



KIMBERLY-CLARK* STERLING*
Nitrile Exam Gloves

***The Solution to Latex Gloves:
Why Nitrile Is the Better Alternative***




Kimberly-Clark

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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 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.

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.

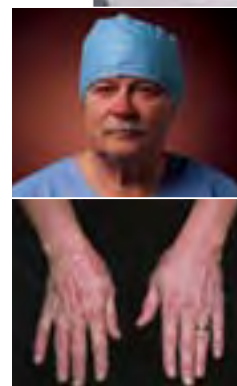
One of the quickest ways to reduce this risk is obvious: switch to latex-free gloves. Yet, some institutions seem reluctant to make the change.

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 is 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

WHO IS AT RISK?

- **Latex sensitivity varies from less than 1% to 6% of the general population.^{2,3}**
- **Between 35-70% of children with spina bifida are at particularly high risk.⁵**
- **Those prone to allergies, numbering nearly 50 million in the U.S.⁷**
- **Those with a history of multiple surgeries or who use catheters.^{2,8}**

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 for allergic reactions to latex.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}

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.^{9,10}

Based on an average of eight international studies from 2001 through 2006, the percentage of latex sensitized healthcare workers is approximately 6.2%^{11,12,13,14,15,16,17,18}

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.¹⁹

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 1979.²⁰ 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.²¹

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.^{22,23} 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 between 1993 and 2002.²²
- 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.⁴²

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.²⁴ 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.⁴

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.²⁵ However, if exposure cannot be prevented, sensitized workers with severe asthma and other life-threatening latex allergic reactions must be removed from the workplace.¹⁹

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.¹⁹

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.

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. Overall treatment for Type I allergy, ranging from diagnosis to emergency care following an anaphylactic episode, is estimated at \$218,000 per employee.²⁶
- 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.²⁷

More than one million new and replacement nurses will be needed by 2012.²⁸

More than 40% of nurses working in hospitals reported being dissatisfied with their jobs.⁴⁴

Competition for Nurses

The current shortage of nurses in the U.S. is expected to intensify. According to the U.S. Bureau of Labor Statistics, more than one million new and replacement nurses will be needed by 2012.²⁸ As competition for nurses increases among healthcare facilities, those not yet latex-safe could find themselves at a disadvantage in attempting to attract the best nursing talent.

Professional nursing associations present a unified front on the issue of latex exam gloves:

- AORN Guidelines state that latex-allergic individuals should use only non-latex gloves and avoid all products containing latex.¹
- The Massachusetts Nurses Association recommends non-latex examination gloves be used in all healthcare settings and that "...patients, nurses, other healthcare professionals and staff should not be exposed and sensitized to natural rubber latex..."²⁹

- The American Nurses Association and the Organization of Maine Nurse Executives recommend that all healthcare institutions eliminate the unnecessary use of latex gloves.^{30,31}
- The New York State Nurses Association believes that, generally, natural rubber latex exam gloves should not be used.³²

An effort to create a latex-safe environment generates loyalty among current workers and helps ensure that a facility will not be eliminated from consideration by potential candidates for future positions.

Litigation

Disability from occupationally induced allergies is compensable under Workers' Compensation law.²⁰ 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.²⁰ 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.³³
- 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.³⁴
- 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.³⁵

U.S. Federal Guidelines

- The Occupational Safety and Health Administration (OSHA) has indicated that a “safe zone” may be needed to protect workers already sensitized to latex, and healthcare facilities may be required to develop policies and procedures for reducing the risk of natural rubber latex allergies in the workplace. It has also recommended that there be procedures for reporting and managing cases of allergic reactions.³⁶
- The National Institute for Occupational Safety and Health (NIOSH) has published recommendations for minimizing latex-related health problems in workers, while still protecting them from infectious materials. Recommendations include reducing exposures, using appropriate work practices, training and educating workers, monitoring symptoms, and substituting non-latex products when appropriate.³⁷
- The Food and Drug Administration (FDA) has ruled that all medical devices containing natural rubber latex must contain the following warning in bold print: **Caution: This product contains natural rubber latex which may cause allergic reactions.**¹

European Regulations

- Europe’s Control of Substances Hazardous to Health (COSHH) Regulations identify latex 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.”³⁸

U.S. State Legislation

- Several states are considering legislation regarding the use of latex gloves. In 2001, Rhode Island became the first state to pass a law banning the use of latex gloves in the foodservice industry. While the state doesn’t prohibit the use of latex gloves in healthcare, it does place restraints on use and has instituted pressure to replace latex gloves with non-latex alternatives.³⁹

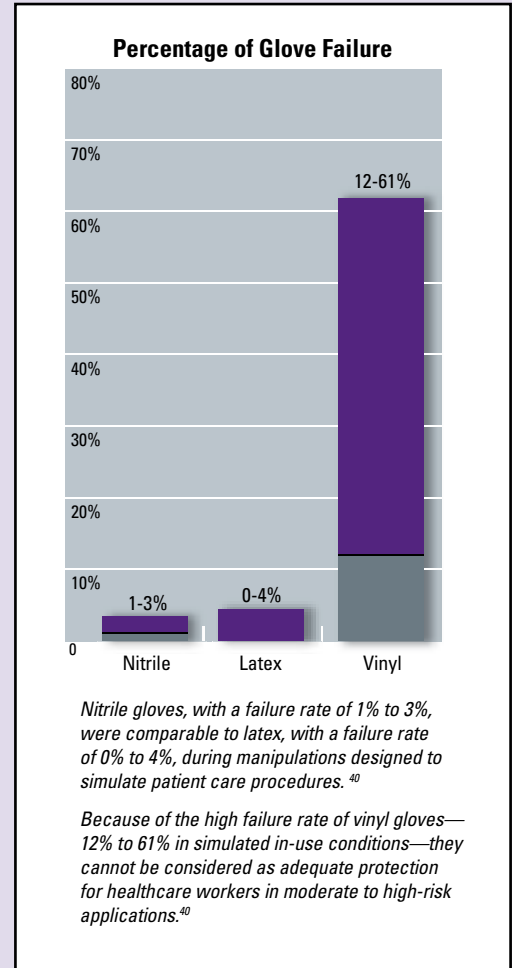
The Nitrile Solution

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.⁴⁰

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,⁴⁰ 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.⁴⁰
- 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.⁴⁰



A Latex-Free Cost/Benefit Analysis

In the United States, a study⁴¹ 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.^{22,25,42}

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.⁴³

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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If, for any reason, our products do not meet your expectations, please let us know your comments or suggestions for improvement. Your input will result in a concerted effort on our part to meet your requirements. Our goal is to provide quality products that completely meet your needs time after time.

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