A review of current literature on epidemiology of immediate glove irritation and latex allergy

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Natural rubber latex (NRL) allergy has attained world-wide importance with the diagnosis of glove hypersensitivity, contact urticaria, rhinitis, conjunctivitis, asthma and anaphylaxis. In the present report, the latest literature of the epidemiology of NRL allergy is reviewed, an account on the incidence of NRL allergy (19 new cases of contact urticaria/100,000 workers per year) among health care workers is given and the prevention of NRL allergy is discussed. Among health care workers, NRL allergy has gained prominence particularly with the spread of AIDS and an increase in the use of rubber gloves for barrier protection. For screening NRL allergy, a simple and quick test based on a self-administered questionnaire has been presented, but it needs further evaluation before routine use can commence. Further analytic studies will show if the use of low allergen gloves reduces the incidence of NRL allergy.

Key words: Allergy; incidence; natural rubber latex; occupational disease; prevention; review; screening.

INTRODUCTION

The use of protective gloves, first experimented with by Halsted in 1890, has progressively increased among health care workers to reduce the risk of contracting the human immunodeficiency and hepatitis B viruses. The increased use of gloves has led to numerous undesirable cutaneous and mucosal reactions. Skin symptoms associated with the use of protective gloves are mainly caused by skin irritation rather than by allergy. Although these reactions are a particular problem for hospital employees who have to wear gloves — not only for their own safety but for the safety of patients — non-allergic dermal and mucosal irritation is only briefly mentioned in recent medical literature. Unfortunately, the number of objective methods for verifying immediate dermal and mucosal irritation is rather small. Instead, natural rubber latex (NRL) induced allergic manifestations are well-known and, due to increasing reports on severe systemic reactions, world-wide attention has recently focused on the threat of NRL allergy.

Originally, contact urticaria, rhinitis and eyelid oedema were identified as an immediate manifestation of NRL allergy. Since then, several researchers have established severe systemic reactions of NRL allergy, e.g., asthma and anaphylaxis, which may result in permanent disability or even death. The usual clinical diagnosis of NRL allergy is based on a history of prompt intolerance reactions in skin or mucous membranes provoked by NRL products, on skin testing and on serum analyses for specific NRL antibodies. Both skin testing and serum analyses have been used in epidemiological studies aimed at determining occurrence rates of NRL allergy. To improve occupational health and safety, there is a need to identify health care workers with NRL allergy. Unfortunately, for use in occupational health personnel, an easy and quick tool for mass screening for NRL allergy is lacking. However, a simple and quick test with a sensitivity of 84% and specificity of 98% has been presented for screening NRL allergy among health care workers. The test is based on a self-administered questionnaire, but still needs further evaluation in a larger sample of workers before it can be used as a screening tool.

NRL allergy is increasingly recognized, with a prevalence of 3-12% reported in health care workers and the highest prevalences found in the USA and Canada. Recently, NRL allergy resulting in allergic rhinitis and asthma has gained prominence. NRL allergens have been shown to adhere to glove powder, which can act as...
a potent aeroallergen. Today, the main allergens in NRL have been characterized. Measurements of NRL aeroallergen concentration in areas where powdered NRL gloves are frequently used have shown a 20-fold variation. However, even extremely low amounts of NRL gloves are frequently used have shown a 20-fold increase in the concentration. NRL have been characterized.

**EPIDEMIOLOGY OF IMMEDIATE GLOVE IRRITATION AND NRL ALLERGY**

The prevalence of self-reported glove irritation has varied from 14% (in dental staff and hospital personnel) to 56% (in operating room staff and hospital personnel). Table 1 lists the prevalences of self-reported glove irritation in several studies on health care workers. Standardized questionnaires and other methods for prevalence studies of glove irritation are lacking. Variations of skin symptoms (drying of skin, itching, redness, urticaria, hand eczema) associated with glove-wearing have been used in defining glove irritation. In discussing the data, it is necessary to know the questionnaire criteria for the 'cases'. In many studies no specified criteria for glove irritation have been stated. The highest prevalence rates have been reported when the criteria consist of only one skin symptom associated with glove-wearing. The lack of standardized methodology makes the comparison of glove irritation between studies very difficult. In most cases the cause of the glove irritation remains unclassified due to the lack of a diagnostic test.

Prevalence of NRL allergy in the general population

The exact prevalence and incidence rates of NRL allergy among the general population have not been clarified. However, prevalence in the general non-atopic population is estimated to be less than 1%. According to the findings of the Pirkanmaa Health Care District, Finland, the minimum overall prevalence of NRL allergy is 33/100,000 (0.03%) inhabitants. In the USA, anti-latex IgE antibodies (IgE concentration ≥ 1.5 IU/ml) have been detected in 2% of samples from healthy volunteer Red Cross blood donors.

Prevalence in subgroups with high NRL exposure

Several subgroups have been identified as having a high exposure to NRL. Health care workers, housekeepers and greenhouse workers need to use NRL gloves in their workplace. On the other hand, employees working in an NRL products manufacturing plant can have environmental exposure to NRL. Children with spina bifida and urogenital abnormalities have repeated surgical procedures during which direct contact with NRL gloves occurs.

**Health care workers.** The prevalence rates of NRL allergy among health care workers according to occupation are summarized in Table 2. The prevalence of NRL allergy found in hospital employees varied from 3-12%. In Japan, at one university hospital none of the nurses, medical clerks, operation room nurses, examiners, pharmacists or dieticians presented with NRL-specific IgE by RAST, while in nine workers (1.5%) elevated levels of NRL-specific IgG could be detected by enzyme linked immunosorbent assay. Skin prick testing was not performed in these workers, and IgG antibodies only show the previous exposure to NRL. In another study, the high percentage of NRL-allergic employees found by Yassin et al. was biased due to their selected study population. Their study followed an extensive NRL allergy awareness programme for all hospital employees and more symptomatic employees may have been more willing to voluntarily participate in the study. The selection bias, however, can not be judged if the response rate is not reported.

A wide variety of prevalence rates have been found in different occupations. This difference is not surprising because repeated exposure to NRL is essential for the development of NRL allergy, and glove-wearing time

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**Table 1** Prevalence rates (%) of self-reported glove hypersensitivities and diagnosed natural rubber latex allergy in several studies on health care workers

<table>
<thead>
<tr>
<th>Author</th>
<th>Country</th>
<th>No.</th>
<th>Response rate (%)</th>
<th>Male (%)</th>
<th>Female (%)</th>
<th>%</th>
<th>No.</th>
<th>%</th>
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<tr>
<td>Beaudouin et al</td>
<td>France</td>
<td>907</td>
<td>-</td>
<td>87</td>
<td>-</td>
<td>-</td>
<td>3</td>
<td>24</td>
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<td>1,043</td>
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<td>-</td>
<td>14</td>
<td>143</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Lagier et al</td>
<td>France</td>
<td>248</td>
<td>93</td>
<td>87</td>
<td>41</td>
<td>102</td>
<td>11</td>
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<td>77</td>
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<td>-</td>
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<td>38</td>
<td>5</td>
<td>4</td>
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<td>Wrangsjö et al</td>
<td>Sweden</td>
<td>233</td>
<td>90</td>
<td>90</td>
<td>37</td>
<td>86</td>
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<td>534</td>
<td>64</td>
<td>89</td>
<td>56</td>
<td>298</td>
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<td>Norway</td>
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<td>0.5</td>
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<td>Stingani et al</td>
<td>Italy</td>
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<td>90</td>
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<td>0.3</td>
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<tr>
<td>Kaczmarek et al</td>
<td>USA</td>
<td>385</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<td>660</td>
<td>-</td>
<td>23</td>
<td>153</td>
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<tr>
<td>Liss et al</td>
<td>Canada</td>
<td>1,351</td>
<td>66</td>
<td>91</td>
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<td>164</td>
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<tr>
<td>Leung et al</td>
<td>Hong Kong</td>
<td>1,472</td>
<td>74</td>
<td>79</td>
<td>31</td>
<td>450</td>
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</table>

* NRL = natural rubber latex.

b The participants included 40 employees identified as sensitive to NRL before the survey.
Table 2 Prevalence rates (%) of natural rubber latex allergy among health care workers in occupational groups

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Author</th>
<th>Country</th>
<th>No.</th>
<th>Response rate (%)</th>
<th>Female (%)</th>
<th>%</th>
<th>No.</th>
<th>Diagnostic method</th>
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<td>Finland</td>
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<td>-</td>
<td>6</td>
<td>8</td>
<td>SPT</td>
</tr>
<tr>
<td></td>
<td>Lagier et al.(^{24})</td>
<td>France</td>
<td>197</td>
<td>74</td>
<td>87</td>
<td>11</td>
<td>21</td>
<td>SPT</td>
</tr>
<tr>
<td></td>
<td>Cormio et al.(^{22})</td>
<td>Finland</td>
<td>77</td>
<td>99</td>
<td>-</td>
<td>5</td>
<td>4</td>
<td>SPT</td>
</tr>
<tr>
<td></td>
<td>Wrangsjö et al.(^{33})</td>
<td>Sweden</td>
<td>57</td>
<td>77</td>
<td>93</td>
<td>5</td>
<td>3</td>
<td>SPT and RAST</td>
</tr>
<tr>
<td></td>
<td>Konrad et al.(^{34})</td>
<td>Switzerland</td>
<td>101</td>
<td>-</td>
<td>-</td>
<td>16</td>
<td>16</td>
<td>SPT</td>
</tr>
<tr>
<td>Dental staff</td>
<td>Wrangsjö et al.(^{33})</td>
<td>Sweden</td>
<td>176</td>
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<td>89</td>
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<td>4</td>
<td>SPT and RAST</td>
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<td></td>
<td>Yassin et al.(^{35})</td>
<td>Ohio</td>
<td>13</td>
<td>-</td>
<td>-</td>
<td>38</td>
<td>5</td>
<td>SPT</td>
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<tr>
<td></td>
<td>Tarlo et al.(^{36})</td>
<td>Canada</td>
<td>131</td>
<td>-</td>
<td>-</td>
<td>63</td>
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<td>Turjanmaa(^{12})</td>
<td>Finland</td>
<td>54</td>
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<tr>
<td></td>
<td>Beaudouin et al.(^{23})</td>
<td>France</td>
<td>110</td>
<td>-</td>
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<td>Arellano et al.(^{37})</td>
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<td>Ohio</td>
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<td>France</td>
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<tr>
<td></td>
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<td></td>
<td>Vandenplas et al.(^{19})</td>
<td>Belgium</td>
<td>189</td>
<td>94</td>
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<td>5</td>
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<td></td>
<td>Douglas et al.(^{39})</td>
<td>Australia</td>
<td>140</td>
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<td>-</td>
<td>22</td>
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<td>SPT</td>
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<tr>
<td></td>
<td>Lisa et al.(^{14})</td>
<td>Canada</td>
<td>788</td>
<td>66</td>
<td>91</td>
<td>13</td>
<td>106</td>
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<tr>
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<td>Saikle(^{40})</td>
<td>Canada</td>
<td>230</td>
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<td>88</td>
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<td>RAST</td>
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<td></td>
<td>Yassin et al.(^{35})</td>
<td>Ohio</td>
<td>41</td>
<td>-</td>
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<td>94</td>
<td>64</td>
<td>5</td>
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<td>SPT</td>
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</table>

* NRL = natural rubber latex.
* SPT = skin prick test.

varies in different tasks. In rooms in which powdered NRL gloves are used, counts of up to > 3,667 starch particles per cubic metre of air have been detected.\(^{42}\) Furthermore, the concentration of NRL aeroallergens has been reported from 10–100 times higher in areas where surgical gloves are frequently used compared with areas where gloves are seldom used. Recent studies indicate that the use of powder-free NRL gloves may prevent measurable airborne NRL exposure.\(^{43,44}\) In epidemiological studies, the assessment of percutaneous or respiratory exposure to NRL is difficult due to the varying allergenic properties of different types of NRL gloves which the workers have used.

These prevalence rates have resulted in an increasing number of health care workers who have been sensitized to NRL.\(^{45}\) From 1990–93, for example, 104 workers among 342 Mayo Medical Centre employees who reported symptoms related to exposure to NRL were confirmed to have NRL allergy by skin prick test.\(^{46}\) In one of the University Hospitals in Paris, employees who spontaneously contacted occupational health care services due to glove-related hand dermatosis were examined and an overall prevalence rate of 2.3% for occupational NRL allergy was found.\(^{47}\)

In housekeeping personnel, NRL allergy incidence has been 2–4% in small cohorts consisting of 50 housekeeping staff employees.\(^{19,48}\) In a Spanish cohort, 5% of 418 greenhouse workers who needed to use NRL gloves in their workplace had NRL allergy.\(^{49}\)

Workers in plants manufacturing NRL products. In a factory producing surgical gloves, positive skin test to NRL occurred in 11% (7/64) of workers.\(^{6}\) Recently, the prevalence of type I NRL allergy was 9% (2/22) among workers in a NRL doll manufacturing plant.\(^{50}\)

Patients with congenital abnormalities. The prevalence of NRL allergy has been between 18–65% in children with spina bifida, depending on the centre where the investigations have been performed.\(^{51–53}\) Multiple mucosal or vesicular exposures to NRL commonly cause sensitization. Because of frequent urethral catheterizations, multiple surgeries and ventriculoperitoneal shunt placement (all early in life), patients with spina bifida are at particular risk. Furthermore, some urogenital abnormalities frequently require multiple surgical procedures and urethral catheterizations which increases the risk of developing NRL allergy. In a recent report from Venezuela, however, the prevalence of NRL allergy was as low as 4% in a group of 93 patients with spina bifida.\(^{54}\) The low prevalence may be due to a low level of NRL exposure. In addition, the patients were non-multiply operated, the surgeon's gloves were frequently washed and resterilized and non-latex bladder catheters were used.

Incidence of NRL allergy

In Finland, statistics on occupational diseases have been compiled since 1964 by the Finnish Institute of Occupational Health. According to the Act on the Supervision of
Labour Protection, a physician is obliged to report cases of occupational disease to the Provincial labour protection authority. Furthermore, notification of every new case of an occupational disease reported to insurance companies is sent to the Finnish Register of Occupational Diseases. Information from these sources is combined so that each new occupational disease is registered only once. According to the Register of Occupational Diseases, during 1985–91, a total of 97 cases of NRL allergy were reported to the Register.

During 1992–96, 262 new cases of contact urticaria due to NRL and 29 new cases of NRL-induced occupational rhinitis were registered, representing a nearly threefold increase of NRL allergy in Finland as compared with the previous five year period. Of the 262 workers, 59% were health care workers (135 women and 20 men; 87% and 13%, respectively). In order to calculate the incidence rate of NRL-induced contact urticaria among health care workers during 1992–96, the base population (cohort) can be defined by using information from the Finnish 1991 census data file. The cohort consists of wage earners in the age group of 25–64 years at the end of 1991: altogether 145,647 health care workers (women, 86%; men, 14%). When this cohort was followed to the end of 1996 a total of 138 new cases of NRL-induced contact urticaria were reported to the Register of Occupational Diseases (Table 3). During 1992–96 the mean incidence rate of NRL-induced contact urticaria per year was 19/100,000 health care workers (women, 19/100,000; men, 18/100,000).

### Risk factors of NRL allergy

A history of atopic symptoms (risk ratio: 4.5) in latex-sensitive and non-sensitive NRL-exposed nurses has been found at a frequency of 21% and 4.7%, respectively. Furthermore, comparison between sensitized and non-sensitized physicians resulted in an odds ratio of 9.1 (95% confidence interval = 7.5–11.6) for atopic physicians. As risk factors, frequent exposure to NRL and the atopic constitution are synergistic. In a study of 569 subjects routinely tested for NRL allergy, the subjects were categorized into subjects with no risk factor, non-atopic subjects exposed to NRL, atopic subjects not exposed and exposed atopic subjects. NRL allergy was obtained in 0.4%, 7%, 9% and 36% of the groups, respectively. NRL allergy occurs predominantly in women. This may, however, be partly due to the predominance of females in the field of health care. After adjusting for age and sex, a comparison between sensitized and non-sensitized nurses resulted in an odds ratio of 4.2 for nurses belonging to a non-White race. Owensby and co-workers, however, found that prevalence of anti-NRL IgE antibodies was not related to race.

A history of hand dermatitis has been demonstrated in 60% of latex-sensitive and 17% of non-sensitive employees. In concordance with this Lagier et al. found no relationship between ongoing hand eczema and percentage of reactions to NRL in a cohort of 197 operating room nurses. According to Wrangsjö et al., overall three out of four latex-sensitive patients also had a food allergy. The association between NRL and food allergy is partly due to common antigens in fruits and NRL.

### PREVENTION OF NRL ALLERGY

In community medicine, as the clients of medical professionals are the populations, the broad requirements of preventive medicine are regulation, education and service.

#### Regulation

There are several key aspects in the European legislation:

1. The medical Devices Directive 93/42/EC will come into full force in July 1998. This document will lay down guidelines on aspects of the technical qualities of gloves, but it will not mention the barrier properties or allergen levels associated with NRL products.

2. European standards covering the physical properties of medical gloves already exist and it seems likely that they will need to be modified to match emerging knowledge about irritation problems.

3. Biological safety specifications are currently under review by a special committee of the EU. The European Committee for Standardization (CEN) will establish maximum levels of extractable proteins and also provide a standardized methodology for measuring the levels of extractable antigenic proteins in latex gloves. In gloves, the differences both in allergen content and the allergen profiles produce difficulties in standardization procedures. Biochemical measurement of the protein level in NRL including a procedure for solubilizing NRL proteins has been suggested for quality assurance in the
manufacture of low-protein NRL for hypoallergenic products.\textsuperscript{63} Immunological assays, however, are essential for determining hypoallergenicity.\textsuperscript{16,64,65} Recently, a novel IgE-ELISA-inhibition method for measuring NRL allergen levels in medical gloves has been presented. The ELISA method is technically easy to use, inexpensive and suitable for the analysis of large numbers of NRL gloves.\textsuperscript{66}

The protein content of NRL products can be reduced considerably by washing, heat treatment, chlorination and enzyme digestion.\textsuperscript{63,67} In glove manufacture, furthermore, using an alternative powdering process instead of wet-powdering may reduce NRL allergen contamination in end products.\textsuperscript{68} Wet powdering of NRL gloves may increase the risk of the contamination of the cornstarch, especially if the content of NRL allergens is high in the dipped products.

Education

For educational purposes, the Medical Devices Agency of the UK National Health Service has produced a booklet titled 'Latex Sensitisation in the Health Care Setting — Use of Latex Gloves'. The document contains recommendations including: (1) information about hypersensitivity which must be disseminated to all health care workers; (2) strategies for managing patients admitted to hospital when screening for NRL allergy; (3) staff guidance about how to deal with patients who have a history of NRL allergy; (4) recommendations for occupational health physicians in the health service who need to take the problem more seriously and (5) a reminder that problems should be reported to the Medical Devices Agency when they are identified. If all of these steps are taken, it should be possible to substantially reduce future problems caused by NRL allergy.

More information needs to be given to those who are purchasing medical devices for the use of health care workers. It is necessary to inform local purchasers about NRL allergy and the potential danger of aerosolized glove powder. To prevent inhalation of glove powder contaminated with NRL allergens, avoidance of the continued use of powdered gloves is suggested. By using immunospecific assays such as RAST inhibition and enzyme-linked immunospecific inhibition assay, the National Agency for Medicines, Finland, has since 1995 established information on the allergenicity of several surgical and examination gloves commercially available on the open market, and the data have been sent to all hospitals and municipal health care centres in Finland, and commercial retailers of medical gloves. In two Swedish university hospitals, the allergenicity of a sample of medical and surgical gloves has been measured by the specific IgE antibody inhibition assay, and the results have been given to the local glove purchasing employees.\textsuperscript{65} In one hospital in Canada, by removing glove powder and moving to powder-free, low protein NRL gloves they reduced the overall costs of NRL allergy, and surprisingly also reduced glove purchase costs.\textsuperscript{69}

Until NRL products are labelled, it is important for physicians to familiarize themselves with the routes of sensitization, variations in assay methods and the type and amount of allergen in products, in order to select the safest product for patient use and personnel protection. In hospitals and dentistries, NRL gloves and special devices such as catheter balloons cannot easily, in the short term, be replaced by synthetic materials. Economic as well as quality-control aspects are problematic. In situations where the risk of spreading bacterial or viral infections through glove perforation is high, the disadvantage of using unsterile PVC gloves is the larger number of pinholes as compared with NRL gloves.\textsuperscript{70}

Occupational health service

Health care workers are exposed to a variety of cutaneous irritants and allergens and a high prevalence of cutaneous problems.\textsuperscript{71} Workers with irritation to gloves should eliminate unnecessary glove usage.\textsuperscript{3} In such cases, changing the type of gloves worn, changing the type of soap used for scrubbing, or the use of cotton liners and emollients may be an effective treatment. These workers may benefit from more education regarding cutaneous hazards and preventive strategies in the occupational health service. An early diagnosis of pre-symptomatic disease is a cornerstone of clinical preventive medicine. Occupational health personnel who have groups of health care workers as clients need to decide how to seek an early diagnosis of NRL allergy. It can be achieved by means of screening, case finding or a periodic health examination.

In cases of NRL allergy, the avoidance of all NRL products is the only measure that can avert a serious allergic reaction to NRL. The individual health care worker with acquired NRL allergy must inform his/her colleagues about it, and make clear that it is a serious health problem. The use of powder-free NRL gloves by co-workers may enable health care workers sensitized to NRL to continue work in their current position.\textsuperscript{42} To date, NRL avoidance is difficult due to inadequate, and at times deceptive, product labelling.\textsuperscript{72} Health care workers with NRL allergy should be warned that when they become patients, mucosal or parenteral exposure to NRL may result in anaphylaxis, even if the reactions during occupational exposure have been relatively mild. It seems to be common for health care workers to make a self-diagnosis regarding the offending agent.\textsuperscript{8,21,73} Among US Army dentists, a variety of 'trial and error' protective strategies were employed, including 56% of the dentists changing to other gloves, 7% using medicated creams before putting on gloves and 6% using vinyl liners.\textsuperscript{71} Recently, in operating room staff, a variety of preventive practices and differences between nurses and surgeons have been found, suggesting the need for more education related to these matters.\textsuperscript{73} Occupational health personnel should inform health care workers about the importance of an accurate diagnosis of NRL allergy.
CONCLUSIONS

In cross-sectional studies of health care workers, self-reported hypersensitivity is fairly common and closely associated with the use of medical gloves. To date, there are not any diagnostic tests or standardized criteria for the diagnosis of glove hypersensitivity. This makes further analytic studies of the causation of glove hypersensitivity difficult. Among health care workers with glove hypersensitivity, NRL allergy can be verified in a minority of subjects. In cross-sectional studies, a wide variation of the prevalence rate of NRL allergy has been found. This variation can be explained by the differences in glove wearing routines, and differences in the quantity as well as quality of NRL allergens in medical gloves. Further analytic studies are needed to determine if the use of low allergen gloves will reduce the incidence of NRL allergy. Today, vinyl gloves should be used in preference to latex gloves whenever possible. However, when high strength, tack and tensile properties are needed for protection in health care service, the characteristics of NRL gloves have not been surpassed by any synthetic glove material.

REFERENCES

32. Owby DR, Owby HE, McCullough J, Shafer AW. The prevalence of anti-latex IgE antibodies in 1000 volunteer


