

Primary prevention of natural rubber latex allergy in the German health care system through education and intervention

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Background: The development of occupational asthma and allergic skin reactions caused by natural rubber latex (NRL) allergy are risks for health care workers. There are few published studies to suggest that intervention programs to reduce exposure will lead to primary prevention of sensitization. **Objective:** This study assesses the effects of intervention to reduce the incidence of NRL allergy in personnel working in health care facilities insured by the German statutory accident insurance company for health care workers, Berufsgenossenschaft für Gesundheitsdienst und Wohlfahrtspflege, with approximately 3 million insured employees, by switching to powder-free NRL gloves.

Methods: The timing of introduction of intervention strategies, such as education of both physicians and administrators, together with regulations demanding that health care facilities only purchase low-protein, powder-free NRL gloves are reported. We reviewed the annual numbers of reported suspected cases of NRL-caused occupational allergies and the amount and type of gloves used in German acute-care hospitals since 1986.

Results: The purchase of powder-free NRL examination gloves exceeded that of powdered gloves for the first time in 1998. This only became true for powder-free NRL sterile gloves 2 years later in 2000. The incidence of suspected occupational NRL allergy cases rose until 1998 and has declined steadily since. There was a 2-year lag between the beginning of the decline in the purchase of powdered NRL examination gloves and the beginning of a decline in suspected NRL-caused occupational asthma cases.

Conclusions: Despite the effect of increased recognition of NRL allergies, education about NRL allergies in health care facilities combined with the introduction of powder-free gloves with reduced protein levels has been associated with a decline in the number of suspected cases of occupational allergies caused by NRL in Germany on a nationwide scale. These results clearly indicate that primary prevention of occupational NRL allergies can be achieved if these straightforward and practical interventions are properly carried out and maintained. (*J Allergy Clin Immunol* 2002;110:318-23.)

Key words: Occupational asthma, natural rubber latex allergy, powder-free latex gloves, latex allergens, primary prevention

Recent investigations have shown that up to 17% of health care workers (HCWs)¹⁻⁶ are sensitized to natural rubber latex (NRL) allergens. The proteins present in gloves and other products made of NRL and the inhalation and skin contact with this material are responsible for sensitization.⁷⁻⁹ Even though there have been recommendations to use powder-free and low-allergen gloves as preventive measures, there are few investigations that have studied the effects of interventions involving decreases in NRL protein over time.^{10,11} Turjanmaa et al,¹² in Finland, reported cessation or declines in sensitization after changes in powder, allergen levels, or both in gloves in hospitals. In a cross-sectional study Levy et al¹³ found that no cases of sensitization occurred among dental students using powder-free gloves, whereas 5% to 15% of those using powdered gloves were sensitized. To our knowledge, no reports on a nationwide level have been published.

In a previous study we were able to show that by switching to powder-free NRL gloves, detectable NRL aeroallergens were completely removed in a health care facility. Sensitized HCWs were able to remain at work by supplying them with NRL-free gloves, thus showing that these simple and practical measures led to a successful secondary prevention of NRL allergy in HCWs.¹⁴ However, the investigation was not able to answer the question as to whether primary prevention might also be achievable by adopting these measures.

This report describes some of the methods and regulations that were adopted in Germany to educate personnel and policy makers about the dangers of the continued use of powdered NRL gloves and how these efforts have changed the glove-purchasing policies in acute-care hospitals and the incidence of reported suspected cases of NRL allergies among HCWs in Germany.

METHODS

Educational and regulatory measures

In December 1995, an interdisciplinary work group from the departments of dermatology, allergy, and occupational medicine of 7 German universities met in the Berufsgenossenschaftliches Forschungsinstitut für Arbeitsmedizin (BGFA), Bochum, Germany, to decide on recommendations concerning the prevention of NRL allergy in HCWs and allergic patients. Those guidelines for hospital administrators and personnel were published in several scientific journals¹⁵ and were also distributed by the BGFA. Two efforts by

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Abbreviations used

BGFA:	Berufsgenossenschaftliches Forschungsinstitut für Arbeitsmedizin
BGW:	Berufsgenossenschaft für Gesundheitsdienst und Wohlfahrtspflege
HCW:	Health care workers
NRL:	Natural rubber latex
OA:	Occupational asthma

state government organizations need to be specifically mentioned. In 1997 and 1998, the 2 largest German states, North-Rhine Westphalia and Bavaria, sent out informational material and questionnaires to hospital administrators asking about the use of powdered NRL gloves and pointing out that the use of powdered NRL gloves causes skin and respiratory allergies. An information leaflet concerning NRL allergy and stressing avoidance of powdered NRL gloves that was to be distributed by several semigovernmental statutory accident insurance companies responsible for any compensation claim by a worker was developed in 1996, and widespread distribution started in 1997. The greatest information campaign was carried out by the Berufsgenossenschaft für Gesundheitsdienst und Wohlfahrtspflege (BGW), the statutory accident insurance company for health care that is responsible for accident insurance, worker's compensation, and preventive measures. All private physicians' and dentists' offices, as well as all private and church-run hospitals (nearly 60% of all German hospitals with almost half of all hospital staff), are insured by the BGW. In 2000, the BGW insured 3,028,563 individuals. In 1997 and 1998, an information package with scientific and popular information concerning NRL allergy was mailed to all insured institutions. Fourteen regional informational events were organized that addressed the need for preventive measures, as well as the costs of switching to powder-free NRL gloves and the difficulties of convincing surgeons in particular of the obligation to switch to powder-free NRL gloves. During that time, our successful prevention study that was sponsored by the BGW ended, and the results were first presented at those meetings.¹⁴

In the regulatory field a new version of the compulsory technical regulations for dangerous substances (TRGS 540) was published in December 1997. This explicitly stated that only low-allergen, powder-free NRL gloves should be used and that the use of powdered NRL gloves was not permissible in the workplace.

Glove-use data

The glove data were provided by the Gesellschaft für Pharma-Informationssysteme mbH for the period from 1986 until 2000. The numbers represent the purchases of all acute-care hospitals by projecting from a sample of 280 hospitals. Data for the former East Germany have been incorporated since 1991. Separate numbers for powder-free NRL gloves became available in 1992.

Epidemiologic data regarding cases of suspected NRL allergies

Every physician and dentist is required by law to report a suspected occupational disease to the appropriate statutory accident insurance company. The number of reported cases of suspected NRL allergies (both skin and respiratory) became available from 1996 until September 2001 for all HCWs insured by the BGW. We extrapolated an estimate for the 2001 data from the known information up to September 2001. A detailed analysis of the insurance data made it possible to determine the number of insured personnel and the number of suspected cases in all BGW-insured acute-care hospitals and all German dentists' offices.

Patients

A different subgroup of patients was evaluated for the determination of latency periods between exposure to NRL and the development of allergic symptoms. Between September 1992 and December 1997, we evaluated the histories of 70 HCWs, mostly referred to the BGFA from local BGW offices (64 female and 6 male subjects; age range, 19-46 years), for the evaluation of workers' compensation of occupational asthma (OA) caused by NRL allergy (occupational disease no. 4301, obstructive airways disease [including rhinitis] caused by allergens). Inclusion criteria were a positive history of allergic respiratory symptoms when exposed to powdered NRL gloves at the workplace and a rhinitic or asthmatic reaction during challenge tests with powdered NRL gloves, as previously described. All subjects filled out 2 questionnaires, one dealing with their working and general medical history and one developed for occupational NRL allergy among HCWs.¹⁶ For the statistical analysis, we divided the subjects into 4 subgroups according to the time they started work and assumed that the start of work was identical to the beginning of NRL exposure at the workplace: 1986 to 1987 (n = 19; mean age, 21 years and 2 months; median age, 20 years and 3 months); 1988 to 1989 (n = 16; mean age, 20 years and 5 months; median age, 18 years and 4 months); 1990 to 1991 (n = 24; mean age, 20 years and 11 months; median age, 18 years and 4 months); and 1992 to 1993 (n = 11; mean age, 21 years and 11 months; median age, 19 years and 2 months).

Statistics

Statistical evaluations were performed with the SPSS for Windows software package (version 10.0.7S [German version]).

The correlation between purchase of powdered NRL examination gloves and the number of suspected cases of NRL-caused OA was analyzed with the Pearson correlation coefficient. The comparison of the 4 subgroups with a total of 70 patients with confirmed OA was performed with the Kruskal-Wallis test.

RESULTS

The greatest increase in the use of powdered NRL gloves was registered in 1990, when the purchase of non-sterile examination gloves more than doubled, from 166 million pieces in 1989 to 364 million pieces. The second largest increase took place in 1995, when a peak of 738 million powdered gloves was bought, resulting in an increase of 151 million from the previous year. Afterward, the number of purchased powder-free NRL examination gloves increased dramatically, and by 1998, sales of these surpassed the purchase of powdered NRL examination gloves (Fig 1 and Table I).

In 1986, only 37% of all nonsterile examination gloves were made of NRL, 38% were made of polyvinyl chloride, 18% were made of polyethylene, and the remaining 6% were copolymer gloves. This ratio increased to 75% in 1992 and reached 86% in 2000.

In 1992, the first year when powder-free NRL gloves were registered, they comprised only 1.0% of sales. By 2000, their market share had reached 85.3% of all non-sterile examination gloves bought by acute-care hospitals (Table I).

The number of sterile surgical gloves increased between 1990 and 1992, mainly because of the addition of data from the former East Germany. A decline in the use of powdered gloves started in 1997, and in 2000,

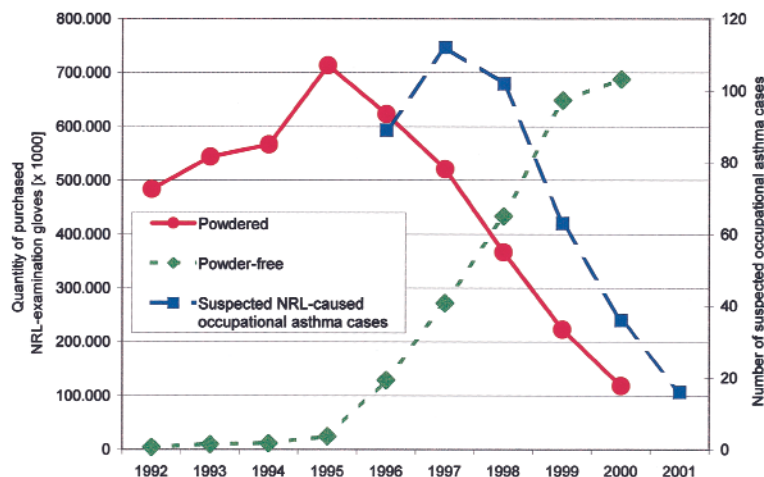


FIG 1. Purchase of nonsterile NRL examination gloves in all German acute care hospitals plus registered suspected cases of NRL-caused occupational asthma in private and church-run acute care hospitals from 1996 to 2001.

TABLE I. Glove-purchase data for German acute-care hospitals (GPI Krankenhausforschung)

Year	Nonsterile examination gloves, total ($\times 1000$)	Nonsterile NRL examination gloves ($\times 1000$)	Powder-free NRL examination gloves, %	Sterile NRL surgical gloves ($\times 1000$)	Powder-free sterile NRL surgical gloves, %
1986	161,358	60,449	NA	82,288	NA
1987	220,670	107,954	NA	86,062	NA
1988	255,674	127,947	NA	92,827	NA
1989	244,166	166,053	NA	84,921	NA
1990	524,987	364,951	NA	90,584	NA
1991	630,938	474,341	NA	107,107	NA
1992	649,029	488,894	1.0	119,116	NA
1993	727,713	553,783	1.8	116,770	6.8
1994	775,551	586,598	1.8	108,178	6.8
1995	902,682	664,985	3.1	133,190	7.9
1996	907,274	750,792	17.0	112,730	10.7
1997	942,344	773,551	32.6	107,894	14.9
1998	903,514	754,639	51.4	110,421	26.2
1999	1,030,991	869,789	74.4	113,813	46.8
2000	931,747	801,940	85.3	112,105	66.9

Data from the former East Germany are included from 1991 onward.
NA, Not available.

more powder-free than powdered sterile surgical NRL gloves were bought (Table I).

The total data for reports of suspected cases of occupationally caused NRL allergies are given in Table II. After an increase from 1996 to 1998, there has been a steady decline of suspected cases until 2001 for both skin and respiratory diseases in all fields of health care insured by the BGW.

The records for acute-care hospitals show a significant linear correlation ($r = 0.97$, $P = .0016$) between the purchase of powdered NRL examination gloves and the number of suspected OA cases, with a lag time of 2 years (Fig 2).

The number of suspected cases in dentists' offices declined after 1998 but has remained stable at a higher level when compared with that seen in acute-care hospitals (Fig 3).

In the 4 subgroups of 70 patients with confirmed OA who were examined at our office, there was a significant

decrease ($P < .0001$, Kruskal-Wallis test) of the interval between the start of work and first symptoms and onset of OA, respectively (Fig 4). The age of the subjects at the start of work was comparable. The self-reported first symptoms were urticaria in 39 (56%) subjects, urticaria combined with other symptoms in 8 (11%) subjects, rhinitis or asthmatic symptoms in 16 (23%) subjects, and solitary conjunctivitis in 1 subject. Of the 70 subjects with a confirmed occupational NRL allergy, only 3 (4%) reported signs of a bronchial obstruction among their first allergic symptoms.

DISCUSSION

The number of powdered NRL gloves purchased in acute-care hospitals in Germany for use in operating theaters and for examination purposes has dramatically fallen since 1996, after a massive increase beginning in 1986.

Historically, there were 2 main reasons for the increased use of powdered NRL examination gloves in Germany: (1) the increasing environmental pressure to reduce the use of polyvinyl chloride gloves because of their difficulty to decompose in landfills (lack of biodegradability) and potential to pose a pollution hazard when burned in incinerators and (2) the need to protect HCWs against infectious diseases, mainly HIV and hepatitis.

It was interesting to note that it took 2 years longer to reduce the percentage of powdered sterile NRL gloves below the purchasing level of powder-free NRL gloves when compared with the decrease in use of powdered examination gloves. A similar observation was also made in a study by Liss and Tarlo,¹⁷ who report that at the largest teaching hospital in Ontario, Canada, substitution of low-protein, powder-free NRL gloves for nonsterile powdered gloves took place in 1995, whereas replacement of powdered sterile NRL gloves with lower-protein, powder-free NRL gloves occurred in 1997, 2 years later.

Powder containing high levels of glove protein is suspected to trigger a sensitization to NRL. The accepted secondary prevention in NRL-sensitized individuals, especially HCWs, is to terminate any exposure to NRL products because further personal use of latex products or bystander exposure from coworkers might result in maintaining or worsening of sensitivity and health effects. It was our hypothesis that the use of powder-free, low-protein NRL gloves would reduce the incidence of sensitization and asthmatic symptoms.

A positive significant correlation between the use of powdered NRL gloves and the reported suspected occupationally caused cases of NRL allergy can be statistically confirmed by our data. The average time period between the start of work and first symptoms and first respiratory symptoms of 15 and 27 months, respectively, in workers with confirmed NRL allergy would explain the 24- to 36-month lag between the peak of glove use and the peak of reported cases, as well as the subsequent decline. In this study we only included patients who started work after 1986 because the glove database only contains information from 1986 until 2000. Our previous report on latency periods included a different subset of patients who had started work as early as 1975. In that group 63 patients had first symptoms of an allergy to NRL after an average of 58.7 months.¹⁸

The predominance of women (91%) in our study group replicates the female/male ratio of 89% versus 11% in nurses and assistance personnel in the German health care system (1999).

The available glove data only cover the acute-care hospitals, whereas the numbers for the physicians' and surgeons' offices are not known. Haamann¹⁹ presented data showing that the use of powdered NRL examination gloves and sterile gloves in dentists' offices remains at 43% and 49%, respectively. This is in agreement with our findings that the number of reported cases of NRL allergy have not decreased as much as in acute-care hospitals.

The first indication that reduction of powdered NRL gloves in a hospital environment led to a decrease in NRL

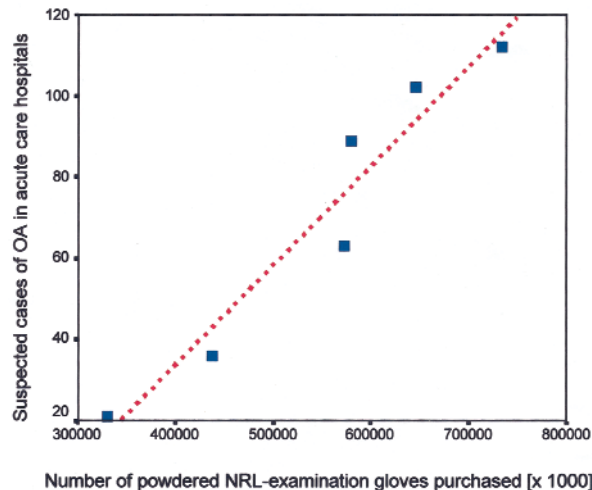


FIG 2. Correlation between purchase of powdered NRL examination gloves and the number of suspected cases of NRL-caused occupational asthma, with a lag time of 2 years (Pearson correlation coefficient, $r = 0.97$; $P = .0016$).

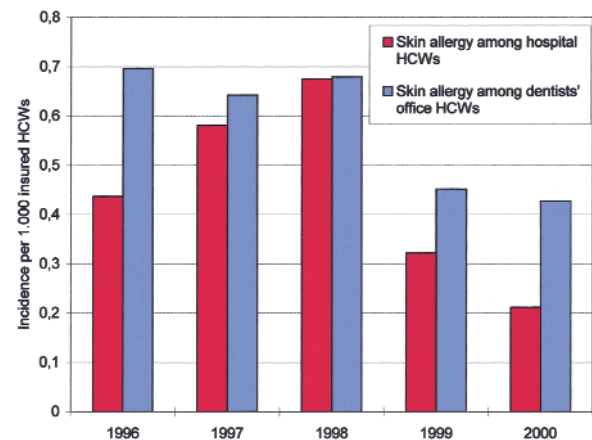


FIG 3. Incidence of suspected cases of occupationally caused NRL skin allergies in acute care hospital and dental office HCWs.

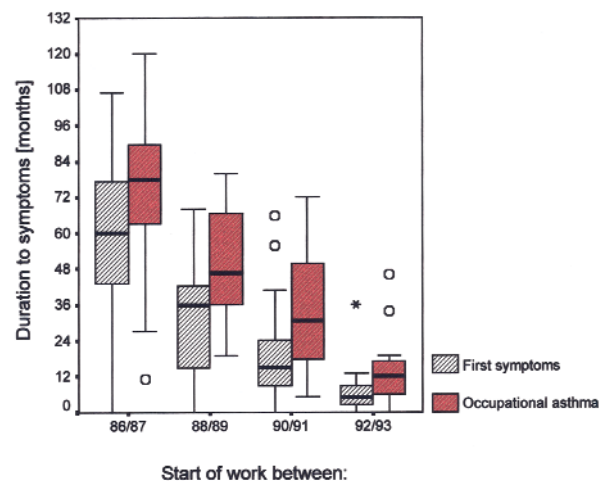


FIG 4. Interval between start of work and first NRL allergy symptoms and occupational asthma in 70 HCWs who began work between 1986 and 1993 ($P < .0001$; Kruskal-Wallis test).

TABLE II. Number of insured members of the BGW, total incidence of suspected cases of occupational skin disease and OA, and NRL-caused incidence

Year	No. of insured persons	Skin allergy cases	Suspected occupational disease		
			No. of NRL-caused skin allergy cases (%)	OA cases	No. of NRL-caused OA cases (%)
1996	3,235,412	6239	664 (10.6)	1003	280 (27.9)
1997	3,000,103	5969	846 (14.2)	1025	365 (35.6)
1998	2,899,409	6440	884 (13.7)	974	378 (38.8)
1999	2,877,176	5800	567 (9.8)	863	278 (32.2)
2000	3,028,563	5578	435 (7.8)	745	165 (22.1)
Jan 2001-Sep 2001	NA	4088	217 (5.3)	491	80 (16.3)

NA, Not available.

allergy incidence was published in 1998, when no new cases of sensitization among HCWs in a powder-free environment were found, whereas 2 new cases of positive skin prick test responses could be documented where use of powdered NRL gloves had been maintained.^{7,8}

The increase in reported cases from 1996 to 1998 is probably not only caused by an increase in the incidence of NRL allergies but also caused by the information campaign that reached every physician's office in 1997 and 1998. Before that period, knowledge about NRL allergies had been mostly limited to allergy specialists. With increased knowledge, general practitioners, as well as surgeons and other physicians, were more likely to identify and report work-related NRL allergies. Therefore we assume that the steady decline in reported cases from 1998 until 2001 corresponds to a real reduction in the incidence of NRL allergy among HCWs insured by the BGW.

Tarlo and Liss^{9,17} also reported that despite the effect of increasing recognition, the introduction of gloves with reduced powder, protein, or both, as well as other interventions, have been associated with declines in the number of cases of NRL-caused OA in Ontario, Canada.

We could show that there was a significant decrease in time from onset of work until the first symptoms of NRL allergy were reported in subjects who started working in the health care environment during the time period between 1986 and 1993. The findings imply that there might be a relationship between the increase of NRL glove use and the time it takes for sensitization and allergy toward NRL to develop. This holds true for allergic skin symptoms, as well as for symptoms of the respiratory tract, such as rhinitis and asthma. However, it was not possible to determine the true amount of exposure in each individual subject, and therefore no clear dose-response relationship can be postulated.

Recommendations to use powder-free, low-protein NRL gloves or non-NRL gloves have been available (eg, by the Occupational Safety and Health Administration in the United States and other organizations in many other countries).^{11,20} Up to now, only reports at the level of the individual patient or hospital have shown that these recommendations are successful.^{7,9,14,21-23}

Our data for approximately half of all German hospital staff and all HCWs in dentists' offices concerning reported suspected cases of NRL-caused OA, skin symp-

toms, or both show a decrease since 1997 to 1998. The numbers indicate that the preventive measures to avoid occupational NRL allergy, mainly the complete replacement of powdered NRL gloves with low-protein, powder-free gloves and the use of NRL-free materials by sensitized individuals, not only provided for a successful secondary prevention by keeping sensitized HCWs in the workplace. The proposed measures also led to a decrease of the incidence of NRL allergies in HCWs, clearly indicating that primary prevention can also be achieved if these straightforward and practical interventions are properly carried out and maintained.

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REFERENCES

- Grzybowski M, Ownby DR, Peyser PA, Johnson CC, Schork MA. The prevalence of anti-latex IgE antibodies among registered nurses. *J Allergy Clin Immunol* 1996;98:535-44.
- Arellano R, Bradley J, Sussman G. Prevalence of latex sensitization among hospital physicians occupationally exposed to latex gloves. *Anesthesiology* 1992;77:905-8.
- Lagier F, Vervloet D, Lhermet I, Poyen D, Charpin D. Prevalence of latex allergy in operating room nurses. *J Allergy Clin Immunol* 1992;90:319-22.
- Turjanmaa K. Incidence of immediate allergy to latex gloves in hospital personnel. *Contact Dermatitis* 1987;17:270-5.
- Yassin MS, Lierl MB, Fisher TJ, O'Brien K, Cross J, Steinmetz C. Latex allergy in hospital employees. *Ann Allergy* 1994;85:626-31.
- Kelly KJ, Kurup V, Zacharisen M, Resnick A, Fink JN. Skin and serologic testing in the diagnosis of latex allergy. *J Allergy Clin Immunol* 1993;91:1140-5.
- Liss GM, Sussman GL, Deal K, Brown S, Cividino M, Siu S, et al. Latex allergy: epidemiological study of 1351 hospital workers. *Occup Environ Med* 1997;54:335-42.
- Sussman GL, Liss GM, Wasserman S. Update on the Hamilton, Ontario latex sensitization study [letter]. *J Allergy Clin Immunol* 1998;102:333.
- Tarlo SM, Easty A, Eubanks K, Parsons CR, Min F, Juvet S, et al. Outcomes of a natural rubber latex control program in an Ontario teaching hospital. *J Allergy Clin Immunol* 2001;108:628-33.
- Roy A, Epstein J, Onno E. Latex allergies in dentistry: recognition and recommendations. *J Can Dent Assoc* 1997;63:297-300.
- Shoup AJ. Guidelines for the management of latex allergies and safe use of latex in perioperative practice settings. *AORN J* 1997;66:726, 729-31.

12. Turjanmaa K, Reinikka-Railo T, Reunala T, Palouso T. Continued decrease in natural rubber latex (NRL) allergen levels of medical gloves in nationwide market surveys in Finland and co-occurring decrease in NRL allergy in a large University hospital. [abstract]. *J Allergy Clin Immunol* 2000;104:S373p.
13. Levy DA, Allouache S, Chabane MH, Leynadier F, Burney P. Powder-free protein-poor natural rubber latex gloves and latex sensitisation [abstract]. *JAMA* 1999;281:988.
14. Allmers H, Brehler R, Chen Z, Raulf-Heimsoth M, Fels H, Baur X. Reduction of latex aeroallergens and latex-specific IgE antibodies in sensitized workers after removal of powdered natural rubber latex gloves in a hospital. *J Allergy Clin Immunol* 1998;102:841-6.
15. Baur X. Natural latex allergy. Recommendations of an interdisciplinary work group. *Anaesthesist* 1996;45:653-6.
16. Allmers H, Huber H, Wirtz C, Kirchner B, Raulf-Heimsoth M, Baur X. Exposure testing with powdered gloves in 60 healthcare workers with latex allergy. *Dtsch Med Wochenschr* 1997;122:1308-12.
17. Liss GM, Tarlo SM. Natural rubber latex-related occupational asthma: association with interventions and glove changes over time. *Am J Ind Med* 2001;40:347-53.
18. Allmers H, Kirchner B, Huber H, Chen Z, Walther JW, Baur X. The latency period between exposure and the symptoms in allergy to natural latex. Suggestions for prevention. *Dtsch Med Wochenschr* 1996;121:823-8.
19. Haamann F. Erfolgreiche Prävention von Latexallergien durch eine Schwerpunktaktion der BGW. 28. Sicherheitsfachtagung Krankenhaus 2001. Celle: Ströher Druck; 2001.
20. Witt SF. Technical information bulletin—potential for allergy to natural rubber latex gloves and other natural rubber products. Occupational Safety and Health Administration (OSHA), April 12, 1999. Available at: URL: <http://www.osha-slc.gov/html/hotfoias/tib/TIB19990412.html>.
21. Tarlo MS, Sussman G, Contala A, Swanson MC. Control of airborne latex by use of powder free gloves. *J Allergy Clin Immunol* 1994;93:985-9.
22. Baur X, Chen Z, Allmers H. Can a threshold limit value for natural rubber latex be defined? *J Allergy Clin Immunol* 1998;101:24-7.
23. Saary J, Tarlo SM, Kanani A, Holmes DL. Reduction in rates of latex sensitivity among dental students and staff after changes in latex gloves [abstract]. *Am J Respir Crit Care Med* 2001;163:A809.