American Latex Allergy Association

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.[1-3] 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.[4-8]

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[9-11] 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.[12-15]

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.[16-21]

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%.[22-28] 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 antilatex 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.[29-33]

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.[34-36] 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.[8, 31, 37-43]

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.[3] 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.[2,3,44] 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.

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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:

1. Extractable latex allergen levels. Latex allergen levels of different brands of gloves may vary more than 500 fold.[45, 46] 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.
2. Content labeling of consumer goods. Consumer goods may contain sufficient quantities of latex to elicit severe reactions.[47] A requirement for latex content labeling of consumer goods phased in over 1-2 years should increase consumer safety with minimal market disruption.
3. 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.[48-51] 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.
4. 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,[43,52] and evaluation of the predictive value of a positive skin or in vitro test.

5. 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.[53] 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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Slinger, WI 53086
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