

# Cause and Effect Analysis of Closed Claims in Obstetrics and Gynecology

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**BACKGROUND:** Identifying the etiologies of real or perceived adverse clinical events and undesired outcomes is an important step in improving patient safety and reducing malpractice risks. Systematic analysis of obstetrics and gynecology-related risk management files allows a more complete examination of ways that human and systems factors may contribute to adverse events.

**OBJECTIVE:** To learn the medical complaints of patients who experienced apparent adverse events, the general causes of those adverse events, and the significant specific causal factors involved in obstetrics and gynecology-related risk management cases.

**METHODS:** This was a retrospective analysis of 90 consecutive obstetrics and gynecology-related internal review files opened by a medical center's risk managers between 1995 and 2001. Each file was analyzed to identify factors that may have contributed to or caused unanticipated adverse events. The main outcome was the pattern of contributing factors when they were aggregated into categories.

**RESULTS:** Fifty percent of cases were associated with inpatient obstetrics. Factors that may have contributed to adverse events were identified in 78% of cases, and most had more than one contributing factor. Thirty-one percent of adverse events were associated with apparent communication problems. Clinical performance issues were identified in 31% of cases, diagnostic issues in 18% of cases, and patient behavior contributed to 14% of adverse events.

**CONCLUSION:** Diagnostic, therapeutic, and communication issues were the most common factors identified. Although the generalizability of these data are unknown, all obstetrics and gynecology departments face multiple challenges in assuring consistent quality care. Analysis of claims files may help identify opportunities for improvement.

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## LEVEL OF EVIDENCE: II-3

Specialists in obstetrics and gynecology practice in a litigious environment and face pressure to improve health care quality.<sup>1</sup> The Harvard Medical Practice Study<sup>2,3</sup> found that 1.5% of hospitalized obstetrics patients experience an adverse event and that 38.3% of these outcomes were related to negligent care. Recent Institute of Medicine reports<sup>4,5</sup> have also drawn attention to the need for practitioners to adopt measures aimed at improving patient safety.

Improving women's health care, assuring patient safety, and reducing malpractice risk are important goals for medical centers, physicians, and their insurers. Identifying the reasons for real or perceived adverse events is an important first step toward these goals. Various methods, including autopsy review, closed claim analysis, patient satisfaction surveys, and diagnosis-specific patient chart analysis have been used to develop guidelines for quality improvement or tracking error and malpractice in obstetrics and gynecology.<sup>6-12</sup> However, research in this specialty has not concentrated on identifying common themes or systems contributing to adverse events.

Although obstetrics and gynecology departments typically review adverse events in quality assurance activities, analysis of individual cases does not always promote improvements in patient safety.<sup>13</sup> Aggregating data from many incidents may permit more effective identification of recurring or systems errors.<sup>8,12</sup> The objective of this study was to systematically examine obstetrics and gynecology-related risk management files to assess the presentations, causes, and characteristics of real or perceived adverse events. Risk management files were used because they are more numerous than lawsuits<sup>14</sup> and provide richer information than medical records at less cost.<sup>15</sup> These files contain relevant medical records augmented by interviews with the care team and, sometimes, expert reviews of the case. These interviews and



case reviews often describe issues, concerns, observations, and inter- or intradepartmental relationships or processes that are not normally included in the medical record. With these additional elements, the files are more likely to reveal recurring and underlying issues associated with both technical and nontechnical aspects of care than the medical record.

We aimed to answer the following specific questions: What were the chief medical complaints of patients who experienced apparent adverse events? What were the significant specific factors involved in these cases? What appeared to be common general contributing factors to or causes of adverse events? Answers to these questions might suggest opportunities for system improvement and provide a model for medical centers desiring a method to identify factors that are associated with adverse events.

## MATERIALS AND METHODS

This study was a structured retrospective analysis of consecutive risk management records from a single institution. All patients were treated in an urban academic department of obstetrics and gynecology. For perspective, annual clinical activity during the study period included approximately 3,500 admissions, 2,000 deliveries, 1,200 gynecologic procedures, and 40,000 ambulatory visits. Care was provided by attending physicians, residents, and medical students. All patients are seen by an attending physician.

We analyzed 90 consecutive risk management case review files that were opened during a 7-year period between January 1995 and December 2001. All files had been “closed,” either because the statute of limitations had passed without a claim being filed or because a claim had been settled, withdrawn, or adjudicated by arbitration or court proceedings. No files were excluded. The box (“Sequence of Procedures”) depicts the sequence by which these cases were identified and analyzed. The risk management process may be initiated by patient allegations of adverse events, formal or informal incident reports, or inquiries from attorneys. All reports are screened. Files are opened only in cases judged to represent potential liability or the need to defend threatened claims. Claims files contain a summary of the perceived adverse event and a copy of relevant medical records. They may also include summaries of interviews with the personnel involved, expert medical and legal opinions, and any other material pertinent to the event. The risk managers participating in this project have an excellent history of fully investigating adverse events and identifying events that could lead to lawsuits. Over the previ-

ous 10 years, fewer than 2% of claims had not been anticipated.

### Sequence of Procedures

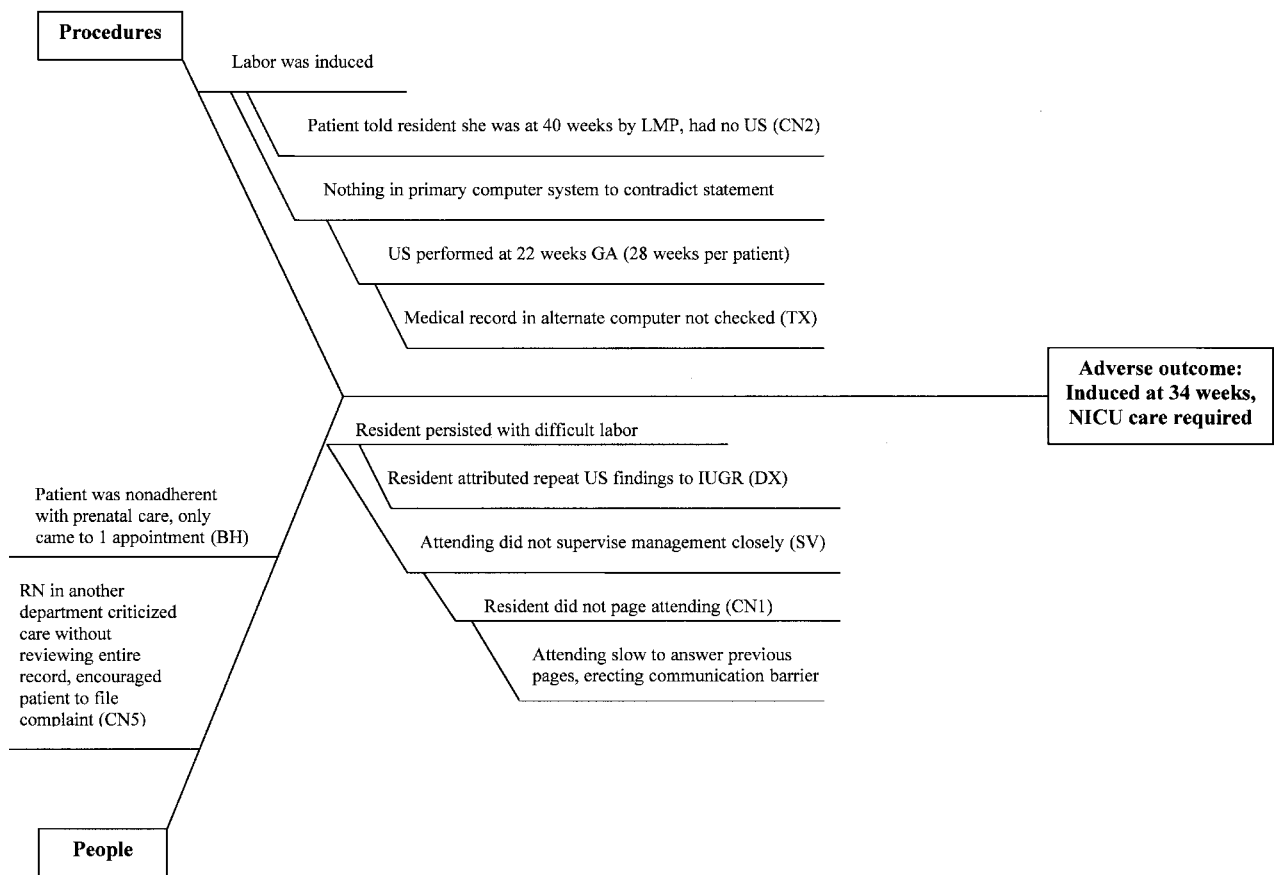
1. Occurrence of adverse event or potential adverse event.
2. Adverse event reported to Risk Management Office.
3. Risk Management Office evaluates the event and opens a case review file if potential liability is identified or legal action threatened.
4. All cases associated with the obstetrics and gynecology department were distributed randomly to members of a multidisciplinary review group, each of whom is the primary analyst.
5. Primary reviewers present case and analysis to multidisciplinary review group.
6. Review group achieves consensus or evaluates additional case information until consensus is achieved.

Case files were distributed to and initially evaluated by individual members of a team that included a labor and delivery nurse manager, 2 nurse-trained risk management claims investigators, a second-year medical student, and a researcher. Each served as the “primary reviewer” for a number of cases.<sup>16,17</sup> The analysis employed Ishikawa or “fishbone” diagrams.<sup>18</sup> The person serving as primary reviewer for a case identified all actions, events, and environmental circumstances that appeared to contribute to the event. The reviewer also attempted to rule out factors that likely did not contribute to the adverse event. All participants signed a strict pledge of confidentiality.

Fishbone diagrams were created for each case to depict relationships between the adverse event and its contributing factors.<sup>18</sup> Figure 1 illustrates a composite case example. In this example, a patient was induced prematurely, in part because of problems with diagnosis, communication, patient behavior, and resident supervision, resulting in an unnecessary neonatal intensive care unit (NICU) stay for her son.

The primary reviewer assigned codes to the apparent contributing causes from a list of 120 descriptions (Harvard Risk Management Foundation. Malpractice claims description codes [unpublished]). For example, if the review suggested that the physician failed to educate the patient about signs of a postoperative complication, leading to delayed care, the code for “inadequate discharge instruction” from the general category of communica-





**Fig. 1.** A hypothetical 35-year-old G3P2 who missed her prenatal care presents for induction claiming she is at 40 weeks by last menstrual period. The cause-and-effect diagram depicts aspects of her care and the adverse outcome following the decision to induce labor. LMP, last menstrual period; US, ultrasound examination; GA, gestational age; NICU, neonatal intensive care unit; IUGR, intrauterine growth restriction. Example codes: CN1, communication among caregivers relevant to outcome; CN2, communication between patient and caregiver relevant to outcome; CN5, jousting; BH, patient noncompliance; DN, incomplete/missing document; DX, misdiagnosis; SV, resident supervision issue; TX, patient history documented but overlooked.

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tion-related items was assigned to the case. As many codes as needed were assigned to each case to capture all the possible factors contributing to the alleged adverse event.

Primary reviewers presented their analysis to the rest of the review team. The team met to consider each file, challenging the primary reviewer to support the code assignments and offering alternate explanations until the team reached a consensus. Disputes were resolved by applying precedents established in previous projects, including obtaining, analyzing, and coding additional information. The physician author did not assign codes, but clarified and arbitrated questions about technical and procedural issues.

The index of concordance between primary review-

ers' initial code assignments and the final consensus-based codes was 84% (number of agreements divided by number of agreements plus disagreements), suggesting adequate initial coder training and general consistency among the judges. The codes that changed, however, reinforce the importance of multidisciplinary team reviews. Specifically, in our experience, judges' varied backgrounds, professional training, perspectives, and even biases promote revelation and evaluation of a case's "entire picture." Individual reviewers may focus on selected aspects of a case but may discount or overlook others whose significance they do not fully appreciate until reviewers with complementary expertise point them out. Traditional methods of determining "inter-rater reliability" do not apply when the expertise of raters



varies considerably, as in multidisciplinary case review teams. The team approach is essential to achieve comprehensive evaluations.

After stripping the data of identifiers to preserve patient confidentiality, codes for each case were collected in a computer spreadsheet and analyzed with descriptive statistics (frequency counts and proportions). We also recorded the patient's reason for presentation and consultant services involved. The Vanderbilt University Institutional Review Board reviewed and approved this project.

## RESULTS

Cases were categorized into 3 service areas (gynecologic surgery, inpatient obstetrics, and outpatient clinic). Cases were then grouped by "chief complaints" (Table 1). Forty-five (50%) of the 90 cases were associated with inpatient obstetrics, 34 (38%) involved gynecologic surgery, and the remaining 11 (12%) involved ambulatory patients. The clinical presentations were diverse but representative of the overall patient population treated at the institution.

Inpatient obstetrics adverse events were associated with inpatient monitoring and treatment of both early and late complications of pregnancy (eg, preeclampsia, preterm labor, premature rupture of membranes, scheduled induction, vaginal birth after cesarean, and abruption). Gynecologic surgery cases involved patients with benign problems or malignant disease and included operative injury, postoperative complications, or hospital complications. Most outpatients presented for either evaluation of pelvic/abdominal pain or routine prenatal care.

The reviewers aimed to identify potentially avoidable factors that contributed to adverse events. In 78% of cases ( $n = 70$ ), reviewers identified at least one such factor. In the remaining 22% of cases, reviewers acknowledged an undesired outcome, but could identify no potentially preventable underlying factor.

Table 2 describes the general categories of underlying or contributing factor for the 90 cases. Because reviewers often identified issues from multiple categories within a single file, category percentages are independent and their sum exceeds 100%.

Communication failures were associated with 28 (31%) of the adverse events. In 19 of these cases (21% of all cases), communication failures (disruptions in the flow of critical information from caregiver to caregiver or between patient and caregiver) appeared to contribute directly to the medical outcome. In one example, miscommunication between the primary team and a consulting team led to the administration of an inappropriate

**Table 1.** Classes of Patient Presentations in Cases Associated With Adverse Events

Presentation	No. of Cases (%)
Labor and delivery	45 (50)
Term labor	8 (9)
Scheduled induction	6 (7)
Preterm labor	5 (6)
Pregnancy-induced hypertension	4 (4)
Premature rupture of membranes	4 (4)
Scheduled cesarean delivery	4 (4)
Vaginal birth after cesarean	2 (2)
Decreased fetal movement	2 (2)
Abdominal pain	1 (1)
Sepsis	1 (1)
Abruption	1 (1)
Chest pain	1 (1)
Trauma	1 (1)
Spontaneous abortion	1 (1)
Abscess	1 (1)
Circumcision	3 (3)
Gynecologic surgery	34 (38)
Cervix, adnexal cancer	8 (9)
Pelvic pain	7 (8)
Pelvic support defect	6 (7)
Fibroids	5 (6)
Ovarian mass	3 (3)
Abscess	2 (2)
Nonviable fetus	1 (1)
Endometrial cancer	1 (1)
Tubal ligation	1 (1)
Ovarian mass	3 (3)
Ambulatory	11 (12)
Abdominal pain	3 (3)
Routine prenatal care	2 (2)
Contraception	1 (1)
Dysfunctional uterine bleeding	1 (1)
Cervical competence	1 (1)
Pelvic pain	1 (1)
Breast mass	1 (1)
Nonviable fetus	1 (1)

medication. Communications that upset the patient or family (but did not otherwise contribute to the medical outcome) occurred in 13 cases (14%). In some of these cases, patients expressed frustration because they did not understand the role of the various care providers or did not understand the medical decisions. Although these events did not affect the medical outcome, they adversely impacted the family's satisfaction with the care received and provoked the family to question the institution's and providers' concern for patient safety.

Issues related to patient diagnosis and treatment apparently contributed to the adverse event in 18% and 31% of the cases, respectively. Most appeared on their surface to reflect problems with an individual provider's medical decision-making or technical skills. After multi-



**Table 2.** General Categories and Specific Causes of Adverse Events

Category/Cause	No. of Cases (%)*
Communication	28 (31)
Patient dissatisfaction only	13 (14)
Among caregivers	9 (10)
Between patient and caregiver	6 (7)
Jousting	5 (6)
Treatment and surgery	28 (31)
Surgical performance issue	9 (10)
Choice of therapy	7 (8)
Delay/incorrect timing	5 (6)
Informed patient choice	5 (6)
Circumcision injury	3 (3)
Inadequate assessment or monitoring	3 (3)
Inadequate continuity of care	2 (2)
Premature discharge home	1 (1)
Improper location of care	1 (1)
Failure to obtain consult	1 (1)
Diagnosis	16 (18)
Delayed diagnosis	9 (10)
Misdiagnosis	5 (6)
Failure to order test	2 (2)
Test results not reviewed	2 (2)
Test results not reported	1 (1)
Problem scheduling needed test	1 (1)
Patient Behavior	13 (14)
Documentation	8 (9)
Incomplete documentation	6 (7)
Lost progress notes or report	2 (2)
Administration	8 (9)
Failure to follow policy	3 (2)
Lack of policy for situation	2 (2)
Insurance issue	2 (2)
Billing issue	1 (1)
Equipment issues	7 (8)
Resident supervision	4 (4)
Consent issues	4 (4)
Environment issues	3 (3)
Medication error	3 (3)
Resuscitation issues	1 (1)
No issue identified	20 (22)

\* Specific causes are independent and their sums may exceed the category total. For instance, multiple failures of communication were detected in several case files.

disciplinary analysis, however, it was determined that system problems often contributed to the adverse events or permitted them to occur. For instance, apparent treatment or diagnosis errors might have been exacerbated by communication failures. Among the 28 adverse events involving treatment or surgical performance issues, 7 were complicated or permitted by communication errors. Of the 16 cases involving diagnostic errors, 5 were influenced by apparent communication failures. The issue then becomes not only why initial diagnostic or therapeutic flaws occurred, but also why they were not caught and averted by better communication oversight or system controls.

Patient behavior contributed to 14% of all adverse events, including instances of substance abuse, drug-seeking behavior, or noncompliance. Reviewers noted that failure to follow a policy or the absence of a policy or protocol might have contributed in 9% of cases (eg, incorrectly completing autopsy or insurance forms in a fashion that upset the patient or family and stimulated legal action).

Documentation issues were identified in 9% of cases. These problems included incomplete documentation (7%) and lost documentation (2%). In 2 cases, the documentation issue appeared to contribute directly to the adverse event. In both of these, failures to document significant ultrasound or laboratory findings in the appropriate section of the medical record resulted in misdirected patient management on subsequent visits.

Adverse events associated with equipment issues were reported in 8% of cases. No specific piece of equipment was implicated twice. Most events resulted in the rapid replacement of the problematic device (such as, intra-uterine pressure catheter or suture material). One case involving equipment issues illustrates how the system can contribute to adverse events. An unnecessary cesarean delivery was performed because a new, technologically advanced ultrasound machine had unique settings that resulted in an error in assessing fetal cardiac rhythm. The unique machine and inadequate training predisposed the sonographer and attending physician to error.

The remaining adverse events were associated with rare situations rather than recurrent systems factors. For example, 3 files were opened on a day when surgeries were terminated prematurely because of smoke from a fire in another section of the hospital.

## DISCUSSION

This study identified and described common characteristics of obstetric and gynecologic care in a cohort of patients for whom risk management files were opened. The types of clinical issues presented by the study group were generally representative of the institution's obstetric and gynecologic patient population. Risk management files are initiated for a variety of reasons, but a real or perceived adverse event is required. Initiating a file does not prejudge that an adverse event or poor outcome occurred or that the incident was avoidable.

Our data demonstrate that 78% of risk management files associated with obstetrics and gynecology appeared to have at least one potentially preventable underlying cause. The findings suggest that interventions aimed at reducing preventable adverse events should not only include traditional continuing medical education updates, but also target systems factors associated with



adverse events. While this project proved useful for individual and organizational performance improvements at the study institution, our procedures can also be used by others seeking to supplement existing methods of quality improvement and malpractice risk reduction.

Like other researchers, we found that clinical performance issues predominated among the factors associated with poor outcomes.<sup>8,11</sup> Review on a case-by-case basis likely would suggest that these were idiosyncratic events resulting from individual slips and lapses. However, our aggregated data revealed clusters of common issues that suggested opportunities for system-level improvement. For example, we found that almost one third of the files involved apparent failures in communication (Table 2). Previous studies have identified communication issues as a significant factor in dissatisfaction with obstetric and gynecologic care as well as patient/family motivation to file malpractice lawsuits.<sup>10,19</sup> Even in cases where our review identified no adverse medical outcome, poor communication between caregivers and patients or family members led to notable patient dissatisfaction or threatened litigation. Obstetric and gynecologic physicians, case managers, and risk managers should agree upon strategies for dealing with angry patients after the disclosure of an adverse event or the perception of one.

Obstetrics and gynecology departments collaborate with many other services, as both the recipients and providers of consultant advice. As a result, errors in judgment or communication made by obstetric and gynecologic physicians affect care provided by other services and vice versa. For example, several files described incidents in which other services criticized obstetric and gynecologic care without first having reviewed the records. These episodes of “jousting” played a role in patient/family decisions to pursue legal action. Failures of communication or flow of information between caregivers can affect the care provided by others.

How might such findings be used to drive quality improvement? Once problem patterns with shared roots are identified, the clinical service can develop strategies to solve them. In part, as a result of the present findings, the obstetrics and gynecology department changed its algorithm for alerting/beeping key physicians and staff in emergencies, participated in crew resource management training,<sup>20</sup> and implemented a unified electronic medical record that forces responses regarding essential patient data. Computerized physician order entry and teamwork tools may also improve information flow and help prevent miscommunications.<sup>21,22</sup>

Inadequate documentation is common,<sup>23</sup> and it compromises legal defense in approximately one third of obstetric and gynecologic cases.<sup>11,24</sup> Documentation issues (eg, lost or unrecorded data or verbal orders) may

have contributed to adverse events in 8 cases (9%) in this series. In some cases, the use of parallel record systems apparently created confusion about the location of information. Documentation issues appeared to contribute directly to the medical outcome in 2 cases. Although this is 2 cases too many, it appears that in the overwhelming majority of cases the institution’s computerized medical record and team care promoted recording of relevant clinical data. In the remaining 6 cases, problematic documentation appeared to play no role in the adverse event, but it did complicate potential legal defense. Those 6 cases represent incidental discoveries of deficiencies in documentation and suggest that our method can uncover or reinforce systems issues of interest to department leaders. The study institution has since implemented centralized paperless systems to prevent some types of documentation and communication error. Regardless of the system used, the need to document thought processes and discussions remains an important part of medical training.

Patient behavior (eg, nonadherence and substance abuse) is impossible to control outside the hospital and may be hard to predict at the hospital, but it was a factor in 14% of the cases. Although some adverse events may not be preventable when patients’ behavior interferes, a respectful approach, good communication, safe boundaries, and careful documentation may help a great deal if litigation ensues.

Obstetrics and gynecology departments can use risk management files to drive quality improvement efforts. In a litigious environment, however, any quality improvement–related uses for these data depend upon their protection from legal discovery. Justifying this protection in turn depends upon actually using such data to identify and resolve common causes of adverse events.

The extent to which these data generalize is unknown. Other obstetrics and gynecology groups may experience different rates and causes of the real and perceived adverse events described in risk management files. We propose that this review methodology can uncover system problems that are unique to other institutions.

Claim file analysis depends upon the accuracy and completeness of investigators’ reports. Many of the issues we identified (eg, problems with informed consent or environmental hazards) were very rare considering both the volume of services provided and number of risk management files opened over the target period. Nevertheless, they may represent the tip of a larger problem and may still warrant further consideration as an opportunity for process improvement.

Corollary limitations are that underlying issues may not emerge, allegations may prove groundless (thus our references to “alleged” or “apparent” problems), and risk



managers' criteria for deciding whether or not to open a file on a particular case may vary. Recall that the insurer participating in this project had an excellent history of fully investigating adverse events and identifying events that could lead to lawsuits: fewer than 2% of lawsuits brought against the entire institution over the previous 10 years were "surprises." In this series of obstetric and gynecologic cases, 22% of files suggested no preventable causes of the adverse event, suggesting that departmental staff and risk managers had a low threshold for investigating possible adverse events. Risk managers attempt to identify as many adverse events as possible, but we do not know the completeness of detection. Underreporting—especially when errors were involved—has been routinely documented in the literature.<sup>25–27</sup> Important patterns could be missed if patient outcomes did not meet the expectations of either department personnel or patients, thus triggering reports to risk management. Risk managers' efforts directed to investigating incidents and the basis for their decisions about whether to open files undoubtedly varied. Nevertheless, the potential problem patterns we uncovered are consistent with those described in studies of medical malpractice, and it is likely that some system-level etiologies are similar across medical institutions.<sup>8,11</sup>

Obstetricians and gynecologists and department leaders can use the research methods applied in this study to investigate causes of adverse events and medical errors in their own departments. Simple, descriptive management tools such as cause-and-effect diagrams and coding systems can be useful in identifying issues for problem solving. Involvement of physicians is key because patient safety is unlikely to improve unless the physicians understand the causes of adverse events and provide leadership in quality improvement. Collaborating with risk managers and encouraging broad departmental involvement in patient safety and quality improvement research will have great potential for leading to safer policies, establishing more cooperative environments, and reducing errors and unexpected adverse events, and if malpractice risks are reduced, the efforts may prove cost-effective.

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