Bandolier Extra
Evidence-based health care December 2001

LATEX ALLERGY

Written (RA Moore) in early 1995

Implications for patients and health care workers

Natural rubber products have been used widely for many years. Allergic reactions to rubber, and especially immediate allergic reactions, have only been recognised in the last decade, with the first report appearing in 1979.

The reasons for this apparent increase and emergence of large numbers of latex-sensitive persons are unknown, but there are two possible explanations.

During the 1980s the use of latex medical products increased tremendously in response to AIDS and a more general recognition of possible sources of transfer of infectious agents through contact with body fluids. As a result, the use of items like latex gloves increased amongst all health care professionals at points of possible exposure to patients or body fluids. Today, doctors, nurses and laboratory personnel will use latex gloves frequently; a decade ago their use was much less prevalent, and almost unheard of in laboratories and nursing.

This sudden increase in demand for latex products, especially in latex gloves, has meant that new manufacturers have come into being, that new industrial processes are likely to have evolved, and that perhaps new or subtly different sources of raw material are being used. Products used today may have higher concentrations of allergens as a result of some or all of these changes, or new latex allergens may have been created.

One thing is certain, that there is a very high population in regular contact with latex products. As well as medical and dental personnel, workers in the food processing and rubber industry are subject to occupational exposure to latex. The need to avoid exposure to body fluids now extends to other areas of society; thus police officers now routinely use latex gloves when dealing with injured people. Even criminals use latex gloves routinely to avoid problems with fingerprints.

A different aspect to occupational exposure to latex in health care is that the recipients of health care are also subject to exposure. Patients undergoing operation are obviously exposed to latex during the procedure. Perhaps less obvious, but just as important are procedures like dentistry and anal or vaginal examination.

About one million people work in the NHS, and a significant proportion are subject to exposure to latex. This alone is a significant proportion of the UK population. As will be seen later, there are other high risk groups of patients which can be added to this, making latex allergy a very significant health problem. Changes are inevitable, and this will impact on NHS Supplies.

What is Latex?

Latex is used in the medical literature as a description of either the sap of the Brazilian rubber tree (Hervea brasiliensis) or to products made by dipping forms into the sap (gloves, balloons, condoms). Allergic reactions seem to be against proteins naturally present in latex sap; proteins constitute about 1% of liquid latex sap.

There is little agreement on the precise number or characteristics of the protein allergens present in liquid latex. Proteins with molecular weights of 5,000 to 80,000 have been studied, but a protein of molecular weight 14,600 seems to be the major allergen.

During the industrial processes of vulcanisation proteins may be altered, and at least one allergen has been found in latex gloves that was not present in rubber sap. The normal source material for medical-use latex goods is ammoniated latex, and the processes used include heating to 130 C for 30 minutes in the final phase of glove manufacture. The allergens can be leached from the finished product and are found in the corn starch powder present in medical-use gloves. This powder becomes airborne easily, and inhalation may be one source of contact with latex.

Changes in allergen structure over time may occur after manufacture, as slow chemical changes take place in the matrix of the latex products. Low levels of ammonia contamination in the latex may be responsible for some of these changes, though they are not well documented.

Do many products contain latex?

Yes. The following lists on page 2 are not meant to be exhaustive, but give some indication of the many different sources of latex in hospitals and elsewhere.

Products that may involve latex

Common Medical Devices	Anaesthesia and Operating Room Equipment	Miscellaneous Products
Adhesive tape	Blood pressure cuffs (bladder and tubing)	Adhesive tape
Ambu bags	Bile bags	Balloons
Band-Aids and similar	Chest drainage units	Condom
Bulb syringes	Drapes	Camera eyepiece
Colostomy pouch	Electrode pads	Diaphragm
Condom urinary collection devices	Endotracheal tubes	Dummies
Dental cofferdams	Epidural catheter injection adapters	Household work gloves
Elastic bandages	Eye shields	Paint
Electrode pads	Head straps	Raincoats
Enema tubing kits	Injection ports on iv bags	Shower cap
Fluid warming blankets	Laparoscopy insufflation hoses	Swimming fins
Gloves - examination and sterile	Linear/Burr hole drapes	Tennis/squash shoes
Haemodialysis equipment	Latex cuffs on plastic tracheal tubes	Underwear
Mattresses on stretchers	Latex injection ports on iv tubing	
Neonatal incubator	Multidose vial stoppers	
PCA syringes	Needle counting systems	
Protective sheets	Naso-pharyngeal airways	
Rubber gloves	Oral-pharyngeal airways	
Rubber pads	Porous tape	
Stethoscope tubing	Penrose tubing	
Stomach and GI tubes	Rubber suction catheters	
Tourniquets	Rubber breathing circuits	
Urinary catheters	Rubber ventilation bellows	
Vial stoppers	Rubber masks	
Wound drains	Rubber tourniquets	
	Surgical masks	
	Teeth protectors & Bite blocks	
	Vented basic solution sets	

As can be seen, there is a very long list of products into which latex is incorporated. It is probable that some products are much more of a problem than others, and in medicine gloves are the biggest single problem. However, it should also be remembered that for some individuals, be they health care workers or patients, any contact with latex can be life-threatening.

What is latex sensitivity?

There are three different types of reactions to natural rubber latex. They are irritation, delayed hypersensitivity (allergic contact dermatitis) and immediate hypersensitivity (anaphylactic symptoms).

Irritation is classed as a non allergic condition. For most affected persons the irritated skin is dry and crusty, and the symptoms resolve when contact with latex ceases.

Delayed hypersensitivity presents as a chemical allergy. The skin area affected becomes dry, crusty and leathery with eruptions appearing as sores and blisters. This response occurs between six and 48 hours after contact. Repeated latex exposure causes the skin condition to expand beyond the area of contact. Many people with delayed hypersensitivity have a history of atopy (allergy, dermatitis, or asthma).

Immediate hypersensitivity is an allergic response mediated by IgE (an antibody found in the circulation). On the skin this can present as hives that migrate beyond the point of contact with latex. Systemic allergic symptoms can include itching eyes, swelling of lips or tongue, breathlessness, dizziness, abdominal pain, nausea, hypotension, shock and, potentially, death.

These symptoms are likely to result from a massive release of histamine at a local or whole body level. This results from binding of the latex allergen to sensitised receptors on mast cells.

Are there tests for latex allergy?

Yes. There are several tests available. It is commonly thought that skin prick testing is the `gold standard' of sensitivity testing. In general, latex is introduced into the skin in small quantities at a pinprick site. Positive results are swelling or reddening of the skin, and these can be graded according to size. There are several methods, including intradermal injection, but the latter is probably very dangerous because of the possibility of life threatening anaphalactoid reactions with latex. Even skin prick testing is thought by some to be dangerous.

The problem with skin prick testing is that testing has to be performed with the allergen against which the patient is allergic. There are different types of allergen extracts available, some which may not contain the particular allergen. Extracts of offending material may be made, for instance from gloves.

There are also safer in vitro tests. In these, a blood sample is taken from the patient (avoiding introducing latex and precipitating anaphylactoid reactions) and tested for the presence of IgE antibodies specific to latex. There are a number of tests from different manufacturers, and they also use different latex extracts.

It has been shown that processes which link allergen proteins using amino groups give very good results when compared with skin prick testing. In one study, of 52 skin-prick latex positive patients, 50 were positive by blood tests.

The excellent results now possible from blood tests, combined with their relative low cost and freedom from danger of immediate hypersensitivity associated with skin prick testing makes them the method of choice, though there are differences between manufacturers in kit quality for latex (though not necessarily for other allergens).

Studies which have used immunoassays to detect latex-specific IgE have been reviewed critically [1]. Skin and serological testing have been compared directly, and either may be used as a reliable method of diagnosing latex allergy [2].

How many health care workers are likely to be affected?

There have been a number of studies of latex allergy in hospital workers. As latex allergy has become more widely recognised as an occupational health problem the studies have become larger and better.

In 1992, the Association of Operating Room Nurses were given a questionnaire which included questions on latex allergy. Of the 1,738 respondents (79%), 30% reported latex reactions and 30 of these nurses (5%) had a skin test positive for latex, with 8 admitted to hospital for suspected latex reactions.

In a recently reported study 224 hospital employees [3] were interviewed and skin prick tests performed to six common allergens, one non latex synthetic glove extract and four different latex glove extracts. There were 136 nurses, 41 laboratory technicians, 13 dental staff, 11 physicians, 6 respiratory therapists and 17 housekeeping and clerical workers.All tested negative for the non latex glove but 38 (17%) tested positive for latex extracts. The incidence in the different groups is shown in Table 1.

Table 1: incidence of latex allergy

Group	% Positive for Latex
All subjects	17
Nurses	18
Laboratory Technicians	21
Dental personnel	38
Respiratory therapists	17
Physicians	9
Housekeeping & Clerical	0

Table 2: Effects of atopy and exposure are more than additive

Group	Atopy	Exposure	Latex Positive %
I	0	0	0.37
II	0	+	6.85
III	+	0	9.44
IV	+	+	36.36

Those subjects who were latex positive had significantly greater history of bronchial asthma, reported significantly more symptoms when using latex gloves (urticaria, rash, itching, sneezing, nasal congestion, itchy watery eyes and cough), and were significantly more likely to test positive for common allergens (pollen, cat epidermis and dust mites).

The prevalence of latex sensitivity of 17% in this study has been supported by abstracts which have reported prevalences of 14% in healthcare workers.

The consequences of latex allergy in health workers are not insignificant. Five cases in the USA have been reviewed [4], and give a good picture of the problems at the individual level. Anecdotal reports in Europe and elsewhere indicate that a number of legal cases involving latex allergy and hospital workers are pending.

How many patients are affected?

The only good data concern patients with spina bifida, who have multiple surgical and medical procedures. One study of 50 patients aged 2 to 21 years showed that 60% had latex allergy defined by history, serological and/or skin prick tests [5]. This study also showed that allergic patients had undergone significantly more surgical procedures than nonallergic patients (9.5 versus 6.7).

A different study [6] looked at 93 consecutive children with spina bifida; 38% were positive for latex antibodies by serological testing and 10% had clinical allergy to latex. The serological test was non-standard, and it may be that this underestimated the prevalence.

In a third study [7] 110 spina bifida children were studied using postal questionnaire, and 12% were found to have clinical allergy to latex. Clinical allergy underestimates the presence of IgE antibodies by about four times [6].

In summary, it is likely that about 10% of patients with spina bifida will have clinical allergy, and 50-60% will have IgE antibodies specific for latex.

The problems are not found only in spina bifida, however. While systematic surverys have not been carried out, it is not unlikely that a number of patients with frequent exposure to latex during surgery will have developed latex sensitivity. The consequences are severe. There is at least one reported case of anaphylactic death after rectal examination with a latex finger stool due to unexpected latex sensitivity. There is one documented case of repeated graft rejections caused by latex allergy.

Are there predisposing factors?

One recent French survey has begun to indicate which patient groups may be at risk; 569 subjects were examined in a prospective study of risk factors in latex hypersensitivity [8]. There were five groups:-

I 272 with no risk factors

II 73 non atopics exposed to latex

III 180 atopic subjects not exposed

IV 44 exposed atopic subjects

V 13 subjects with a history of intraoperative anaphylaxis

The results showed that both atopy and exposure to latex increased the likelihood of latex sensitivity, and that the effects were more than additive, as shown in Table 2.

All the patients in group V had positive skin prick and serological tests for latex; eight were atopic and seven had multiple previous surgical procedures (eight or more).

Frequency of exposure to latex thus raised the likelihood of sensitisation 19-fold (from 0.37% to 6.85%) in nonatopic subjects and 4-fold (from 9.44% to 36.4 %) in atopic subjects. One third of atopic subjects exposed to latex will have latex sensitivity.

Is latex sensitivity a real problem?

In the USA the occurrence of latex sensitivity reactions to various medial problems requires a formal reporting process, currently through the Device Experience Network. The Medical Device Reporting Program (MDR) is a mandatory reporting system for those cases in which death or serious injury may have been caused by a medical device. There is a similar system (Practitioner Reporting Program, or PRP) which is voluntary and collects complaints concerning medical devices.

More than 1000 MRP/PRP reports concerning latex have been logged. The top three product-related complaints involved barium enema tips (15 deaths, more than 400 injuries), latex patient examination gloves (more than 376 injuries) and surgeon's gloves (more than 67 injuries).

All of this suggests that latex allergy is, indeed, a real problem which needs to be addessed sensibly in the health care sector, for both patients and employees.

What is happening in the USA?

There are several recent and important publications which demonstrate what is happening in the USA. The American Academy of Allergy and Immunology has produced a task force report on allergic reactions to latex [9]. It makes a number of serious recommendations:-

1: Patients in high risk groups should be identified.

2: All patients, regardless of risk status, should be questioned about a history of latex allergy.

3: All high risk patients should be offered testing for latex allergy.

4: Procedures on all patients with spina bifida, regardless of history, should be performed in an environment free of latex.

5: Procedures on all patients with positive history, regardless of risk group status, should be performed in an environment free of latex.

6: An environment free of latex is one in which nolatex gloves are used by any personnel. In addition there should be no latex accessories that come into direct contact with the patient.

7: Low risk patients with negative histories are extremely unlikely to react to latex. At this time, routine testing is not recommended for persons with negative histories.

8: Patients identified as latex allergic by either history or testing should be advised to obtain a Medic Alert bracelet and self-injectable adrenaline. Medical records should be appropriately labelled.

The American Association of Nurse Anaesthetists has produced a Latex Allergy Protocol [10]. It is short and extremely thorough.

The way in which the Arkansas Children's Hospital has described its quality improvement approach to latex precautions [11] is detailed but readable (written by a nurse), and gives an excellent account of how a problem can be approached and overcome.

All of this demonstrates just how seriously latex allergy is being taken in the USA, as other reviews show [12,13].

Any problems with testing?

There is just one cautious note to be added here. Certain fruits (banana, avocado, chestnut and kiwi fruit) appear to crossreact with latex in allergy testing. These food allergies are extremely rare, and could not account for the large number of positive reactors in exposed and atopic individuals.

The clinical significance of cross-reaction is unknown, but it is likely that patients with crossreacting IgE antibodies will react when exposed to crossreacting allergens. Thus people with food allergy to chestnut may react when exposed to latex, and vice-versa.

Can we test for latex allergen in the environment?

Yes. Because latex allergen is not confined to items like gloves, but can become airborne (especially with glove powder), it can become present in the environment, especially in heavily used areas like treatment rooms and operating theatres.

The ELISA-type assays using liquid allergens can be used to identify and quantify latex allergen in the environment (swab eluates, for example) by a simple modification.

What are the implications for healthcare?

Latex allergy isn't going to go away. Perhaps 30% of the population has allergy (is atopic). This is a large at-risk group in whom a latex sensitivity of perhaps 10% could be expected - or 3% of the whole population.

A large part of the UK workforce suffers occupational exposure to latex - perhaps as many as one million (4%) of the workforce. This group would be expected to have a 6% risk of latex sensitivity.

The crude estimate of people at risk in the UK is about 1.5 to 2 million. Patients are increasingly exposed as all healthcare workers now use gloves, and the numbers of exposed, and thus sensitised, individuals will increase.

Thus latex allergy is going to become an important issue for hospitals and health authorities as providers of healthcare, purchasers of healthcare, and as employers. Legal issues are not insignificant.

What are the implications for NHS Supplies?

The present state of opinion in Europe on the subject of latex allergy is that it is not seen as such a big problem as it is in the USA and Canada. This is not uncommon, and it is likely that the next 2-3 years will see a rapid crumbling of the present ostrich view.

The implications are that there will then be a much increased demand for latex-free products. This is more than gloves, as earlier tables have shown. A wide variety of products and a wide variety of suppliers will be involved.

This is an opportunity for NHS Supplies to be proactive. NHSS can begin discussions with suppliers about non-latex alternative products now, anticipating demand later. Once products are available it can make these available to customers, and even begin to make customers aware of the problem. The protocols from the USA referred to in an earlier section would not be difficult to reproduce with copies going to each ward.

There are a large number of possible initiatives, but detailed discussion is deferred at this time. Priority areas appear to be gloves, barium enema sets and urinary catheters; non-latex or hypoallergenic alernatives should be urgently sought.

Method

The literature was searched using MEDLINE, using the search terms "allergy and latex". Databases from 1990-1994 were searched. Abstracts of identified papers were read on-screen and irrelevant papers were excluded. Printed abstracts of selected papers were read, and hard copies of the most relevant items obtained through library services to produce this review.

References:

1: DR Ownby, J McCullough. Testing for latex allergy. Journal of Clinical Immunoassay 1993 16: 109-113.

2: KJ Kelly, V Kurup, M Zacharisen, A Resnick, JN Fink. Skin and serological testing in the diagnosis of latex allergy. Journal of Allergy and Clinical Immunology 1993 91: 1140-5.

3: MS Yassin, MB Lierl, TJ Fischer, K O'Brien, J Cross, C Steinmentz. Latex allergy in hospital employees. Annals of Allergy 1994 72: 245-9.

4: A Rosen, D Issacson, M Brady, JP Corey. Hypersensitivity to latex in health care workers: report of five cases. Head & Neck Surgery 1993 109: 731-4.

5: PI Ellsworth, PA Merguerian, RB Klein, AA Rozycki. Evaluation and risk factors of latex allergy in spina bifida patients: is it preventable? Journal of Urology 1993 150: 691-3.

6: LL Tosi, JE Slater, C Shaer, LA Mostello. Latex allergy in spina bifida patients: prevalence and surgical implications. Journal of Paediatric Orthopaedics 1993 13: 709-12.

7: ML Pearson, JS Cole, WR Jarvis. How common is latex allergy? A survey of children with myelodysplasia. Developmental Medicine and Child Neurology 1994 36: 64-9.

8: D-A Moneret-Vautrin, E Beaudoin, S Widemer, C Mouton, G Kanny, F Prestat, C Kohler, L Feldmann. Prospective study of risk factors in natural rubber latex hypersensitivity. Journal of Allergy and Clinical Immunology 1993 92: 668-77.

9: Task Force on Allergic Reactions to Latex. Journal of Allergy and Clinical Immunology 1993 92: 16-18.

10: American Association of Nurse Anaesthetists Latex Allergy Protocol. Journal of the American Association of Nurse Anaesthetists 1993 61: 223-4

11: S McNatt. Aquality improvement approach to latex precautions. Today's OR Nurse. March/April 1994: 22-28.

12: C Shaer, JE Slater. Latex allergy in children. Current Opinion in Paediatrics 1993 5: 700-4.

13: J Markey. Latex Allergy. Implications for healthcare personnel and infusion therapy patients. Journal of Intravenous Nursing 1994 17: 35-39.

This paper was prepared by Dr RA Moore in late 1994 using the best evidence available at that time.