



Latex or Synthetic Gloves? Risk Reduction Strategies

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- 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

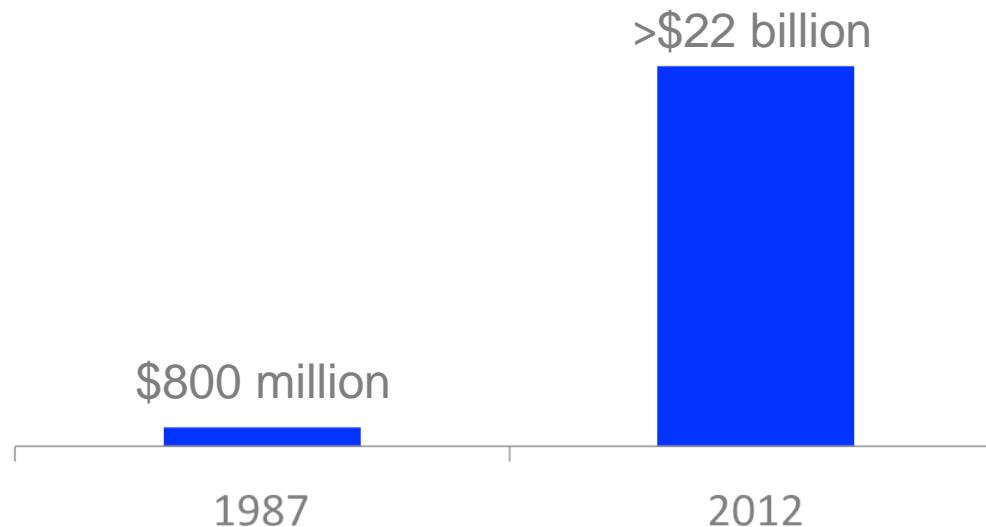
- Natural Latex Rubber (NRL) allergy is a significant medical concern affecting healthcare workers as well as general population^{1,2}
 - No distinction in race or gender
 - Can arise at any point of life
- An acquired allergy²
- There is no cure or vaccine, only prevention^{1,2}
 - Prevention by avoiding 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 material¹
- 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}



Latex Sensitivity vs. Latex Allergy

Allergy

- Demonstrated outward expression of the disease^{1,2}
- Positive skin prick test
- Local or systemic reactions can occur



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

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 yrs³



20% of American adults (1 out of 5) are sensitive to latex⁵

Patients with Increased Risk of Latex Allergy

Patients at Increase Risk^{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, quadraplegia



Latex Allergy in Labor and Delivery

- 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 surgery¹
- Possible risk factors^{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 foods¹

Fruits ^{2,3}			Vegetables ^{2,3}	Plants/Nuts/Other ^{2,3}	
Melons	Tomato	Lychee	Carrot	Peanut	Wheat
Apple	Papaya	Fig	Spinach	Chestnut	Buckwheat
Cherry	Kiwi	Pineapple	Bell Pepper	Walnut	Rye
Coconut	Mango	Avocado	Potato	Hazelnut	Oregano
Apricot	Passion Fruit	Banana	Celery	Soybean	Sage
Strawberry	Plum	Grape	Zucchini	Chick Pea	Dill
Loquat	Nectarine	Persimmon		Castor Bean	Sweet Pepper
Pear	Peach	Citrus Fruits		Sunflower Seed	Cayenne Pepper
					Shellfish

AORN recommends questioning about latex reactivity & skin/serologic testing should be considered in these patients⁴

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 gloves⁶
- 70% of all reported adverse events from latex allergies are from healthcare workers⁶



Rise in Incidence of Latex Allergies & Sensitization

- Increase in glove usage in non-traditional areas¹
- Increase use and wear time of latex gloves in traditional users^{1,2}
- Products high in residual extractable allergens^{1,2}
 - Increase in number of manufacturers and poorly regulated factories^{2,3}



LATEX ROLE IN ALLERGIC REACTIONS

What is Latex?

- A milky liquid natural substance from rubber trees¹
 - Mainly consists of a polymer providing strength & elasticity¹
 - Also contains sugars, lipids, nucleic acids, and highly *allergenic proteins*
- 40,000 different household products with latex²
- 17,600 medical devices with latex
 - Gloves, airways, intravenous tubing, syringes, stethoscopes, catheters, dressings and bandages²⁻⁴



Routes of Latex Exposure

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



FDA Required Latex Labeling/Claims

Latex Products Labeling*¹

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 Claim¹

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 Gloves²

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.

Non-latex (Synthetic) Gloves

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

1. LATEX-FREE

2. NON-LATEX

3. SYNTHETIC



U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

LATEX ALLERGY REACTIONS

Types of Reactions to Latex Products

Most common

Less common



Irritant Contact Dermatitis^{1,2}

Allergic Contact Dermatitis^{1,2}

Immediate Reaction Hypersensitivity^{1,2}

Cause	Mechanical or thermal injury	Chemical exposure May occur after repeat exposure	Exposure to latex proteins on glove surface or bound to powder in air or on objects
Onset	Gradual over days or weeks	Rash begins 6 to 48 hours	Within minutes or up to 2 hours later
Symptoms	Scaling, drying, cracking of skin	Red, raised, palpable area with bumps, sores, cracks	Mild: skin redness, hives, itching Severe: facial swelling, urticaria, respiratory distress

Latex Allergy Morbidity and Mortality Risk

Consequences of Latex Allergy

- Anaphylaxis
 - Latex is the 2nd leading cause of anaphylaxis in the O.R.^{1,2}
 - Up to 6% of anaphylactic episodes end in death²
 - Half of all latex related allergic reactions occur during OB/GYN procedures³
- Occupational asthma due to aerosolized latex⁴
 - 5% increase in risk of developing asthma for each cumulative year of exposure to latex within workplace
- Risk of acquiring other antigen sensitivities⁵

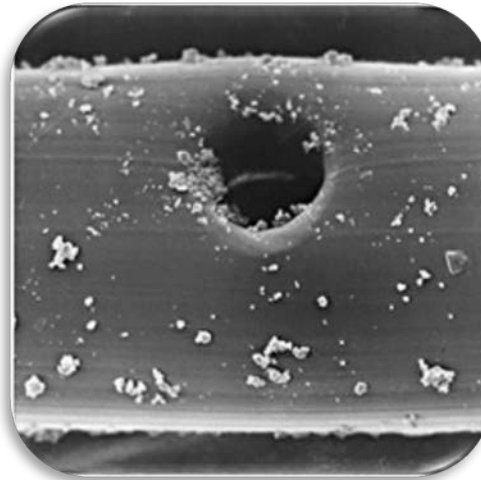
Impact of Latex Allergy

- Career path¹⁻⁴
 - 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 adjustments¹
 - Impacts the use of many household items and workplace devices
- Avoiding medical care¹
 - Seeking timely medical care due to justified fear of latex exposure

POWDER GLOVES & LATEX ALLERGY

Glove Powder Serves as a Vector

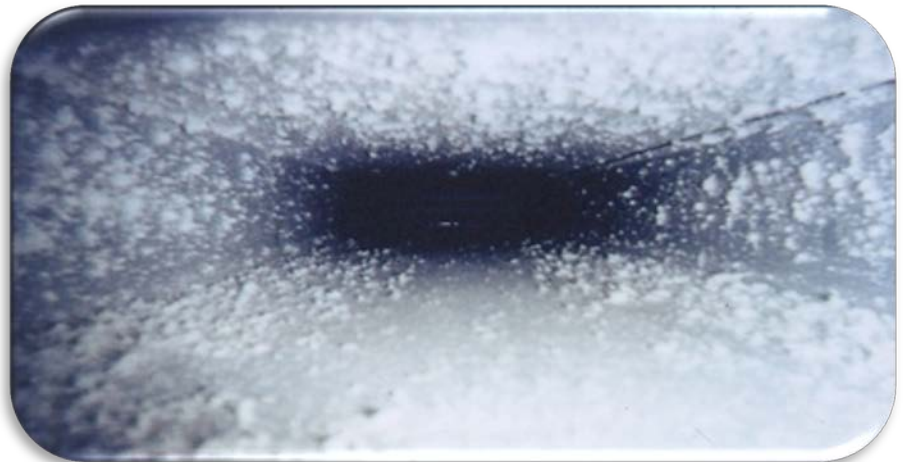
- Latex protein binds to starch glove powder
- Powder can settle on instruments, equipment, clothing, patient tissue



Starch Glove Powder and Asthma

- 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 Can Impact Wound Healing

Starch glove powder on surgical gloves can, and will, at times, trigger

- Foreign body reaction¹
- Adhesion formation^{1,2}
- Granuloma formation^{1,2}
- Reduced resistance to infection¹
- Delayed wound healing¹



Movement Away from Glove Powder

- Market is moving towards powder-free^{1,2}
 - In October 2016, 90% of surgical glove sales were powder-free³
- Reduction in use has been documented to reduce risk for developing latex allergy²
- FDA posted final rule to ban powdered surgeon's and patient examination gloves, and absorbable powder for lubricating a surgeon's glove.¹
 - 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

AORN Guidelines

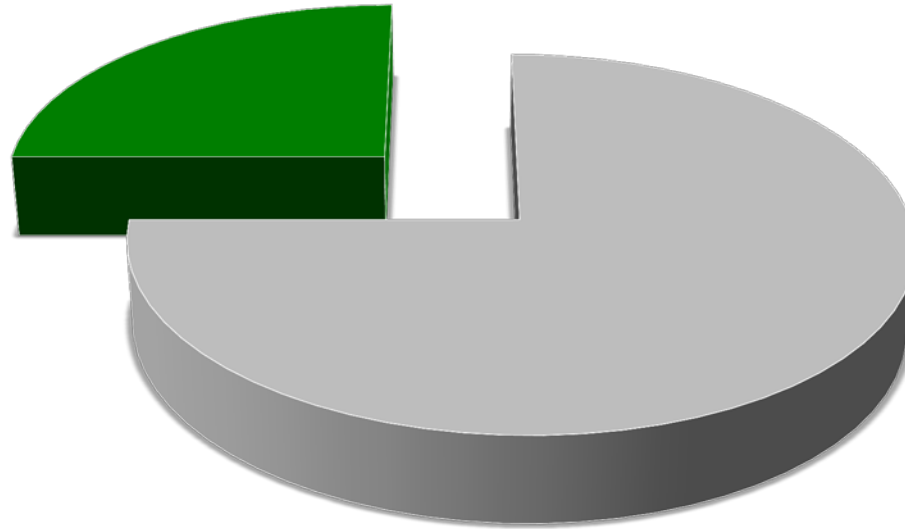
- Prevent complications in current latex allergic or sensitized individuals
- Prevent the development of latex allergy or sensitization



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

Educational Needs Among Healthcare Workers

**Only 25% of
healthcare workers
checked patients for
latex allergy**



- 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

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 for Healthcare Facilities

Latex Allergy Guidelines¹⁻³

- 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

Screening Questionnaire for Natural Rubber Latex Sensitivity

LATEX SCREENING TOOL

IMPORTANT NOTICE: These guidelines are not intended to be all inclusive. Individuals who are uncertain whether they are or may have sensitivities to natural rubber latex should consult their physician.

1. Have you ever been told by a doctor that you have an allergy to any latex product? ☐ Yes ☐ No
If yes, to what specifically did the doctor say you were allergic to? _____

2. Have you ever had a reaction to the following personal sources of latex?

	YES	NO		YES	NO		YES	NO
Ace Bandages	<input type="checkbox"/>	<input type="checkbox"/>	Dental Cofferdames	<input type="checkbox"/>	<input type="checkbox"/>	Pacifiers	<input type="checkbox"/>	<input type="checkbox"/>
Adhesive Tape	<input type="checkbox"/>	<input type="checkbox"/>	Erasers	<input type="checkbox"/>	<input type="checkbox"/>	Rubber Balls	<input type="checkbox"/>	<input type="checkbox"/>
Baby Bottle Nipples	<input type="checkbox"/>	<input type="checkbox"/>	Face Masks	<input type="checkbox"/>	<input type="checkbox"/>	Rubber Bands	<input type="checkbox"/>	<input type="checkbox"/>
Bandages	<input type="checkbox"/>	<input type="checkbox"/>	Foam Pillows	<input type="checkbox"/>	<input type="checkbox"/>	Rubber Cement	<input type="checkbox"/>	<input type="checkbox"/>
Balloons	<input type="checkbox"/>	<input type="checkbox"/>	Garden Hoses	<input type="checkbox"/>	<input type="checkbox"/>	Rubber Gloves	<input type="checkbox"/>	<input type="checkbox"/>
Belts	<input type="checkbox"/>	<input type="checkbox"/>	Golf Grips	<input type="checkbox"/>	<input type="checkbox"/>	Shoewear	<input type="checkbox"/>	<input type="checkbox"/>
Brassieres	<input type="checkbox"/>	<input type="checkbox"/>	Hot Water Bottles	<input type="checkbox"/>	<input type="checkbox"/>	Suspenders	<input type="checkbox"/>	<input type="checkbox"/>
Carpet Backing	<input type="checkbox"/>	<input type="checkbox"/>	Latex Cuffs	<input type="checkbox"/>	<input type="checkbox"/>	Teething Rings	<input type="checkbox"/>	<input type="checkbox"/>
Clothing	<input type="checkbox"/>	<input type="checkbox"/>	Milking Machines	<input type="checkbox"/>	<input type="checkbox"/>	Tennis Grips	<input type="checkbox"/>	<input type="checkbox"/>
Condoms	<input type="checkbox"/>	<input type="checkbox"/>	Ostomy Bag	<input type="checkbox"/>	<input type="checkbox"/>	Weather Stripping	<input type="checkbox"/>	<input type="checkbox"/>
Consets	<input type="checkbox"/>	<input type="checkbox"/>	Paint	<input type="checkbox"/>	<input type="checkbox"/>			

3. Do you have a history of:
 Contact Dermatitis ☐ Yes ☐ No Asthma ☐ Yes ☐ No Hay Fever ☐ Yes ☐ No
 Autoimmune Disease ☐ Yes ☐ No Eczema ☐ Yes ☐ No

4. Do you have any food allergies? ☐ Yes ☐ No
 If yes, are you allergic to any of the following?

Bananas <input type="checkbox"/> Yes <input type="checkbox"/> No	Milk <input type="checkbox"/> Yes <input type="checkbox"/> No	Avocado <input type="checkbox"/> Yes <input type="checkbox"/> No	Peaches <input type="checkbox"/> Yes <input type="checkbox"/> No
Potato <input type="checkbox"/> Yes <input type="checkbox"/> No	Tomato <input type="checkbox"/> Yes <input type="checkbox"/> No	Kiwi <input type="checkbox"/> Yes <input type="checkbox"/> No	Papaya <input type="checkbox"/> Yes <input type="checkbox"/> No
Chestnuts <input type="checkbox"/> Yes <input type="checkbox"/> No	Other _____		

5. After handling latex products, have you experienced:

Chapping or cracking of hands <input type="checkbox"/> Yes <input type="checkbox"/> No	Redness <input type="checkbox"/> Yes <input type="checkbox"/> No
Runny nose/Congestion <input type="checkbox"/> Yes <input type="checkbox"/> No	Hives <input type="checkbox"/> Yes <input type="checkbox"/> No
Itching (hands, eyes, etc.) <input type="checkbox"/> Yes <input type="checkbox"/> No	Swelling <input type="checkbox"/> Yes <input type="checkbox"/> No
Other _____	

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*

	Estimated Costs	Yearly Estimated Total (1 per week x 52 weeks)
Contaminated disposables (Specialty packs not included)	\$300	\$15,600
Idle O.R. Costs	\$1,560 per hour	\$81,120
Resterilization of Reusable items	>30 minutes	26 hours
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

In-Use Failure Rate of Surgical Gloves

- 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

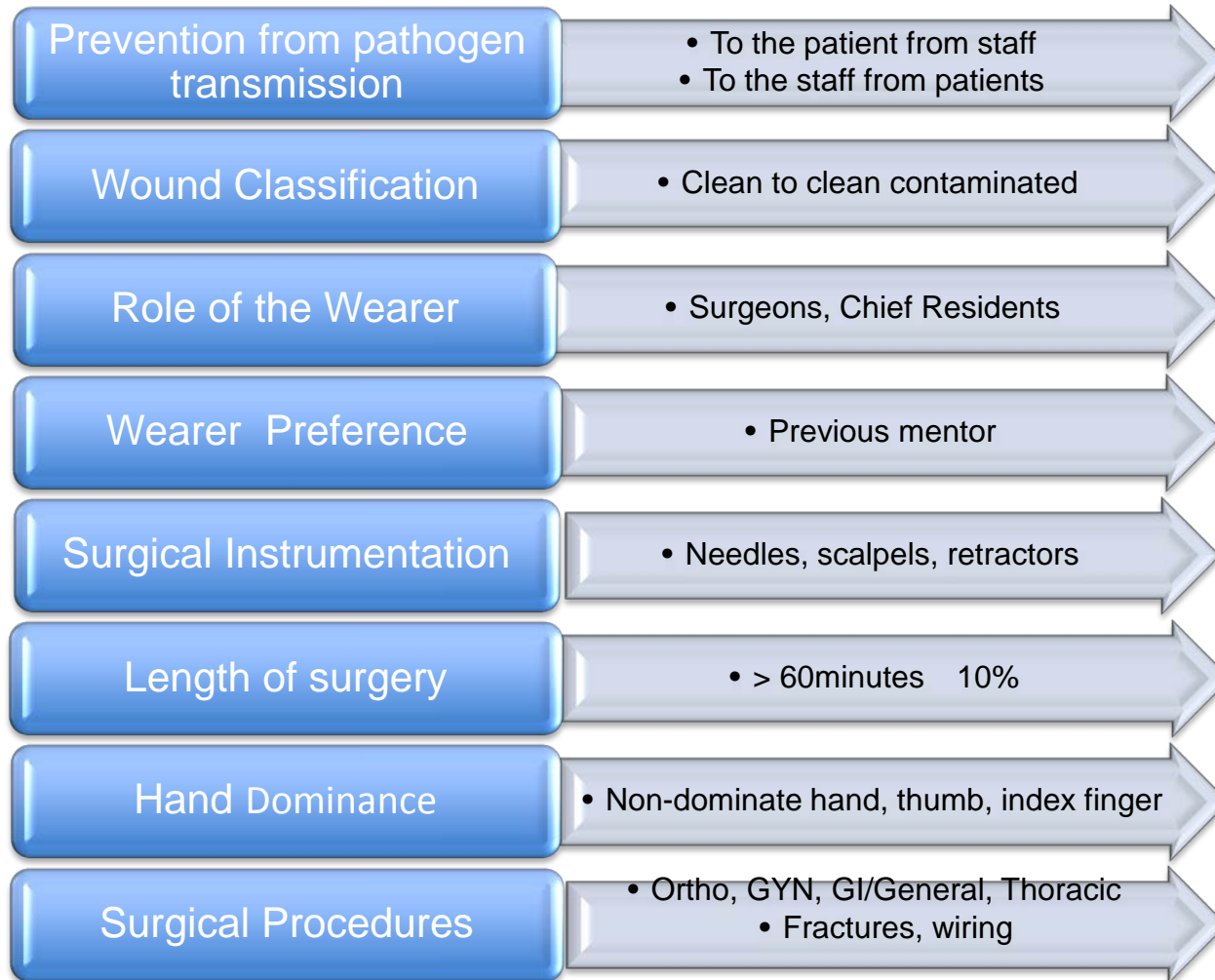
Can You Define
In-Use Failure?

A cessation of
proper
functioning

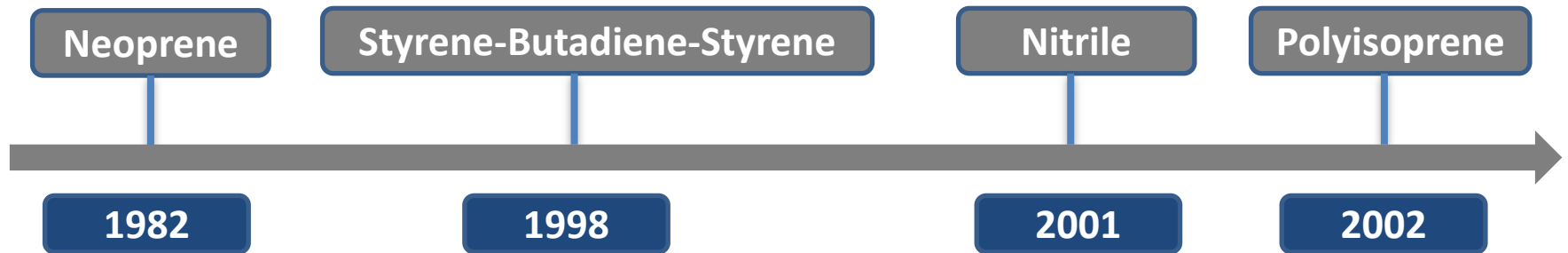
A decline in
strength or
effectiveness

Nonperformance
of what is
expected

Risks and Challenges of *Surgical Glove Failures*



Evolution of Non-latex (Synthetic) Gloves



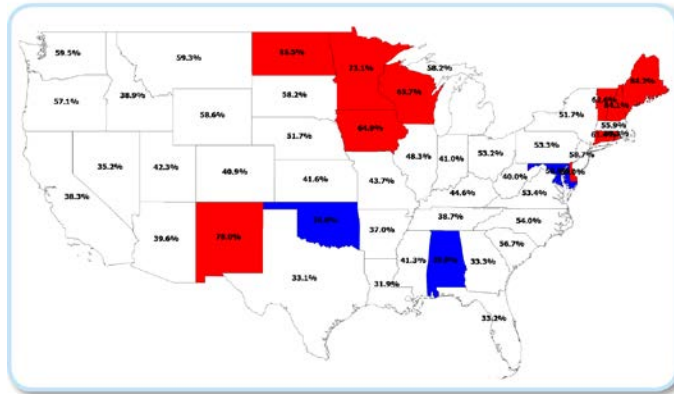
2013 FDA Labeling of Products Without NRL

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

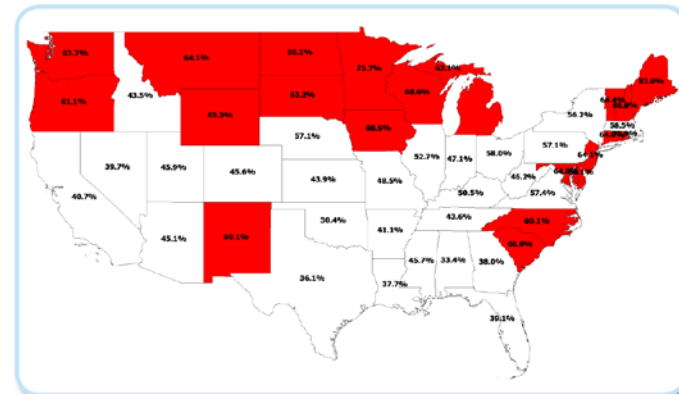
Increase in Utilization of Non-latex (Synthetic) Gloves

(% PF Latex usage in volume)

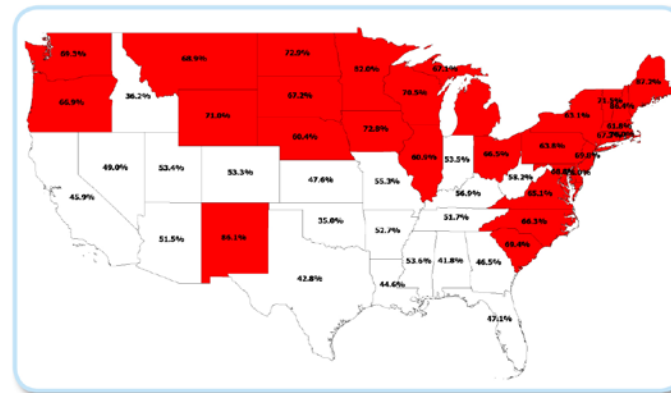
SYNTHETIC GLOVES¹ (2014)



SYNTHETIC GLOVES¹ (2015)



SYNTHETIC GLOVES¹ (2016)

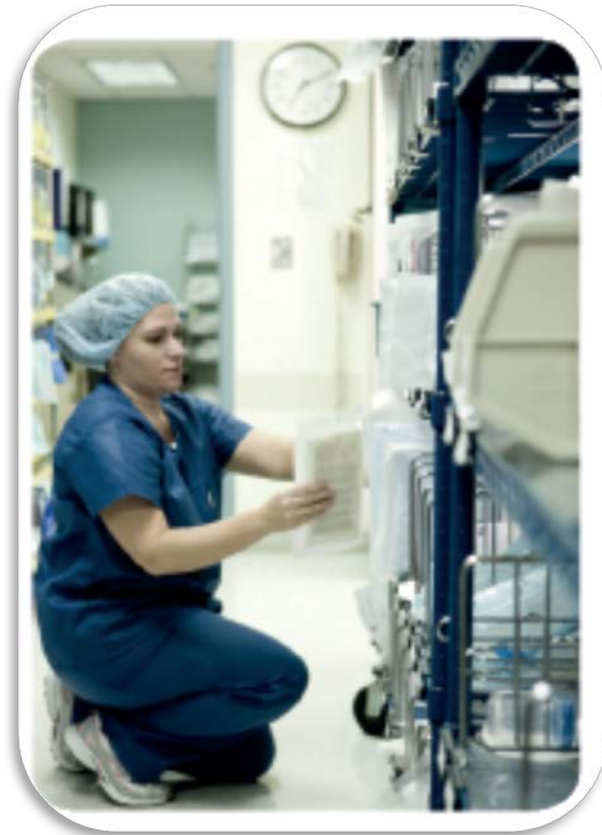


■ <30% ■ >30-59% ■ >60%

**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

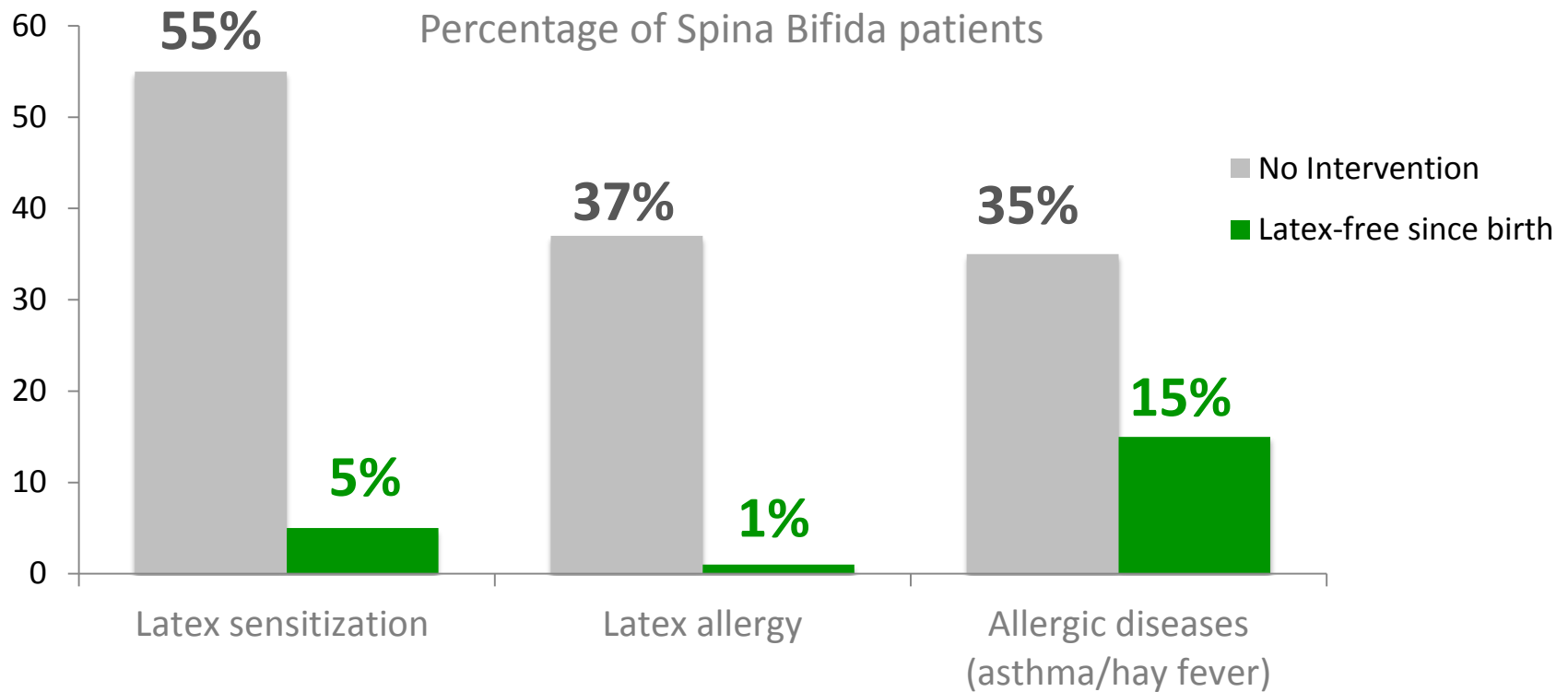
- Staff may have misconceptions about synthetic gloves¹
 - Cost, protective features, tactile quality²
- A well-planned program ensures smooth transition¹
 - Explain rationale for the move to a latex-free O.R.



Studies show that most physicians find synthetic gloves as effective and comfortable as latex equivalents¹

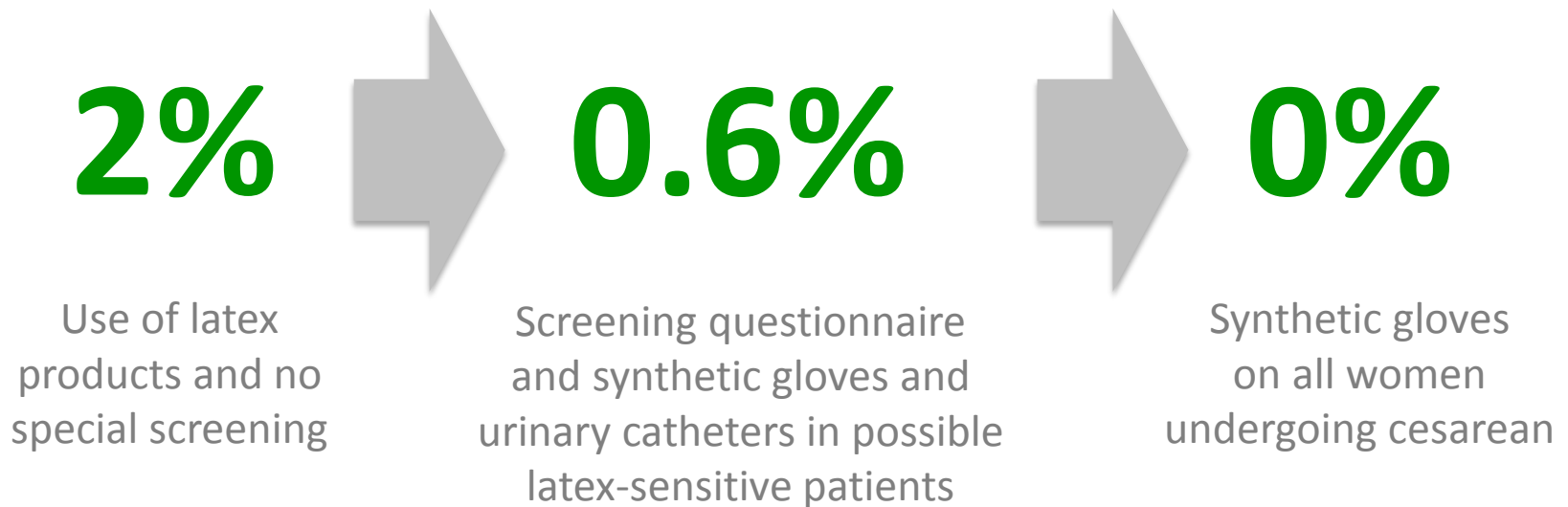
Impact of Latex-Free Approach in Spina Bifida Patients

- 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



*Tertiary-care Hadassah Hebrew University Medical Center

Examples of Latex-Free Approaches

Rockford Memorial Hospital

- 396-bed, 12,000 annual surgeries
- Before transition: 100 teardowns 12 months
- Transition to latex-free undergloves 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



SUMMARY

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

Benefits of a Latex-Free Approach

- 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^{1,2}
- Converting to synthetic gloves also decreases latex allergy symptoms and sensitization in healthcare workers³
- Synthetic gloves are effective and rated as comfortable as latex equivalents⁴
- Costs are offset by decreasing the need for O.R. teardowns and reducing the risk of latex anaphylactic reactions and healthcare worker disability⁵

Please Remember...

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