ignored patients and their families are most likely to seek legal advice. Conversely, fewer medical malpractice claims are filed against physicians who are committed to listening and responding to concerns.[23]

The Center for Medicare Services regulations considers any complaint that

cannot be addressed by the "staff present" to be a "grievance" that requires a written response to patients and or families.[6] As a result, those written responses should be thoughtful, empathetic, and they should answer the question that was asserted by the grieving party. At times, grievances are complex and a letter is ineffective at resolving the underlying conflict. When that occurs, alternative dispute resolution programs may be considered as a method to mitigate malpractice claims.

Alternative Dispute Resolution Programs Can be Useful in Mitigating Litigation Exposure

An alternative dispute resolution program is a program that creates a forum for the grieving party to express his/her concerns directly to the organization and physicians. When utilized, it can result in greater clarity about the patient's experience, which can benefit both the organization and the physicians involved. One type of alternative dispute resolution program is mediation, which is defined as a facilitated conversation, often between the physician and their patients (Table 1).[24] The facilitator of this conversation is a neutral, third-party, mediator whose main purpose is to avoid misunderstandings and reach a mutually agreeable resolution. This improves patient/physician communication, results in mutual understanding, and allows them to achieve common ground. In many states, participating in these alternative dispute resolution programs is beneficial to the physician because the communication exchanged is confidential and not subject to discovery in medical malpractice claims or other legal proceedings. With this protection, physicians can communicate honestly, candidly, and without fear. The benefit for the grieving party—generally the patient or family—is that they receive a forum, in which to be heard and get real answers. Organizations that choose to create such programs should consult with their health care risk managers or legal counsel to ensure that the appropriate steps are taken to sure that the program is optimally beneficial for all participants.

Regulatory Agencies Also Present Potential Risks to Organizations and Providers

There are a number of regulatory bodies such as the Attorney General, Department of Health, and Office of Civil Rights may reach out to physicians for a variety of reasons. If or when approached by a regulatory body, it is important to validate the request preferably in writing and confirm the identity of the requestor. Before in-person communication, consult the health care risk manager to determine whether legal counsel representation may be warranted. Caution should be noted that sharing of privileged or peer review information with regulatory agencies may erode its protection.

Another regulatory agency that presents potential risks for physicians and other providers is the licensure board. In virtually every state, licensing boards can investigate complaints asserted by the public against health care providers. These licensing boards may bring disciplinary sanctions at their discretion. Often, the threshold for conducting an investigation is much lower than what is required to file a lawsuit because the boards exist to protect the public. For that reason, physicians and other health care providers should be mindful of the possibility of these investigations as well.

Here are some important items that physicians should be aware of if approached by a licensure board investigator. Licensed physicians must participate in licensure investigations as a condition of their license. The licensed physician will be notified of the investigation by an investigator. In some states, this notification may occur through email or phone or the investigator may seem at the licensed physician's office. Because these are personal investigations in the physician's license, the facility, legal team, or insurer are often not notified of the investigation. For that reason, it is important for physicians to remember that they may have an attorney represent him/her in the process because the potential consequence of the investigation is the inability of the physician to practice. To that end, notifying the health care risk manager at the facility early in the process is advantageous.

The Food and Drug Administration (FDA) regulates medical devices and is charged with ensuring their safety. Product failures and malfunctions have a legal significance and may be overlooked as reportable by physicians. There is a federal law mandating reporting serious adverse drug reactions to any product use that results in death, serious injury, and illness.[25,26] There are some notable product failures and recalls impacting the obstetric and gynecologic patient population. In 2022, the FDA infant formula monitoring resulted in a national infant formula shortage. Intrauterine contraceptive devices and transvaginal mesh have been known to be on medical device recall and or FDA watch lists. Consult risk management for questions related to medical products including drugs, biological products, medical devices, dietary supplements, infant formula, and cosmetics that impact patient care. Timely reporting to provide evidence of good faith compliance with the FDA could potentially mitigate the risk of class action suits.

Using Electronic Media Has Illuminated Additional Areas of Risk

Health care had significant growth in the use of electronic media over the past years, but the worldwide pandemic rapidly intensified its use. Unless provided by secure information technology programs, email, and cell phone texting are not secure methods of communication and are considered the property of the email provider. They are discoverable by law and, therefore, caution should be used if sharing patient-specific data. Email disclaimers should be utilized.[24] Since the 2020 pandemic, health care providers have been faced with workflow challenges related to social distancing including in-person meetings.[9] Thus, the use of video technology for remote learning and workplace meetings has become more prevalent and efficient. Health care providers should be cognizant of regulations surrounding audio and video recordings. It is important to be aware that unauthorized notice of audio recording is a violation of the statute in certain state laws. In some states, consent of all parties is required for audio recording in private or public conversations. Thus, be mindful of your conversation, texts, or emails as when things go wrong, they may be found on social media. Confidential information and peer protection are paramount to education, training, and quality of care. Be aware of the risks of eroding peer protection or protected health care information by completely avoiding audio recordings or transcriptions. A written summary is preferred over recordings and transcription. Table 4 shows meetings that should not be recorded or transcribed.

Precautions should be taken when using personal electronic equipment with protected health information, work-related activities, or intellectual property. Because of privacy restraints and laws regarding electronic devices, health care providers

TABLE 4. Electronic Meetings That Should Not be Recorded

Examples
Hospital patient safety/risk meetings
Root cause analysis/adverse event meetings
Morbidity/mortality conferences
Formal peer review meetings
Peer evaluation discussions for ensuring the standard of care
Never event discussions
Patient safety incident reviews
Protected health information discussions
Privileged/legal meetings
Employee performance reviews or discussions

are prohibited from use of their personal devices. However, patients and families may have exceptions depending upon the policies of the organization such as childbirth. Generally, photographs are prohibited. Depending on the circumstances, these data may become the property of the organization, which physicians practice or discoverable by law. There are circumstances where the court of law may subpoena personal electronic equipment. The electronic footprint to recreate physician actions is easily accessible in this high-technology and digital environment. Legal requests for electronic data of parking garages, operating room suites, mobile devices, and computer log-ins are commonplace. When in doubt, the health care risk managers serve as an excellent resource for questions related to electronic media,

Summary

Prudent health care organizations and physicians recognize the value of health care risk management and use it to mitigate areas of legal exposure and professional risk, especially those specializing in obstetrics and gynecology. The real benefit of health care risk management to those groups is the department's ability to provide thoughtful analysis and planning because of its additional perspective. In particular, it is the department's knowledge of clinical care as well as the applicable laws and regulations that make it uniquely suited to protect the organization and providers. In contrast, failure to involve a health care risk manager early exposes providers and the organization to potentially avoidable risks and further heightens the likelihood of medical malpractice claim litigation. Indeed, the benefit of engaging health care risk management as a clinical and conflict resolution partner cannot be overstated.

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