

Natural Rubber Latex Allergy Update

“Don’t let latex Irritate You”

By Lilia R. Faustino, RN, BSN, CPN(C)

Latex allergy is a major health issue, not only to health care workers who provide direct patient care but also to individuals in environmental services, dietary, and pharmacy, engineering and medical record departments who also have potential for sensitization. The severity of latex reactions to individuals allergic to this substance has forced the health care workers, rubber industry and The Food and Drug Administration to address this growing problem.

“Seventeen years ago, Dr. Dale Long, a general practitioner in Indiana, thought he was allergic to powder inside the latex surgical gloves; whenever anyone in the O.R. would put on or remove surgical gloves; the powder would fly and he’d start to wheeze and hold his breath. Eventually, he was diagnosed to have latex allergy but managed to continue to work for a while by administering epinephrine every fifteen minutes whenever he was at the hospital. No longer able to practice in a health care facility, he is now the medical director at a prison.

1988 - Dr. Barbara Tucker Pinchoff, was forced to give up her anesthesiology practice due to latex allergy. She went into anaphylactic shock during the C-Section delivery of her second child. She thought she was allergic to Fentanyl used in the epidural, but an allergy to latex was diagnosed two years later. Unwilling to stop working, she hoped that taking medication and avoiding latex as much as possible would be enough to bring her allergy under control. Despite of all these precautions, she went into anaphylactic shock on the job six months later. Now she is on total disability.”¹

¹Excerpt from an article by Margaret Veach, AM News Correspondent published in *American Medical News* - October 13, 1997 the American Medical Association.

Both physicians are allergic to natural rubber latex, the milky sap from which surgical and examination gloves are made. They are not alone - it is estimated that 10% -17% of US Health care workers are sensitive to latex. Exactly how many of these workers are physicians is not known. Latex - sensitive doctors are very reluctant to discuss their conditions for fear of losing their jobs and are concerned about being stigmatized or thought of as a quitter. Physicians are beginning to come forward. In August 1997, Dr. Pinchoff established a forum of physicians living with latex allergies and those concerned about stopping the increase of latex sensitization. They called this forum PALS (Physicians Against Latex Sensitization).

In order to understand latex allergy, the nature of the manufacturing of latex needs to be understood. Let me take you back to a brief review of the manufacturing process of natural rubber Latex gloves.

Natural Rubber Latex Glove Manufacturing Process²

1. Natural latex - containing protein is harvested from H. Brasiliensis rubber tree.
2. Auto-coagulation of natural latex is prevented by addition of ammonia.

² Hamann, Curtis, P. "Natural Rubber Latex Protein Sensitivity in Review" *American Journals of Contact Dermatitis*, Vol 4 No. 1 March 1993 4-21

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3. Natural latex is centrifuged and concentrated from 30 - 60% solids. Removal of serum phase reduces concentration of H₂O soluble protein.

4. Processing and attributes of the finished device depend on the addition of many chemicals to the natural latex. Significant type IV allergens include the accelerators and antioxidants.

5. Porcelain formers attached to a continuous chain are cleaned to remove debris from the previous cycle.

6. Formers are dipped in an emulsion to apply cornstarch powder as a releasing agent and a compound that coagulates liquid natural latex on contact.

7. Releasing agent and coagulants are oven dried.

8. Formers dipped into natural latex and a uniform film is deposited.

9. The coagulant and heat convert the natural latex from liquid to solid.

10. Rotating brushes contact the rotating formers and a cuff is rolled onto the glove.

11. Formers pass through warm H₂O baths to remove soluble protein and excess additives.

12. Cross-linking of the polyisoprene polymers is catalyzed by heat and requires an accelerator.

13. Cornstarch is applied to the outer surface of the natural rubber latex as a detacking agent.

14. The gloves are stripped from the porcelain formers.

The crucial variables that influence the degree of chemical removal are: a) Length of time in leaching tanks; b.) Rate of H₂O exchange; c) H₂O temperature.

To convert these gloves to powder free - chlorination wash is necessary which is the additional reduction of the H₂O soluble protein. It is also determined that chlorination has a measurably detrimental impact on the aging and physical properties of natural latex gloves.

Manifestations Of Latex Allergy

Latex sensitivity can manifest as:

Type I or Type IV.

Type I - Reaction produces immunoglobulin E antibodies on exposure to allergens. The antibodies bind receptors on mast cells and basophils. Future exposure can cause release of the contents of the cells, producing a hypersensitivity reaction. Symptoms appear rapidly as listed in the table. If absorbed through the skin, latex allergens can produce urticaria; if produced in the blood, they can result to anaphylaxis, a severe reaction. Life threatening symp-

toms include breathing trouble and rapid loss of blood pressure.

Type I (IgE- Mediated) Reactions + Immediate Hypersensitivity; Less common; Nasal puritus; Rhinorrhea Conjunctival puritus; Excess lacrimation; Conjunctival edema; Scleral edema; Wheezing; Bronchospasm; Angina; Tachycardia; & Progressively severe hypotension.

Type IV - The allergens activate T-lymphocytes and macrophages, thereby causing tissue damage. Symptoms are less severe than Type 1.

Type IV (Cell-Mediated reactions) + Delayed Hypersensitivity; More common; Contact puritus; Erythema; Vesicular lesions; Contact Urticaria; Eczema.

Instituting preventive measures is the most effective way to avoid a latex hypersensitivity in a patient. If an anaphylactic reaction does occur, provide volume expansion with normal saline or lactated Ringer's solution, administer 100% oxygen, and administer epinephrine in a 0.5 to 1.2 microgram/kg bolus. Management of diphenhydramine 0.5 to 1 mg/kg IV., methylprednisone 1 to 2 mg/kg IV, and ranitidine 0.5 to 10 mg/kg.³

The American Academy of Allergy and Immunology recommends that all people who have risk factors for latex allergy be tested for this allergy. Several testing methods are available. Useful tools for confirming latex allergy include: A skin prick test, (SPT); An intradermal test, (IDT); or a radioallergosorbent test, (RAST).

Although the SPT and IDT have the advantages of availability, low cost and rapid provision of results, they also have the potential to cause a full systemic reaction. In May 1995, the FDA approved the AlaStat latex allergen (Diagnostic Products Corporation, Los Angeles, CA), which uses liquid allergens to detect specific IgE's. This test is far superior to the other available test methods, particularly in terms of its reliability and consistency.

Patients with none of the risk factors, listed in the chart on the following page, 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 (Hadjiadiadis et al.,

³ Foley, Colleen, OR Pharmacist, Educational Services.

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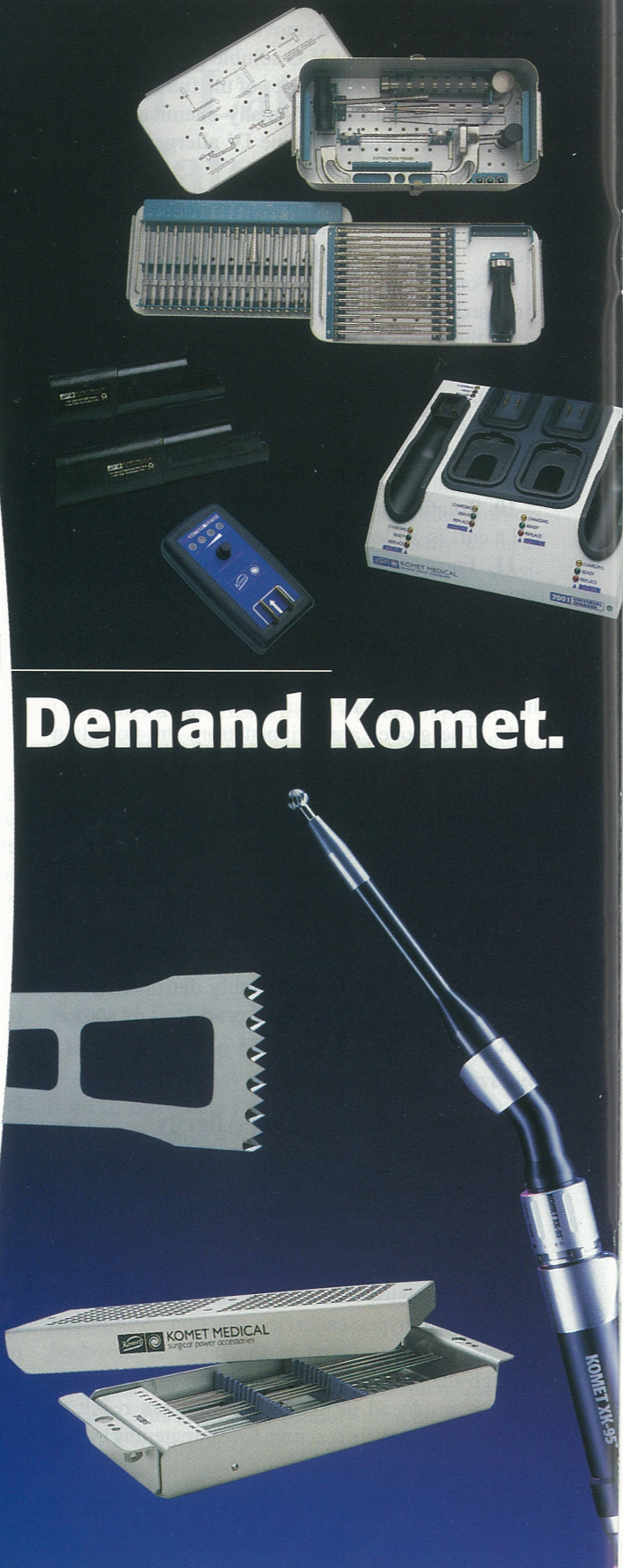
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Risk Groups

Patient Risk Groups	Prevalence of Latex Sensitization
Patients with spina bifida and congenital genitourinary abnormalities...	18 - 73% [1]
Health Care Workers (housekeeper, lab workers, dentists, nurses).....	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.

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 first report of an immediate hypersensitivity to latex originated in Germany in 1927. The earliest known cases in the United States were reported in 1988, after several deaths resulting from an allergic reaction to the latex tip of barium enemas.

Why The Sudden Rise?

Although Natural Rubber Latex (NRL) has been used in the health care facility for nearly 100 years, the number of reported cases of latex allergy has risen sharply only within the past 10 years. The most plausible is the introduction of universal precautions in an effort to prevent the spread of Hepatitis B and HIV infection (Centers of Disease Control 1987).

With the universal precautions, a single blood and body fluid precaution must be used with all patients at all times, as it is assumed that the 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 production and has resulted in greater exposure of predisposed health care workers and patients to latex products. Increased demands for latex gloves created changes in glove processing and manufacturing including shorter wash and shelf time, which have

increased the amount of latex protein antigens in gloves and other products. Despite improvements to the manufacturing process to reduce 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 levels.

Another reason for the increased prevalence relates to the greater familiarity with latex allergy and the corresponding increased recognition and reporting of it.

Early January, 1998 - *The Boston Globe On-Line* stated that a consumer group urged the government to ban powdered latex gloves, to withdraw powdered latex gloves from the market, citing dangerous allergic reactions that potentially affect tens of thousands of health care workers and millions of patients. Dr. Sidney Wolfe, Director of Public Citizens Health Group Research said, that studies show 1- 2% of the general population and 5 - 21% of health care workers are sensitized to latex allergens. From August 1996 to August 1997 the FDA received 305 reports of allergic and anaphylactic reactions to latex gloves, a figure Dr. Wolfe estimated as a tenth of the actual incidence, partly because the link between latex and allergic reactions is the first now being commonly made. He believes there probably have been a number of deaths associated with latex gloves that have not been properly reported.

Many hospitals across the country began addressing the issue of latex sensitivity several years ago. In 1993, Shriners' Hospital for Sick Children, in Springfield, Mass. became one of the first hospitals in the United States to go "Latex-Safe". The hospital now uses only powdered non-latex gloves.

Another facility that has made major changes is the Mayo Clinic. Three years ago, the clinic undertook a study to identify gloves low in latex allergens. By phasing out high allergen latex gloves entirely, the facility is now "Latex-Safe".

At Harvard's Brigham and Women's Hospital in Boston and Miami's Jackson Memorial Hospital, as many as 12 to 14 O.R. healthcare workers a day, were unable to work and had to be reassigned to desk jobs because of their allergic reactions. Jackson Memorial began experiencing problems with latex allergies in 1994. In May 1995, 98 employees had to be treated for problems relating to the gloves.

Apart from the human cost, sticking with powdered latex gloves can be expensive for hospitals. Latex allergies have also resulted in costly absences and compensatory claims. At Jackson Memorial Hos-

pital, two worker compensation settlements exceeded \$100,000 each and the on going expenses cost over \$370,000.

In 1998 the FDA encouraged glove makers to produce a powder-free product as stated by Dr. Bruce Burlington, medical device Chief. The FDA would not ban powdered gloves because so few alternatives are sold today that hospitals would face serious shortages. Powdered latex gloves make up the vast majority of the U.S. surgical glove market. Powder-free latex gloves make up about 26% of the market. Vinyl gloves, a relatively new product, are a small portion of the market. The FDA Associate Commissioner, William Hubbard, said the agency will soon start writing regulations to minimize these risks, but he would not provide specifics.

Scientists say that latex risk is exacerbated by gloves coated with cornstarch powder, which absorbs latex protein and emits them in dust as people pull the gloves on and off. The powder itself can cause complications including infections scar tissue when it gets inside surgical wounds as stated by Dr. Richard Edlich of the University of Virginia.

The FDA warned surgeons in 1971 to wash their hands after donning the gloves to remove some of the powder. In September, 1997 the FDA ordered every latex containing medical product to carry Allergy Warning labels.

Guidelines For The Management of Latex Allergies And Safe Latex Use in Health Care Facilities ⁴

These guidelines for Management of Latex Allergies and Safe Latex Use in Health Care Facilities were developed with the cooperation of several organizations and individuals in both Canada and the United States. They are intended as framework to guide health care facilities 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 judgement and available scientific information.

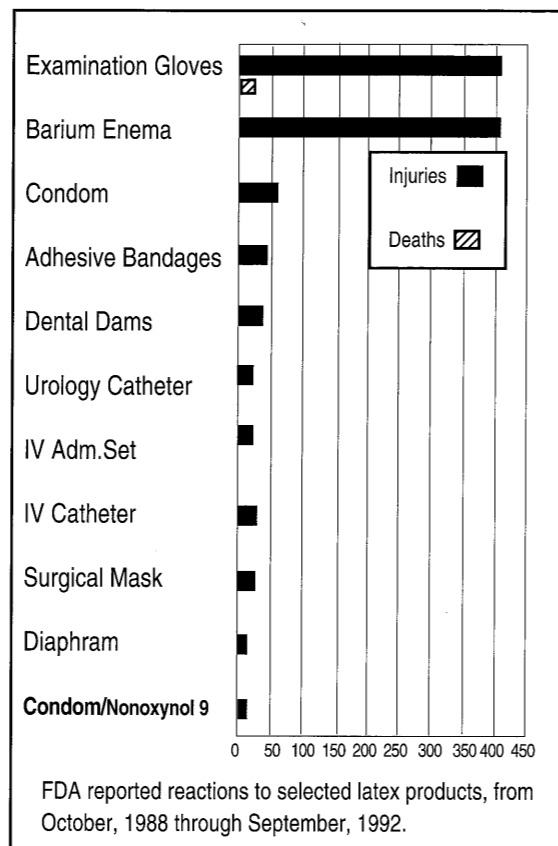
Patient Guidelines

Efforts should be made to avoid latex exposure from birth in all children with spina bifida or other

⁴Sussman, Gordon M.D. and Gold, Milton M.D. - Guidelines for Management of Latex Allergies. pp. 1- 21.

medical conditions which require early and repeated operation, intervention or instrumentation, particularly if this involves the genitourinary system. In particular:

- 1) Spina bifida patients have 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 early in life.

2) 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 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 O.R. suites would also be monitored for airborne latex allergens (Swanson et al., 1993), as the patient should not have any direct 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, pre-medication 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).

Establishing a Latex-Free Environment ⁵

In the hospital setting, all departments should be involved in providing a Latex-free environment. Although the Occupational Safety and Health administration, Centers for Disease Control and the FDA, are all obtaining information on latex allergy, little guidance on this issue currently is available. The following suggestions may help:-

- 1) Develop policies and procedures for screening,

⁵ OR Pharmacy Service Bulletin -1998 pp. 1- 5

identifying, and handling the latex-sensitive patient

2) Identify hospital products that contain latex. The purchasing or materials managements department should generate a master list and should circulate it to all relevant departments. Alteration of latex-containing products (e.g. by covering the rubber components of a blood pressure cuff) or identification of latex-free alternatives is necessary.

3) Mandate that non-latex gloves be worn when caring for latex-sensitive patients. Many hospitals now purchase only powder-free gloves, because the powder can act as a carrier for the latex protein.

4) Develop a program to educate staff on the signs and symptoms of a latex reaction, screening of patients, and treatment of an allergic reaction to latex.

5) Develop a procedure for identifying patients who are latex sensitive, including having patients wear wristbands, flagging their charts, and posting signs both outside the doors to their rooms and inside the rooms to alert health care workers that latex precautions are in effect. Ancillary departments (e.g., pharmacy, and laboratory) should be notified that a particular patient is latex sensitive.

6) Educate patients and their families on the potential severity of latex sensitivity. Patients should be encouraged to wear Medic Alert bracelets (MedicAlert, Turlock, CA) and to avoid latex containing products in the home.

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.

1.) All new employees, shall be given questionnaires to determine the risk or presence of latex-related problems. Recognition of signs and symptoms must be identified, and encourage employees to report them.

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

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

4.) 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.

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

It should be emphasized that it is impossible to make an operating room completely latex free. The objective should be a "Latex-Safe" environment for allergic individuals through the use of non-latex products, and for non-allergic individuals through the use of low-protein, powder free gloves.

The exact latex-avoidance measures necessary to inhibit IgE - dependant allergic sensitization reactions are not clearly initiated. There have been rare case reports of systemic reactions from I.V. tubing after needle punctures of the rubber ports, presumably due to latex allergy (Shwartz and Zurowzki 1993). However, another study found latex-allergenic proteins in a multi-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 guideline 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 U.S., the FDA published proposed mandatory labeling of latex rubber in medical devices in the June 24, 1996 "Federal Register". The proposed regulations 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 and 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. Health care professionals should encourage a clear description and quantitative value for latex chemical addi-

tives and supporting test results. Hypoallergenic gloves often contain latex proteins which are responsible for severe life threatening IgE dependant allergic reactions. Manufacturers should remove the hypoallergenic label from products and relabel them with all product components. Legislation is needed to clarify the issue by directing the manufacturer to provide information on the protein content, chemical-additive content and powder content of gloves.

The danger of starch powder in aerosolizing latex allergens needs to be adequately addressed by both the manufacturers and the 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 sufficient in preventing dispersion of allergens.

Hospitals can be "Latex Safe"

High-risk patients need to be informed that hospitals can be made "Latex Safe," but not totally latex free. The danger 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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