Latex or Synthetic Gloves? Risk Reduction Strategies
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Objectives

• Discuss the role of latex gloves in Natural Rubber Latex (NRL) allergy
• Identify the prevalence and risks of acquiring a latex allergy
• Differentiate 3 common types of latex reactions
• Discuss management strategies for common types of latex reactions
• Describe issues associated with latex gloves and glove powder
• Review the properties of selecting appropriate gloves
• Discuss risk reduction trend moving toward synthetic products
OVERVIEW OF LATEX ALLERGY
Natural Rubber Latex Allergy

- Natural Latex Rubber (NRL) allergy is a significant medical concern affecting healthcare workers as well as general population\textsuperscript{1,2}
  - No distinction in race or gender
  - Can arise at any point of life
- An acquired allergy\textsuperscript{2}
- There is no cure or vaccine, only prevention\textsuperscript{1,2}
  - Prevention by avoiding latex and prudent selection of barrier protection are the interventions of choice

Role of Latex Gloves in Latex Allergy

- Latex has been the “Gold Standard” in glove material\(^1\)
- Powdered latex gloves are the largest single contributor to latex aeroallergen levels in a healthcare facility\(^1,2\)

20 Fold Increase in Medical Glove Use\(^1,3,4\)

<table>
<thead>
<tr>
<th>Year</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1987</td>
<td>$800 million</td>
</tr>
<tr>
<td>2012</td>
<td>$22 billion</td>
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</tbody>
</table>

Latex Sensitivity vs. Latex Allergy

Allergy
- Demonstrated outward expression of the disease\(^1,2\)
- Positive skin prick test
- Local or systemic reactions can occur

Sensitivity
- Development of an immunologic memory (IgE) to specific proteins\(^1,2\)
- May or may not show symptoms
- The latency period ranges from several weeks to as long as 30 yrs\(^3\)

\(~1-2\%\) of Americans have latex allergy (up to 6 million Americans)\(^4\)

20\% of American adults (1 out of 5) are sensitive to latex\(^5\)

References:
2. OSHA. Potential for Sensitization and Possible Allergic Reaction To Natural Rubber Latex Gloves and other Natural Rubber Products. 2008.
Patients at Increased Risk\textsuperscript{1,2}

- Spina bifida and congenital urogenital abnormalities have the highest prevalence of latex allergy (up to 75% for spina bifida)
  - Multiple surgeries and procedures during infancy/childhood
  - Genetic predisposition (spina bifida)

- Patients with early or frequent mucosal contact

- Atopic individuals
  - Those individuals with known food allergies

- Multiple surgeries or latex exposed procedures

- Cerebral palsy, mental retardation, quadriplegia

2. 2015 AORN. Recommended Practices for a Safe Environment of Care. 239-263.
• 5.1% prevalence in pregnant women undergoing cesarean section deliveries¹
  – Number of Cesarean² deliveries: 1,293,267
  – Percent of all deliveries by Cesarean²: 32.8%

Latex Allergy in Labor and Delivery

• 3x higher than nulliparous women undergoing gynecologic surgery\textsuperscript{1}

• Possible risk factors\textsuperscript{1,2}
  – Women (70% higher risk than men)
  – Hormonal changes
  – Immunomodulation
  – Multiple exposures to latex during prenatal care
  – Contact with highly absorbable vaginal mucosa
  – Oxytocin

Latex Allergy in Patient with Food Allergies

Approximately 30-50% of latex allergic patients have hypersensitivity to particular plant-derived foods\textsuperscript{1}

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<thead>
<tr>
<th>Fruits\textsuperscript{2,3}</th>
<th>Vegetables\textsuperscript{2,3}</th>
<th>Plants/Nuts/Other\textsuperscript{2,3}</th>
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</thead>
<tbody>
<tr>
<td>Melons</td>
<td>Tomato</td>
<td>Peanut</td>
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<tr>
<td>Apple</td>
<td>Papaya</td>
<td>Chestnut</td>
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<tr>
<td>Cherry</td>
<td>Kiwi</td>
<td>Walnut</td>
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<td>Coconut</td>
<td>Mango</td>
<td>Hazelnut</td>
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<tr>
<td>Apricot</td>
<td>Passion Fruit</td>
<td>Soybean</td>
</tr>
<tr>
<td>Strawberry</td>
<td>Plum</td>
<td>Chick Pea</td>
</tr>
<tr>
<td>Loquat</td>
<td>Nectarine Peach</td>
<td>Castor Bean</td>
</tr>
<tr>
<td>Pear</td>
<td>Melons</td>
<td>Sunflower Seed</td>
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<td></td>
<td>Pear</td>
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</tbody>
</table>

\textsuperscript{1} AORN recommends questioning about latex reactivity & skin/serologic testing should be considered in these patients\textsuperscript{4}

Other Patient Types to Consider

- Cancer/chemotherapy patients
- Asthma patients
- Transplant patients/organs
- Unconscious patient arriving in E.R.
Latex Allergy Among Healthcare Workers

Healthcare Worker Risk

- Prevalence between 2-17%\(^1\)
  - With atopy: 24%\(^2\)
  - O.R. personnel: 33.5%\(^3\)

- Number of years worked in healthcare setting and wearing gloves >1 hour increases risk of acquiring latex allergy\(^4,5\)

- 1 out of 50 healthcare workers become sensitized each year from latex gloves\(^6\)

- 70% of all reported adverse events from latex allergies are from healthcare workers\(^6\)

References:
• Increase in glove usage in non-traditional areas\textsuperscript{1}

• Increase use and wear time of latex gloves in traditional users\textsuperscript{1,2}

• Products high in residual extractable allergens\textsuperscript{1,2}
  
  – Increase in number of manufacturers and poorly regulated factories\textsuperscript{2,3}

LATEX ROLE IN ALLERGIC REACTIONS
What is Latex?

- A milky liquid natural substance from rubber trees\(^1\)
  - Mainly consists of a polymer providing strength & elasticity\(^1\)
  - Also contains sugars, lipids, nucleic acids, and highly allergenic proteins

- 40,000 different household products with latex\(^2\)
- 17,600 medical devices with latex
  - Gloves, airways, intravenous tubing, syringes, stethoscopes, catheters, dressings and bandages\(^2-4\)

Routes of Latex Exposure

- Skin absorption
- Inhalation
- Ingestion
- Mucosal absorption
- Intravenous

**Latex Products Labeling**

Caution: This product contains natural rubber latex which may cause allergic reactions. The packaging of this product contains natural rubber latex which may cause allergy reactions.

*only a requirement for medical products (and their packaging)*

**Low-Protein Claim**

This product contains 50 micrograms or less of total water extractable protein per gram of latex by Modified Lowry.

Caution: Safe use of these gloves by latex sensitized individuals has not been established.

**Powdered Gloves**

Warning: Powdered gloves may lead to foreign body reactions and the formation of granulomas in patients. In addition, the powder used on gloves may contribute to the development of irritant dermatitis and Type IV allergy, and on latex gloves may serve as a carrier for airborne natural latex leading to sensitization of glove users.

There are three words that are commonly used to describe non-latex products:

1. LATEX-FREE

2. NON-LATEX

3. SYNTHETIC
LATEX ALLERGY REACTIONS
# Types of Reactions to Latex Products

## Most common

<table>
<thead>
<tr>
<th></th>
<th>Irritant Contact Dermatitis&lt;sup&gt;1,2&lt;/sup&gt;</th>
<th>Allergic Contact Dermatitis&lt;sup&gt;1,2&lt;/sup&gt;</th>
<th>Immediate Reaction Hypersensitivity&lt;sup&gt;1,2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cause</strong></td>
<td>Mechanical or thermal injury</td>
<td>Chemical exposure</td>
<td>Exposure to latex proteins on glove surface or bound to powder in air or on objects</td>
</tr>
<tr>
<td><strong>Onset</strong></td>
<td>Gradual over days or weeks</td>
<td>Rash begins 6 to 48 hours</td>
<td>Within minutes or up to 2 hours later</td>
</tr>
<tr>
<td><strong>Symptoms</strong></td>
<td>Scaling, drying, cracking of skin</td>
<td>Red, raised, palpable area with bumps, sores, cracks</td>
<td>Mild: skin redness, hives, itching Severe: facial swelling, urticaria, respiratory distress</td>
</tr>
</tbody>
</table>

Consequences of Latex Allergy

• Anaphylaxis
  – Latex is the 2nd leading cause of anaphylaxis in the O.R.\textsuperscript{1,2}
  – Up to 6% of anaphylactic episodes end in death\textsuperscript{2}
  – Half of all latex related allergic reactions occur during OB/GYN procedures\textsuperscript{3}

• Occupational asthma due to aerosolized latex\textsuperscript{4}
  – 5% increase in risk of developing asthma for each cumulative year of exposure to latex within workplace

• Risk of acquiring other antigen sensitivities\textsuperscript{5}

Impact of Latex Allergy

• Career path\textsuperscript{1-4}
  • May avoid certain positions within the operating room due to allergy
  • 45% of healthcare workers changed jobs directly as a result of latex allergy
  • Study shows healthcare workers who changed jobs experienced a 24% reduction in salary

• Lifestyle adjustments\textsuperscript{1}
  • Impacts the use of many household items and workplace devices

• Avoiding medical care\textsuperscript{1}
  • Seeking timely medical care due to justified fear of latex exposure

POWDER GLOVES & LATEX ALLERGY
Glove Powder Serves as a Vector

- Latex protein binds to starch glove powder
- Powder can settle on instruments, equipment, clothing, patient tissue

Aerosolized latex bound to powder became a leading cause of occupational asthma among health care workers. The prevalence of latex protein-induced occupational asthma is estimated to be 2.5 - 6% in healthcare workers.

“Patients with confirmed sensitizer-induced occupational asthma should have no further exposure to the causative agent, since the best outcome is achieved with early diagnosis and complete avoidance of exposure.”
Starch glove powder on surgical gloves can, and will, at times, trigger

- Foreign body reaction\textsuperscript{1}
- Adhesion formation\textsuperscript{1,2}
- Granuloma formation\textsuperscript{1,2}
- Reduced resistance to infection\textsuperscript{1}
- Delayed wound healing\textsuperscript{1}

Movement Away from Glove Powder

- Market is moving towards powder-free $^{1,2}$
  - In October 2016, 90% of surgical glove sales were powder-free $^{3}$
- Reduction in use has been documented to reduce risk for developing latex allergy $^{2}$
- FDA posted final rule to ban powdered surgeon’s and patient examination gloves, and absorbable powder for lubricating a surgeon’s glove.
  - Powdered gloves present an unreasonable and substantial risk of illness or injury
  - The risk cannot be corrected or eliminated by labeling or a change in labeling

MANAGEMENT & PREVENTION STRATEGIES
Risk Reduction of Latex Allergy

AORN Guidelines

- Prevent complications in current latex allergic or sensitized individuals
- Prevent the development of latex allergy or sensitization

“The only effective preventative strategy at this time is latex avoidance” - AORN

Educational Needs Among Healthcare Workers

- Nearly 3 out of 4 healthcare workers were unable to recognize the presentation of a Type I latex allergy
- 84% considered that they would benefit from training about latex allergy and the use of different types of gloves in clinical care

Only 25% of healthcare workers checked patients for latex allergy

Managing Latex-Sensitive Patients

Preparation in caring for known latex allergy patients are costly and labor intensive\(^1\),\(^2\)

- Flag Patient
- Synthetic powder-free gloves
- Hand washing
- Removal of latex products from environment
- Notify departments they will visit in advance
- Latex – safe procedure room
- If non, first case of the day
- Bypass potential areas of risk such as preoperative holding, waiting areas, etc.

Managing Latex Allergy in Healthcare Workers

- Avoidance of latex in the workplace reduces both symptoms and markers of sensitization in latex-allergic individuals.
- 90% of latex allergic healthcare workers reported resolution of work-related symptoms once switched to synthetic gloves (skin, respiratory, and systemic symptoms resolved).
- 88% who had positive latex serological test showed a reduction in serum levels of specific IgE after 15 months of latex avoidance.

Latex Allergy Guidelines\(^1\)-\(^3\)

- Latex allergy program
- Latex allergy task force
- Policies/Protocols
  - A latex-safe environment should be mandatory for all latex-sensitized patients
- Consultation services
- Review of glove usage
- Latex product list
- Latex safe environment
- Identify high-risk patients
- Patient testing

Asking “Do You Have a Latex Allergy?” Is Not Enough

Many patients are not aware they have or are at risk of having a latex allergy

When Policies & Procedures Aren’t Followed

$4.7M awarded for wrongful death of a patient who experienced anaphylactic shock to latex

- Immediate reaction soon after anesthesia
- Hospital failed to identify latex allergy and take appropriate precautions
- Patient’s history form was not addressed
  - Allergy to chestnuts

RISK ASSESSMENT AND REDUCTION
Latex Allergies Can Have Profound Impact on Hospital Resources

- Treating anaphylactic episode
- Workers compensation
- O.R. teardown
- Idle O.R. time
- Time for staff to prepare a latex-safe environment
- Work productivity
### Example of Losses Due to O.R. Teardowns*

<table>
<thead>
<tr>
<th></th>
<th>Estimated Costs</th>
<th>Yearly Estimated Total (1 per week x 52 weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contaminated disposables</td>
<td>$300</td>
<td>$15,600</td>
</tr>
<tr>
<td>(Specialty packs not included)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Idle O.R. Costs</td>
<td>$1,560 per hour</td>
<td>$81,120</td>
</tr>
<tr>
<td>Resterilization of Reusable items</td>
<td>&gt;30 minutes</td>
<td>26 hours</td>
</tr>
</tbody>
</table>

**Total**                                                           | **$96,720**          |

*This data is from one hospital’s estimated losses due to O.R. teardowns

APPROPRIATE GLOVE SELECTION
Selecting the Appropriate Glove

- Synthetic vs. latex
- Barrier protection
- Durability
- Tactile
- Cost

- Antigenic protein level
- Pyrogenicity
- Easy to don
- Powder-free
- Chemicals utilized

- Total protein level

• Failure rate of surgical gloves can vary by brand and manufacturer

• Impact of in-use failure
  – Increase risk of exposure to pathogens
  – Cost and time needed to replace gloves

Definition of an In-Use Failure

Can You Define In-Use Failure?

A cessation of proper functioning

A decline in strength or effectiveness

Nonperformance of what is expected

Webster/Free Dictionary
Risks and Challenges of Surgical Glove Failures

- Prevention from pathogen transmission
  - To the patient from staff
  - To the staff from patients

- Wound Classification
  - Clean to clean contaminated

- Role of the Wearer
  - Surgeons, Chief Residents

- Wearer Preference
  - Previous mentor

- Surgical Instrumentation
  - Needles, scalpels, retractors

- Length of surgery
  - > 60 minutes 10%

- Hand Dominance
  - Non-dominate hand, thumb, index finger

- Surgical Procedures
  - Ortho, GYN, GI/General, Thoracic
    - Fractures, wiring

References:
The FDA recommends manufacturers use the labeling statement – “not made with natural rubber latex” – to indicate when latex was not used as a material in the medical product or product container.
Increase in Utilization of Non-latex (Synthetic) Gloves
(% PF Latex usage in volume)

SYTHETIC GLOVES\(^1\) (2014)

SYTHETIC GLOVES\(^1\) (2015)

SYTHETIC GLOVES\(^1\) (2016)

Reference: GHX2012-2016
NON-LATEX ENVIRONMENT
FOR RISK REDUCTION
Benefits of a Latex-Free Environment

• Reduced O.R. teardown time and costs
• Healthcare worker exposure
• Pediatric exposure
• Latex lawsuits
• Worker’s compensation
• Standardization
• Latex proteins
• One less worry
Potential Resistance to Implementing Latex-Free Approach

- Staff may have misconceptions about synthetic gloves\(^1\)
  - Cost, protective features, tactile quality\(^2\)
- A well-planned program ensures smooth transition\(^1\)
  - Explain rationale for the move to a latex-free O.R.

Studies show that most physicians find synthetic gloves as effective and comfortable as latex equivalents\(^1\)

Impact of Latex-Free Approach in Spina Bifida Patients

- Latex-free from birth of spina bifida patients (10 year analysis)

Impact of Latex-Free Approach on Anaphylaxis Rate

Change in rate of latex anaphylaxis in women undergoing cesarean delivery upon implementation of different protocols

2% → 0.6% → 0%

Use of latex products and no special screening → Screening questionnaire and synthetic gloves and urinary catheters in possible latex-sensitive patients → Synthetic gloves on all women undergoing cesarean

*Tertiary-care Hadassah Hebrew University Medical Center

Reference: London S. Latex-Free Works Best to Prevent Anaphylaxis During Cesareans. OB/GYN News. 5/30/12.
Examples of Latex-Free Approaches

**Rockford Memorial Hospital**
- 396-bed, 12,000 annual surgeries
- Before transition: 100 teardowns 12 months
- Transition to latex-free undergoes to set up the O.R. to eliminate all latex contamination from the start
- After transition: 1 teardown in 12 months
- Savings: $186,000

**Johns Hopkins Hospital**
- 34,000 employees, 46,000 annual patient admission
- Full operating room conversion providing improved safety to staff and patients

There is no known cure

- While symptoms may resolve quickly with latex avoidance therapy, detectable IgE indicated continued sensitization remains beyond 5 years.¹
- It has been estimated that 1 in 50 healthcare workers becomes sensitized to latex each year through exposure to latex gloves.²
- The latency period ranges from several weeks to 30 yrs³
- Many facilities have switched to a latex-free environment as a risk reduction measure

• Switching to latex-free has been shown to decrease latex sensitization and allergy rates in spina bifida patients and eliminate latex anaphylaxis in caesarian surgeries\textsuperscript{1,2}
• Converting to synthetic gloves also decreases latex allergy symptoms and sensitization in healthcare workers\textsuperscript{3}
• Synthetic gloves are effective and rated as comfortable as latex equivalents\textsuperscript{4}
• Costs are offset by decreasing the need for O.R. teardowns and reducing the risk of latex anaphylactic reactions and healthcare worker disability\textsuperscript{5}

Please Remember…

• Complete your registration and evaluation forms in the back of your booklet.