

Management of a Patient With a Latex Allergy

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Case Summary

A young woman with a history of multiple allergies, including a latex allergy, presented for a colectomy for diverticulitis with ureteral stent placement. After a sign-in and time-out, the urology team performed a cystoscopy and bilateral ureteral stent placement. An 18F Foley catheter was opened onto the sterile field and placed by the urology team. Prior to proceeding with the case, the urology and nursing teams identified that a latex catheter had been inserted.

Consider the Options

One option is to stop the operation and remove the catheter as soon as the error is discovered. This would delay treatment of the patient's diverticulitis and expose her to the risks associated with anesthesia again. However, anaphylaxis may take 30 to 60 minutes to manifest after an exposure¹ and vigilant monitoring is required.

The latex catheter may be replaced with a latex-free one and the operation continued, especially if the surgeon has reliable information that the patient's prior allergic reactions have been mild. However, close monitoring for any reaction is paramount because past reactions may not predict future ones, and mucosal and parenteral exposures to latex may be associated with more severe reactions than cutaneous or respiratory routes.² In this case, the patient has been intubated for the operation, ensuring a secure airway.



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However, in the case of a severe reaction, it would not be possible to continue with the procedure; thus, the surgeons risk having to stop in the middle of an unfinished operation, leaving the patient with an incision and/or dissection but without a definitive procedure.

Event reporting to the proper hospital risk management personnel as well as disclosure to the patient and her family are necessary. Some hospitals have dedicated risk managers while others may not, but there should always be an assigned resource available around the clock. This person can advise on how to communicate the event to the patient. The risk manager can facilitate an analysis of the root cause of a serious adverse event, in collaboration with the relevant medical and nursing leaders. Depending on the level of actual or potential harm, this may be the chief medical officer, chief of staff, surgeon in chief, chairman of surgery, and/or the chief nurse executive (Audio at times 2:10 and 23:40).

In addition, even if a medical error did not result in an undesirable patient outcome, the patient and her family should be informed of the event. Open communication between physician and patients is not only important from ethical, transparency, and quality-of-care standpoints, but it may also help prevent medicolegal issues.³

The urology team realized that the latex catheter had been placed in error. The latex catheter was promptly removed and replaced with a latex-free catheter. However, the patient began to manifest increased peak airway pressures and became hypotensive. Because a subclavian central line had been placed prior to the start of the operation, the airway pressure and blood pressure issues were initially attributed to a ten-

sion pneumothorax. A needle was placed into the chest cavity followed by a chest tube, but no air was returned. There is no definitive test to confirm anaphylaxis, but discussion among the operating team helped to highlight the patient's continued ventilatory issues, hypotension, and exposure to a known allergen. Because this triad is consistent with an anaphylactic reaction, the patient was given diphenhydramine, methylprednisolone, and an epinephrine drip before being transferred to the intensive care unit (ICU) for monitoring (Audio at time 3:08).

Root Cause Analysis

In this organization, a root cause analysis is conducted by having the entire clinical team review the chronology of events, points in the process that failed to operate as intended, and the "why" for each failure. The root cause analysis is led by the chief medical officer and is organized around exploration of systems of care (not individual failures) to support a culture of improvement rather than blame.

The root cause analysis identified several key findings regarding system failure modes. The first and most important was the lack of reliable communication about patient allergies in the operating room (OR). Although the allergy was noted in the patient's chart in the preoperative area, not everyone in the OR was aware of the allergy. A preoperative briefing and time-out were completed per protocol before the urology team began its part of the operation, but the allergy was not mentioned. The allergy record did list latex as an allergen but did not specify the patient's past reactions.

Other issues were identified related to supplies and staff knowledge. This OR was stocked only with latex-containing catheter kits, although organization policy was to also stock latex-free. During the interview, staff could not articulate which products might contain latex. They also tended to minimize the clinical significance of latex sensitivity, perceiving that most allergic reactions were minor and that many patient-reported allergies were not actual allergies.

Correct the Errors

1. **Communication.** The root cause of the failure to communicate the patient's allergy was identified as the lack of any systematic process to include allergies in the preoperative briefing. Effectively communicating this patient's latex allergy to the entire OR team may have helped avert this error.

Best practice for briefing and time-out is to use a systematic checklist and ensure that each item is addressed. The World Health Organization presurgical checklist⁴ is widely used for this purpose, but it must be implemented with fidelity. The checklist calls for identification of allergies during the briefing, which then offers an opportunity to plan for necessary adjustments to supplies. If an allergy is identified during the briefing, the time-out could offer a final opportunity to confirm that there are no latex-containing products in the room since it includes a step for the team to address "anticipated critical events."

It was also noted that the preoperative record documented the allergy incompletely; a complete record should include the allergen, route/type of exposure, and the patient's reaction (Audio at times

0:40 and 21:26). This was classified as an *incidental finding* rather than a root cause; however, such an omission could cause harm, so this process was flagged for improvement.

Corrective Action. The hospital clarified the OR communication safety process to ensure that allergies are verified and documented in the preoperative area, that they are communicated through a codified handoff process from preoperative to OR, and that there is consistent attention to the checklist during the briefing, including patient allergy information. The electronic medical record was engineered to prompt for allergies; communication occurred through SBAR (situation/background/assessment/recommendations); and a check during briefing along with training and monitoring were implemented to confirm these processes were followed.

2. **Equipment Management.** Effective equipment management may help improve error-prone processes. The lack of ready access to latex-free catheters in the OR may have contributed to the error in this case. In response, the hospital evaluated the clinical and cost issues associated with creating a latex-safe OR environment. It was decided that nonlatex catheters would not be appropriate for all patients, but that all rooms should have them available. This was the policy already in place, and a separate investigation was conducted to determine how the supply stocking process overlooked this room.

Corrective Action. The supply chain team had not managed and monitored supply stocking adequately, and a separate improvement effort was applied to improve reliability of stocking catheters, vinyl nitrile (nonlatex) surgical gloves, and other supply items (Audio at times 0:40 and 10:43).

3. **Education.** The root cause analysis also uncovered a general lack of awareness of latex allergy prevalence and proper prevention strategies. There was a widespread lack of knowledge as to which products contain latex, and there are no national standards regarding the labeling of latex products.

The root cause analysis team discovered that many OR staff perceived latex allergies and severe reactions as rare. Many staff cited examples in which a patient was identified belatedly as latex-allergic but had not experienced an adverse reaction. These experiences may not be unusual given the wide range of allergic reactions from a latex exposure. In addition, patients may report a latex allergy even when not formally evaluated for one. Physician awareness of patient populations (as well as health care workers) at high risk for latex allergies⁵ may also aid in elevating staff vigilance as appropriate.

Bottom Line

1. Allergies may be severe. Detailed information about past exposures and reactions should be obtained from patients and documented by all relevant clinicians.
2. A checklist may be a valuable resource to reduce error, especially when a patient is transitioning between care areas.
3. Physicians play a key role in establishing a culture of safety that encourages all staff to "speak up" and to participate in care planning and implementation.
4. Minimizing process errors often requires addressing equipment management and availability.

This lack of awareness could have contributed to the mistaken impression that a latex allergy was not a vital detail in patient care processes. In addition, once the error was discovered but before the patient began to manifest symptoms of anaphylaxis, there was lack of clarity among the OR team regarding management of an allergic response.

Corrective Action. The OR staff received additional training regarding latex allergy prevalence, allergic reactions, and prevention strategies. A senior faculty member in allergy/immunology created a summary of prevention and response guidelines for similar situations. Staff were trained on the guidelines, which were posted in the on-line policy manual.

Outcome

The patient was transferred to the ICU and stabilized. During the same hospitalization, she was able to undergo her original planned procedure without any reported surgical or anesthetic complications. Patient allergy information is now communicated from the preoperative holding areas to the OR staff via the OR charge nurse and is addressed during the briefing and time-out. Latex-free catheter kits are available in all ORs and latex-safe ORs are being implemented. Staff education regarding latex allergies and proper response protocols have been enhanced. No similar events have occurred in the OR.

Audio and CME

Listen to the accompanying audio program for more information about managing patient allergies. In some instances, the answers to CME questions are in the audio and not the text of the article (Audio at time 15:19). Take the quiz at <http://jamanetwork.com/cme.aspx>.

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