

# Management of Latex Allergy

## Chapter 1:

### *Latex Allergy: An Emerging Healthcare Problem*

Allergy to natural rubber latex, commonly referred to as latex, appears to have been an uncommon occurrence before 1980 and the origin of the current proliferation of cases remains unknown.<sup>(1-3)</sup> Initial European reports of latex hypersensitivity described an unusual frequency of anaphylactic and other significant reactions in individuals, the majority of whom were health care workers, and confirmed the presence of latex-specific-IgE in a majority of cases.<sup>(4-8)</sup>

In the United States, attention to latex allergy was prompted by reports of several fatalities due to anaphylaxis induced by latex retention balloons used in barium enema procedures<sup>(9-11)</sup> and by frequent intra-operative anaphylaxis among children with spina bifida, a fact later attributed to the high prevalence of latex allergy among these children which was most probably induced by early and repeated exposures.<sup>(12-15)</sup> During the last five years, increasing evidence has accumulated that latex allergy has become a major occupational health problem, which has become epidemic in scope among highly exposed healthcare workers and in others with significant occupational exposure. Reports from multiple centers in different countries, using a variety of assessment instruments and criteria, are remarkably uniform in finding that between 8% and 17% of exposed healthcare workers, numbering well over one hundred thousand employees, are at risk for latex reactions.<sup>(16-21)</sup>

Among highly exposed patients, sensitization rates vary more widely, but in the most studied group, children with spina bifida, the prevalence ranges from 10% to 65%.<sup>(22-28)</sup> Further, elevated levels of latex specific antibodies are not confined to individuals in high risk groups alone; recent studies in Detroit and in the United Kingdom have demonstrated that more than 6% of blood donors have measurable antilatax IgE. The clinical significance of such antibody sensitization requires further clarification. However, since latex anaphylaxis has been reported among patients with no recognizable risk factors, this finding mandates a cautious attitude on the part of healthcare givers who direct procedures that expose mucosal and/or serosal surfaces to high concentrations of latex antigen.<sup>(29-33)</sup>

The personal and institutional consequences of latex allergy are considerable. Sensitized workers may develop occupational allergies, including urticaria, rhinoconjunctivitis, asthma and anaphylaxis which are probably primarily mediated by elevated workplace levels of latex allergen carried by latex glove donning powders.<sup>(34-36)</sup> Medical

procedures on sensitized personnel, including routine dental and pelvic examinations, may be complicated by anaphylactic events.

Disability issues are undefined in this "new" disease and in some instances, insurance carriers and health industry employers have been reluctant to support legitimate claims by affected workers. Those workers and patients most severely allergic may experience significant acute reactions from unintentional encounters with latex contained in a large number of household products and from cross-reactive food allergens.<sup>(8, 31, 37-43)</sup>

At the same time, the lack of information concerning the latex content of medical devices has resulted in severe allergic reactions in inadvertently exposed patients and in enormous duplication of effort by hospital and clinic occupational health units trying to maintain timely lists of "safe" goods for their latex allergic patients and workers. These unnecessary health care system costs and excess patient risks should be avoided.

The list of "unknowns" in latex allergy is lengthy. The natural history and progression has yet to be determined; anecdotal observations of some allergic healthcare workers suggest that sensitization may be long-standing, perhaps due to continued latex exposure outside the workplace.<sup>(3)</sup> Other than a history of atopy, risk factors for developing latex allergy are unclear; some studies have suggested that glove associated dermatitis, a very common condition, may increase risk substantially.<sup>(2,3,44)</sup> Epidemiologic studies to date have been confined to single timepoint prevalence assessments; longitudinal and case-control studies to delineate incidence, prevalence, and risk factors are urgently needed.

As indicated, workman's compensation issues remain undefined and some workers who have suffered anaphylactic reactions have been urged to return to their workplace without appropriate safeguards in place. Safety rules regarding latex exposure, especially latex aerosols, must be established. The gravity of this health care problem requires appropriate changes in patient care practices, occupational health guidelines, and effective leadership by governmental regulatory agencies to ensure that the welfare and safety of patients and of healthcare workers is not jeopardized by potentially harmful medical devices, including latex gloves. At a minimum, updating medical device regulations to require content labeling for natural rubber latex and to discard use of the term "hypoallergenic" as applied to latex and nonlatex gloves (as proposed by the Office of Compliance and Surveillance of the Center for Devices and Radiological Health of the United States Food and Drug Administration in a letter issued in March 1993), deserves immediate implementation.

The development of a comprehensive approach to safeguarding patients and healthcare workers should be viewed as an urgent priority. This

may require the cooperation and input of other relevant governmental agencies such as the Occupational Safety and Health Administration (OSHA) and the National Institute of Occupational Safety and Health (NIOSH) of the Centers for Disease Control, members of the rubber industry, as well as appropriate medical specialists and patient groups. The American College of Allergy, Asthma and Immunology suggests that following proposals be addressed immediately:

**Extractable latex allergen levels.** Latex allergen levels of different brands of gloves may vary more than 500 fold.<sup>(45, 46)</sup> The availability of several "low allergen" gloves demonstrates that the manufacturing technology to produce such gloves is available and commercially viable. Maximal levels of extractable allergen should be mandated effective no later than January, 1997.

**Content labeling of consumer goods.** Consumer goods may contain sufficient quantities of latex to elicit severe reactions.<sup>(47)</sup> A requirement for latex content labeling of consumer goods phased in over 1-2 years should increase consumer safety with minimal market disruption.

**Diagnostic testing.** The lack of appropriate commercially-available reagents for the diagnosis of latex allergy forces physicians to choose between utilizing their own "homemade" nonstandardized reagents for skin tests, a practice that has caused some severe reactions even in research protocols, or utilizing in vitro tests, which are less sensitive and may involve substantial time delay in obtaining results.<sup>(48-51)</sup> We urge that the FDA create a "fast-track" evaluation process for skin prick testing and, as an interim measure, permit commercial distribution of latex reagents that have proved safe and useful in other countries.

**Epidemiologic surveillance.** Appropriate epidemiologic studies of latex allergy should be funded to help identify the causes of this medical problem and to minimize the risk factors in its pathogenesis. Among the issues that need to be addressed are long-term trend analysis of incidence and prevalence of latex allergy, the possible evolution of contact to systemic reactions, delineation of the role and progression of allergies to foods that cross-react with latex,<sup>(43,52)</sup> and evaluation of the predictive value of a positive skin or in vitro test.

**Patient-Worker safety.** Sensitized workers must be provided a safe environment. Utilization of low-allergen powdered gloves may prevent measurable airborne latex exposure thus reducing symptoms among allergic employees and may result in reduced incidence of new sensitization in exposed healthcare workers.<sup>(53)</sup> However, creation of "safe" areas where only nonpowdered latex or nonlatex gloves are used may be required for some highly sensitive individuals.

All of the proposed measures are justifiable in terms of patient and employee health and welfare alone. The costs of initiating these proposals would appear to be small in comparison to the savings

expected from reducing the administrative, medical, disability, and liability costs of latex allergy .

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**Position Statement, American College of Allergy, Asthma & Immunology**

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## **Management of Latex Allergy**

### **Chapter 2:**

#### **About Latex Allergies**

**The incidence of serious allergic reactions to latex has increased in recent years. In rare cases, these allergies can be fatal. Health care workers and others who are frequently exposed to products containing latex should be aware of the potential for developing an allergic reaction. Individuals who exhibit symptoms of the allergy should be alerted to the need to avoid future exposure to latex products.**

#### **What is natural rubber latex?**

**Natural rubber latex is a processed plant product derived almost exclusively from the tree *Hevea brasiliensis* found in Africa and Southeast Asia. Natural rubber latex should not be confused with butyl- or petroleum-based synthetic rubbers. Synthetic products, including latex house paints, have not been shown to pose any hazard to latex-sensitive individuals.**

#### **What is latex allergy?**

**An allergy, or immediate hypersensitivity reaction, occurs when the body's immune system is sensitized to a foreign protein and reacts by forming a specific type of antibody, called an IgE antibody, specifically directed against this protein. This kind of antibody is responsible for a wide variety of allergic responses which may range from hives to allergic rhinitis (hay fever), asthma, or rarely, life-threatening allergic attacks (anaphylaxis). These allergic reactions are provoked by exposure to common allergens including cat dander, ragweed pollen or antibiotics, such as penicillin. Latex allergic individuals make allergic**



**antibodies directed against one or more proteins that are found in natural rubber latex.**

**What triggers the allergic reaction to latex?**

**When individuals allergic to latex come into direct contact with latex an allergic reaction may follow. Receiving medical or dental care from someone wearing a latex glove, blowing up a balloon or breathing in glove donning powder are all common examples of circumstances where allergic reactions to latex have been triggered.**

**What products contain natural rubber latex?**

**Latex is a common component of many medical supplies, including disposable gloves, airway and intravenous tubing, syringes, stethoscopes, catheters, dressings and bandages. Many of these medical devices come into contact with mucous membranes, which enhances the absorption of latex proteins that can trigger an allergic reaction. Latex gloves also frequently are implicated in allergic reactions due to the repeated direct exposure of the wearer's hands to latex proteins or due to airborne latex proteins that are absorbed by powders used to lubricate some latex gloves.**

**While latex also is found in as many as 40,000 consumer products, including condoms, balloons, athletic shoe soles, tires, underwear leg and waist bands, rubber toys, nipples and pacifiers, these seem to cause problems in the most sensitive patients.**

**What are the symptoms of latex allergy?**

**Allergy to latex proteins is a new medical problem with symptoms similar to those seen in individuals who are allergic to bee venom or cat dander. Reactions on exposure to the allergen are generally acute and may mimic hay fever or asthma, with symptoms such as nasal congestion, hives or difficulty breathing. The most severe cases can result in anaphylaxis, a potentially fatal reaction that affects many parts of the body at once. Symptoms of anaphylaxis are usually immediate, progress rapidly and may include a dangerous drop in blood pressure, flushed skin, difficulty breathing, swelling of the throat, tongue and nose, and loss of consciousness. Emergency medical attention should be sought at the first sign of an anaphylactic reaction.**

**Skin problems resulting from the use of latex and non-latex gloves are frequently confused with latex allergy. Contact dermatitis is a frequent problem in glove wearers which can be caused by frequent hand-washing and drying with irritating soaps, skin abrasions from donning and removing gloves and irritation of skin covered by an impermeable barrier. It can also be caused by contact allergy to one or several of the chemicals used in the production of rubber gloves. These are usually local skin problems but can involve larger areas. These local skin**

problems are not life-threatening, but may precede the development of latex allergy if latex exposure is continued.

How do symptoms develop?

In most cases, latex allergy develops after repeated exposures to latex. It should be noted, however, that direct physical contact with latex-containing products is not needed to trigger the allergic reaction. Cases of anaphylaxis have resulted from inhaling latex proteins, which can be absorbed by the powder that is used to lubricate some latex gloves. When the gloves are snapped on and off, the proteins become airborne and can pose a risk to some individuals with latex hypersensitivity.

How common is latex allergy?

It is difficult to say how widespread the problem of latex allergy may be. More than 1,700 cases of latex allergic or anaphylactic reactions, including 17 deaths, have been reported to the U.S. Food and Drug Administration (FDA) since 1988. It is assumed that many other cases go unreported.

Known risk groups include:

- ❑ Health care workers and others who wear latex gloves. (Individuals who have a history or who will be undergoing multiple surgical procedures, such as children with spina bifida.)
- ❑ Individuals with a history of progressive allergic reactions to foods known to cross-react with natural rubber latex.

Other risk factors are less defined but appear to include a history of:

- ❑ Allergic rhinitis (hay fever) or any other allergy.
- ❑ Hand dermatitis, particularly if severe or if changing in severity in those who wear latex gloves.
- ❑ Outside of these recognized risk groups, latex allergy is very uncommon, with estimates of less than a 1 percent prevalence in the general population.

Why is latex allergy more prevalent now?

The introduction of Universal Precautions in health care settings to prevent the spread of AIDS and hepatitis B resulted in a dramatic increase in glove usage. According to the U.S. Food and Drug Administration, most of the gloves used are imported into the United States and the number of such gloves increased by 247 percent from 1991 to 1996 to over 18 billion pairs of gloves. Latex gloves are the largest source of direct contact with latex products and the major

**source of latex aeroallergen in areas where powdered latex gloves are in use.**

**Who is most at risk of developing a life-threatening anaphylactic reaction to latex?**

**The risk of anaphylaxis appears to be greatest in individuals with prior allergic reactions to latex-containing objects or prior, unexplained reactions or anaphylaxis during a medical or surgical procedure. Health care providers with a history of severe or worsening latex-glove-induced eczema, hives or work-related rhinitis or asthma-like symptoms should be especially cautious.**

**What foods are known to cross-react with latex?**

**Some foods to which latex allergic patients frequently demonstrate sensitivity include avocado, banana, chestnut, kiwi, raw potato, tomato, stone fruits (such as peach, plum, cherry), hazelnut, melons, celery, carrot, apple, pear, papaya, and almonds. Reactions are less common but have been reported to peanut, peppers, citrus fruits, coconut, pineapple, mango, fig, passion fruit, condurango bark and ugli fruit.**

**Reactions to many foods have been reported in latex allergic patients. In many cases, researchers have confirmed the presence of cross-reacting proteins with proteins found in latex. It is now thought that many of these allergenic proteins are plant defense proteins found widely in the botanical realm.**

**While food allergy is common in latex allergic individuals, neither the presence nor the distinct food allergies can be predicted for any patient. More severe latex reactions do appear to necessarily increase the risk of food reactions. Initial manifestations of food allergy can be severe and even anaphylactic. Latex allergic patients should have personal epinephrine syringes available at all times for this reason alone.**

**Patients with a history of food allergies to foods known to cross-react with latex rubber, particularly if expanding to new foods and progressive in severity, should be considered at risk for latex allergy as well.**

**How can latex allergy be prevented?**

**All products and medical devices that come in contact with individuals at risk should be reviewed for possible latex content.**

**Respiratory exposure to latex proteins can take place in the absence of skin contact, since latex glove donning powders bind latex proteins in the gloves and carry them into the air. In recognition of this fact and that powdered latex gloves are the major source of latex aeroallergen, the American College of Allergy, Asthma and Immunology has issued a joint statement with the American Academy of Allergy, Asthma and**

**Immunology calling for usage of only non-powdered low-allergen gloves. Synthetic and vinyl gloves may be acceptable alternatives.**

**How can health care workers protect themselves from developing latex hypersensitivity?**

**Health care workers who must wear gloves with a history of latex sensitivity must stop wearing latex gloves and their co-workers must not use powdered gloves. Care should be exercised in the choice of substitutes, since all synthetic or non-latex products are not equally impermeable to blood-borne pathogens.**

**Health care workers with a history of glove-associated skin irritations, or contact dermatitis, should use alternative gloves (which may include latex gloves) and topical treatments to relieve their symptoms. Petroleum-based products have been shown to compromise the barrier function of latex gloves, and care should be taken in the choice of treatments used to relieve contact dermatitis.**

**How is a suspected latex allergy confirmed?**

**A skin prick test may be done to test for latex allergy, but there are currently no licensed reagents commercially available for the test. Recent research has demonstrated latex skin testing with reagent currently available in Canada and Europe has better diagnostic sensitivity than the current available FDA approved blood tests. Because of the potential for a life-threatening anaphylactic reaction to the test itself, skin prick tests for latex allergy should be performed only under the close supervision of an allergy specialist. An allergist-immunologist also can perform a blood test to confirm the presence of IgE anti-latex antibodies. There are currently three FDA-approved blood tests: the Alastat, the CAP and the Hycor assay. Skin patch tests are used to evaluate the cause of skin irritations, or contact dermatitis, caused by chemicals inherent in rubber gloves.**

**How are latex allergies treated?**

**The best treatment for latex allergy is avoidance. Allergy specialists can provide latex allergic patients with information which will help them identify situations that place them at risk; strategies for avoiding an allergic reaction; and information about sources of natural rubber latex exposure and ways to avoid skin and mucosal contact.**

**Patients with latex allergy are at risk of asthma on exposure to latex-containing aerosols and should try to avoid areas where powdered latex gloves or their products are used.**

**Personal measures including warning bracelets and adrenaline syringes, like those commonly used for bee sting allergic patients, should be worn or carried at all times. Unexpected exposures to latex**

during dental, medical or surgical procedures may be prevented by warning health care providers of latex allergy prior to any scheduled visit and at the time of emergency visits.

Allergic reactions to a wide variety of fresh fruits, vegetables, legumes and nuts may complicate the course of latex allergy. Most commonly, banana, avocado, kiwi, hazelnut, raw potato, tomato, papaya, citrus, celery or stone fruits are involved.

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## **Management of Latex Allergy**

### **Chapter 3:**

#### ***Management of Latex Allergy***

As a measure of infection control, all health professionals are urged to observe universal precautions. During the last fifteen years, an increasing number of dental professionals has started using gloves during all dental procedures to reduce the risk of disease transmission. The use of latex gloves has resulted in sensitization to latex of patients and practitioners. Allergic reactions to natural products items used in health care settings have become of increasing concern.

#### **Epidemiology**

In July 1991 the U.S. Food and Drug Administration issued a medical alert on allergic reactions to latex-containing medical devices, and requested that all physicians report patients who demonstrated allergic reactions to latex.

An international conference, "Sensitivity to Latex in Medical Devices," was held in Baltimore in Nov. 1992 to discuss the etiology, clinical evaluations, product development and research on reactions to latex, and to educate technologist, radiologist and nurses about latex allergy.

The American Academy of Allergy and Immunology formed a special committee to study the proposed FDA guidelines and other issues related to latex protein allergy. In 1992, Midmarc, which insures about 14% of medical product manufacturers asked its clients to begin labeling all products containing latex or natural rubber.

The efforts to monitor the latex allergic reactions among patients and practitioners produced results. The U.S. Food and Drug Administration received 1,118 reported cases of reactions to latex in a four-year period. There were 19 cases involving rubber dams, 407 involving examination gloves (both patients and health care workers reporting reactions to latex); and 77 reports involving surgeons' gloves, mostly involving patients. In addition, there were many published accounts of reactions to rubber dams and gloves used in dental procedures.

The FDA estimates that about 6 to 7% of medical personnel may be allergic to latex. There is evidence that dental professionals may be more allergic to latex than the general population. A survey of periodontists, hygienists, and dental assistants found that 42 percent reported adverse reactions to occupational materials, most of which were related to dermatoses of the hands and fingers. Atopic individuals reported the most severe reactions.

Atopy is an inherited tendency to develop some type of allergy, including several forms of allergies such as hay fever, eczema, and asthma. Individuals with spinal cord deformities, including spina bifida, also have an extremely high incidence of latex protein allergy, ranging from 18 to 40 percent. It is suggested that health care professionals should consider all spina bifida patients inherently allergic to natural rubber.

### **Introduction of Protein Allergens During Manufacture**

The history of allergy to latex products in humans goes back several decades. As early as 1913 there were reports of rubber glove dermatitis among public utilities linemen. Some common symptoms were itching, subsequent swelling and vesiculation on the hands, all of which are common to urticaria.

Over the years there has been a steady increase in the number of cases of hand dermatoses resulting from the use of rubber gloves, from six cases in 1949 to 40 cases in 1954. According to one theory about latex allergy, latex gloves inhibit epidermal cell proliferation and cause pronounced complement activation in vitro. In gloved hands, small skin lesions have little chance of healing and skin becomes sensitized to latex allergens.

The raw ingredient of natural rubber products is latex, a white milky sap extracted from tropical trees. Latex sap contains spherules of rubber, which are associated with a small amount of protein. Most natural

rubber proteins, however, are found in a hydrophilic portion of the sap called serum.

Ammonia is the preservative added to the sap which hydrolyzes the sap proteins, changing and degrading them. The end result is numerous protein allergens making it difficult to identify the specific proteins that cause the allergic reaction. This is why to this date there is no standardized test for latex allergy.

The next step in the making of natural rubber products is centrifuging the latex sap and collecting the rubber spherules. Centrifugation removes many impurities but not all serum proteins which may induce allergic reaction in many individuals are removed during this step.

There is yet another step that introduces allergens to rubber products such as gloves. Chemicals used in the manufacture of dipped products, such as gloves and condoms, may be responsible for cell-mediated or delayed Type IV allergy. Type IV allergic reactions range from simple irritations and contact dermatitis and, usually, occur 24 to 48 hours after exposure and affect only the exposed area.

Liquid latex undergoes vulcanization process during which it is subjected to sulfur and heat, turning the liquid mass into hardened rubber. The final manufacturing step calls for leaching of rubber products. During leaching, products are soaked in hot water to finalize curing. To reduce the possibility of latex antigens or processing chemicals seeping into final products in increasing concentrations, leaching water is replaced constantly during the curing process.

Proteins migrate toward heat during leaching. In dipped products produced on molds, as is the case with rubber gloves, leaching can bring allergens to the surface. The gloves are removed from the mold inside out which means that the wearer's skin will come in contact with the highest concentrations of allergens. The surface proteins can be removed with exhaustive washing, but that may make them unusable. The gloves are removed from the mold using cornstarch powder which may also be contaminated with latex protein allergens. The attempt to remove the powder by exhaustive washing creates the same problem of creating microholes in the gloves, rendering them unusable.

### **Allergy Development**

The following factors contribute to allergy development:

- a) Repeated exposure to an antigen increases sensitivities to that agent. This is why medical and surgical personnel and individuals undergoing surgery have a high incidence of latex allergy.
- b) Duration of exposure Surgeons and health care workers who wear gloves for extended periods of time are more prone to allergic reactions.

**c) Moist skin Latex antigens are water soluble making individuals with moist skin more susceptible to allergic reaction.**

**d) Hand lotions and creams also increase the amount of protein that transfers from the glove to the wearer.**

**e) Cornstarch has been linked to latex allergy in some research. Most gloves are powdered with cornstarch which can adsorb allergens from the latex. These adsorbed antigens could sensitize patients to latex during surgery if these particles contaminate wounds. Powders unadulterated with latex antigens have not been shown to cause allergic responses.**

### **Diagnosing Allergies**

**Allergies are difficult to diagnose because reactions vary from simple irritations to mild allergic reactions (such as wheezing, localized rashes or swellings) to anaphylactic reactions. These reactions vary from one individual to another and often produce different reactions in the same individual under seemingly similar circumstances.**

**Those most likely to have reactions are patients with spina bifida, persons who have undergone repeated surgery that involved extensive contact with rubber tubes or post-surgical drains and other rubber products, and patients with a history of other types of allergy.**

**The variations in allergic reactions can be attributed to the variation in the quality and quantity of protein in latex products. Adding to the variability is the property of latex proteins to attach themselves to powders used in gloves, allowing them to be airborne causing reactions without actual physical contact.**

**Latex proteins may be solubilized, attached to the cornstarch powder lubricant of gloves or found in an insoluble state.**

**All of the above factors contribute to the great variability in reactions to allergens found in latex products.**

### **Allergic Reactions**

**Patient allergic reactions to latex encountered in dentistry vary in type and intensity. Many health care workers who are allergic to latex first notice erythema, rashes, pruritis or similar problems with their hands. These are symptoms of allergy, either delayed or immediate. Delayed reaction allergies initiate small breeches in the skin. This allows latex to enter the bloodstream, resulting in an immunoglobulin E allergy.**

**The common approach to dealing with such problems is to ignore them, endure them or use steroid creams to alleviate the symptoms. Unfortunately, this allows the body to build even greater levels of**



antibodies to latex proteins. Years may pass while immunological symptoms escalate, as the individual continues to ignore them.

This can worsen the allergy culminating in anaphylaxis when the individual undergoes some type of surgical procedure.

Anaphylactic reaction is an immediate hypersensitivity response, commonly known as Type I immunologic reaction. Other Type I reactions are penicillin allergy, bee sting reactions, extrinsic asthma and allergic rhinitis.

Atopic individuals typically experience Type I chronic allergic reactions such as hay fever and eczema. Acute Type I reactions, such as asthma, urticaria and systemic shock are considered anaphylactic responses.

These reactions are mediated by IgE antibodies and progress in two phases: rapid and slow reactions. IgE antibodies can be found on mast cells in the tissues or basophils in the blood. When the latex antigen and an antibody attached to the mast cell or basophil react with each other, the cell rapidly releases its granules. These granules contain histamine, heparin, serotonin and arachidonic acid.

Common symptoms of the rapid phase of an anaphylactic reaction include:

- ❑ constriction of smooth muscles that have H<sub>1</sub> receptors, including bronchioles, leading to asthmatic reaction; gastrointestinal tract, producing diarrhea and vomiting; genitourinary, causing involuntary urination; endothelial cells, inducing edema;
- ❑ dilation of smooth muscles lining arterioles, which have H<sub>2</sub> receptors, precipitating a drop in blood pressure leading to shock.

The slow phase begins six to 12 hours after exposure to the allergen, leading to painful erythematous induration of the skin and prolonged bronchoconstriction, as well as increased gastric, respiratory and lacrimal secretions.

The rapidity, severity and scope of an allergic reaction are probably dependent on the route of exposure. A surgical procedure introducing antigens directly into the bloodstream is much more likely to cause acute anaphylaxis than a procedure where skin barrier is broken. In the latter case, the patient may suffer from angioedema or wheal and flare (hives) reaction. This may be the only clue that the patient could be allergic to latex proteins.

According to the FDA, mucous membranes may be especially reactive in the latex sensitive patient, so the dental health care worker should be cognizant of the possibilities of allergic reaction.

## Precautions Against Latex Reactions

Latex reactions are a source of concern in the delivery of health care. Three American Dental Association councils have issued a report with recommendations for minimizing adverse reactions to latex in the dental office. By including questions about latex allergy in the patient medical history and using alternative materials where indicated, dentists may prevent many allergic reactions to latex.

In patients, adverse reactions to latex may range from simple irritations or mild allergic reactions (e.g., wheezing, rash) to anaphylaxis. Latex sensitivity is more common in patients with spina bifida, those who have undergone repeated surgery involving extended contact with latex products, and patients with other types of allergy.

When taking the medical history, the dentist should inquire about the presence of any allergic reaction following contact with latex gloves or balloons. When a positive history is elicited, staff should use gloves made of vinyl or other synthetic polymers in place of latex; non-latex dental dams may be made of synthetic polymer glove material. Dentists may recommend that the patient undergo immunologic evaluation or wear a medical alert bracelet.

Among dental health care workers, the latex reactions that may occur include irritations, contact dermatitis, and anaphylaxis. Increased exposure to latex may heighten the risk and severity of reactions. Gloves should be worn only when needed for infection control purposes or to protect hands from chemicals or contaminated instruments. When changing gloves, hands should be allowed to dry completely before putting on gloves, and use of a skin lotion may help prevent irritation. Contact dermatitis should be treated promptly, with the affected worker limiting latex exposure during treatment.

To prevent anaphylactic reactions in latex-sensitive patients, clinicians may use synthetic gloves. Such gloves, however, may be vulnerable to solvents used in dentistry. For alternatives to latex gloves and other devices, see Table 1.

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Table 1.- Substitutes for Latex Dental Products

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<i>Latex Product</i>	<i>Substitute</i>
Rubber bite blocks	Molt mouth prop: Remove latex sleeve, wrap with gauze
Rubber dam	Synthetic glove

Orthodontic elastics	Closing springs
Prophylaxis cups	Prophylaxis brushes
Blood pressure cuff	Plastic disposable cuff; or contact area may be covered
Anesthetic cartridges	Anesthetic drawn from ampules or vials
Penrose drain	Drain made with synthetic glove

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Courtesy of Snyder HA, Settle S: J Am Dent Assoc 125: 1089-1097, 1994

Although immediate hypersensitivity to rubber is relatively common among patients with regular exposure to the material, severe anaphylactic reactions are unusual. One such reaction, possibly from sensitization to latex rubber gloves during numerous operations and vaginal examinations, is reported below:

**Case Report** Woman, 31, experienced facial and eyelid swelling, throat tightness, and shortness of breath with wheezing 10 minutes after leaving a hospital consultation. During the consultation, the patient's gynecologist had conducted a vaginal examination while wearing a rubber glove. Her general practitioner arrived and found the patient moribund. Anaphylaxis was diagnosed, and the woman was given adrenaline, chlorpheniramine, and hydrocortisone. The patient went into respiratory arrest during transfer to the hospital but survived. Her medical history included delayed hypersensitivity to nickel and multiple operations. The patient also reported a previous and less severe episode of facial swelling and wheezing after blowing up some balloons for a party.

Immediate hypersensitivity to latex rubber was believed to have caused the anaphylactic episode. The patient experienced a complete recovery and was discharged 24 hours after the incident. She was given syringes preloaded with adrenaline (0.5 ml 1/1000) for intramuscular injection and 240 mg oral terfenadine to use at the onset of another attack.

Blood tests done 36 hours after the reaction showed normal C3 and C4 concentration of 0.12 g/l, which ruled out angioedema. A prick test using a 1-cm-square piece of latex rubber revealed a positive hypersensitivity reaction 10 minutes later. No such reaction was noted when a control polythene glove was used. Prick testing with natural rubber latex showed a 5-mm wheal and 15-mm flare; no reactions were seen in six control individuals. Patch tests with various other rubber chemical were negative.

Four months after the initial reaction, the patient experienced another attack of wheezing and shortness of breath after the flow of air from a

deflating rubber cushion was directed at her face. During the episode, she injected the adrenaline given to her for home use. The reaction was less severe than the initial event, but hospital admission was still necessary.

### **Case Histories Related to Latex Glove Allergy**

Latex gloves worn during dental treatment can lead to adverse patient reactions, ranging from contact urticaria to systemic anaphylaxis. Patients experiencing adverse effects after contact with latex gloves or chemicals involved in the manufacture of latex are reported, as are measures that can help reduce the occurrence of allergic or anaphylactic reactions.

Those most likely to have reactions are patients with spina bifida, persons who have undergone repeated surgery that involved extensive contact with rubber tubes or post-surgical drains and other rubber products, and patients with a history of other types of allergy.

**Case 1** The first patient, a 76-year-old woman, noted a red area on the left side of the neck after preliminary impressions were obtained prior to provision of a maxillary partial denture. On examination, erythematous areas on the left side of the neck extending from the angle of the mandible toward the chin were noted. A smaller, bilateral erythematous area also was observed at the angle of the mouth. The inflammation subsided within 24 hours. The affected areas corresponded to the area likely to be in contact with a gloved hand during treatment. An allergy to latex was therefore suspected and confirmed by patch testing. The patient was effectively managed during later visits by an operator wearing vinyl gloves.

**Case 2** The second patient, a 42-year-old woman, was noted to have increasing swelling to the left side of her lip during maxillary left first molar restoration, which was not associated with the injection site or treatment-related trauma. Over the course of an hour, the swelling spread across the midline, although no increase in size was noted thereafter. The swelling subsided after 6 hours, and the lip returned to normal size 24 hours later. The patient had reported slight swelling to the lip during previous dental treatment. Latex-allergy-related angioedema was suspected, and tests for allergy to local anesthesia solution and latex verified the diagnosis. The patient's history was significant for allergies to various foodstuffs, as well as aspirin, hay fever, asthma, and eczema. Vinyl gloves were worn during subsequent treatment.

**Case 3** The third patient was a 60-year-old man who experienced circumoral erythema after undergoing general dental treatment. The patient was then referred to the dental hospital for further management, at which time he reported having previously noted a reddening of the scalp after wearing a rubber swimming cap, as well as multiple allergies.

Patch testing was performed, and results indicated allergy to various chemicals used during latex glove production. Treatment was successfully carried out by an operator wearing polyvinyl overgloves.

**Conclusions** Patients can experience adverse reactions after contact with latex gloves worn during dental treatment. Many patients who have latex hypersensitivities also have a history of other allergic conditions, such as hay fever. Allergy history should be obtained before undertaking treatment. Patients also should be questioned about any symptoms experienced after contact with latex-containing objects and any allergic or anaphylactic reaction that may have occurred after a medical procedure. When allergy is suspected, additional testing is necessary. Vinyl gloves or polyvinyl overgloves may be used for individuals with an identified latex allergy.

**Treatment** Immediate diagnosis and treatment of severe systemic anaphylaxis is needed to prevent death. The differential diagnosis includes vasovagal reaction, asthma, myocardial infarction, dysrhythmia, anxiety-related fainting, and effect of sedatives or local anesthetics. If a patient with anaphylaxis is unconscious, cardiopulmonary resuscitation should begin. For rapid-onset reactions, epinephrine should be given; if the practitioner cannot administer it intravenously, an intramuscular injection may be given with EpiPen, EpiPen Jr., Ana-Guard Epinephrine, or Ana-Kit. The deltoid is the recommended site of injection. If the primary symptoms are delayed-onset hives and itching, intramuscular injection of antihistamines is needed.

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## **Management of Latex Allergy**

### **Chapter 4:**

#### ***Guidelines for the Management of Latex Allergies and Safe Latex Use in Health Care Facilities***

**Gordon Sussman, M.D. and Milton Gold, M.D.**

#### **Outline:**

**Acknowledgment**

**Disclaimer**

**Introduction**

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- **Background**
- **Reactions Caused by Latex**
- **Risk Groups**
- **Reasons for the Increased Prevalence**

**Latex Allergy Guidelines for Health Care Facilities and Medical Clinics**

- **Latex Allergy Program**
- **Identification of High-Risk Patients**
- **Prevention and Management of Latex-Allergic Individuals**
- **Avoidance Issues**

**References**

**Appendix 1: Contributors**

**Appendix 2: Latex Allergy Questionnaire**

**Appendix 3: Patch Test Methodology for Glove Intervention**

**Appendix 4: Treatment for Severe Allergic Reaction**

**Use in Health Care Facilities**

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***This monograph was adapted for application in the United States with authors' permission by the American College of Allergy, Asthma & Immunology, August 1996.***

#### ***Disclaimer***

***These guidelines were developed by the authors through dialogue with and contributions from other stakeholders. These guidelines are intended as a framework to guide a health care facility in the management of safe latex medical product use. The decision to use latex or non-latex products in specific circumstances is the responsibility of individual facilities and health care professionals based on informed judgment and available scientific information.***

***Use of these guidelines is for information purposes only. The authors, the Canadian Healthcare Association and the American College of Allergy, Asthma & Immunology are not responsible for their application, or for facilities' decisions in the use of medical products.***

## **Use in Health Care Facilities**

### **Introduction**

**Natural rubber latex, commonly referred to as latex, is a common component of many medical supplies used in the hospital environment. Although latex is most often associated with disposable gloves, other items which may contain latex include airways, intravenous tubing, syringes, stethoscopes, catheters, dressings and bandages.**

**The reporting of allergic reactions to latex has dramatically increased in the past six years. The increased numbers of latex-allergic individuals have prompted the establishment of guidelines for patient care, such as those developed by the American College of Allergy, Asthma & Immunology ("Interim Recommendations to Health Professionals & Organizations Regarding Latex Allergy Precautions," March 1992). Frequent users of latex products may develop allergies to latex proteins, with resulting allergic reactions varying from mild to life-threatening. This document provides guidelines for management of individuals that are working with or exposed to latex in the health care facility**

environment. These guidelines were developed with the cooperation of several organizations and individuals in both Canada and the United States (see Appendix 1).

## Description of Latex Allergy

### Background

Natural rubber latex is a processed plant product of which over 99% of the world's supply is derived from the latex or the milky cytosol of the tree *Hevea brasiliensis* found in Africa and Southeast Asia. Latex is produced by specialized lactifer cells and is composed of various chemicals: lipids, phospholipids and proteins. The proteins are responsible for allergic sensitization predisposing to IgE mediated reactions. There are 200 other plant species capable of producing latex, but only one other, the guayule bush, has the potential to produce enough for commercial use.

After the harvesting process, ammonia and other preservatives are immediately added to the latex to prevent degradation. Other chemicals including anti-oxidants (phenylenediamine) and accelerators (thiurams, carbamates) are added to give the latex its desirable properties. Porcelain molds are then dipped into these latex concentrates to produce products of different shapes and sizes, such as balloons, gloves and condoms. The accelerators speed up the vulcanization or curing process in which the rubber precursors are cross-linked.

The chemical additives are responsible for some local skin reactions (for example, allergic or chemical sensitivity contact dermatitis), but are virtually never the cause of immediate generalized allergic reactions or anaphylaxis. These latter reactions are almost invariably due to immediate allergic sensitization to latex proteins themselves.

Natural rubber latex should not be confused with synthetic rubber (for example, butyl or petroleum-based). Synthetic rubber poses no hazard to latex-sensitive individuals (Jones et al., 1996).

## Reactions Caused by Latex

### Contact Dermatitis

Contact dermatitis, including both irritant and allergic responses, is the most common clinical reaction associated with latex and its additives. (Heese et al., 1991).

### Irritant Contact Dermatitis

Irritant contact dermatitis is a non-allergic skin rash characterized by hand erythema, dryness, cracking, scaling and vesicle formation. These changes may be due to sweating or rubbing under the glove and from



residual soaps and detergents in prolonged contact with the gloved cutaneous surface (Fay, 1991).

### **Allergic Contact Dermatitis**

Allergic contact dermatitis (ACD), or chemical sensitivity contact dermatitis, is a specific immune response of sensitized lymphocytes to chemical additives contained in latex products. This response is known as delayed hypersensitivity. Clinically at the outset, there may be an acute eczematous dermatitis on the dorsum of the hands often with vesicle formation. The lesions typically appear 48-96 hours after exposure. Subsequently, the skin may become dry, crusted and thickened. Etiologic agents involve chemical additives, such as accelerators or antioxidants. Thiurams and carbamates are commonly implicated agents, but ACD can potentially occur to any latex chemical additive (Conde-Salazar et al., 1993).

Contact dermatitis may be involved in latex sensitization. Irritant or allergic contact reactions reduce the barrier properties of the skin and allow absorption of larger amounts of chemicals or proteins. This is thought to increase the risk of latex sensitization. An increased frequency and progression through ACD may precede the onset of latex allergy (Charous et al., 1994). The use of cotton liners for protection under the gloves or the use of non-latex gloves should reduce sensitization and is recommended for individuals with irritant or ACD.

### **Immediate Allergic Reaction**

An immediate allergic reaction (or IgE mediated hypersensitivity reaction) is caused by latex proteins which directly sensitize the patient and subsequently cause allergic symptoms, including rhinitis (Carrillo et al., 1986), conjunctivitis (ibid.), urticaria (Nutter, 1979), angioedema (Axelsson et al., 1988), asthma (Seaton et al., 1988), anaphylaxis (Axelsson et al., 1987) and death (Ownby et al., 1991).

Direct contact with the medical product is not needed for sensitization to latex. Allergenic latex proteins are also adsorbed on the glove powder which, when latex gloves are snapped on and off, become airborne and can be directly inhaled (Lagier et al., 1990). Direct latex exposure at mucosal or serosal surfaces also occurs by repeated use of rubber catheters (Meerpol et al., 1993) or gloves used intraoperatively during abdominal or urologic surgery (Gerber et al., 1989; Gold et al., 1991).

Serious anaphylactic reactions have occurred in many different settings including vaginal deliveries (Laurent et al., 1992) and examinations (Axelsson et al., 1987); medical procedures, such as barium enema examinations (Ownby et al., 1991); dental procedures, with rubber gloves or cofferdams (Gratten and Kennedy, 1985); while donning gloves (Swanson et al., 1993); and intraoperatively, most commonly

during abdominal or genitourinary surgery (Gerber et al., 1989; Gold et al., 1991).

### Risk Groups

Populations at risk for developing latex allergy and the prevalence of latex sensitization in these groups are listed below.

#### Patient Risk Groups Prevalence of Latex Sensitization

Patients with spina bifida and congenital genitourinary abnormalities	18-73% [1]
Health care workers (housekeepers, lab workers, dentists, nurses, physicians)	3-17% [2]
Rubber industry workers	11% [3]
Atopic patients (asthma, rhinitis, eczema)	6.8% [4]
Patients who have undergone multiple procedures	6.5% [5]

[1] Slater et al., 1991; Kelly et al., 1994. [2.] Sussman et al., 1995; Turjanmaa, 1987; Zoltan et al., 1992; Lagier et al., 1993; Arellano et al., 1992. [3.] Tarlo et al., 1990. [4.] Shield and Blaiss, 1992. [5.] Moneret-Vautrin et al., 1993.

In addition to these risk groups, individuals who have certain food allergies, including banana, avocado, chestnut, apricot, kiwi, papaya, passion fruit, pineapple, peach, nectarine, plum, cherry, melon, fig, grape, potato, tomato and celery, may also have a coexisting latex allergy (Kurup et al., 1994). Other implicated foods and food products include apple, pear, carrot, hazelnut, wheat, rye, mugwort, profilin, potatin, plant stress proteins and ficus. The latex sensitivity may appear before, at the same time or after the development of the food sensitivity. Questioning about latex reactivity and skin and serologic testing should be considered in this group. However, not all patients with these food allergies will require latex avoidance, and similarly, not all patients with latex allergies will have problems with these foods.

Patients with none of the above risk factors may still be allergic to latex. A recent study of 1,000 volunteer blood donors found a 6.4% prevalence of serum specific anti-latex IgE antibody (Ownby et al., 1994). A second study reported 10 out of 224 (4.5%) allergy clinic patients with a positive skin test to latex (Hadjiliadis et al., 1995). Most of these patients were symptomatic on latex exposure, but the full extent of the clinical relevance of these results is unknown. The fact that symptomatic latex

allergy has been reported in the absence of known risk factors suggests that these findings may have significance for some affected individuals (Charous, 1994).

The frequency of clinical reactions to latex has not been determined for those with intermittent use of rubber gloves, such as police officers, ambulance attendants, funeral home workers, firemen, restaurant workers, painters and gardeners.

### **Reasons for the Increased Prevalence**

There are several theories that explain the recent increase in prevalence of latex allergy. The most plausible is the introduction of universal precautions in an effort to prevent the spread of hepatitis B and HIV infections (Centers for Disease Control, 1987). With universal precautions, a single standard of blood and bloody body fluid precautions must be used with all patients at all times, as it is assumed that these fluids are potentially infectious. One of the main ways of complying with universal precautions is through the use of gloves. This has created a growth industry for latex glove production and has resulted in greater exposure of predisposed health care workers and patients to latex products.

Increased demand for latex gloves created changes in glove processing and manufacturing, including shorter wash and shelf times, which have increased the amount of latex protein antigens in gloves and other products (Levy et al., 1992). Despite improvements to the manufacturing process to reduce the protein allergens, high levels of extractable latex antigens are still being found in latex gloves. Recent research has indicated that not all manufacturers have lowered the allergen level (Jones et al., 1994). Low-protein latex gloves are now being evaluated for allergenicity (Yunginger et al., 1994).

Another reason for the increased prevalence relates to the greater familiarity with latex allergy and the corresponding increased recognition and reporting of it (Kelly et al., 1994). For general reviews on the origins of latex allergy, see Truscott (1995) and Charous et al. (1994a).

### **Latex Allergy Guidelines for Health Care Facilities and Medical Clinics**

#### **Latex Allergy Program**

A facility-wide strategy to manage latex allergies in the health care environment should include the formation of latex allergy task force and the development of appropriate facility policies, awareness and educational initiatives.

#### **Latex Allergy Task Force**

**A multidisciplinary latex allergy task force should be a regular part of the health care facility employee and patient care committee. The membership of this task force should include representation from the medical staff (medicine, surgery, allergy, anesthesia and radiology), nursing (operating room, ambulatory care, intensive care and general ward care), hospital administration, pharmacy, housekeeping, central supply and occupational health.**

### **Policies**

**Policies should be developed to manage the latex-sensitive individual in all areas of the hospital, with particular attention to high-risk areas. Emergency and X-ray departments, operating rooms, intensive care units, nurseries and dental suites are areas of high latex usage and airborne exposure.**

**A mechanism for the complete and timely evaluation of all suspected latex reactions should be in place. To facilitate reporting of possible latex-allergic symptoms, educational policies should be established for all hospital staff, presurgical and high-risk areas. Education on the potential health risks related to latex sensitivity should be first targeted to areas of high glove usage.**

**Policies regarding occupational latex allergies should address the issues of (1) measures to be taken for latex-related illness, (2) procedures for reallocation of severely allergic employees, (3) allowance of sick leave and workers compensation benefits, including relocation, short-term leave and long-term leave.**

**As the health care environment is continually changing, a regular review of latex allergy policies and procedures will be necessary.**

### **Consultation Services**

**Questions regarding latex allergy should routinely be asked of presurgical patients and prospective hospital employees.**

**A latex consultation service should be available for evaluation of latex allergic individuals. Any possible reaction to latex devices should be immediately reported to the consultation service, which should then conduct an investigation and advise follow-up testing and consultation as appropriate.**

### **Review of Glove Usage**

**As latex gloves are the most common medical product implicated in latex allergies, a facility-wide review of glove usage should be undertaken to determine the appropriateness of use (degree of risk, level of protection, compliance with universal precautions) and thereby prevent the unnecessary use of latex gloves (Sui et al., 1995). Non-**

powdered, low-protein gloves should be the standard in a health care facility with powdered, low-protein gloves available only on request and their use monitored.

Hospitals need to evaluate manufacturer information on non-latex gloves in areas of durability, barrier protection and cost. Substitute gloves, particularly vinyl, need assessment of barrier characteristics because some studies suggest a higher viral leakage rate than latex gloves. Until further studies are done, latex is still considered superior with respect to barrier characteristics against transmissible diseases (Korniewicz et al., 1992).

### Compendium of Products

The hospital should prepare a compendium of all hospital latex products. Ideally this compendium should include information on the content of latex protein. However, at this time, only the protein content of gloves is provided by manufacturers on a voluntary basis.

Lists of non-latex substitutes for medical supplies and devices should also be accessible. (A list has been developed by A.L.E.R.T., Inc. - Allergy to Latex Education and Resource Team, Milwaukee, Wisc.). Since manufacturers are continuously developing non-latex alternatives, a regular review and updating of these lists is recommended.

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### ACAAI Statement Concerning the Use of Powdered and Non-Powdered Natural Rubber Latex Gloves

*This statement was developed by a joint subcommittee of the American College of Allergy, Asthma and Immunology (ACAAI) and the American Academy of Allergy, Asthma and Immunology (AAAAI). It was approved by the ACAAI Board of Regents on the recommendation of the Executive Committee on July 21, 1997.*

IgE-mediated latex allergy is the result of the exposure of susceptible individuals to latex rubber proteins. Medical devices, principally latex gloves<sup>(1)</sup> are the largest single source of exposure to these potent allergens. Exposure to bioavailable allergen may be by direct contact with an offending device<sup>(2, 3)</sup> or by inhalation of allergen carried by cornstarch powder with which most powdered gloves are coated<sup>(4, 5)</sup>. The clinical manifestations of latex allergy range from mild contact urticaria to fatal anaphylaxis.

Allergic sensitization to constituent latex rubber proteins is linked to exposure to latex allergens in the vast majority of cases. Direct exposure to latex allergens results from either contact exposures to

medical devices and latex gloves <sup>(2, 3)</sup> or from respiratory exposure to latex aeroallergen carried by donning glove powders <sup>(4, 5)</sup>.

Latex occupational asthma may result from inhalation of latex rubber proteins carried on glove powder from latex gloves <sup>(6-8)</sup>. Asthma caused by occupational exposure may continue and lead to persistent impairment, and rarely, to disability <sup>(9)</sup>.

These risks of acute allergic reactions and of occupational asthma can be reduced only by curtailing exposure to latex rubber proteins <sup>(10, 11)</sup>. We recommend that the following steps, which utilize currently available devices, be taken to reduce these risks:

- ❑ Latex gloves should be used only as mandated by accepted Universal Precautions standards. The routine use of latex gloves by food handlers, housekeeping, transport and medical personnel in low risk situations (e.g., food handling, bed transport, routine physical examination) should be discouraged.
- ❑ Only low-allergen latex gloves should be purchased and used. This will reduce the occurrence of reactions among sensitized personnel and should reduce the rate of sensitization <sup>(12-14)</sup>.
- ❑ Only powder-free latex gloves should be purchased and used. This will reduce latex rubber aeroallergen levels and exposure. <sup>(15-17)</sup>

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## **Latex-Safe Environment**

**A latex-safe environment should be the goal of the health care facility. Latex-safe carts containing non-latex substitutes should be available in all patient care areas, particularly those with high latex usage.**

**A latex allergy quality assurance program should be established and address the following areas:**

- supervising latex use in the hospital areas**
- developing databases of all latex products**
- developing databases of all latex substitutes**
- assessment and reporting of all latex-related reactions**
- supervising and maintaining latex-safe environments**
- changing to low-protein, low-powder latex gloves.**

## **Identification of High Risk Patients**

**Patients belonging to high risk groups should be identified. The following should be carried out by a physician for all high risk patients:**

**All historical data should be documented with written reports of all reactions to latex (medical, surgical or dental products; household products, such as gloves, clothing or toys). Clinical allergic responses include contact dermatitis, urticaria, angioedema, rhinitis, conjunctivitis, asthma and anaphylaxis.**

**Unexplained allergic/anaphylactic reactions, intraoperative events, a history of multiple surgical procedures, reactions to latex cross-reacting foods, and the presence or past history of documented atopic disorders (asthma, rhinitis or eczema) should be studied and subsequently appropriately identified. A sample questionnaire on patient latex allergies is provided in Appendix 2.**

## **Patient Testing**

**Patient testing should include sensitivities to rubber additives and allergic reactions to latex proteins.**

***Rubber Additives* Patients with hand dermatitis and exposure to latex should be referred for consultation to determine and document sensitivities to rubber additives. Patch testing is the diagnostic method**



for allergen identification in allergic contact, but not irritant dermatitis. In patch testing, immunogenic rubber additive chemicals of appropriate concentration are taped on the patient's back for 48-96 hours. Patch tests are preformed and interpreted according to standardized techniques (see Appendix 3).

All exposed patients with hand dermatitis should also be referred to an allergy specialist to determine if they possess IgE antibody to latex proteins.

Barrier creams used to relieve contact dermatitis can extract latex protein from latex gloves and may enhance skin penetration of allergens. Therefore, these creams should not be used by latex-sensitive patients (Truscott, 1995).

***Latex Proteins*** All high-risk patients in the health care facility should be encouraged to have latex allergy testing.

Low-risk patients with a negative clinical history of known latex reactions do not require allergy testing. The skin tests and in vitro tests available do not have the specificity to evaluate such patients. These individuals should be evaluated only if they have symptoms suggestive of a latex allergy.

***Skin Tests*** Presently, skin testing with allergen extracts is the most sensitive means of detecting IgE antibody.

Skin testing extracts to determine latex protein allergy have included commercial extracts, latex glove extracts and hevea leaves. No standardized latex extract is presently available. One extract used in Canada (Bencard Laboratories, Mississauga, Ontario) has been reported to have 93% sensitivity (Turjanmaa et al., 1994).

Glove extracts are made using a standardized method of soaking glove material in diluent. Extreme caution must be used with glove extracts because of variable allergenic protein levels and the potential for serious reactions from skin tests (Yunginger et al., 1994). Conversely, false negative skin tests may be produced by extracts of gloves with low latex allergen content.

Because of the potential for serious anaphylactic reactions, skin testing must be done by qualified specialists (Kelly et al., 1993), with full resuscitative equipment and medication available in the event of reactions to testing material (see Appendix 4).

***In vitro tests*** In vitro tests measure the IgE response in the serum of a latex-allergic patient. Analysis of the latex proteins has concluded that there are over 240 such proteins, and anti-IgE antibody testing has shown that 25% are associated with the allergic responses (Chambeyron et al., 1992). Latex IgE-binding proteins vary in size and

appear to differ between patient groups. For example, spina bifida patients have IgE antibodies to a 27 kD peptide, whereas health care workers may produce IgE antibodies to a 20 kD peptide (Slater, 1994). Research is ongoing in the characterization of these proteins with the goal of modifying or reducing the offending allergens.

In vitro testing should be done in the following circumstances: to confirm results of skin testing; when skin testing is considered too dangerous to perform; when skin testing is not available.

In vitro immunoassays are designed to measure IgE antibody in serum. Several research and clinical latex-specific IgE assay methods are currently used, including the enzyme linked immunosorbent assay (ELISA), the radioallergosorbent test (RAST) and ImmunoCAP System (Upjohn-Pharmacia, Uppsala, Sweden), and the latex AlaSTAT (Diagnostic Products Corporation, Los Angeles, Calif.). In addition, other research procedures, such as Western blot analysis, have been useful in identifying and characterizing the molecular weights of allergenic latex proteins. In early studies, the RAST displayed a 53% diagnostic sensitivity as compared to skin tests with latex extracts (Turjanmaa et al., 1988). Since then, more recent studies have shown that research assays and clinical tests, such as the AlaSTAT, have increased the sensitivity of allergic skin testing. In one study, this diagnostic sensitivity approached 96% in comparison to skin to skin testing (McCullough and Ownby, 1993). Both skin testing and in vitro assays detect the presence of a latex-specific IgE antibody in the skin and serum, respectively, and do not necessarily predict clinical presentations such as anaphylaxis (Kelly, Kurup et al., 1994). A significant association has been shown between the size of the skin test response and clinical manifestations (Hadjiliadis, 1996). Also, a negative latex-specific IgE test does not rule out a latex allergy. However, it is safest to recommend latex-avoidance precautions to protect all individuals with a positive latex skin test and/or serological test.

### **Prevention and Management of Latex - Allergic Individuals**

All individuals identified as latex-allergic by history or testing should be counseled by a knowledgeable physician. The following precautions apply:

- A medical alert bracelet should be worn to indicate their allergy.
- An epinephrine self-injection kit such as Epi Pen (Center Laboratories, Port Washington, N.Y.) or Ana Kit (Bayer Corporation, Pharmaceutical Division, West Haven, Conn.) should be available in case of latex-allergic reactions.
- Non-latex gloves should be carried by all latex-allergic individuals, as presently, latex substitutes may not be available at all health care facilities

- ❑ There is a risk of increasing allergic reactions if exposure to high levels of latex allergens continues.

## **Guidelines for the Use of Latex and Non-Latex Products**

### ***General health care facility environment***

**Powder-free, low-protein gloves or non-latex gloves should be used throughout the health care facility to reduce exposure to airborne latex particles. The use of high-protein, powdered gloves should be discouraged. Hospitals need to evaluate all non-latex gloves for their durability, barrier protection, and cost.**

**A health care facility should provide a latex-safe environment as follows:**

**Latex-safe environments should be provided for latex allergic patients needing medical, surgical or dental procedures. Latex-safe areas are defined as those containing only non-latex materials. This includes gloves, catheters, IV equipment, surgical tape, tourniquets, ventilation and airway equipment and medication containers without latex stoppers. As this is an evolving field, the allergenic risks of individual medical products are still being identified.**

**Latex-free material should be readily available to health care workers. Emergency carts with latex-free medical products should be available on the hospital wards, especially the emergency suites.**

**Dietary personnel should use non-latex gloves when preparing food for latex-allergic patients. It has been reported that latex-allergic patients have reacted to latex-contaminated foods handled by cafeteria staff wearing latex gloves (Schwartz, 1995).**

**Latex-allergic workers should use only non-latex gloves and other products, and avoid all latex-containing products. Other persons in the same work environment should use powder-free, low-protein gloves or preferably, non-latex gloves.**

### **Patient Guidelines**

**Efforts should be made to avoid latex exposure from birth in all children with spina bifida or other medical conditions which require early and repeated operation intervention or instrumentation, particularly if this involves the genitourinary system. In particular:**

- ❑ **Spina bifida patients have a higher sensitization rate and prevalence of latex allergy (18 - 73%, Table 1) with a higher risk of anaphylaxis during surgical procedures (Slater, 1989). It is believed that this is due to extensive latex exposure in early life.**

❑ **Reports of successful operations in latex-allergic spina bifida patients where the patients have been exposed to latex are misleading. Kelly, Pearson et al. (1994) found that latex- sensitive patients may experience anaphylaxis once every 13.6 exposures. Avoidance from birth is recommended to prevent sensitization and subsequent allergic reactions.**

**All spina bifida patients and all latex-allergic patients should receive detailed explanation and counseling about their allergy and safe alternative products, including the need for careful latex- avoidance procedures during medical, surgical and dental procedures (Sussman and Beezhold, 1995).**

**All hospitalized latex-allergic patients should have proper identification of their latex allergy on armbands, hospital charts, beds and room entrances.**

**Latex allergic patients should be admitted to latex-safe rooms. Latex products should not be used on other patients in these rooms.**

**All hospital personnel entering a latex-safe environment, whether or not they are in direct contact with latex-allergic patients, should only wear non-latex gloves. Hospital personnel who have used latex products prior to attending to the latex-sensitive patients should wash and gown before entering the patient's room to reduce potential exposure to residual latex powder.**

**Surgery of latex-allergic patients should be done in operating room suites that are latex safe. Ideally, the OR suites would also be monitored for airborne latex allergens (Swanson et al., 1993), as the patient should not have any direct or indirect contact with latex.**

**Procedures on latex-allergic patients carried out in the recovery room, intensive care unit, radiology suites, emergency departments, dental suites and other treatment areas require similar latex-avoidance precautions. If latex-safe rooms are not available, elective patients should be booked as the first case of the morning in order to minimize exposure to airborne latex.**

**If a patient has a history of a previous latex anaphylactic event, premedication with antihistamines and corticosteroids may be used in an attempt to minimize the consequences of inadvertent latex exposure. The physician may choose to premedicate latex allergic spina bifida patients no matter how minor their previous clinical reactions. However, premedication by itself has never been validated scientifically and must not be considered a substitute for latex avoidance (Langouet-Astrie et al., 1993).**

**Occupational Latex Allergy Guidelines**

**The responsibility for hospital-related latex illness should be assumed by the facility-based employee health units, occupational staff nurses and physicians. Representatives from these units should be part of hospital committees developed to manage latex-related hospital policies.**

**Questionnaires should be administered to all new employees to determine the risk or presence of latex-related problems.**

**Employees should be educated to recognize the signs and symptoms of possible latex allergy and encouraged to report the development of these symptoms.**

**All high-risk employees should have latex allergy testing. High-risk employees are those who use gloves regularly, have existing allergies, particularly to food, or have hand dermatitis or eczema.**

**Low-risk employees with a negative clinical history of latex reactions do not need allergy testing, but should be evaluated if symptoms suggestive of latex sensitivity develop during their employment.**

**Latex-allergic individuals with positive histories and skin tests should be counseled on the risk of continued work in environments with high latex use and advised to use only non-latex gloves and to avoid all latex-containing products. They should have proper allergic identification and always carry an epinephrine auto-injector device.**

**Persons with irritant or ACD should use cotton liners for protection under latex gloves or non-latex gloves.**

### **Avoidance Issues**

**It is highly unlikely that all patient exposures to latex in a health care facility can be eliminated for the following reasons:**

**It should be recognized that it is impossible to make an operating room completely latex free. The goal should be a latex-safe environment for allergic individuals through the use of non-latex products, and in the case of non-allergic individuals, through the use of low-protein, powder-free gloves.**

**The exact latex-avoidance measures necessary to prevent IgE-dependent allergic- sensitization reactions are not clearly established. There have been rare case reports of systemic reactions from IV tubing after needle punctures of the rubber ports presumably due to latex allergy (Schwartz and Zurowski, 1993). However, another study found latex-allergenic proteins in a multi-dose vial only after 40 punctures of the rubber stopper (Yunginger et al., 1993). Natural rubber latex must be differentiated from butyl rubber, which is used in rubber stoppers, and**

from synthetic rubber in latex paints, neither of which poses hazards to patients sensitized to latex (Yunginger, 1995).

As many as 40,000 consumer products may contain latex. At present, there is no requirement to label rubber products with their latex protein content. No standards exist for the measurement and reporting of latex protein and other substances, making comparison between products difficult. Legislation is needed to change this deficiency of inadequate labeling of sterile and non-sterile gloves and include a quantitative measure of glove protein antigen level.

In the United States, the Food and Drug Administration (FDA), published proposed mandatory labeling of latex rubber in medical devices in the June 24, 1996, Federal Register. The proposed regulations also would disallow use of the misleading term "hypoallergenic" on labels for medical devices that contain latex. These proposals are contained in the formal position paper issued by the American College of Allergy, Asthma & Immunology (Charous et al., 1995). The College also petitioned the FDA for latex content labeling of consumer goods and establishing maximum levels of extractable latex allergen levels in gloves.

Presently, the hypoallergenic labeling on gloves commonly refers to a reduction of rubber- additive chemical responsible for contact dermatitis. A clear definition and quantitative value for latex chemical additives and supporting test results should be encouraged by health care professionals. Hypoallergenic gloves often contain latex proteins which are responsible for severe life-threatening IgE-dependent allergic reactions. Manufacturers should remove the hypoallergenic label from products and relabel with all product components. Legislation is needed to clarify this issue by directing the manufacturer to provide information on the protein content, chemical-additive content and powder content of gloves.

The hazards of starch powder in aerosolizing latex allergens needs to be adequately addressed by both manufacturers and government. Latex gloves have been shown to be the major contributors to latex aeroallergens in hospital operating room environments (Heilman et al., 1996). Appropriate substitutes which do not disperse latex allergens and sensitize patients should be developed. At present, powder-free gloves appear to be adequate in preventing dispersion of allergens.

High-risk patients need to be informed that hospitals can be made latex safe, but not totally latex free. The risk of a reaction still persists. This can be controlled by an increased awareness among health care facility staff, the use of safe latex substitutes and the appropriate use of prophylactic medications where indicated.

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## **ACCAI Calls for Action to Control Risk of Potentially Life-Threatening Latex Allergy**

**ARLINGTON HEIGHTS, IL. —** The American College of Allergy, Asthma and Immunology (ACAAI) has called for significant changes in patient care practices, occupational health guidelines and government regulations to protect patients and health care workers at risk of developing potentially life-threatening latex allergy.

ACAAI's call for action is in a position statement, "Latex Allergy — An Emerging Health Care Problem," published in the July issue of *Annals of Allergy, Asthma and Immunology*, the organization's official medical journal.

"Latex allergy is a serious, increasingly widespread, but largely unrecognized health care problem," said B. Lauren Charous, M.D., chairman of the ACCAI Latex Hypersensitivity Committee, which authored the paper. "Its prevalence in certain high-risk groups has reached epidemic proportions."

Over the last five years, latex allergy has become a major occupational health problem in the United States with more than 100,000 exposed health care workers at risk for latex reactions, the paper states.

Latex allergy develops most commonly in people who have a history of frequent or intimate exposure to it. At high risk are those who have had frequent surgical procedures, particularly in infancy, and workers with occupational exposure, especially to latex gloves. A history of allergies or "hay fever" also may be a significant risk factor. Some studies suggest that individuals who have had dermatitis or rash and wear latex gloves may be at greater risk.

Life-threatening latex reactions recently have been reported in people with no recognizable risk factors. Studies in the United States and England found elevated levels of latex-specific antibodies in over 6 percent of blood donors, the paper reports.

Natural rubber latex, commonly called latex, is used in hospital and medical items, such as surgical gloves, anesthetic tubing, ventilation bags and intravenous lines, and a variety of consumer products, including balloons, condoms, tennis shoe soles, tires, underwear leg and waist bands, rubber toys, nipples and pacifiers. Seven million metric tons of latex are used in the production of latex products each year.

"Developing a comprehensive approach to safeguarding patients and health care workers is an urgent priority," said Dr. Charous of the Milwaukee Medical Clinic, Milwaukee, Wis. "We must ensure that the

welfare and safety of patients and health care workers are not jeopardized by potentially harmful medical devices, including latex gloves."

ACAAI recommends immediate implementation of proposed FDA regulations that would require medical device content labeling for natural rubber latex and ban misleading "hypoallergenic" labeling now permitted on some latex gloves. Beyond these measures, ACAAI recommends a five-pronged approach to help prevent severe reactions in latex-sensitive individuals and reduce the growing incidence of latex allergy, including:

- ❑ Require latex content labeling of consumer goods over the next one to two years.
- ❑ Improve and speed diagnosis of latex allergy by creating a "fast-track" evaluation process for skin prick testing. Until that is accomplished, make latex reagents proven safe and useful in other countries commercially available in the United States.
- ❑ Fund studies to help identify the causes of latex allergy and minimize risk factors contributing to this growing health problem.
- ❑ Provide a safe environment for allergic workers. Use only low-allergen gloves to reduce the amount of latex allergen released into the air. Create "safe zones" -where only non-powdered latex and non-latex gloves and medical devices are used - as necessary to protect highly sensitive workers.
- ❑ Mandate maximum levels of extractable allergen in latex gloves. Latex allergen levels vary 500-fold among different brands of the latex gloves commonly worn by health care workers.

The 3,900-member American College of Allergy, Asthma and Immunology supports professional and patient education on all aspects of clinical immunology and allergy. Board-certified allergists/immunologists complete a three-year residency in either pediatrics or internal medicine, followed by a two-year approved fellowship in allergy and immunology. These physicians are subspecialists in asthma and allergic disease.

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## **Appendix 2: Latex Allergy Questionnaire**

**Circle Y or N**

### **I. Risk Factor Assessment:**

**Exposure History:**

**Are you a health care worker? Y N**

**Do you wear latex gloves regularly or are you otherwise exposed to latex regularly? Y N**

**Do you have a history of eczema or other rashes on your hands? Y N**

**Do you have a medical history of frequent surgeries or invasive medical procedures? Y N**

**Did these take place when you were an infant? Y N**

**Do you have a history of "hay fever" or other common allergies? Y N**

**Do your fellow workers wear latex gloves regularly? Y N**

**Do you take a beta-blocker medication? Y N**

**Circle any foods below that cause hives, itching of the lips or throat, or more severe symptoms when you eat or handle them:**

avocado	apple	pear	celery	carrot	hazelnut
kiwi	papaya	pineapple	peach	cherry	plum
apricot	banana	melon	chestnut	nectarine	grape
fig	passion	fruit	tomatoes	potatoes	

## **II. Contact Dermatitis Assessment:**

**(for patients who wear latex gloves frequently)**

**Do you have rash, itching, cracking, chapping, scaling, or weeping of the skin from latex glove use? Y N**

**Have these symptoms recently changed or worsened? Y N**

**Have you used different brands of latex gloves? Y N**

**If so, have your symptoms persisted: Y N**

**Have you used non-latex gloves? Y N**

**If so, have you had the same or similar symptoms as with latex gloves?  
Y N**

**Do these symptoms persist when you stop wearing all gloves? Y N**

## **III. Contact Urticaria (Hives) Assessment:**

**(for patients who wear latex gloves frequently)**

**When you wear or are around others wearing latex gloves do you get hives, red itchy swollen hands within 30 minutes or, "water blisters" on you hands within a day? Y N**

#### **IV. Aerosol Reaction Assessment:**

**When you wear or are around others wearing latex gloves, have you noted any: Itchy, red eyes, fits of sneezing, runny or stuffy nose, itching of the nose or palate: Y N**

**Shortness of breath, wheezing, chest tightness or difficulty breathing?  
Y N**

**Other acute reactions, including generalized or severe swelling or shock Y N**

#### **V. History of Reactions Suggestive of Latex Allergy:**

**Do you have a history of anaphylaxis or of intra-operative shock? Y N**

**Have you had itching, swelling or other symptoms following dental, rectal or pelvic exams? Y N**

**Have you experienced swelling or difficulty breathing after blowing up a balloon? Y N**

**Do condoms, diaphragms or latex sexual aids cause itching or swelling? Y N**

**Do rubber handles, rubber bands or elastic bands or clothing cause any discomfort? Y N**

#### **Appendix 3: Patch Test Methodology for Glove Intervention**

**Individuals who have skin complaints should be assessed with patch testing. The standard protocol used by the North American Contact Dermatitis Group (NACDG) should be employed as described below. The allergens to be routinely tested include:**

- Black rubber mix 1%**
- Carba mix 3%**
- Ethylenediamine 2HCL 1%**
- Imidazolodiny l urea 2%**
- Mercaptobenzothiazole 1%**
- Mercapto mix 1%**



- O-Phenylenediamine 1%
- Thiuram mix 1%
- Triclosan 2%
- Volunteer-supplied latex glove

If the worker is exposed to glutaraldehyde (Cidex, Sporocidin) in the course of their work, this should also be included.

The allergens are applied to Finn chambers. The Finn chambers are placed on the upper back and affixed with Scanpor tape. The patches are left on for 48 hours. The patches are then removed and the sites left for 15 to 30 minutes to let the pressure effects wear off. The first reading is then completed. At 96 hours, the second reading is performed. The sites are scored as follows:

- 0: Negative or "doubtful" reaction
- 1: Weak (non-vesicular) reaction
- 2: Strong (edematous or vesicular) reaction
- 3: Extreme (bulbous or ulcerative) reaction
- 1R: Irritant reaction

#### Appendix 4: Treatment for Severe Allergic Reaction

Severe allergic reaction consists of symptoms including urticaria (hives), angioedema (swelling), closing of throat or difficulty breathing, lightheadedness and the appearance of flushing of the patient. Reactions can quickly proceed to severe anaphylactic shock. This includes hypotension and collapse.

The treatment consist of:

- Epinephrine 1:1000 0.3 cc subcutaneously stat (children 1:1,000, 0.01mL/kg up to 30 kg).
- Diphenhydramine 50 mg. I.M. stat (children 1 mg/kg up to 50 kg).
- Salbutamol (albuterol) 2 puffs stat. (if patient conscious and wheezy).
- Place patient in a head down position (Trendelenberg).
- Administer oxygen by nasal cannula if patient has cardiovascular or respiratory symptoms.

- Call for immediate assistance from ward/area and arrange transfer to the E.R. stat.

If any doubt regarding the status of the patient, err on the side of caution and have a cardiac arrest called.

- Do not leave patient.
- Ensure patient airway.
- Monitor vital signs.
- Initiate cardiopulmonary resuscitation if required.
- Repeat epinephrine q 10 minutes until patient transferred, if experiencing significant symptoms indicating a need for further epinephrine.

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