The Solution to Latex Gloves:

Why Nitrile is the Better Alternative
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Healthcare-associated infections (HAIs) are a global issue occurring in up to 10% of all hospitalized patients and costing the healthcare system about $6 billion U.S. Dollars per year. Building on Kimberly-Clark’s leadership position in the areas of Operating Room, Infection Control, and Airway Management, our mission is to provide healthcare facilities with clinical solutions to prevent and manage the most severe HAIs, including healthcare worker infections.
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The Solution to Latex Gloves: Why Nitrile is the Better Alternative

Natural rubber latex allergy is a significant medical concern in healthcare today. Latex-sensitive patients and healthcare workers face a serious risk from any product containing latex, with exposure to latex gloves presenting a particular concern. To date, there is no known cure for latex allergy except eliminating exposure to latex products.

One of the quickest ways to reduce this risk is obvious: switch to latex-free gloves. Yet, some institutions seem reluctant to make the change.

This document provides facts to help your institution evaluate your current use of latex gloves and justify the substitution of nitrile gloves. In terms of quality of protection for healthcare workers, reduction in risk of allergic reaction in the entire hospital population, and overall value the proof is here that nitrile is the better solution. It's just one less thing for you to worry about.

Latex Sensitivity and Latex Allergy

The three common reactions associated with latex glove use are:

1. Irritant Contact Dermatitis: The result of damage to the skin caused by factors like soaps and cleansers, multiple handwashings, inadequate hand drying, rubbing inside powdered gloves, or certain chemicals used in manufacturing gloves. Symptoms include dry, crusty hard bumps, sores, and horizontal cracks on the skin.¹

2. Allergic Contact Dermatitis, or delayed hypersensitivity: A Type IV immune reaction, caused by chemical additives used in glove manufacturing, rather than latex itself. Onset of Type IV reactions is slow, usually beginning 18 to 24 hours after exposure and peaking at 48 hours after exposure. Each exposure may lead to increased sensitization and more severe reactions, with symptoms such as red, raised, palpable area with bumps, sores, and horizontal cracks that may extend up the forearm.¹

3. Latex allergy: Characterized by immediate hypersensitivity, a true latex allergy is a systemic Type I IgE-mediated response to plant proteins in natural rubber latex, leading to local swelling, redness, edema, itching, and systemic reactions. Type I reactions are immediate; usually within minutes, symptoms occur such as rhinitis, conjunctivitis, urticaria, laryngeal edema, bronchospasm, asthma, angioedema, anaphylaxis, and death.¹
Both irritant contact dermatitis and allergic contact dermatitis can lead to latex sensitivity. Latex sensitivity is a condition that develops after genetically capable individuals are repeatedly exposed to natural rubber latex. The broken skin barrier caused by dermatitis increases the amount of exposure by allowing latex proteins easy access through the skin. Immunologic memory escalates with increased exposure. When the level of sensitization reaches the individual’s unique threshold level, he or she will express symptoms on subsequent exposure to latex allergens and are considered latex allergic. Anyone with latex sensitivity is at risk of a life-threatening reaction and should be treated in the same manner as a latex allergic individual.1

How Big is the Latex Problem?

Among the General Population

Estimates of the prevalence of latex sensitivity vary from less than 1% to 6% of the general population.2,3 However, due to repeated exposure to latex products, latex protein sensitivity is increasing.4 Expanding use of latex gloves for various household tasks and glove availability at mass market retailers may be factors in the continuing growth of latex sensitivity.

Between 35-70% of children with spina bifida are at particularly high risk.5 Multiple surgeries early in life and frequent exposure to latex devices are considered the primary risk factors for their extreme latex sensitivity.6 Others at high risk include:

- In the U.S., atopic individuals (those prone to allergies), currently numbering more than 50 million in the U.S.7
- People with urogenital conditions, eczema, or a history of multiple surgeries.
- People working in some areas of the rubber industry or in other occupations that require latex gloves, such as mechanics, hairdressers, and food service employees.
- People who must use catheters.2,8

WHO IS AT RISK?

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- Between 35-70% of children with spina bifida are at particularly high risk.5
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Among Healthcare Workers

According to a 2004 report from the National Institute of Environmental Health Sciences, natural rubber latex sensitivity is estimated to occur in 5-18% of healthcare workers, a rate two to three times greater than among the general population. Also, latex exposure has been one of the leading causes of occupational asthma in healthcare workers over the last several years, both in the U.S. and Europe.\textsuperscript{9,10}

It has been estimated that one in fifty healthcare workers becomes sensitized to latex each year through exposure to latex gloves.\textsuperscript{11}

Sensitization develops in individuals genetically predisposed to latex allergy after multiple exposures to natural rubber latex over a highly variable period of time. The latency period ranges from several weeks to as long as 30 years.\textsuperscript{12}

As it is impossible to predict when an exposed individual will become latex allergic and express symptoms, no thresholds for specific latex allergens can be established.
The Correlation Between a Reduction in Latex Exposure and a Reduction in Reported Latex Allergy

The first clear description of immediate hypersensitivity was published in 1979. In the late 1980’s and early 1990’s, there was a dramatic increase in reported cases of latex sensitivity, coinciding with the increased use of natural rubber latex gloves to protect healthcare workers against exposure to AIDS.

After peaking in the mid-1990’s, latex allergy reactions have been steadily decreasing, as more hospitals switch to reduced protein content powder-free latex gloves or to synthetic gloves. Two examples where reduced exposure has led to reduced incidence of latex reactions are:

- The Mayo Clinic in Rochester, Minnesota, where latex allergy cases have declined from 150 to 27 per 100,000 healthcare workers since 1993.

- Several years after switching to low-allergen or non-latex gloves, 160 Finnish healthcare workers with documented natural rubber latex allergy were still performing the same jobs.

It’s clear that there is a direct correlation between a reduction in exposure to latex and a reduction in latex allergy.

While overall the decline in latex allergy reactions has been a positive development, unfortunately in some instances it has led to healthcare workers lowering their guard against latex exposure for themselves and their patients. The risk still exists.
The Latex Problem

Impact on Patients

Unknowingly exposing a latex allergic patient to latex gloves and other latex products can be fatal. Without testing every hospital patient, whether or not they’re in a high-risk category, it’s impossible to tell which ones may be latex sensitive or latex allergic. Therefore, all patients should be assessed for a history of latex allergy.

Impact on Healthcare Workers

For the latex allergic healthcare worker, impact can range from lost time at work, job reassignment to avoid latex contact, and in extreme cases, loss of career.

Under the 1990 Americans with Disabilities Act, reasonable workplace accommodation must be made to allow a disabled worker to perform the essential functions of the job. However, if exposure cannot be prevented, sensitized workers with severe asthma and other life-threatening latex allergic reactions must be removed from the workplace.

Removal from the workplace may cause the individual psychological distress manifesting itself in anger, depression, anxiety, and denial. When someone is unable to maintain his or her current profession, their self-esteem, interpersonal relationships, and economic well-being may be adversely affected.

For co-workers of the latex allergic individual, unwanted overtime may be the result, along with the stress of handling extra duties while the allergy sufferer is off the job.

An online poll of nurses indicated that 88% were concerned with the potential for latex allergic reactions for themselves or their patients with regard to the use of latex exam gloves.
Healthcare-Associated Infection Solutions

Impact on Healthcare Facilities

In a healthcare facility, a latex allergic employee means treatment costs that must be covered by Workers’ Compensation insurance, possible litigation costs, federal or regulatory guideline compliance concerns, rearranging work schedules, and dealing with morale issues among the rest of the staff.

Treatment Costs

- It can cost between $5,000 and $25,000 to treat a single anaphylactic episode resulting from latex allergy. The average overall cost to treat latex allergy is estimated at $218,000 per employee.\(^{19}\)

- For those who cannot return to work due to natural rubber latex allergy, the average total cost, paid by Workers’ Compensation insurance and the healthcare facility, can be as high as $1,163,740 per employee.\(^{20}\)

Litigation

Disability from occupationally induced allergies is compensable under Workers’ Compensation law.\(^{12}\) A worker with natural rubber latex-induced anaphylaxis is considered to be 100% impaired from performing his/her specific job if the job entails exposure to the causative agent.\(^{12}\) Disability costs associated with latex allergies can be large.

- About 70% of reported Workers’ Compensation cases for Type I latex allergy sensitivity have resulted in awards to the worker, and the rate is increasing.\(^{26}\)

- The Iowa Supreme Court set a significant precedent when it declared that latex allergy/sensitivity claims are to be considered work-related accidents rather than occupational diseases. It also ruled that sensitized workers are entitled to receive Workers’ Compensation benefits for loss of functional ability. These rulings will make it easier for injured workers to claim benefits.\(^{27}\)

- In the U.K., a nurse was awarded £350,000 in compensation after she developed a life-threatening allergy to latex while working at two hospitals in Wales.\(^{28}\)
European Latex guidelines

The European committee for standardization has ruled in the European Standard EN 455-3 for medical gloves for single use that medical gloves derived directly from natural rubber latex shall be labeled with the following or equivalent: “Product contains natural rubber latex which can cause allergic reactions”\(^{21}\)

Netherlands

In the Netherlands, a working conditions covenant is in force within the hospital sector, aimed at reducing sickness absenteeism and improving occupational health, safety and welfare\(^{22}\). One of the objectives in the covenant is that all hospitals will move to latex free gloves. At request of this Sector Supervision Committee, TNO Labour has analysed the costs and benefits of introducing non-latex gloves\(^{23}\). The conclusion of the research is that migration to non-latex gloves is inherently desirable, since the increasing prevalence of allergies has considerable cost implications sufficient to warrant a major commitment to corrective action from all parties concerned.

United Kingdom

In the UK, the Alison Dugmore case, in which a nurse won her landmark appeal case after claiming an allergy to latex gloves forced her to end her career, established for the first time in the UK that employers are strictly liable for injuries caused by hazardous substances\(^{28}\).

The UK Health and Safety At work Act 1974 requires minimization of risk by reducing or removing hazard wherever reasonably practicable\(^{24}\). The COSHH (Control of Substances Hazardous to Health) Regulations 2002 asks hospitals to undertake an assessment of any substances used at work that are hazardous to health\(^{25}\). Natural rubber latex is classified as a hazardous substance. Healthcare institutions have a duty to “eliminate, substitute, and limit and control exposure to latex, unless there is a need to use it”\(^{32}\).

As natural rubber latex produces a risk of asthma & dermatitis health surveillance of staff is required. The extent and detail of the health surveillance should be related to the degree of risk identified during the COSHH assessment & determined in consultation with an occupational health professional.
France

In France, a multidisciplinary team from the INRS (National Institute of research and security) is highlighting in a report dedicated to medical workers: “As with each substance responsible for professional diseases, the first preventative measure that should be enforced is the reduction in use of Latex, still today sometimes overused; this can currently often be replaced by other materials.”

Germany

The German committee for labour protection and safety technique (LASI – Länderausschuss für Arbeitsschutz und Sicherheitstechnik) states in the guidelines “Protection for latex allergies” that 10% of medical staff in Germany suffer from latex allergies. From a legal perspective, the use of latex gloves falls under the Labour safety law (Arbeitsschutzgesetz) and hazardous substances act (Gefahrstoffverordnung). The employer is responsible for evaluating the risks associated with the use of hazardous substances as well as defining the required protection (paragraph 5 Abs. 1 ArbschG, paragraph 16 Abs. 4 GefStoffV). Specifically, the Technical guideline for hazardous substances TRGS 540 is relevant: “Powdered latex gloves have to be substituted by powder-free, low allergen latex gloves or other suitable gloves”. Vinyl gloves are, based on their limited safety, not suitable for protection against infection.

Sweden

Most of the County Councils in Sweden work to reduce usage of gloves made by natural rubber latex. PVC gloves are commonly used in Healthcare in Sweden. “A big part of the healthcare workers and patients are allergic to natural rubber latex. Therefore, use latex gloves only when needed.”

“Both PVC and phtalates are on the Kemikalieinspektion’s list (Authority in Sweden) of environmentally unfriendly materials which should be changed to other materials, when possible.”
The Nitrile Solution

To reduce the risk to latex sensitive patients and workers, every facility should take the steps necessary to become latex-safe, which includes identifying acceptable alternatives to known latex-containing products.4

Switching to a synthetic glove, such as nitrile, that is comparable to latex in maintaining excellent barrier protection during use and comparable in its fit and feel, is an important step in creating a latex-safe environment.33

Standardizing on nitrile gloves eliminates confusion and the possibility of accidental latex glove use when treating a latex-sensitive patient. It can also provide cost savings for your facility through code consolidation.

According to a 1999 study by Rego and Roley,33 nitrile is “an equally effective non-latex glove alternative”, a synthetic polymer “that exhibits rubberlike characteristics and barrier properties comparable with latex. Nitrile or latex should be the glove of choice for high-risk situations, including exposure to bloodborne pathogens.”

Nitrile gloves, with a failure rate of 1% to 3%, were comparable to latex, with a failure rate of 0% to 4%, during manipulations designed to simulate patient care procedures.33

Because of the high failure rate of vinyl gloves—12% to 61% in simulated in-use conditions—they cannot be considered as adequate protection for healthcare workers in moderate to high-risk applications.33
A Latex-Free Cost/Benefit Analysis

In the United States, a study at three Georgia institutions—a tertiary care hospital, a community hospital, and an outpatient clinic—was designed to determine the percentage of at-risk employees who would have to become fully or partially disabled to offset the costs of switching to latex-free gloves.

- The cost of a worker who qualified for total disability was calculated at $109,000. As little as 1.1% of workers in the tertiary hospital, 0.45% in the community hospital, and only 0.02% in the outpatient clinic would have to become totally disabled due to latex allergy to offset the additional cost of switching to latex-free gloves.

- The cost of a worker who qualified for partial disability was calculated as $62,000. Only 1.9% of workers in the tertiary hospital, 0.8% in the community hospital, and only 0.04% in the outpatient clinic would have to become partially disabled due to latex allergy to offset the additional cost of switching to latex-free gloves.

- Studies have shown that economically feasible measures to reduce natural rubber latex exposure in healthcare facilities—including switching to non-latex or reduced protein, powder-free latex gloves—can successfully allow most latex-allergic individuals to continue working.\textsuperscript{15,18,35}
**Nitrile Success Stories:**
**Johns Hopkins Medical Institutions**

In the mid-1990’s, the Johns Hopkins Medical Institutions were tracking the progress of more than 300 lawsuits filed by healthcare workers against major latex glove manufacturers. The workers claimed that exposure to latex gloves on the job caused them to develop Type I latex hypersensitivity. In 1997, Johns Hopkins created a multidisciplinary Latex Task Force with a goal of creating a latex-safe environment within all of its medical facilities.

Latex exam gloves were first replaced with vinyl gloves, but continuing concerns about strikethrough and staff dissatisfaction with the fit and performance of vinyl gloves caused the Task Force to conduct further research into latex alternatives.

At the time of the original pilot project, the Task Force had decided that nitrile exam gloves were too costly. However, within a year of switching to vinyl exam gloves, the price of nitrile gloves had fallen to the point where the Task Force could justify the conversion to nitrile, on both a cost and performance basis. Pilot testing of the nitrile exam gloves resulted in a 95% acceptance rate among medical staff.

As a result, the Task Force recommended switching to nitrile exam gloves throughout the facilities, and the conversion to nitrile was successfully completed. A key to this success was the effort to provide education to both patients and clinical staff regarding the risks of latex allergies.36
Nitrile Success Stories:
Henry Ford Health System

While conducting research in the late 1990’s, Dr. Ownby, Head of Allergy at Henry Ford Health System, discovered that a large number of otherwise healthy people suffered from latex allergy. He began a campaign to reduce the amount of latex at the facility and to educate patients, visitors, and employees on the risks of latex exposure.

The Henry Ford Health System started testing employees for latex allergy in 1996. During this time, four nurses left not just the hospital but the healthcare field due to severe latex allergies. All four filed for Workers’ Compensation as a result of their injuries.

In 2000, Henry Ford attempted to eliminate latex exam gloves, but no clear guidelines had been developed for their replacement. Because the facility stocked both latex and synthetic gloves, confusion reigned regarding which glove to use in what situation. Finally, Infection Control, Employee Health, and Safety came together and asked the question, “Is there really a reason to have latex gloves?” The answer was no, because acceptable non-latex options were available. After six months of research and two glove sizing fairs, Henry Ford successfully converted to latex-free exam gloves.

Phyllis Voreis, Director of Regulatory Accrediting and Infection Control at Henry Ford, says that the staff accepted the change after learning that the new gloves would provide the protection they needed. According to Phyllis, “education is the most important thing. People have to see the risks involved with latex and make the decision for themselves. They have to see that you are making the change for their best interest and the patients’ best interest.”
Why Should You Switch to Nitrile?

It’s clear that the best way to reduce risk to patients, employees, and healthcare facilities themselves is to create a latex-safe environment, in part by switching to nitrile gloves.

Converting to nitrile will:

- Greatly reduce absenteeism and occupational disability costs due to latex allergy/sensitivity over time.
- Provide cost benefits by standardizing on fewer glove types, reducing both the number of suppliers used and order frequency, and by increasing order quantities.
- Improve morale among existing employees and help attract new staff members.
- Minimize confusion over choice of gloves.

Helping You Make the Switch

A change in gloves is a major decision that will impact every clinician in your facility, as well as your administrators. Kimberly-Clark can help by providing the information you need to make the best possible latex-free choice for your facility in terms of performance and cost.

- We can provide you with the test data from numerous studies assessing nitrile, vinyl, and latex performance characteristics and educational materials on latex sensitivity.
- Our sales staff will conduct a comprehensive review at your facility to demonstrate precisely what the financial impact of a switch to nitrile gloves should be.
- Our staff medical consultants will assist in educating your employees as to the benefits and proper use of nitrile gloves.

When you’re ready for the better alternative to latex, let your Kimberly-Clark representative help you make the switch. Knowing that your patients and employees are safer and your facility is better equipped to serve their needs is one less thing for you to worry about.
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