Risk Management Review

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Incorrect Gynecological Procedure Results in Loss of Fertility

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Introduction

As healthcare knowledge and technology expand, new risks arise in the hands-on process of healthcare delivery. Some of the changes we have seen over the years include the formation of large, multi-provider practices; the development of new treatment techniques and medical technologies; and increased complexity in the overall healthcare delivery process.

This interesting case from the West Coast shows how these factors can combine to produce an error, causing a catastrophic injury to the patient.

Facts

The patient, a 28-year-old female, had been going to a large, multi-provider OB/GYN practice for several years. Throughout her time at the practice, she had been a patient of Dr. A.

The patient presented to the practice with complaints of pelvic pain. After appropriate testing, Dr. A determined that the patient had a large uterine fibroid. The doctor recommended a hysteroscopy, dilation and curettage (D&C), and ablation of the fibroid using a MyoSure® device.

The patient agreed to this treatment plan. However, before these procedures could be done, the patient was transferred within the practice to Dr. B. The reason for the transfer is not known.

On the date of surgery, the patient completed an informed consent form, which stated she would undergo hysteroscopy and D&C; the form did not mention the use of the MyoSure device. In the patient's preadmission history and physical (H&P), Dr. B stated that a hysteroscopy and D&C would be performed; however, the H&P documentation also stated that NovaSure® ablation would take place.

It is not certain whether Dr. B correctly stated MyoSure and the person who transcribed the H&P misunderstood it, or whether Dr. B mistakenly said NovaSure rather than MyoSure. This error is significant because the two devices are radically different.

MyoSure is a device with a cutting edge that is used to excise the fibroid from the uterine lining following D&C. The NovaSure device, on the other hand, uses electrical current to permanently remove the inner lining of the uterus. Treatment with NovaSure makes subsequent pregnancy very difficult and generally inadvisable because of the permanent change to the uterine lining.

Prior to commencement of the procedure, a timeout was conducted; however, the discrepancy between the consent form and the H&P was not identified. The procedures, including the incorrect NovaSure procedure, commenced and were completed without complications.

During the patient's postsurgical follow-up appointment, she began discussing with Dr. B her desire to pursue pregnancy. At that time, the error was discovered, and Dr. B disclosed to the patient that she would not be able to get pregnant because the lining of her uterus had been removed.

Shortly thereafter, the patient sought legal representation and a claim, in the form of a demand for damages, was filed with MedPro Group. With Dr. B's consent, the claim was settled prior to the initiation of formal legal action. Payment to the patient was in the high range, with legal costs in the low range.

Discussion

This case highlights several potential vulnerabilities that can arise in any surgical case. The first vulnerability was the handoff of the patient's care from Dr. A to Dr. B. Handoffs, or transfers of care, occur in many different situations, such as shift changes, after-hours or vacation coverage, transfers of care between different specialties, or — as in this case — the reassignment of a patient within a practice.

The principal problem associated with handoffs can be summarized in one word: communication — or, more precisely, miscommunication. A simple rule is "miscommunication can lead to mistakes."

In this case, no evidence suggests that Drs. A and B discussed the patient during the time she was transitioning between them. Although a thorough review of the patient's record would likely have helped bring Dr. B up to speed, hearing Dr. A's impressions of the patient (including the patient's goals, concerns, fears, values, etc.), as well as any potential concerns Dr. A might have had, also would have been very beneficial. Additionally, the doctors should have had a detailed

discussion about the proposed surgery before the patient was reassigned to Dr. B.[1]

The second area of vulnerability in this case was the informed consent process. In a technical legal sense, one could argue that the informed consent form the patient completed was inadequate because it did not mention ablation of tissue.

More practically, it is essential for providers to clearly communicate to patients the details, expected outcomes, and likely consequences of any irreversible treatment or procedure that is going to be performed. In this case, such communication did not take place.

Although the correct procedure (ablation of the fibroid) would not require any sort of explicit explanation regarding irreversibility, the procedure that Dr. B ultimately performed did involve the loss of reproductive ability.

A catastrophic result might have been avoided if Dr. B had verified with the patient, one last time before she was sedated, that she understood the procedure would result in the loss of her reproductive capability. This may seem like overkill, but the old rule of carpentry is a good one — "Measure twice and cut once."

The last opportunity to prevent this outcome was during the timeout that occurred prior to surgery. Timeouts are well recognized as an effective risk management technique in surgical cases. They provide an opportunity to verify that the surgeon, the operating room staff, and the patient (if he/she is awake and coherent) all agree on which procedure is taking place on which body part — and that any imaging, the H&P, and the informed consent form also reflect this consensus.

Timeouts are very effective in preventing wrong-site surgery (such as the repair of a ligament on the wrong knee), and they also are especially valuable for surgeries that involve excision of tissue.

Although the H&P and the consent form technically did not disagree in this case — the H&P stated "NovaSure," but the consent form did not state "MyoSure" or "NovaSure" — a reasonably careful review of the H&P during the timeout should have indicated to the surgery team that a fibroid was being ablated — and that a NovaSure procedure would not be appropriate.

Also, because an aspect of the timeout is verifying patient agreement, a perfect opportunity was presented to verify that the patient understood the expected outcomes (as discussed above).

1. MedPro has a guideline on handoffs and care transitions, which is available to all insureds. For a copy of the guideline, contact your MedPro Group risk management consultant.

Summary Suggestions

The following suggestions might be beneficial in preventing the performance of an incorrect surgical procedure:

- Handoffs of any sort should be viewed as a high-risk aspect of patient care, especially in terms of communication between providers.
- When a patient's care is transferred within a practice, the transferring provider and receiving provider should have a thorough discussion regarding the patient. Further, the receiving provider should carefully review the patient's record.
- Providers should clearly communicate to patients the details, expected outcomes, and likely consequences of any irreversible treatment or procedure that is going to be performed, preferably more than once.
- The preoperative timeout should include a careful review of the documentation and verification from the patient that he or she understands what is going to be done and any long-term effects.

Conclusion

Although the facts of the case described in this *Risk Management Review* are somewhat unusual, they are by no means unique. Surgical procedures, treatments, and devices that have similar names increase the likelihood of a mix-up, which could result in a wrongful surgery.

Adhering to proven risk management techniques, including those described previously, may minimize the potential for a surgical error and help enhance patient safety.