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Latex: A Lingering and Lurking Safety Risk

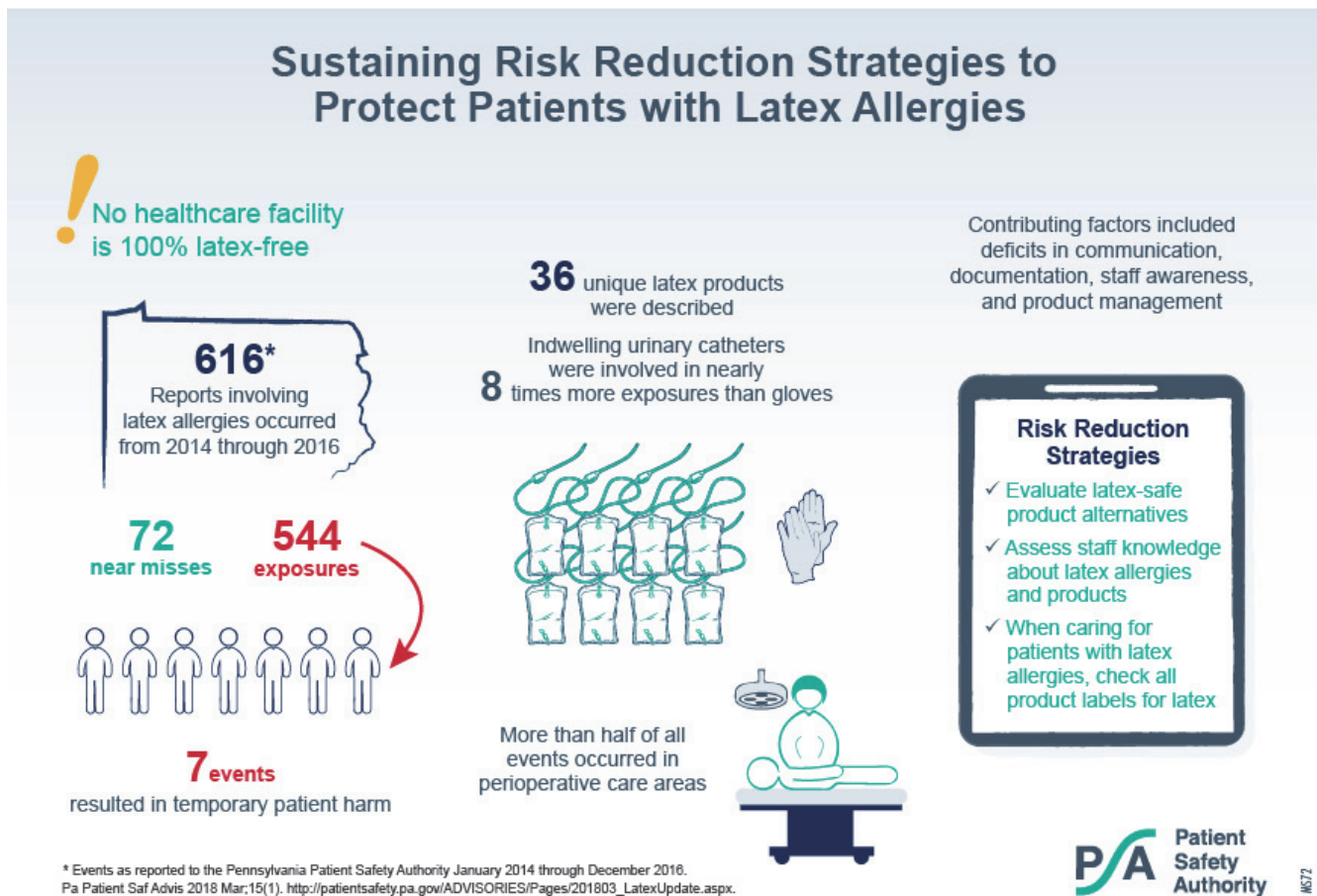
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Abstract



After the topic of latex allergies surfaced in the 1980s, awareness grew and risk reduction strategies were created; however, a review of events reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) questions the persistence of latex exposure protections. Pennsylvania healthcare facilities reported 616 latex-related events through PA-PSRS that occurred from 2014 through 2016, including 72 near miss events. Analysis revealed that latex indwelling urinary catheters were the most common source of inadvertent exposure in patients with documented latex allergies (75.0%, n = 408 of 544). The perioperative care area accounted for the highest number of

both exposures and near misses (57.1%, n = 352 of 616). Event narratives highlight contributing factors such as deficits in communication, documentation, supply management, and staff awareness. Strategies to address these contributing factors may include screening, thoughtful handoffs, evaluation of product alternatives, assessment of staff awareness, and observation of practice patterns.

Introduction

The journey to reduce the incidence of latex allergies exemplifies interdisciplinary collaboration among researchers, healthcare workers, manufacturers, and government agencies.^{1,2} Latex gloves have been the focus of much of the literature on latex allergies because of their pivotal role in the latex allergy epidemic. The increased demand for latex gloves after implementation of universal precautions in the late 1980s coincided with the rise in reported latex allergies.³⁻⁵ Factors contributing to increased latex sensitization during this time period have been studied extensively and include greater use of gloves, higher allergen content in gloves due to changes in manufacturing processes, and conversion from cornstarch to talc donning powder.²⁻⁶ Risk reduction strategies have focused on reducing latex sensitization as well as ensuring the safety of individuals affected by latex allergies.^{2,6,7}

For patients and healthcare workers with latex allergies, the potential causes of a life-threatening reaction extend well beyond gloves. An estimated 40,000 household and industrial products used every day contain latex.⁸ Maintaining a latex-safe healthcare environment is challenging and may become even more so as the affected population grows smaller—due to the success of efforts to decrease sensitization—and there is greater risk of staff being unfamiliar with the issue or overlooking it.

To evaluate the current state of latex events in healthcare, Pennsylvania Patient Safety Authority analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database. As governed by the Medical Care Availability and Reduction of Error (MCARE) Act of 2002 and Act 30 of 2006, a total of 571 acute-care facilities, including hospitals, ambulatory surgery facilities, birthing centers, and abortion facilities, reported through PA-PSRS as of December 31, 2016.^{9,10}

The following analysis evaluates safeguards and risks in the care of patients identified as having a latex allergy in reports submitted through PA-PSRS.

Methods

Analysts identified reports involving latex allergies by querying PA-PSRS for reports of events that occurred from January 1, 2014, through December 31, 2016, containing the keywords "latex" or "rubber."

Analysts manually reviewed all reports and categorized them as exposures, near misses, or exclusions. Breaches in latex precautions that reached the patient were categorized as exposures (i.e., use of a latex product in the care of a patient with a documented latex allergy). Unsafe circumstances that if undetected could have led to an exposure were categorized as near misses. All events containing the keyword "rubber" but not "latex" were excluded. Additional events were excluded based on the following criteria: unrelated to the topic, new or suspected latex allergy, and allergic reaction described in the context of multiple potential allergens.

Exposure events were categorized according to the specific latex product. Events involving exposure to multiple latex products were counted more than once in the product analysis. Taking a Safety-II view, analysts categorized near misses by the success modes that prevented potential exposures.¹¹ Events describing multiple success modes were counted more than once in the success modes analysis. The reported care areas for both exposure and near miss events were grouped into categories of like units and departments.

Analysts conducted a review of the literature to ascertain the history of the latex allergy epidemic, physiological and clinical background on latex allergies, and risk reduction strategies.

Results

The query identified 1,051 reports, of which 435 were excluded, 544 were categorized as exposure events, and 72 were categorized as near miss events.

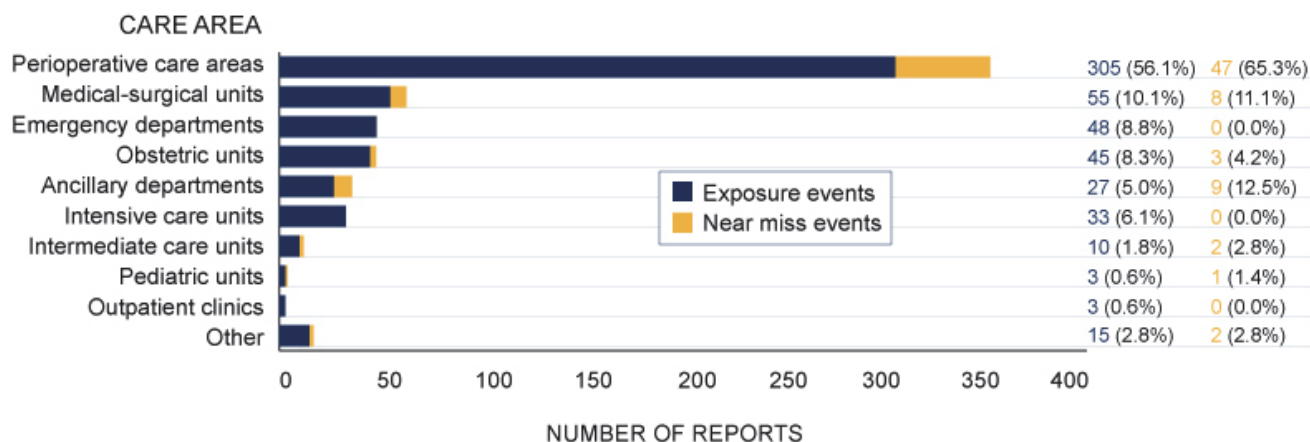
Exposure Events

Harm Score and Care Area

The majority of exposure events (98.7%, n = 537 of 544) were reported as Incidents (i.e., an event that could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services).¹² Seven events were reported as Serious Events, all with a harm score of E (i.e., an event that occurred that contributed to or resulted in temporary harm and required treatment or intervention).¹³ The reactions described in these seven serious events include rash, itching, hives, burning sensation, throat tightness, and hypotension. Medication administration was the most common treatment, and interventions included surgical site irrigation and a return visit to the emergency department after discharge.

More than half of latex exposure events occurred in perioperative care areas, followed by medical-surgical units, and emergency departments (Figure 1).

Figure 1. Latex Exposure Events and Near Miss* Events by Care Area (N = 616)



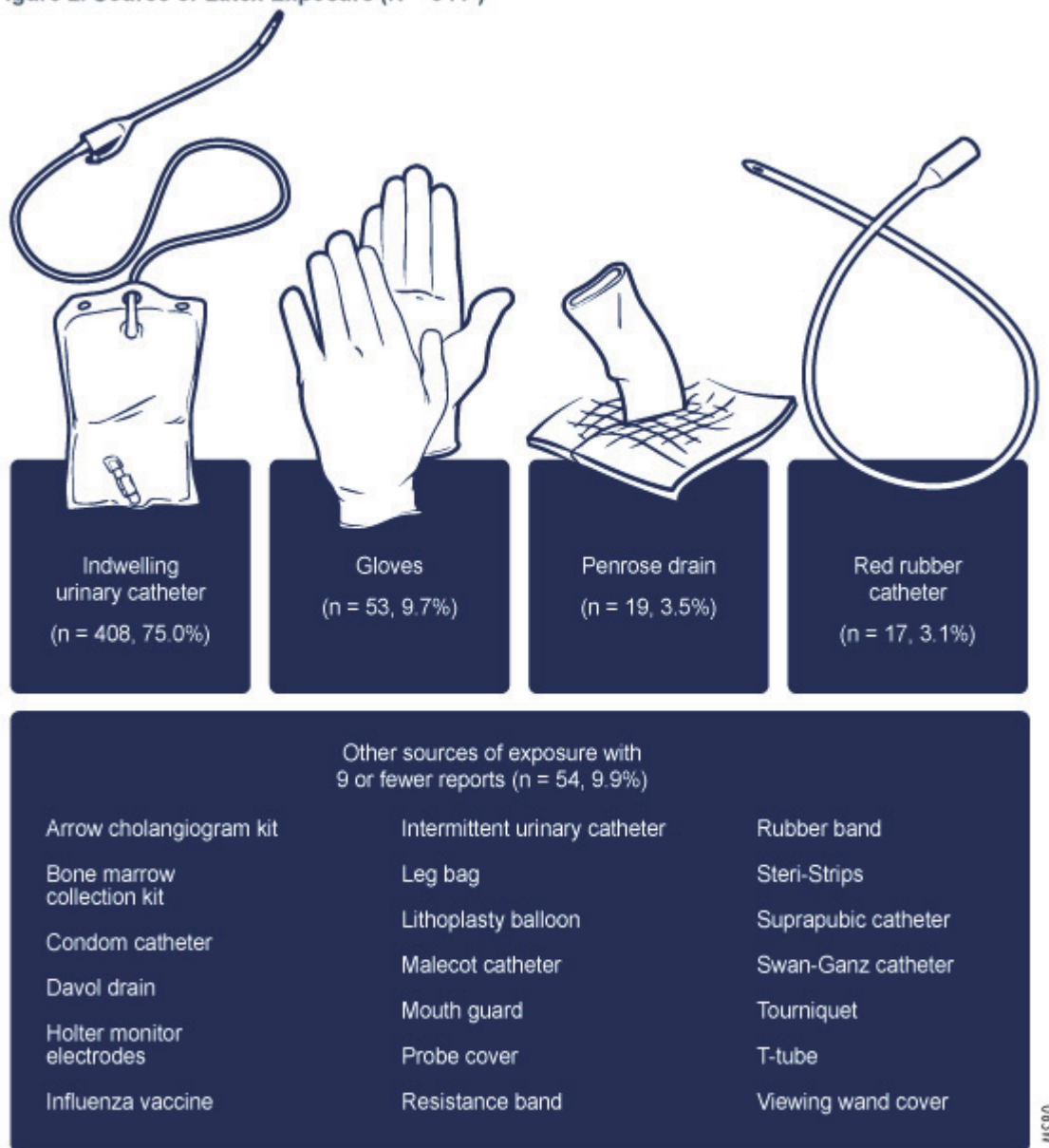
* Breaches in latex precautions that reached the patient were categorized as latex exposure events. Unsafe circumstances that if undetected could have led to an exposure were categorized as near misses.
 Note: As reported to the Pennsylvania Patient Safety Authority, January 2014 through December 2016.

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Product Type

Thirty-six unique medical products were described in the 544 exposure events. Seven reports described exposure to multiple latex products. Indwelling urinary catheters were the most common source of latex exposure described in event narratives, followed by gloves, Penrose drains, and red rubber catheters (Figure 2). Red rubber catheters were used as tourniquets during surgery, intermittent urinary catheters, and feeding tubes.

Figure 2. Source of Latex Exposure (N = 544*)



* These sources of latex exposure total more than the 544 exposure events because some reports described more than one source of latex exposure.

Note: As reported to the Pennsylvania Patient Safety Authority, January 2014 through December 2016.

In the seven Serious Event reports, indwelling urinary catheters were the most common source of exposure (n = 4 of 7), followed by intermittent urinary catheter (n = 1), gloves (n = 1), and Swan-Ganz catheter (n = 1).

Near Miss Events

Care Area

As with exposure events, more than half of the near miss events occurred in perioperative care areas, followed by ancillary departments such as endoscopy and pharmacy, and medical-surgical units (Figure 1).

Success Modes

Event narratives included a variety of success modes that prevented patient exposures (Figure 3). The top three success modes were staff recognition that the patient had no latex allergy wristband, staff identification of the allergy during a preoperative interview, and staff recognition that a latex allergy was undocumented. Sources of missing allergy documentation included the operating room schedule and both paper and electronic health records. After discovery of a latex allergy, 14 events described subsequent operating room teardowns and six described case cancellations in ambulatory surgery facilities.

Figure 3. Success Modes Analysis for Latex Exposure Near Misses (N = 72*)



* These success modes total more than the 72 near miss events because some reports described more than one success mode.

Note: As reported to the Pennsylvania Patient Safety Authority, January 2014 through December 2016.

Themes from Event Narratives

An example of an event report involving insufficient communication with patients is as follows:*

Patient did not specify latex allergy when asked if allergic to anything.

Examples of event reports involving insufficient communication between members of the care team are as follows:

Tech came in to give a break and opened a pair of latex gloves on the sterile field.

Patient's latex allergy not noted until "time out" performed. Operating room set up using latex gloves. Staff had already touched patient wearing latex gloves.

Examples of event reports involving imperfect documentation are as follows:

Patient had latex bracelet on and sticker on chart. Allergy not documented on chart or Anesthesia history and physical.

Latex allergy not noted on schedule. Operating room setup non-latex free. Instruments touched with sterile latex gloves. Needed more

than 1 hour to resterilize instruments.

Examples of event reports involving ineffective product management are as follows:

Nurse inadvertently reached for latex foley instead of latex-free alternative.

Cabinet where latex gloves are kept was not taped shut.

An example of an event report involving limited staff knowledge is as follows:

Resident states that he thought all our foleys were latex-free and had discussed this with another resident prior to inserting the foley.

* The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

Discussion

Review of events reported through PA-PSRS indicates that latex exposures and near misses continue to occur, and latex indwelling urinary catheters are involved in 75% of inadvertent exposures in patients with documented latex allergies. Exposure and near miss data suggests that the perioperative care area is a high risk location as well as a strong safety checkpoint.

Lingering and Lurking Risks

Latex indwelling urinary catheters accounted for 7.7 times more exposures than latex gloves in the events reported through PA-PSRS. Latex products that come in contact with mucous membranes (e.g., urinary catheters) cause more severe reactions than those that contact the skin (e.g., gloves),⁸ which makes the predominance of reports involving indwelling urinary catheters even more concerning. The relatively small number of exposures involving latex gloves aligns with several decades' worth of work to improve the safety and use of gloves made from synthetic alternatives.^{2,14} The risk posed by latex indwelling urinary catheters is not new; reports of anaphylactic reactions to latex indwelling urinary catheters date to the early 1990s.¹⁵ This analysis indicates that in the journey to making healthcare safer for individuals with latex allergies, further study of the safety and use of latex indwelling urinary catheters may be a natural next step.

In this analysis, the majority of latex-related events occurred in the perioperative care area. The quantity and proximity of supplies in this area make it a particularly risky setting for latex allergic patients.³ Latex has been identified as the second leading cause of anaphylaxis during anesthesia, following neuromuscular blocking agents and just slightly more frequent than antibiotics.¹⁶ Success modes analysis demonstrates many risk mitigation activities in the perioperative care area, including identifying patients with latex allergies, identifying latex products already in use, removing latex products from the care area, and reconciling missing safety alerts, such as wristbands. These activities demonstrate the crucial role that all perioperative team members—including surgeons, anesthesiologists, and nurses—play in screening for latex allergies, monitoring environmental safety, and ensuring these risks are communicated to the entire care team.^{3,17,18}

Reactions to latex fall into three categories: irritant contact dermatitis, allergic contact dermatitis, and immediate hypersensitivity.^{5,19} The most common reaction, irritant contact dermatitis, manifests as dry, cracked skin typically on the hands and is not considered a true allergy.^{5,19} Allergic contact dermatitis resembles poison ivy lesions and develops from an allergic reaction to the chemicals used in latex manufacturing.^{5,19} Immediate hypersensitivity is an allergic reaction to proteins in natural rubber latex and can range from mild skin redness hours after exposure to

anaphylaxis within minutes.^{5,19} Although the majority of exposure events in PA-PSRS did not describe the patient having a reaction after the latex product was discontinued, seven serious events did describe reactions resembling that of immediate hypersensitivities.

Contributing Factors and Success Modes

Handoffs

Prevention of latex exposures begins with having knowledge of the patient's allergy and sharing this information with the healthcare team. According to the Joint Commission, "an estimated 80% of serious medical errors involve miscommunication between caregivers during the transfer of patients."²⁰ Described by Anthony and Preuss as "funneling," degradation of information over time sets the stage for adverse events to occur.²¹ In an increasingly electronic world, the assumption that documentation in the electronic health record (EHR) constitutes communication may affect what information is included in handoffs.²² Omission of latex allergy information during patient handoffs was a recurring theme in event report narratives. Receiving providers in turn discovered latex allergies through safety checks including paying attention to information provided by wristband, chart sticker, paper and electronic records, door sign, and preoperative interview.

Preprocedure Patient Assessment

Clinical practice guidelines for procedures such as urinary catheterization and phlebotomy include assessment of patient allergies as a step for safe practice. Event report narratives describe deviance from such guidelines. Possible explanations for such deviations include mental slips, distractions, normalized deviance, assumptions about product safety, production pressure, cumbersome EHR workflows, or accessing the EHR only after task performance.²³ Interventions such as wristbands, door signs, and chart stickers provide visual safety alerts at the point of care. Success modes analysis demonstrates variable compliance but heavy reliance on such visual reminders.

Asking About Allergies

The way in which patients are asked about their allergy history can affect the completeness of the information received. In a study by Al-Niaimi et al., only 33% of 156 surveyed healthcare workers at a large teaching hospital reported routinely checking for a latex allergy when asking patients about allergies.²⁴ Bismil et al. evaluated the difference in 367 orthopedic patients' responses when asked the general question "do you have any allergies?" versus a follow-up question specifically asking about an allergy to latex, iodine, or elastoplast.²⁵ Of the 42 patients with documented allergies to at least one of these allergens, 38% did not report their allergy when asked the general question and 100% reported their allergy when asked the specific question.²⁵ PA-PSRS event narratives describe providers discovering latex allergies only after circling back to explicitly ask patients about an allergy to latex. In the perioperative care area, such late discoveries resulted in operating room teardowns, instrument reprocessing, delayed starts, and cancelled cases. Explicitly asking about an allergy to latex is one way to prevent such delays in care and operational inefficiencies.

Staff perceptions of reported versus actual allergies can affect patient safety. In a root cause analysis involving management of a patient with a latex allergy, Minami et al. identified a staff perception that "most allergic reactions were minor and that many patient-reported allergies were not actual allergies."²⁶ Discounting patient reports of latex reactions overlooks the cumulative risks associated with repeated latex exposures as well as the possibility of subsequent exposures causing more severe reactions.^{5,19}

Product Identification

Beyond knowledge of a patient's allergy, preventing latex exposures requires application of this information when caring for the patient. The notion that hospitals or medical products are "latex-free" is a common misperception. Reliable methods do not currently exist to test products for the allergens that induce latex allergies or to ensure that

products remain free of contamination after manufacturing.²⁷ In 2014, the Food and Drug Administration (FDA) issued guidance recommending that products be labeled as "not made with natural rubber latex."²⁷ Given the quantity, variety, and transitory nature of products in healthcare organizations, reading product labels is the most fundamental yet essential way to protect against accidental exposures.^{28,29}

Limitations

A limitation of this analysis is that harm score and event location are provided by the report submitter. Information about the source of latex exposure and the patient's allergy status also is provided by the report submitter. As with all reporting systems, the type and number of reports collected depend on the degree to which facility reporting is accurate and complete.

Risk Reduction Strategies

The following strategies come from the success modes of near miss event reports and from the literature.

Communication and Documentation

- Establish a latex consultation service to help evaluate and manage latex allergic patients.^{3,30}
- Create an EHR latex allergy alert for indwelling and intermittent urinary catheter orders and an order that specifies to use a latex-safe alternative catheter.
- Inform latex allergic patients and families of your organization's efforts to reduce latex exposure risk and engage them as partners in monitoring the environment and reminding all members of the care team about their allergy.^{4,31}
- Use latex precaution signs as visual reminders and an additional interdisciplinary communication tool. Consider placement on patient doorways, the inside and outside of operating room doors, above the head of the patient's bed, and on the anesthesia station in the operating room.^{7,28,29,32,33}
- Evaluate compliance with visual safety alerts, such as wristbands, signs, and chart stickers or bands. Consider packaging these alerts in a single bag for easier access and application.
- As patients travel throughout the organization, ensure that receiving departments are notified in advance of latex allergic patients to allow time for adequate preparation.^{3,7,28}
- Use patient handoff tools that include communication about patient allergies.^{26,34}
- Use latex-safe alternative gloves to set up the operating room until the patient is brought into the room and the patient's allergy status has been confirmed.²²
- Incorporate a question asking explicitly about latex allergies into preoperative communication, including operating room scheduling forms, nursing-driven preoperative telephone calls, preoperative assessments, preoperative interviews, and preoperative checklists.^{3,17,18,28}
- Include allergies in the preoperative time-out and consider using a checklist such as the one from the [World Health Organization \(http://www.who.int/patientsafety/safesurgery/ss_checklist/en/\)](http://www.who.int/patientsafety/safesurgery/ss_checklist/en/).^{26,35}

Knowledge and Awareness

- Assess healthcare workers' knowledge and practices surrounding latex allergy screening, product labeling, and safety precautions when caring for patients with latex allergies; tailor educational interventions accordingly.^{4,5,24,26}
- When caring for latex allergic patients, check all product labels for latex and ask questions if labeling is unclear.^{28,29}
- Implement a latex allergy annual competency.³³
- Observe indwelling and intermittent urinary catheterization procedures for compliance with checking for a latex allergy prior to beginning the procedure.
- Review incident reports involving latex from the past 12 months to identify trends and opportunities.⁴

Product Management

- Identify and replace as many products as possible with suitable latex-safe alternatives.^{17,28,31,33}
- Evaluate all new product proposals for latex content.²⁸
- Establish a process for reviewing the latex content of all product substitutions sent by vendors and alerting frontline staff of any new products containing latex.
- Use signage in product storage areas to draw attention to products that are stocked as both latex and latex-safe alternatives.²²
- Leverage the bar code technology used for perioperative supply charges to link product information with patient allergy alerts.³⁶
- Make latex-safe supply carts available to all patient care areas.^{3,7,29,30} Establish a process to ensure carts are stocked and checked regularly.
- Ensure powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's gloves are no longer stocked or in circulation at your facility.³⁷

Conclusion

Despite the decreasing incidence of latex allergies, the potential for significant patient harm remains. Evaluation of product safety should go beyond latex gloves; based on PA-PSRS event reports, organizations may benefit from focusing on indwelling urinary catheters and procedures in perioperative care areas.

Notes

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