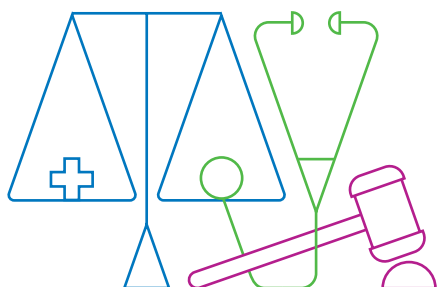


OB-GYN SPECIALTY OVERVIEW



How inadequate documentation of informed consent affects your defense in a malpractice lawsuit.



Brief Facts

- 35 YOF presented to her Ob-Gyn following a positive home pregnancy test.
- Repeat pregnancy test was positive, but an ultrasound was negative for an intrauterine pregnancy. A follow-up ultrasound was also negative for an intrauterine pregnancy.
- The Ob-Gyn diagnosed an ectopic pregnancy and performed a laparoscopy and milked the fallopian tube.
- Following the procedure, patient's hCG levels continued to increase.
- Ob-Gyn ordered an injection of methotrexate to terminate the pregnancy. This also proved to be unsuccessful, and the patient ultimately required a salpingectomy.
- Approximately 57 days after methotrexate administration, the patient became pregnant.
- Patient gave birth to a full-term infant with spina bifida, hydrocephalus, clubfoot, seizure disorder, and Arnold-Chiari II.
- The child underwent multiple surgeries, including VP shunt placement, closure of meningocele, permanent tracheostomy for home ventilation, cranial reconstructive surgery, and placement of a feeding tube. He was incontinent of bladder and bowel, wheelchair bound, and had limited ability to communicate. These were presumed life-long conditions.

Allegations

The Ob-Gyn failed to inform the patient of:

- The general risks of birth anomalies associated with methotrexate treatment.
- The associated risk of conceiving within three months of undergoing treatment.
- The recommended supplementation of folic acid when the patient conceived within that time period.

Plaintiffs' Experts Testified

- Plaintiffs' causation experts testified that methotrexate exposure 57 days before conception caused the infant's birth defects.
- Failure to obtain appropriate informed consent for methotrexate administration.
- Failure to instruct the patient not to become pregnant for at least three months afterward.
- Failure to provide the patient with supplemental folic acid upon learning she was pregnant. They opined that prescribing folic acid early in pregnancy could have prevented the infant's birth defects.

Defense Expert Testified

- Infant's abnormalities were not consistent with methotrexate embryology but were instead consistent with spina bifida, which is not attributable to any particular cause.
- No literature supporting plaintiff's theory that a preconception dose of methotrexate caused the infant's neural tube defects.

Complicating Factors

- **Damages and Life Care Plan:** Plaintiffs' economic experts estimated that the cost of providing care to the child over the course of his lifetime was \$18-\$24 million.
- **Excess Verdict Risk:** Concerns about potential for an excess verdict.
- **Expert Support:** Despite expert support for the Ob-Gyn, lack of documentation posed challenges.
- **Plaintiff Testimony:** Both parents expected to testify that the Ob-Gyn failed to provide them with information about the risks or side effects of methotrexate on fetal health in future pregnancies, including when they could safely resume unprotected sexual intercourse. Additionally, the parents were expected to testify that the Ob-Gyn did not recommend folic acid supplements, which allegedly would have moderated the effects of methotrexate on the developing fetus.
- **Missing Documentation:** There was nothing in the medical records regarding advising the patient when to try to conceive again or when to begin taking prenatal vitamins containing folic acid. The defendant could only testify to what he advised verbally or did as a customary practice.

Resolution

- **Settlement reached:** Case settled due to documentation issues.
- Lack of documentation associated with key issues in the case would be problematic.

Risk Reduction Strategies

Informed Consent Process

1. **Discussion:** Encourage questions and dialogue with patients.
2. **Documentation:** Record risks, benefits, and alternatives discussed.
3. **Patient understanding:** Confirm understanding and agreement.
4. **Educational materials:** Document any materials provided.
5. **Refusals:** Document if the patient refuses treatment.

A physician is responsible for:

- Educating the patient about a proposed course of treatment.
- Discussing the associated risks, benefits, and alternatives, including no treatment.
- Documenting the decision.

Conclusion

Insufficient informed consent documentation can significantly affect the defensibility of a malpractice lawsuit. In this case, the Ob-Gyn's records were silent on key informed consent issues, including the birth anomaly risks associated with methotrexate, a timeframe in which the patient should avoid conception after termination of an ectopic pregnancy, and a recommendation for folic acid supplementation during pregnancy. Had these items been documented, this lawsuit might never have been filed.

OB-GYN DATA & INDUSTRY TRENDS

ProAssurance is a contributing member of the Medical Professional Liability Association (MPLA) closed claims data sharing project. As such, the general data listed below includes claims data showing industry trends specific to Ob-Gyn Surgery claims from 2012 through 2021. Using this information, our risk management department can target specific areas of Ob-Gyn practice to deploy risk mitigation strategies and resources.

Source for data at right:
Data Sharing Project Dashboard
(2012-2021). MPL closed claims.
MPL Association. Retrieved by
ProAssurance (Oct 17, 2023).

“MPLA data shows Ob-Gyn claims are more prevalent and more extreme when compared to other specialties. Our internal data shows that when Ob-Gyns are able to put proper risk management protocols in place, there are usually fewer claims and the claims are often less severe.”

Mallory B. Earley, JD, CPHRM
Assistant Vice President,
Risk Management

How does Ob-Gyn Surgery stack up against all medical specialties?

	Total Closed Claims	Total Paid Claims	Average Indemnity Paid	Total Indemnity Paid
Ob-Gyn Surgery	6,995	2,284	\$455,265	\$1.1 Billion
All Specialties	74,292	19,960	\$351,820	\$7 Billion

Takeaways

- Ob-Gyn Surgery average indemnity was 26% higher than average.
- Ob-Gyn Surgery made up 16% of overall indemnity paid.
- Ob-Gyn Surgery claims made up 11% of paid claims.

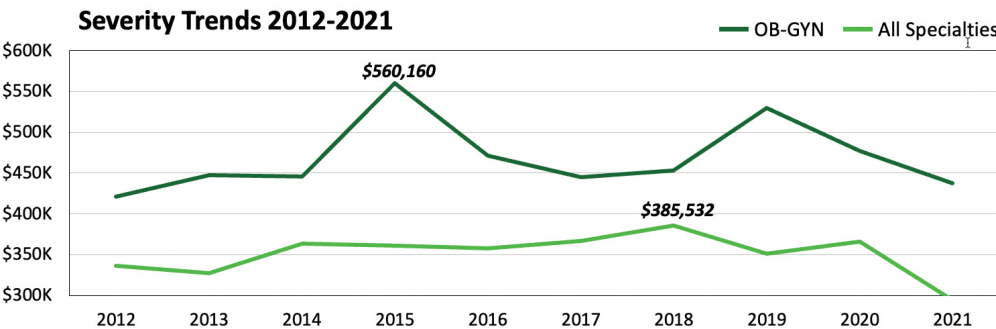
How does Ob-Gyn Surgery compare to other specialties?

Specialty	Total Closed Claims	Total Paid Claims	Average Indemnity Paid	Total Indemnity Paid
Pediatrics	1,316	395	\$464,788	\$184 Million
Ob-Gyn Surgery	6,995	2,284	\$455,265	\$1.1 Billion
Radiology	5,337	1,583	\$401,576	\$636 Million
Anesthesiology	3,012	834	\$394,530	\$325 Million
Internal Medicine	7,434	1,694	\$382,882	\$649 Million
Emergency Medicine	2,139	520	\$371,334	\$193 Million

Takeaways

- Ob-Gyn Surgery had more paid claims than any other specialty from 2012-2021.
- Ob-Gyn Surgery claims ranked 1st for total indemnity paid.
- Ob-Gyn Surgery ranked 2nd highest for closed claims and 1st for paid claims.

Average Indemnity Trends: Ob-Gyn vs. All Specialties



Takeaways

- Ob-Gyn Surgery had the highest average in 2015, with \$560K.
- The highest average indemnity over all specialties was \$386K in 2018.

OB-GYN RISK MANAGEMENT SERVICES



Annual Baseline Self-Assessment (ABSA) with Ob-Gyn Specific Tool

The ABSA is a brief survey that can be completed by the entire healthcare team (physicians included) in a few short minutes. Questions focus on office processes related to medical liability. This approach promotes candid answers to help us identify gaps in knowledge. Aggregated results are then reviewed so that focused educational opportunities can address the gaps. With a better understanding of what puts a practice at risk, we can improve defensibility in the event of a claim.

The ABSA can also have a specialty-specific tool added to the basic assessment that is included at the time of the request to better capture specialty-specific risks. Ob-Gyn is one of our additional tools that gives greater insight into this higher risk area of medicine.



To request the ABSA, scan the QR code.

Online Obstetrics Resources

Labor & Delivery team communication breakdowns can contribute to delivery delays. When delay is followed by infant death or disability, the risk of liability exposure is high. With the goal of increasing patient safety and decreasing medical liability exposure, members of the Labor & Delivery team are encouraged to consider and, where appropriate, implement the risk reduction and patient safety strategies introduced in these resources.

ProAssurance's Risk Management department has built a specific website for Obstetrics resources to include information on Postpartum Depression, Birthing Plans, VBACs, Doulas, Midwives, Patient Discharge During Pregnancy, Practicing Post-Roe, Chaperone Guidelines, and more.



For the full list of Ob-Gyn resources, scan the QR code.



Ob-Gyn Malpractice Case Studies

By presenting actual case histories of malpractice claims, malpractice case studies are intended to help physicians recognize some of the common causes of malpractice claims.



For Ob-Gyn specific case studies, scan the QR code.

Ob-Gyn Risk Management Education

Risk Management provides quality education for physicians, advanced practice providers, practice managers, and staff through online seminars and live virtual webinars often carrying CME credits. Additional educational resources include risk management guidelines, 2-minute videos, Rapid Risk Review podcast, sample forms, and text-based CME publications. No matter the level of time commitment, ProAssurance has an educational offering to fit everyone.

Consultation with Risk Management Consultants

The ProAssurance Risk Management department is here to help you promote patient safety, minimize risk, and improve defensibility of claims by providing comprehensive assessment and training resources that are relevant and easy to share.

Your physicians, administrators, and healthcare staff have access to a team of risk consultants with a wide range of backgrounds, including prior experience as healthcare administrators, attorneys, nurses, and quality professionals. Risk consultants assist insureds with their liability concerns and questions using specialized knowledge of healthcare risk management issues and the Company's experience defending claims.

Helpline: 844-223-9648

Monday through Friday, 8 a.m. – 5 p.m.

Email: RiskAdvisor@ProAssurance.com



“Our Ob-Gyn risk management resources are developed in response to closed claims and validated industry data.

Our goal is to identify risks to keep our physicians out of the courtroom and in the exam room.”

Mallory B. Earley, JD, CPHRM

Assistant Vice President,
Risk Management

OB-GYN ANNUAL BASELINE SELF-ASSESSMENT DATA

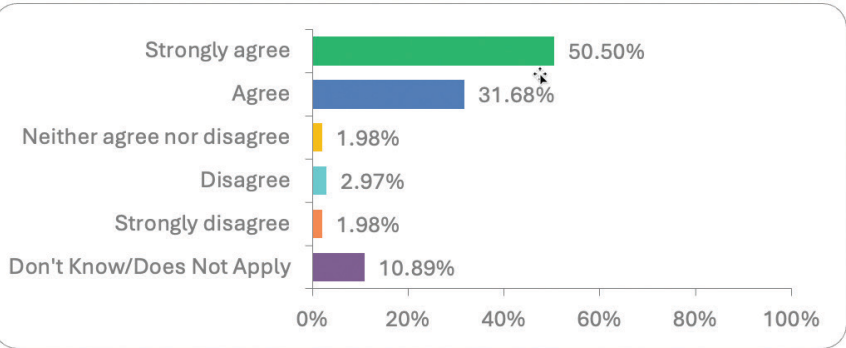
The ProAssurance Risk Management department launched the ABSA in 2024, with Ob-specific questions to identify areas of risk in the practice through surveying both physicians and medical staff.

Here is a sneak peek of a few questions and early results from Q1 and Q2 2024. These questions and charts would be compiled in a full report to share with the practice to show how they answered in comparison to these overall benchmarks. A ProAssurance Risk Management consultant would create a tailored plan and distribute it to the practice with educational resources to improve identified areas of concern.

Sample Results

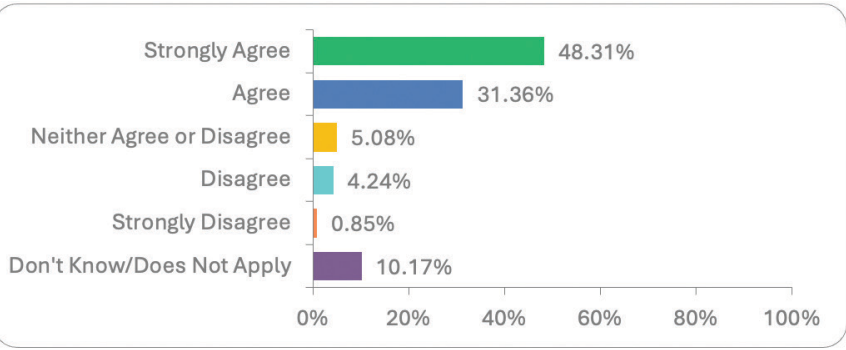
Question:

Your documentation in the prenatal record includes all ACOG-recommended guidelines.



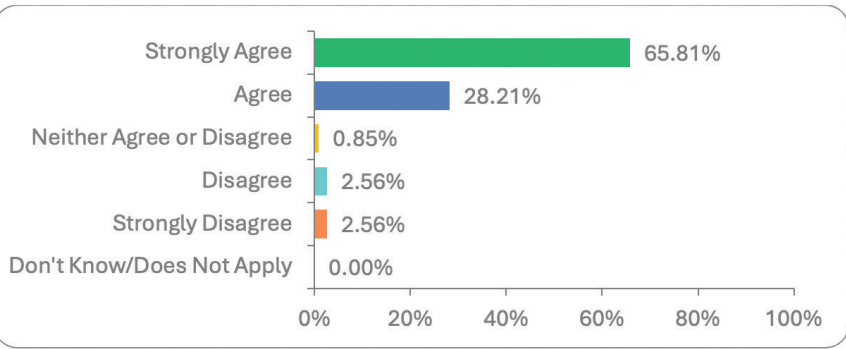
Question:

Birth plans are updated as needed based on provider recommendations and patient preferences and finalized in the 3rd trimester.



Question:

Telephone clinical staff are trained to identify symptoms or situations that require urgent medical attention.



Since the 2024 launch of the ABSA,

3,065

self-assessments were taken by staff at

511

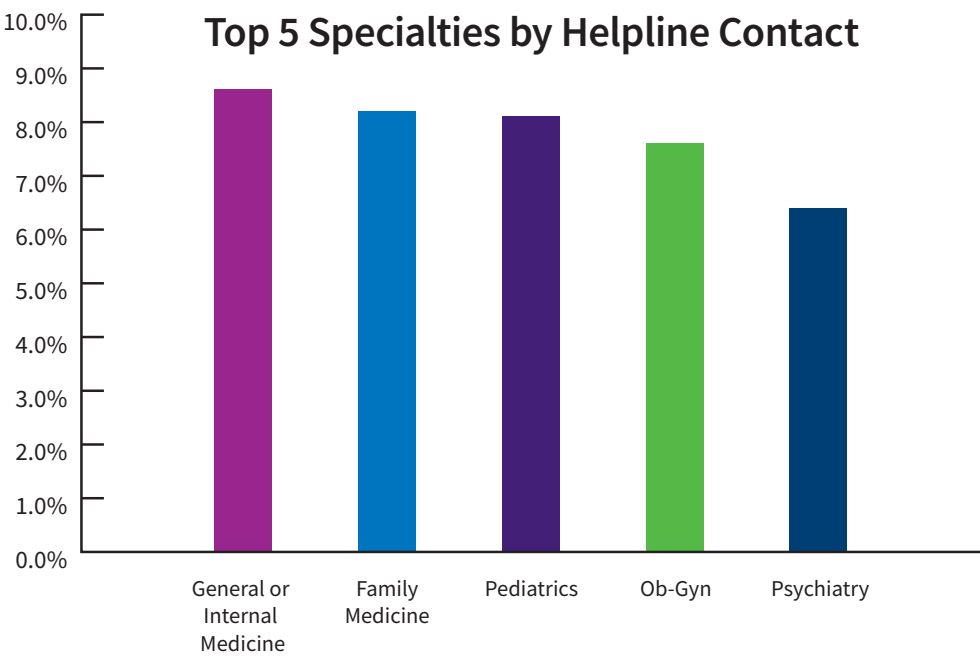
practices to evaluate medical liability risk management knowledge gaps.

These numbers were extracted from 2024 ProAssurance medical professional liability risk management data.

The immediate objective of the ABSA is to find and address current gaps within the individual practice, and there will be benchmarking benefits over time. The aggregate data will allow insureds to compare their practice to others based on specialty, location, group size, and more. The annual nature of the program will allow them to see progress over time.

OB-GYN HELPLINE DATA

Helpline Data Q1 & Q2 2024



2,800+

contacts were made with a ProAssurance Risk Management consultant by Helpline or email.

These numbers were extracted from 2024 ProAssurance medical professional liability risk management data.

Your healthcare team can rely on ProAssurance’s dedicated team of Risk Management consultants for help navigating medical liability trends and improving practice procedures.

Helpline: 844-223-9648
Monday through Friday, 8 a.m. – 5 p.m.
Email: RiskAdvisor@ProAssurance.com

MALPRACTICE CLAIMS DEFENSE

Every action we take in your defense is guided by our mission to protect others. Our proudest achievement is the sheer volume of claims we’ve been able to close without indemnity and without going to trial.

In addition to working for you in and out of the courtroom, we also work tirelessly to be an advocate for medical professionals when it comes to legislation and tort reform that may impact your practice of medicine.

5-Year ProAssurance National Claims Summary, 2020-2024*

19,900+

open malpractice claims managed by ProAssurance.

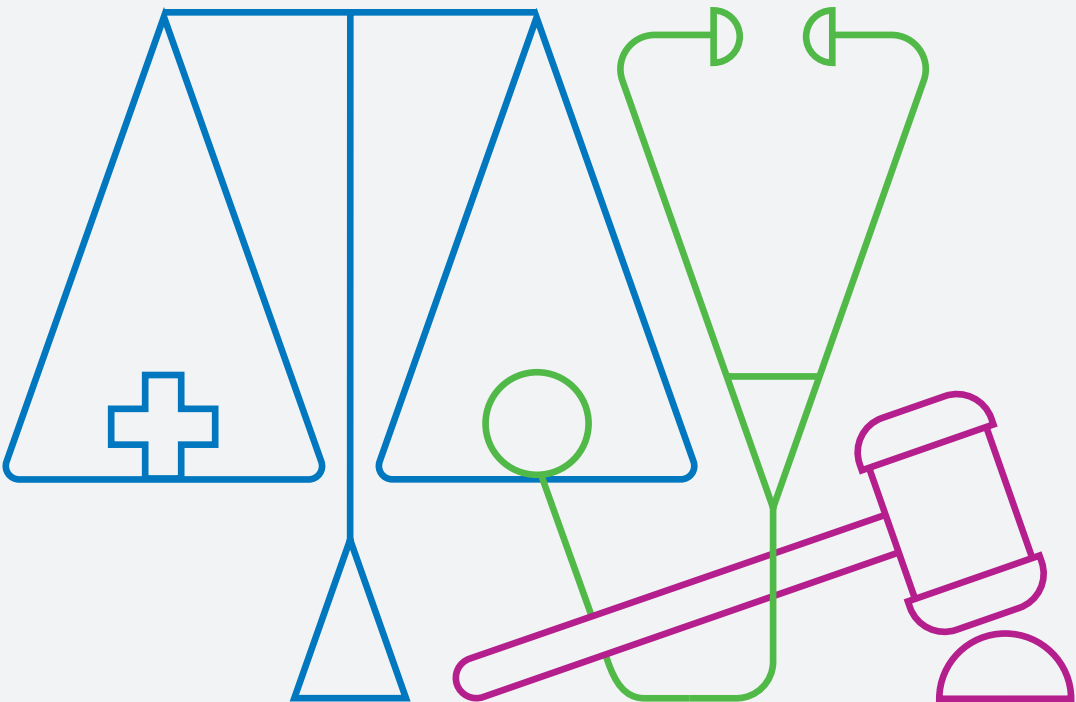
96.6%

of closed claims resolved without going to trial.

77.0%

of claims closed without indemnity (no money was paid to the plaintiff).

*These numbers represent medical malpractice claims from 2020 to 2024 extracted from the ProAssurance MPL claims reporting system.



HELPING OB-GYNs

- Minimize exposure
- Maximize defensibility
- Practice with confidence

We consider all cases seriously, and if our insured receives notice of a potential claim, we provide experienced malpractice counsel, bringing clarity developed on a national scale to the Ob-Gyn claims process.



ProAssurance.com

