

# Reduction of latex aeroallergens and latex-specific IgE antibodies in sensitized workers after removal of powdered natural rubber latex gloves in a hospital

Henning Allmers, Dr. med.,<sup>a</sup> Randolph Brehler, Dr. med.,<sup>b</sup> Zhipping Chen, Dr. rer. nat.,<sup>a</sup>  
Monika Raulf-Heimsoth, Dr. rer. nat.,<sup>a</sup> Hubert Fels, Dipl. Chem. Ing. (TH),<sup>c</sup> and  
Xaver Baur, Dr. med.<sup>a</sup> Bochum and Münster, Germany

**Background:** Respiratory symptoms of natural rubber latex (NRL) allergy in health care workers (HCWs) have been reported in rooms with a detectable allergen load. Preventive measures have been proposed to reduce the risk of NRL sensitization.

**Objectives:** Eliminating powdered NRL gloves from the workplace and giving NRL-free material to sensitized workers has been among proposed preventive measures. To appraise the success of such procedures among HCWs, a prospective study was carried out.

**Methods:** Sensitization of HCWs to NRL was determined by skin prick tests and measurements of specific IgE antibodies. NRL allergen concentrations in room air were measured before and after substitution of powdered NRL gloves with powder-free or synthetic gloves in different departments of a hospital and determined by a competitive inhibition immunoassay.

**Results:** The prevalence of HCWs with positive skin prick test responses and NRL-specific IgE-positive HCWs was 8% (n = 7) among the 90 examined staff members before the intervention started. All 7 reported glove-related allergic symptoms. Six of 7 sensitized subjects had a significant decrease of latex-specific IgE antibody concentrations during follow-up examinations in April and September 1997 ( $P < .003$ ). Within 24 hours after substitution took place, NRL aeroallergen levels (up to 49.9 ng/m<sup>3</sup>) fell below the detection limit in areas with synthetic gloves or powder-free NRL gloves alike. Use of asthma medication and antiallergic drugs could be discontinued by 2 HCWs with NRL-related respiratory tract symptoms.

**Conclusions:** Our results demonstrate that elimination of powdered NRL gloves is a useful device in reducing aeroallergen NRL allergen loads below the detection limit and permitting sensitized or allergic personnel to remain on the job. (*J Allergy Clin Immunol* 1998;102:841-6.)

**Key words:** Immediate-type allergy, latex, latex aeroallergen, occupational asthma, natural rubber latex gloves, glove powder, IgE antibodies

## Abbreviations used

HCW: Health care worker  
NRL: Natural rubber latex  
SPT: Skin prick test

Up to 17% of health care workers (HCWs) exposed to powdered natural rubber latex (NRL) gloves become sensitized to NRL allergens.<sup>1-7</sup> In a recent study we found symptoms of the upper and lower respiratory tract and NRL-specific IgE antibodies only in HCWs employed in rooms with a detectable NRL aeroallergen load.<sup>8,9</sup> Several authors<sup>5,10</sup> have issued recommendations for preventive measures (eg, elimination of powdered NRL gloves and use of nonpowdered NRL or synthetic gloves as an alternative). To determine the efficiency and success of such measures to protect HCWs and patients from the effects of NRL sensitization, allergic reactions, or both, we conducted an intervention study.

## METHODS

### Study setting

The study period lasted from September 1996 to September 1997.

### Participants

Ninety HCWs (26 men and 64 women; age range, 22 to 53 years [median, 32 years]) representing 43% of the staff (n = 211) working in 4 different wards (the pediatric and adult intensive care units and the departments of anesthesiology and surgery) participated in the study. There were no exclusion criteria; anyone who wanted to participate could do so. Each subject answered a questionnaire to determine a history of atopic symptoms and NRL allergy. Follow-up examinations took place in April (history and determination of NRL-specific IgE) and September 1997 (history, skin prick tests [SPTs], and determination of NRL-specific IgE).

SPTs with controls and 8 common aeroallergens (NaCl, histamine, grass pollen, birch pollen, mugwort pollen, cat dander, *Dermatophagoides pteronyssinus*, *Dermatophagoides farinae*, *Alternaria tenuis*, and *Cladosporium herbarum*) and 7 NRL allergen extracts (latex extract Universität Münster [0.1 mg/mL protein], latex extract BGFA [0.01 mg/mL protein], Regent latex milk [Universität Münster undiluted], Regent glove extract [Universität Münster undiluted], PeHa glove extract [Universität Münster undiluted], latex Abello [commercially available], and latex Stallergen [com-

From <sup>a</sup>Berufsgenossenschaftliches Forschungsinstitut für Arbeitsmedizin (BGFA) Institut an der Ruhr-Universität Bochum; <sup>b</sup>the Department of Dermatology, Universität Münster; and <sup>c</sup>Umweltlabor ACB, Münster.

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Reprint requests: Henning Allmers, Dr. med., Bürkle-de-la-Camp-Platz 1, D-44789 Bochum, Germany.

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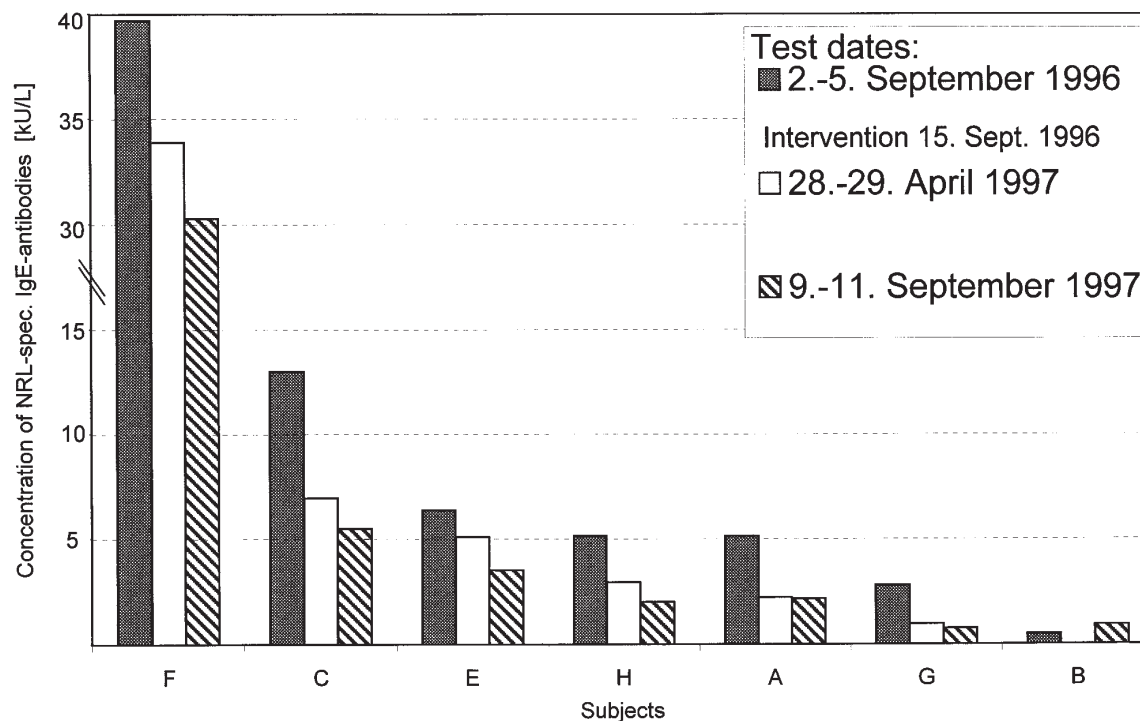


**FIG 1.** Concentration of NRL-specific IgE antibodies in 7 subjects exposed to aerogen NRL allergens before and 12 months after the end of exposure. IgE decrease during 12 months without exposure is highly significant as determined by using the 2-sided Page test ( $P < .003$ ).

mercially available]) were carried out, and the results were read after 15 minutes. Total IgE and NRL-specific IgE was measured by the CAP system (Pharmacia, Uppsala, Sweden). The NRL-specific IgE antibodies were measured after each round of examination, and all samples from participants who had a detectable level of antibodies were reexamined concurrently at the end of the study.

## Interventions

A floor on a surgical ward was used as the control area; powdered NRL gloves were used there throughout the study. The pediatrics intensive care unit was switched to non-NRL gloves. The pediatrics ward, general surgery, and orthopedics operating room, as well as the surgical clinic and the adult intensive care unit, were changed to powder-free NRL gloves. A changing room used by personnel working with powdered NRL gloves was also studied. Personnel with a sensitization to NRL allergens were always given a supply of non-NRL gloves after the initial examination in September 1996. To make sure that the intervention was immediate, all participating wards and areas were switched to the alternative gloves on the same day. All gloves that were not compatible with the study design were removed. One exception occurred when powdered gloves were used because of supply problems within the first 2 days after intervention took place. A physician in the surgical clinic used powdered NRL gloves. In the pediatrics examination room we assume that there was another unauthorized use of powdered NRL gloves, but the source could not be established.

## Measurements

Area samplers (Probenahmpumpe MF 70, DEHA Haan & Wittmer GmbH, flow rate 5 to 70 L/min; Probenahmpumpe Tec-

ra Bravo H 2, flow rate 5 to 70 L/min) with a flow rate of 10 L/min were used for 24-hour measurement periods in 7 different areas: the examination room in the pediatric ward (9 measurement periods), the examination and treatment room in the surgical clinic (13 measurement periods), the floor of the surgical ward (5 measurement periods), the changing room (5 measurement periods), 2 air conditioning intake ducts for the operating rooms (9 measurement periods), and the adult intensive care units (8 measurement periods). In all rooms except the changing room 3 measurement periods were carried out before the intervention took place. In March and September 1997, measurements were performed during 3 subsequent 24-hour periods at the chosen sites.

The placement of the samplers was chosen to reduce interference with routine work as much as possible while trying to measure within the area of greatest contamination (worst case scenario). Usually those areas were close to the storage areas where gloves were donned or the garbage bins in which the gloves were placed after use. Sampling took place over periods of approximately 24 hours. A flow rate of 10 L/min was used to collect air samples on a cellulose acetate filter with a pore diameter of 0.2  $\mu$ m (Sartorius, Germany).

## Determination of NRL aeroallergens

NRL allergen content in air samples was determined by an immune inhibition assay as described previously.<sup>8,9</sup> Briefly, filters with airborne particles were removed from the area air sampler and cut into pieces of approximately 2  $\times$  1 mm. NRL allergens were extracted from the filter pieces in 20 mL of 0.1 mol/L acetate buffer, pH 8.0, containing 0.1% 3-[(3-cholamidopropyl)dimehylammonio]-1-propane sulfonate (CHAPS). The extracts were then filtered

through a 0.45- $\mu$ m membrane filter (Sartorius AG, Göttingen, Germany), freeze-dried, and redissolved in 400  $\mu$ L distilled water. Determination of NRL allergens in extracts were performed by a competitive inhibition immunoassay with the Pharmacia CAP system in which the commercial NRL ImmunoCAP allergen from Pharmacia was used as solid-phase allergen. A standard inhibition curve was constructed by competition between a reference laboratory standard extract prepared from NRL sap from Malaysia containing 7.5 mg of protein per milliliter (determined by modified Lowry method) and the solid-phase NRL ImmunoCAP allergen for specific IgE binding by using a pooled serum of 12 NRL-sensitized subjects (IgE antibodies to latex, 15.6 kU/L). The IgE binding to the solid-phase ImmunoCAP allergen could be completely inhibited by 1  $\mu$ g reference latex allergen extract, indicating that our reference extract used in the study covered all latex allergens on the solid-phase ImmunoCAP. Quantification of latex allergen in sample extracts was achieved by preincubating 20  $\mu$ L extract solution with 40  $\mu$ L pooled serum (overnight at 4°C) to compete with ImmunoCAP latex allergen in the inhibition assay (in duplicate). The inhibition capacity of the sample extract was then compared with that of the reference standard NRL allergen. The results were expressed as NRL allergenic protein mass per cubic meter of air.

### Glove counts

To determine a correlation between the number of gloves used and the airborne allergen load, we attempted to collect all gloves being used in the following areas during 3 24-hour periods: the examination room in the pediatric ward, the examination and treatment room in the surgical clinic, the floor of the surgical ward, and the laminar flow room of the pediatric intensive care unit.

### Statistics

Statistical evaluations were performed with the SPSS for Windows software package (version 6.1.3, nonparametric tests) and with StatXact 3 software package (Cytel Software, Cambridge, Mass).

### RESULTS

Ninety of 211 eligible HCWs participated in the baseline examinations. Ten (11%) had NRL-specific IgE antibodies during the initial exam in September 1996. Seven of those 10 had a positive SPT response to NRL allergens and reported glove-related symptoms ranging from urticaria to asthmatic symptoms. No substantial differences were seen in SPT responses when comparing the 7 different NRL extracts (with the dilutions indicated above), and no systemic reactions occurred during SPTs in any of the participants. The other 3 subjects with NRL-specific IgE antibodies had a negative SPT response and did not report NRL-related allergic symptoms. During follow up, we reexamined 49 subjects (54%) in April 1997 and 62 subjects (69%) in September 1997. The 7 NRL- and IgE-positive subjects with positive SPT responses participated in all examinations; only 1 stopped working in the hospital because as a nurse in the neonatology ICU, she needed to be present in the delivery room where powdered gloves were still being used to take care of preterm babies. Two workers initially reported symptoms of the respiratory tract and had to use antihistamines or metered-dose inhalers during work. After switching of gloves, the symptoms disappeared, and use of medication could be

**TABLE I.** NRL glove-related symptoms at initial examination

|             | Negative SPT<br>responses<br>(n = 83) | Positive SPT<br>responses<br>(n = 7) | P value* |
|-------------|---------------------------------------|--------------------------------------|----------|
| Itching     | 36                                    | 7                                    | .032     |
| Wheals      | 4                                     | 6                                    | .0004    |
| Sneezing    | 6                                     | 5                                    | .0098    |
| Rhinitis    | 3                                     | 5                                    | .005     |
| Stuffy nose | 2                                     | 3                                    | .243     |

\*As determined by the Kolmogorov-Smirnov test.

**TABLE II.** History of atopy

|                       | Negative SPT<br>responses<br>(n = 83) | Positive SPT<br>responses<br>(n = 7) | P value* |
|-----------------------|---------------------------------------|--------------------------------------|----------|
| Hay fever             | 20                                    | 4                                    | .481     |
| Asthmatic symptoms    | 6                                     | 1                                    | 1.0      |
| Atopic dermatitis     | 6                                     | 1                                    | 1.0      |
| Atopic family history | 29                                    | 5                                    | .36      |

\*As determined by the Kolmogorov-Smirnov test.

terminated. Six subjects had latex-specific IgE antibody concentrations larger than 1 kU/L in September 1996. In five of those we found that concentrations were halved within 1 year. The highest concentration was found to be 40 kU/L, and it fell to 30 kU/L within the year (Fig 1). The decrease of NRL-specific IgE antibodies in all 7 subjects during 12 months without NRL exposure is highly significant (2-sided Page test,  $P < .003$ ). No new cases of sensitization could be detected in the other participants.

The 7 subjects with latex-specific IgE antibodies and positive SPT responses to latex extracts had significantly higher levels of total IgE (Mann-Whitney U test,  $P = .0047$ ) than the other 83 participants in the study. Mean total IgE was 145.9 kU/L (SD, 98.1) in the latex-allergic group and 61.8 kU/L (SD, 80.0) in the negative group. A history of NRL glove-related symptoms was significant for wheals, sneezing, and rhinitis (Table I). Symptoms of atopy (hay fever, asthma, atopic dermatitis, and atopic family history) were not significantly associated with latex allergy (Table II).

Atmospheric allergen loads of NRL allergens between 0.86 ng/m<sup>3</sup> and 49.93 ng/m<sup>3</sup> were detectable when the sampling was performed directly inside the rooms where powdered NRL gloves were used.

NRL aeroallergen was present (1.03 to 10.58 ng/m<sup>3</sup>) on each measurement period on the surgical ward floor used as a positive control area (where powdered NRL gloves were not substituted). In a second measurement campaign in March 1997, we found NRL aeroallergens (0.61 ng/m<sup>3</sup>) only on 1 of 3 days in the control area. In September 1997, we were not able to detect any aeroallergens there.

Within 24 hours (1 measurement period) after use of powdered gloves was terminated, allergen loads fell below the detection limit. In the surgical clinic 1 senior

**TABLE III.** NRL allergen concentration in the air (ng/m<sup>3</sup>)

| Date of air sample | Glove change                                 |                                                   |                                               |                                                      |                                         |                                   |                                 |
|--------------------|----------------------------------------------|---------------------------------------------------|-----------------------------------------------|------------------------------------------------------|-----------------------------------------|-----------------------------------|---------------------------------|
|                    | Powder-free NRL gloves; adult ICU (air duct) | Powder-free NRL gloves; operating room (air duct) | Non-NRL gloves; pediatrics, laminar flow room | Powder-free NRL gloves; pediatrics, examination room | Powder-free NRL gloves; surgical clinic | No change of gloves; control ward | No use of gloves; changing room |
| Sep 11, 1996       | BDL                                          | BDL                                               | BDL                                           | 4.13                                                 | 1.97                                    | 4.25                              | ND                              |
| Sep 12, 1996       | BDL                                          | BDL                                               | BDL                                           | 1.76                                                 | 1.73                                    | 4.58                              | ND                              |
| Sep 13, 1996       | BDL                                          | BDL                                               | BDL                                           | BDL                                                  | 49.93                                   | 10.58                             | ND                              |
| Sep 14, 1996       | ND                                           | ND                                                | ND                                            | Error                                                | BDL                                     | ND                                | ND                              |
| Sep 15, 1996       | BDL                                          | BDL                                               | 1.98                                          | Error                                                | BDL                                     | 1.03                              | ND                              |
| (intervention)     |                                              |                                                   |                                               |                                                      |                                         |                                   |                                 |
| Sep 16, 1996       | BDL                                          | BDL                                               | BDL                                           | BDL                                                  | BDL                                     | 3.51                              | ND                              |
| Sep 17, 1996       | BDL                                          | BDL                                               | BDL                                           | 0.94                                                 | 0.86                                    | ND                                | BDL                             |
| Sep 18, 1996       | BDL                                          | BDL                                               | BDL                                           | BDL                                                  | BDL                                     | ND                                | BDL                             |
| Sep 19, 1996       | BDL                                          | BDL                                               | BDL                                           | BDL                                                  | BDL                                     | ND                                | BDL                             |
| Sep 20, 1996       | ND                                           | BDL                                               | BDL                                           | BDL                                                  | BDL                                     | ND                                | BDL                             |
| Sep 21, 1996       | ND                                           | ND                                                | ND                                            | ND                                                   | BDL                                     | ND                                | ND                              |
| Sep 22, 1996       | ND                                           | ND                                                | ND                                            | ND                                                   | BDL                                     | ND                                | ND                              |
| Sep 23, 1996       | ND                                           | ND                                                | ND                                            | ND                                                   | BDL                                     | ND                                | ND                              |
| Sep 24, 1996       | ND                                           | ND                                                | ND                                            | ND                                                   | BDL                                     | ND                                | ND                              |
| Mar 11, 1997       | ND                                           | ND                                                | BDL                                           | Error                                                | BDL                                     | 0.61                              | ND                              |
| Mar 12, 1997       | ND                                           | ND                                                | BDL                                           | Error                                                | BDL                                     | BDL                               | ND                              |
| Mar 13, 1997       | ND                                           | ND                                                | BDL                                           | Error                                                | BDL                                     | BDL                               | ND                              |
| Sep 22, 1997       | ND                                           | ND                                                | BDL                                           | BDL                                                  | BDL                                     | BDL                               | BDL                             |
| Sep 23, 1997       | ND                                           | ND                                                | BDL                                           | BDL                                                  | BDL                                     | BDL                               | BDL                             |
| Sep 24, 1997       | ND                                           | ND                                                | BDL                                           | BDL                                                  | BDL                                     | BDL                               | BDL                             |

ICU, Intensive care unit; BDL, below detectable limit; ND, not determined.

physician did not get a supply of powder-free gloves of his size on the second day after the transition, forcing him to use powdered NRL gloves. An allergen load of 0.86 ng/m<sup>3</sup> was measured that day. After this individual was outfitted with powder-free gloves, the detection limit was not exceeded for the remaining 7 measuring intervals.

In the examination room of the children's ward, there was a detectable load of NRL aeroallergens 2 days after the intervention took place, without the cause being known. Use of powdered gloves still in the possession of an individual was discussed but not proven.

No allergen load could be detected in the changing room where gloves were not used.

It was not possible to detect NRL aeroallergens on samples taken within the air stream of the air conditioning system for the intensive care unit and operating rooms. The results are summarized in Table III.

When measurements of aeroallergen latex allergens were repeated in March and September 1997, no detectable allergen load could be detected in the rooms where only powder-free latex gloves were used. The results of the glove counts in the different rooms/areas were so heterogeneous that it was not possible to determine a correlation between the number of gloves used and the aeroallergen concentration.

## DISCUSSION

Several investigations demonstrate that powdered NRL gloves are the source of atmospheric NRL aeroal-

lergen.<sup>4,5,11,12</sup> Heilman et al<sup>13</sup> showed that switching to low-allergen gloves resulted in a significant reduction of NRL aeroallergen levels. In an investigation of the staff in our health care facilities, we found that respiratory symptoms and NRL-specific IgE antibodies were only present in employees who had worked in rooms with a detectable NRL allergen load.<sup>8,9</sup> These findings are in accordance with our hypothesis that direct allergen contact to the mucosa of the upper and lower respiratory tract is an important cause for the development of sensitization against NRL allergens. Currently there are no epidemiologic studies linking sole skin contact and sensitization to NRL allergens. Brehler et al<sup>14</sup> found a significantly lower prevalence in operating room staff in the UK, where only powder-free gloves have been used in the last decades, in comparison with German HCWs working in operating rooms with powdered NRL gloves. Therefore we pursued the hypothesis that once the major source of NRL aeroallergens is removed by using powder-free NRL or synthetic gloves, NRL aeroallergen levels will drop below the detection limit, and the risk of NRL sensitization will decrease. Another advantage in this approach is the reduction or elimination of airborne exposure to NRL allergens for HCWs and patients in whom respiratory symptoms have already developed.

Except for 1 sample in the surgical clinic and 1 sample in the children's examination room, no NRL aeroallergen could be detected in any sampling period (24 hours) after the replacement of powdered gloves. These results indi-

cate that in areas such as operating rooms and intensive care units that need to be prepared for NRL-sensitized patients, a removal of powdered NRL gloves will result in an elimination of NRL aeroallergens within 24 hours and probably sooner in rooms with air conditioning.

Because of the delicate working conditions in operating rooms and intensive care units, we tried to determine whether NRL aeroallergen levels could be detected within the airstream of the air conditioning units of those areas. That way we did not interfere with any procedures that might be impaired by measuring inside of these facilities. However, it was not possible to detect any NRL allergens in our samples, probably because of the much higher air flow rate within the air ducts ( $10 \text{ m}^3/\text{s}$ ) as opposed to that inside the rooms ( $<0.5 \text{ m}^3/\text{s}$  to  $2 \text{ m}^3/\text{s}$ ).

Another very interesting aspect of the study was the fact that NRL aeroallergen was present ( $1.03$  to  $10.58 \text{ ng}/\text{m}^3$ ) on each measurement period on the surgical ward floor used as a positive control area (where powdered NRL gloves were not substituted) in September 1996. In April 1997 we only found NRL aeroallergens ( $0.61 \text{ ng}/\text{m}^3$ ) on 1 of 3 days, and in September 1997 we were not able to detect any aeroallergens. Inquiries at the glove-manufacturing company revealed that they had decreased the amount of corn starch powder used during manufacturing after the summer/fall period of 1996 to remain competitive in the market because awareness of the NRL allergy problem had become an issue in many hospitals at the management level (personal communication).

Swanson et al<sup>4</sup> showed that surgical scrub suits in operating rooms with detectable NRL aeroallergen levels were contaminated with NRL allergens. To determine whether the NRL allergens adherent to clothing of personnel working in areas contaminated with NRL aeroallergens results in detectable release of NRL allergens into the atmosphere, we performed measurements in a changing room where HCWs changed their clothing before and after work shifts. No NRL aeroallergens could be detected, suggesting that even though work clothing might be contaminated with NRL allergens, changing of these clothes will not result in significant NRL aeroallergen levels.

In our study group sensitization to NRL allergens as determined by NRL-specific IgE antibodies and positive SPT responses was 8%. No new cases of sensitization occurred in areas where only powder-free gloves were used during the 1-year follow-up period. Because of the high fluctuation of personnel, we could not determine whether any new sensitization occurred in the control ward where powdered NRL gloves were still being used. No allergic symptoms caused by NRL were reported during the follow-up period. Use of asthma medication and antihistamines could be discontinued by 2 staff members with allergic asthma and rhinitis before the intervention took place. In a recently published study Sussman et al<sup>15</sup> found very similar results for the measurement of aero-gen latex allergen concentrations and a decline of allergen content in powdered gloves during the length of the investigation. Another very interesting finding that seems to support our hypothesis that inhalation of NRL is a

main cause for sensitization was the phenomenon that conversion from negative SPT responses to NRL to positive SPT responses to NRL occurred both in the group using powdered gloves and in the group using powder-free gloves but that clinical symptoms were only reported by the participants in the powdered group.

Our earlier investigation of 26 HCWs who had given up work showed a trend of decreasing latex-specific IgE antibody concentrations over time; however, those subjects were examined only once after NRL exposure was terminated, and no follow-up data was available.<sup>16</sup> The results of this study clearly show a decrease of latex-specific IgE antibody concentrations within 1 year after continuous exposure to NRL allergens was terminated. Occasional contact by short exposure to NRL aeroallergens (eg, when walking through areas that were not included in the intervention and where powdered NRL gloves are still being used) does not seem to cause antibodies to be maintained at levels that continuous exposure would induce. However, it should be noted that even if NRL-specific IgE levels fall below the detection limit, severe allergic reactions might still occur on reexposure.

We conclude that substitution of powdered NRL gloves with powder-free NRL gloves or gloves not containing NRL is a useful device in reducing NRL aeroallergen loads below the assay detection limit within 24 hours. NRL allergen load adhering to clothing does not seem to cause a significant atmospheric contamination. To prevent detectable atmospheric contamination with NRL aeroallergens, the use of nonpowdered NRL gloves is a sufficient measure. HCWs sensitized and even allergic to NRL can remain on the job if exposure to NRL can be avoided. Banning of powdered NRL gloves in the workplace and a supply of NRL-free material for sensitized individuals seems to be a sufficient prevention strategy.

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