

# Latex Allergy

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## Abstract

IgE-mediated allergy to natural rubber latex is a new health hazard about which information has been evolving for the past decade. This sensitivity poses a particular threat to children with congenital malformations or a history of multiple surgical interventions, and to individuals with high workplace exposure, such as health care workers. The only currently available treatment is complete avoidance of latex, which may require a change of workplace and loss of career. Latex allergy can lead to chronic occupational asthma, anaphylaxis, and even death. Preventive measures must be taken, in part because no treatment is available. This article provides an overview of latex allergy, and recommends some measures that may prevent its continuing dissemination and reduce its life-threatening risk.

**Key Words:** Latex allergy, environmental allergy, occupational allergy.

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## Introduction

THE EMERGENCE of a new medical entity is a rare event and is often met with skepticism. However, the number of people experiencing serious allergic reactions to latex has increased significantly since the late 1980s. Prior to that time, latex was not considered to be an allergen. Now, however, it is apparent that latex allergy poses a major problem for an increasing number of patients, health care workers, and institutions, often threatening both health and livelihood. So why the cynicism about latex allergy? It may simply be a reaction to the word "allergy." Many individuals who are not susceptible to allergies look upon any allergy as a sign of weakness of body or mind, as a deception by those trying to evade work or responsibility, or as more nuisance than anything else. Doctors tend to disbelieve anything they didn't learn in medical school, with a kind of rigidity that many would like to attribute only to the "older generation." This particular allergy should be of special interest and concern to anesthesiologists who treat patients with this condition at an especially vulnerable time, in the operating room, and who are themselves at high risk of developing latex allergy. For a more in-depth examination of latex allergy, please see the article by Brehler and Kutting (1).

## What Is Latex Allergy?

Patients and health care workers are regularly exposed to significant amounts of natural rubber latex from latex gloves. There are three categories of reactions to gloves worn as barrier protection (Table 1). Unfortunately, these are often grouped together as "latex allergy" or "latex glove reactions." Irritant dermatitis is an entirely non-immunologic response to glove use, and allergic contact dermatitis is a type IV or cell-mediated immunologic response to the chemical additives (including thiurams and carbamates) used to process most gloves; therefore, while these adverse reactions are byproducts of glove use, they are not symptoms of latex protein allergy. The immediate hypersensitivity IgE-mediated latex-protein reactions (type I) are the only reactions that are truly latex allergies. This immediate hypersensitivity is the only reaction to latex that is life-threatening and that has many effects that reach far beyond the localized area of exposure.

Signs and symptoms of latex allergy include eczema, contact and generalized urticaria and rhino-conjunctivitis. More serious reactions include asthma, anaphylaxis, and even death. The dose of allergen, route of exposure, and individual sensitivity influence the type and severity of the reaction. According to the American Academy of Allergy, Asthma & Immunology (AAAAI), the greatest danger of severe reactions occurs when latex comes in contact with moist areas of the body or internal surfaces during surgery, because more of the allergen can be absorbed into the body (2). Since intact skin provides a good barrier, the absorption of latex

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**TABLE 1**  
*Glove Reactions*

Reaction	Clinical Manifestation	Mechanism	Antigens	Diagnosis
Irritant	Skin red, dry, does not extend beyond contact site	(non-immune)	None	
Type IV Delayed	Skin red, dry, pruritus at site of contact, eczema, erythema, weeping, vesiculation, may extend beyond contact site	Cell-mediated	Manufacturing additives	Patch testing
Type I Immediate	Eczema, urticaria, angioedema, laryngeal edema, asthma, rhinitis, anaphylaxis	IgE	Small MW latex proteins	SPT, RAST, provocation testing

MW = molecular weight; RAST = radioallergosorbent test; SPT = skin prick test.

allergens is facilitated when this protective barrier is compromised, as with contact dermatitis or open wounds, thereby increasing the likelihood of an allergic reaction.

The respiratory tree is another important port of entry. Cornstarch lubricating powder adsorbs latex proteins during the glove manufacturing process. When these particles are aerosolized during routine glove use, everyone in the immediate area is exposed to latex without obvious contact.

A third route for high exposure to allergens occurs when internal and mucous membranes are exposed, as with patients who have undergone multiple surgical or invasive procedures (including patients with spina bifida) (3, 4). Latex is presently implicated as a leading cause of intraoperative anaphylaxis, causing up to 19% of such reactions (5, 6). This high prevalence is due in part to the high level of exposure sustained during surgery with latex gloves.

### What Is Natural Rubber Latex?

“Latex” is an emulsion of various compounds and does not necessarily imply derivation from the rubber tree. Natural rubber latex (NRL) is a plant product commercially harvested from the Brazilian rubber tree, *Hevea brasiliensis*. It is a complex intracellular product containing the rubber particle cis-1,4 polyisoprene, as well as hundreds of proteins, many of which have been identified as allergens. NRL is usually processed into 2 types of com-

mercial goods: most (90%) is processed into dry sheets (which are converted into molded rubber goods such as tires, shoe soles and vial stoppers), while the remainder is used for dipped rubber products (such as gloves, condoms, and balloons). These dipped products are the chief sources of bioavailable latex allergens (7).

The products which most commonly cause reactions are gloves, balloons and condoms. Gloves and balloons have by far the highest allergen content (Table 2) (8). This is why efforts to limit latex exposure in the medical environment focus on gloves. Although their allergen content is not very high, condoms can cause severe reactions because they come into contact with mucous membranes. Thus, the severity of reaction depends on both the allergen content of the item and its use.

Allergen units (AU) are determined with an ELISA (enzyme-linked immunosorbent assay) method in comparison with a standard preparation (9). The latex allergen content of different products depends largely upon the method of manufacture: dipped products, such as gloves, have a higher protein content than molded products. The proteins are especially concentrated on the surface of the glove, due to vulcanization or curing, which makes the product elastic. Although the amount of allergenic proteins, which are primarily water soluble, can be reduced if gloves are washed and leached, these steps add to the cost of the gloves. Nonsterile examination gloves are generally less “processed” and

**TABLE 2**  
*Extractable Latex Allergens in Some Medical and Consumer Rubber Items (6)*

Items/Manufacturer	Allergen (AU/mL)
Trojan ribbed condom/Carter Products (New York, NY)	50
Anesthesia breathing circuit Rebreathing bag/Intertech Resources, Inc. (Lincolnshire, IL)	50
Intravenous T-connector/Medex, Inc. (Hilliard, OH)	<5
Nasopharyngeal airway/Porges Corp. (Fairfield, NJ)	<5
Rubber balloon/Betta Products, Inc. (Chatsworth, CA)	4700
Baby pacifier/Playtex Inc., Family Products Div. (Stamford, CT)	<5
EZY infant care ortho nipples/Apothecary Products, Inc. (Minneapolis, MN)	<5
Evenflo wide-base nipples/Evenflo Products Co. (Ravenna, OH)	<5
Bodyguard nonsterile exam gloves/Jason Marketing (Huntington Beach, CA)	2,856–31,673

AU = allergy unit

have a higher protein content than sterile surgical gloves.

The methods used to reduce the “stickiness” of NRL can impact the allergenicity of the product. Powders used to prevent gloves from sticking to the mold (“mold-release compound”) such as cornstarch powder, which also aids in the donning and removal of these gloves, can markedly increase direct and indirect exposure to latex allergens through the aerosolization of latex allergens. In contrast, chlorination, a process used to decrease “tackiness,” decreases the amount of allergen present.

All of these elements influence the allergenicity of a particular glove or other product. Although the Food and Drug Administration (FDA) Center for Devices and Radiological Health is setting glove standards, there is currently no requirement or regulation for maximum protein or powder content. This creates a product selection quandary when attempting to select products that will effectively reduce latex exposure. Because of this lack of regulation, latex allergen content can fluctuate as much as

several thousand-fold, even within the same brand and type, and at different times (10).

### Protein and Powder

Latex allergy is an IgE antibody-mediated response to certain proteins present in NRL. Tests are available to measure the amount of total protein present, but they do not distinguish between allergenic and non-allergenic proteins. The modified Lowry assay, which is used most frequently, is relatively inexpensive and simple to perform, but becomes less accurate below protein levels of 50 µg/g. More recently, immunochemical assays have been developed, such as the latex ELISA for antigenic protein (LEAP) and radioallergosorbent test (RAST) assays, which are accurate to much lower levels of allergen and measure allergen as opposed to total protein content. Even though the Lowry method lacks the sensitivity and specificity of immunochemical methods (which are 150 times more sensitive), this assay method has become the current national standard, as ASTM D5712 (11). Many gloves currently on the market are designated “low protein” or have their protein levels printed on the package; however, the FDA does not require such labeling. Moreover, “safe” levels have not been established (12).

Many latex gloves, especially those that are produced cheaply, carry large amounts of powder. While the powder, usually cornstarch, is immunologically innocuous for most people, there is evidence that it contributes to granuloma formation, delayed wound healing, and increased infection rates in some individuals (13). The powder binds with latex proteins and is small enough to be inspired easily (14). As a result, latex proteins are constantly being inhaled in any environment where powdered gloves are in frequent use. The amount of airborne allergen is directly related to the frequency of changes of powdered gloves (15). In addition, the powder carries the proteins into the air and the air circulation systems of buildings as well as onto hair, clothing, charts, etc.

Education regarding gloves is essential. For the protection of their patients and themselves, physicians should insist on powder-free gloves and should be aware of the protein content of the gloves they use. According to the American College of Surgeons (16), “The ideal glove is one with less than 1 microgram/gm of allergen by the LEAP test and one to 14 allergen units/mL on the RAST inhibition assay. One should at least insist the gloves be less than

10 by LEAP assay or less than 100 allergen units on the RAST.”

### Incidence

Various studies of the incidence of latex allergy have defined it in different ways, and of course the definition will influence the results. Evidence for latex allergy can be elicited by a thorough history, or by RAST, skin prick testing (SPT), or provocation testing. Patients born with spina bifida have the highest prevalence of latex allergy of any known group, with sensitization rates of 30–65% (17). This high rate is probably due to the frequent occurrence of invasive procedures, such as catheterizations with latex catheters, and frequent surgery with latex gloves (4). Multiple reports of perioperative anaphylaxis in these patients in various parts of the country prompted the Centers for Disease Control and Prevention (CDCP) to alert medical personnel to this danger in 1991 (18). Physicians should report all episodes of anaphylaxis during procedures requiring general anesthesia, through their respective state health departments, to the Epidemiology Branch, Hospital Infections Program, in the Center for Disease Control's (CDC's) National Center for Infectious Diseases (telephone 404-639-1550).

The most important common denominator for latex allergy is frequent exposure to latex. Atopic individuals who experience ongoing exposure to NRL are at greater risk for developing latex allergy. Groups at increased risk therefore include patients who have undergone multiple operations and workers, including physicians, nurses, dentists, food service workers, factory workers and day care workers, with occupational exposure to gloves. The incidence of latex allergy among health care workers and individuals with high occupational exposure is 5–17% (19–25).

There are industry-based reports suggesting that NRL exposure does not affect the sensitization rate of latex allergy. These reports are based on analysis of stored sera from phase 1 of the National Health and Nutrition Examination Survey (NHANES III 1988–1991) (26), which were tested for antibodies to latex to estimate the prevalence of latex sensitization in this representative sample of the U.S. population. Because of continuing scientific uncertainty about the results, this analysis has not been published in a peer-reviewed journal; therefore, the CDC warns that these reports should be read with caution. The NHANES survey was not designed

to assess latex allergy; therefore, information regarding actual latex exposure of participants was never gathered. Because employment and job title may not indicate the extent of exposure to latex, individuals must be categorized specifically with regard to their exposure. For example, a psychiatrist, with no ongoing latex exposure, is categorized in most studies of prevalence as a health care worker. On the other hand, there was the well-known case of a farmer who developed anaphylaxis intraoperatively and was later shown to have latex allergy. His doctors were baffled until they discovered that he had donned and doffed latex gloves many times a day to protect himself from pesticides.

Presence of latex-specific serum IgE is not synonymous with clinical latex allergy. In most studies, those with clinical latex allergy are a subset of a larger group with latex-specific IgE. It is possible that those with latex-specific IgE who are asymptomatic may progress to symptomatic disease as the result of continued exposure (27). Our experience leads us to agree with the incidence of clinical latex allergy cited by Brown et al. (28) of at least 2% in highly exposed medical personnel. There are about 100 attending anesthesiologists in the Anesthesia Department at Mount Sinai. One of us (BZP) has severe clinical latex allergy and has been unable to work since March 1997. Another staff member has also had to leave the practice of anesthesiology because of latex allergy. A third member of the department has latex allergy, but has been able to continue to work by practicing personal latex avoidance and taking a variety of medications. This individual has never experienced anaphylaxis in response to latex. Several residents in the department either have or suspect that they have latex allergy, but prefer to remain anonymous for fear of jeopardizing their training and future ability to get a job.

### Diagnosis

A knowledgeable physician should counsel all individuals with a strong history of latex allergy. Experienced physicians will often perform *in vitro* tests, as well as skin or challenge, testing to confirm the diagnosis. The only FDA-approved test for latex allergy is the RAST. The latex-extract skin prick test (SPT) is considered more sensitive and specific than the RAST; it is not yet FDA approved but appears to be safe and efficacious. Since only one-quarter of patients with a positive skin test

are symptomatic, this test must be interpreted with caution (29). If a positive result is associated with a suggestive clinical history, these tests can be considered diagnostic; however, as a screening tool, RAST testing is of uncertain value.

Ideally, conflicting results, either history-positive/test-negative, or history-negative/test-positive, should be confirmed with further studies. A latex glove provocation procedure can be used to confirm sensitivity. The procedure involves pricking the skin on the dorsum of the hand followed by application of a high-allergen glove (30). Wheal and flare at the puncture site are diagnostic. This provocation has also been used in clinical trials of NRL test extracts. Inhalation challenge by qualified personnel with experience in managing anaphylaxis may be used as an alternative for some subjects (31).

In many circumstances, logistical or time constraints prevent extensive evaluation. For history-negative/RAST or skin-test-positive individuals in the occupational setting, it would be prudent to limit direct contact with latex products and to use latex alternatives as appropriate. For patients, a positive latex test must be taken very seriously despite the absence of prior symptoms. There are many examples of anaphylaxis in previously asymptomatic persons who undergo invasive or surgical procedures or even rectal (32) or vaginal (33) examinations. Exposure and reaction to latex via mucosal contact can be many times greater than with occupational or casual exposure.

Further testing (such as skin prick testing or latex glove use tests) must be done for history-positive/RAST-negative persons. Up to 25% of patients with true latex allergy will not have latex-specific serum IgE, but rather cell-bound IgE (34). Furthermore, serum IgE may be transiently cleared from the bloodstream by overwhelming exposure to latex antigen.

In order to make a diagnosis of latex allergy, the only absolute requirement is an index of suspicion. The case of one patient illustrates this point. During the cesarean delivery of the patient's second child 13 years ago, she developed anaphylactic shock about 10 minutes into the surgical procedure. No attention was paid to the fact that four latex-gloved hands had been placed within her abdominal cavity. Anaphylaxis was recognized and treated promptly. Since epidural fentanyl was the only drug the patient had received prior to the event, it was considered to be responsible and was reported as such (35). Subsequently, an allergist famil-

iar with the issue diagnosed latex allergy. A retraction was then published (36). One wonders how many episodes of latex allergy, anaphylaxis, and even death have been wrongly attributed to other causes.

It is vital to be aware that about 50% of latex allergy subjects also have a food hypersensitivity (37, 38). The most common culprits are avocado, banana, kiwi and chestnut, but other foods have been reported as well. If individuals present with anaphylaxis due to these foods, latex allergy must also be suspected.

## Management

The cornerstone of latex allergy management is avoidance. Desensitization has not proved successful thus far. Patient education is essential, especially since health care provider education and acceptance of latex allergy is so variable. Excellent professional resources are available on the internet (39) as well as from local and national support groups. Patients must be counseled to wear a medic-alert bracelet, and to carry an epi-pen and other appropriate medications with them at all times. They must be aware of products and environments most likely to trigger reactions and, if necessary, educate their health care providers. Although there are thousands of products that contain NRL, only a small number of them (such as gloves and toy balloons) contain a sufficient allergen load to present an immediate risk to most individuals with latex allergy (8).

Allergen content of items varies greatly. In daily life, balloons present a significant risk (children's birthday parties, department store displays) and must be avoided. Another area of risk is the use of latex gloves in food service (40, 41). Latex gloves are often used when preparing uncooked foods, such as salads. When powdered high-protein gloves are used to toss a damp salad, the allergenic proteins are transferred to the food, and can cause severe reactions in a latex-allergic individual who eats it. However, the most dangerous environments are medical facilities. A visit to the dentist or gynecologist requires foresight and cooperation. The unplanned need to utilize ambulance or emergency room services can be life threatening.

## Management of Patients in the Hospital

Many elaborate protocols have been developed to protect patients with diagnosed or suspected latex allergy in the hospital and operat-

ing room. These vary in specifics, but all include labeling the patient, labeling the chart, alerting all departments (nursing, dietary, pharmacy, x-ray, housekeeping, etc.), placing the patient in isolation in an area where no latex gloves are used, and scheduling the patient as the first case of the day in the operating room to minimize airborne latex. These protocols also include provision in the hospital of a latex-free cart, and/or a latex-free crash cart. The institution of latex avoidance protocols has reduced the incidence of intraoperative anaphylaxis (42). Unfortunately these protocols, which are baroque in their complexity, may fail to protect the patient fully and can lead to a false sense of security. A colleague with severe latex allergy unknowingly ate an item that had been handled with latex gloves. Driving in his car shortly thereafter, his mouth began to swell; he developed progressive urticaria and bronchospasm, and began to feel some respiratory stridor. He drove to the nearest emergency room and was able to inform them that he was having an allergic reaction to latex. He was placed on a stretcher, and a latex-free cart was wheeled up. Nevertheless, a person attempting to be helpful thought that this patient might soon require intubation and placed a box of powdered latex gloves next to his head. Fortunately, subcutaneous epinephrine, followed by oral medications, relieved his respiratory distress.

### Management of Health Care Personnel

Many individuals working in the health care field have the mistaken notion that people with latex allergy can return to the workforce if they are simply provided with non-latex gloves. This wishful thinking is dangerous and can lead to heightened sensitivity and, ultimately, to the loss of a career. Individuals with latex allergy can become exquisitely sensitive to latex proteins that are spread throughout the health care environment. Powder is a major culprit, since it carries latex allergens all over the hospital or other setting. Those who continue to work using non-latex gloves in an otherwise unchanged environment are at high risk to develop occupational asthma, which can have lifelong consequences (43).

With ongoing exposure, individuals may require less and less allergen to cause a reaction, a phenomenon known as priming (44). Another complicating factor is the variability in the amount of latex exposure. An allergic person may seem fine for several days, followed by a

day when his rhino-conjunctivitis and asthma are almost uncontrollable. The individual is often puzzled by this symptom variability, and his colleagues may question his veracity. The explanation may lie in large part in the variability of allergen exposure, which depends on factors such as ventilation and glove batch. In addition, an individual's responsiveness to a standardized allergen challenge may vary over time.

### Strategies for Combating Latex Allergy

The optimal approach to controlling latex allergy is for an institution to stop using products containing NRL. Some institutions, notably Johns Hopkins, now use non-latex gloves throughout the institution. The benefits should be dramatic, since the allergen contribution of products other than gloves is tiny by comparison. This NRL reduction strategy eliminates the issue of environmental contamination by airborne latex allergens. It also significantly reduces the risk of occupational asthma for those already sensitized. The risk of allergic reactions associated with direct or indirect latex exposure is reduced for everyone in the environment, and there is no need for elaborate protocols to protect patients with latex allergy.

A second approach is to ban all powdered latex products and provide non-latex gloves for those who need them or choose not to expose themselves. This has been termed the "latex-aware" or "latex-reduced" approach, and has been adopted at some institutions, especially those children's medical centers that treat many spina bifida patients (45). At the Mayo Clinic, a multidisciplinary latex-allergy task force recommended that low-allergen gloves be used throughout the institution (46). Despite the concern that lower-allergen gloves would be more expensive, no correlation between glove cost and allergen content was found. Mayo Clinic was able to consolidate purchases and save money.

Another proposal has been the creation of "latex-free" zones within an institution. This shows a fundamental lack of understanding of latex allergy. You cannot quarantine or restrain a protein; it can become airborne and be carried on clothing, hair, and charts. However, in geographically isolated areas of an institution, such as laboratories, this strategy may be of some benefit.

Environmental and product standards have yet to be developed; therefore, it is critical to develop goal-oriented terms and objectives that

are practical and clear. "Latex-free" is the term used to describe products that are not manufactured from NRL. "Latex-safe" is the term most often used to describe an environmental and product standard which does not place latex-allergic individuals at risk for allergic reactions and heightened sensitivity, either by direct or indirect (inhalation) latex exposure. In addition, a latex-safe environment is one which reduces the risk of others developing latex allergy by the elimination of significant latex exposure.

### Governmental Responses

The only regulatory response to the latex allergy epidemic thus far came in September 1998, when the FDA required labeling of all medical products that contain latex and banned the misleading label "hypoallergenic" (47). The National Institute for Occupational Safety and Health (NIOSH) has made some recommendations regarding latex allergy, including the use of low-allergen, powder-free gloves (48). However, NIOSH is a governmental agency responsible for conducting research and making recommendations for the prevention of work-related illnesses and injuries, but has no regulatory powers. The Occupational Safety and Health Administration (OSHA), which does have such powers, has yet to generate any standards specific to latex exposure (49).

### Latex Allergy: The Future

Some latex glove manufacturers have instituted changes in their glove manufacturing process to reduce latex allergen levels. However, there are no government regulations regarding allergen content. Until there are, latex gloves will probably remain a public health problem. Voluntary labeling of gloves with their protein and powder content can help institutions protect their employees by lowering latex allergen exposure. Legal pressures on the rubber industry (litigation from injured or disabled parties) or, to some degree, pressures from the medical profession and advocacy groups, may bring about further improvements.

Many believe that the transition toward a latex-safe environment will be costly. However, a recent analysis of the financial impact, including the potential cost of disability payments, concluded otherwise (50). Two strategies, latex-safe versus status quo, were studied in three health care settings. Even with extremely low rates of latex allergy disability, the move to a latex-safe

environment was deemed to be cost-effective. Reduced sick time and enhanced work performance are thought to be additional benefits.

Ultimately, government regulations (and penalties) will probably be necessary to ensure that changes take place. The FDA has had proposed limits on powder and protein on medical gloves in the Federal Register since July 1999 (51), but no regulatory action has been taken to date.

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