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Latex allergy at work

Part 1: Exposure, sensitisation and the law

In the first of two articles on latex allergy, Jane Paul looks at latex as a cause of occupational asthma and what can be done to prevent exposure.

Latex is the fifth largest and the fastest growing occupational cause of asthma in the UK[1]. This has prompted renewed calls for action to control the risks of latex exposure both inside and outside the workplace.

Up to 17% of all healthcare workers[2,3], 10% of patients admitted to UK hospitals[4] and between 1% and 6% of the general population[5] (up to 3.5 million people are thought to be sensitised to latex (affected by latex allergy and sensitisation), and therefore at risk of allergic reactions (to latex). In some cases the reaction can be severe.

The rapid increase in the number of reported cases of latex allergy over the past two decades has been largely attributed to the introduction of universal precautions to protect people against transmission of viral infections, such as hepatitis and HIV. Sales of latex examination gloves soared in the late 1980s and 1990s, greatly increasing occupational exposure to latex.

Despite representing a hazard primarily for healthcare workers, latex exposure is not confined to the workplace, it is also an issue for the general population: it is widely used in a vast range of products and environments. Workers, managers, visitors, students, children, contractors, temporary and agency staff, patients, consumers and service users are exposed to latex in their daily lives.

What is latex allergy?

The term latex is used to describe both a natural state (the milky juice of some plants including rubber trees and Poinsettia) and synthetic rubber states. Natural rubber latex (NRL) comes from the *Hevea brasiliensis* tree and is widely used in the manufacture of rubber products. Latex allergy refers to an allergic reaction to NRL proteins (Type I), or to chemicals used in its manufacturing (Type IV).

Latex is used in a wide variety of products, including protective equipment, medical devices, barrier contraceptives, infant feeding equipment, flooring and soft furnishings. The main source of occupational exposure is in the healthcare sector.

What are the risks?

The risks associated with latex are twofold: sensitisation, and allergic reaction (Type I or Type IV).

When someone is exposed to an allergen (eg NRL proteins) it may cause his or her immune system to become sensitised. Once sensitised, if they are re-exposed to the same allergen, this may lead to an allergic reaction.

Sensitisation is permanent and cannot be reversed, but it has been found that symptoms can be reduced with early diagnosis, as long as further hazardous exposures are avoided.

There are two types of latex allergies:

- Type IV – a reaction to the allergenic chemical additives or chemicals used during the manufacturing process. The reaction (allergic contact dermatitis) is delayed by up to 48 hours after exposure but is confined to the skin.
- Type I – an immune response to allergenic NRL proteins. Reaction is more rapid, usually within 30 minutes, and includes histamine response with symptoms ranging from hayfever-type symptoms, rhinitis and eye inflammation to respiratory obstruction, asthma or anaphylactic shock and possible death.

Not everyone is affected, and reactions also vary – some are more severe than others. Cross-allergic reactions are also possible, particularly with certain fruit such as banana, avocado or kiwi fruit.

How are people exposed to latex?

Occupational exposures vary, but the main cause of latex sensitisation and latex allergies at work are latex gloves – particularly the powdered variety. Routes of entry include direct contact with skin or mucous membranes, inhalation or invasive procedures.

It is important to understand the mechanisms involved, as this helps to explain the risks associated with latex gloves and medical devices.

NRL proteins in latex materials can leach into water or be absorbed into the cornstarch powder used in powdered latex gloves, or into other substances such as food. Sweat and water increase this leaching. Cornstarch powder is not in itself allergenic but it readily binds with the NRL-proteins in powdered latex gloves. This increases the risks of hazardous exposure to NRL proteins because it allows them to become airborne and then inhaled. When the wearer handles powdered latex gloves (particularly on removal), the allergens are spread into the air, and particles can contaminate not only the breathing zones of those in the vicinity, but also ventilation systems and air filters.

Who is at risk?

Many people are at risk if they are repeatedly exposed to NRL proteins in their work or as patients. However, some groups are more susceptible than others.

1. *Sensitised people* – these include individuals with:

- a history of anaphylaxis due to NRL;
- a history of Type I allergy/sensitisation to NRL; and

■ a history of Type IV chemical sensitivity (allergic contact dermatitis).

2. *Groups at high risk of sensitisation* – these include individuals who do not have a history of NRL sensitivity but with a history of repeated surgery, dental treatment or invasive procedures, or of having an atopic nature/ multiple allergies, especially specific fruit allergies.

3. *People who do not have a history of sensitisation or high risk factors for sensitisation* – they may still be at risk from hazardous exposure to latex. However, German research shows that removal of powdered latex gloves is effective in preventing sensitisation in at-risk occupations in health care settings[6].

The main occupational groups at risk are in the healthcare and residential care sectors, but risks are not confined to these sectors or occupations.

Risks to non-sensitised people

The risks to non-sensitised people are that they will become sensitised and go on to develop allergic reactions to latex. In the general population, atopic people are at particular risk, with some children sensitised at a very young age.

Risks to sensitised people

The risks to sensitised individuals are that, with continued exposure, they may develop allergic reactions. Researchers in German hospitals have found that the average time periods between starting work and (a) first symptoms and (b) first respiratory symptoms in cases of confirmed NRL allergy caused by powdered latex gloves were 15 and 27 months respectively[6].

Latex sensitisation is permanent

Early intervention can be effective in controlling and managing latex allergy, but sensitisation is permanent. The following is an extract from a University of Maryland School of Medicine report that describes the precautions taken by a sensitised, former endoscopy nurse to create an allergen-free environment.

This nurse-turned-patient suffered severe Type I allergic reactions to latex in her workplace, including persistent occupational asthma, and subsequently developed sensitivities to foods and reactions to a variety of environmental sensitisers and irritants.

"She had no carpets and she used a central vacuum with a canister that is taken outside the house to clean. The house was equipped with central air conditioning, a heat pump and special filters, and the ducts were cleaned. There was no smoking in the house. She washed the linens in hot water and used material that is impermeable to dust mites to cover her bed. ... she used plain soap to wash her linoleum floor, and unscented laundry detergent. She did not spray chemicals to clean her shower and tub; rather she used hot water under pressure. ... [She] did not socialise in public places, except for a couple of restaurants where no latex gloves were used and smoking was prohibited."

Despite this, her symptoms continued to persist more than three years after being removed from her workplace. She became depressed because she could no longer work as a nurse, and needed numerous daily medications to control her symptoms and emergency treatment in the event of a severe reaction.

Source: Amr S and Bollinger M (2003). Latex allergy and occupational asthma in healthcare workers: adverse outcomes. *Environmental Health Perspectives*. Doi:10.1289/ehp.6612 (available at http://dx.doi.org/).

Risks of extreme reactions/shock

Individuals may have such severe reactions to latex that their hypersensitivity becomes chronically disabling and potentially fatal, including asthma and, more rarely, anaphylaxis. Latex allergy has caused deaths.

In a survey of 205 UK hospitals published in 2000, researchers found that 505 patients with latex allergy underwent surgery. Of these reported cases, there were four deaths, 18 major anaphylaxes and 483 minor complaints such as skin rash. In the same survey, 239 theatre staff reported latex allergic reactions, including one severe anaphylactic reaction. Yet the survey found that less than one-third of UK hospital theatres had latex-free products set aside for use[7].

Consequences and costs

The consequences of latex allergy are far-reaching. For the individuals affected, there are many costs apart from that to their health and the limitations placed on their quality of life. There are potential long-term costs involving loss of earnings, possible loss of job or career opportunities, reduced pension entitlements if forced into ill-health retirement through disability, and continued disadvantage in the labour market. There are also the costs of adjustments in people's personal lives and home environments if they are affected by Type I allergy. For example, flooring, carpets, furniture, mattresses and clothing may need to be replaced with latex-free items.

Prevention and control

Risk control and latex allergy management involves different levels of intervention, based on the principles of primary, secondary and tertiary prevention. Risk assessment is required in each case. The aims are:

■ to prevent and minimise sensitisation (*primary prevention*) and to maintain protection from biological hazards whilst protecting patient health;

■ to ensure early detection of adverse reactions/ early diagnosis of latex allergy (*secondary prevention*) (NB diagnosis requires identifying the likely source of latex exposure in the workplace) and manage sensitised individuals and their future protection; and

■ to address the needs of sensitised individuals for treatment, employee assistance, support and rehabilitation (*tertiary prevention*).

How can risks be reduced?

Risk reduction for latex allergy starts with identifying hazards and carrying out risk assessments to find ways of removing the hazards at source. This means tackling the problem in manufacturing as well as in the workplace. There are several options:

■ eliminate powder and substitute less hazardous substances for NRL;

■ minimise NRL content and/or allergenic chemicals in the manufacturing process;

■ use latex-free packaging/minimise NRL content;

■ ensure accurate, comprehensible information on NRL content and risk prevention;

■ limit unsafe supplies – remove ability to select/ purchase hazardous items; and
■ ensure correct selection and control use of PPE and other work equipment.

Removing the hazard from the work and care environment also means providing ready access to latex-free equipment and latex-safe work environments where possible, avoiding use of powdered latex gloves by elimination or substitution, and controlling both NRL content and exposure to it. People who are at high risk of sensitisation to allergens are advised to avoid direct exposure to latex, even if they have no specific history of latex sensitisation[6]. Once sensitised, people should not be exposed to latex. Clear and unambiguous warning signs and labeling are needed to alert purchasers, patients and users to the presence of latex.

Secondary prevention involves early detection of sensitisation/allergy and its causes, and interventions to avoid further hazardous exposures. This is important because people with Type IV allergic reactions may go on to develop Type I allergies not only to latex but also to other environmental allergens. Sensitised individuals should avoid exposure to latex, and they require a latex-safe environment. Special precautions should be taken to prevent direct contact with latex during surgery or medical treatment.

Tertiary prevention requires measures to be taken to ensure future protection as well as an effective response to allergic reactions – both Type I and Type IV, including effective emergency response in the event of severe reaction or shock. Removal of allergens from the work environment is the first option, but removal of the individual may be necessary for their protection if residual risks remain – if so, the individual and the alternative environments will need to be assessed, and appropriate treatment provided.

These interventions require action in different areas – from manufacturing, marketing and procurement to employment practices, service delivery, product handling and use.

Latex and the law

Latex products and their use are regulated in various ways, nationally and internationally.

Medical devices are regulated under the EU Medical Devices Directives (MDDs) (Directives 90/385, 93/42 and 98/79), transposed at national level in the UK's Medical Devices Regulations 2003 (MDR) and enforced by the Medicines and Healthcare Products Regulatory Agency (MHRA), an executive agency of the UK Department of Health, following the merger of the former Medical Devices Agency (MDA) with the Medicines Control Agency (MCA) on 1 April 2003. Within the European Union, the Medical Device Directive requires that:

■ neither the clinical condition nor the safety of the patient or user must be compromised by the product or its use;
■ risks must be acceptable when balanced against benefits to patients; and

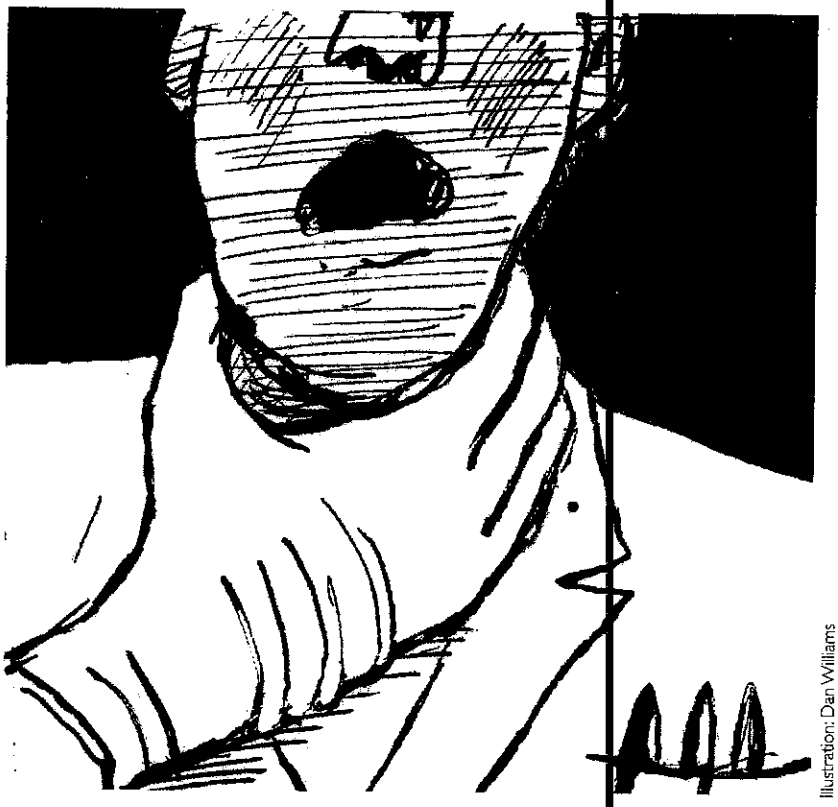

Illustration: Dan Williams

■ risks must be eliminated or reduced in accordance with the state of the art.

The former MDA's Device Bulletin *Latex sensitisation in the healthcare setting (use of latex gloves)*[8], issued in 1996, advises healthcare establishments to have a policy in place to address the purchase and safe use of gloves within their establishments and make arrangements to safeguard patients and staff. These arrangements include providing specific information about latex sensitisation to healthcare workers, health surveillance of staff and ensuring that any adverse reactions are recorded and reported. A further Safety Notice: *Latex medical gloves (surgeons' and examination) powdered* (SN 9825) was issued by the MDA in June 1998.

In Europe there are harmonised European standards (CEN) applying to gloves, and there are parallel developments in quality standards elsewhere involving limits on protein, powder, particle-residue and physical properties. Product labeling is regulated by the Chemicals (Hazard Information and Packaging for Supply) Regulations and, where applicable, under the Medical Devices Directive and related UK regulations. However, this is a significant problem area and campaigners have called for mandatory labeling standards to aid accurate and unambiguous identification of NRL protein content for all NRL-containing products (for example, "hypoallergenic" does not mean latex-free!).

Patient/client safety is subject to various regulatory processes, including clinical governance. Occupational exposure often coincides with patient/client exposure. In some cases, sensitised workers may be at risk as

Web links

HSE Latex web page www.hse.gov.uk/latex.
Latex Allergy Support Group www.lasg.co.uk
Allergy UK www.allergyuk.org/.
British Dental Association www.bda.org.
Association of British Healthcare Industries www.abhi.org.uk
Medicines and Healthcare Products Regulatory Agency (MHRA) www.medical-devices.gov.uk.

patients when undergoing treatment or testing for occupationally induced latex allergy. The NPSA is encouraging reporting of adverse events to the Agency so that lessons can be learned about future prevention.

Claims under civil law for personal injury due to occupational exposure to latex have been significant. Litigation settlements quoted by Leigh Day & Co, a firm that has acted for a number of latex-sensitive claimants, have ranged from £40,000 to £500,000[5].

In November 2003[9], NRL was added to the list of prescribed causes of occupational asthma for the purposes of the Industrial Injuries Scheme. Anaphylaxis resulting from NRL allergy in healthcare workers is also to be classed as a prescribed disease. These changes will come into force later this year.

What else is being done?

Research findings around the world have highlighted the scale and nature of the problem of latex sensitisation, but have also shown that it can be prevented.

In Germany, Dr Henning Allmers of the University of Osnabrück and colleagues reported on primary prevention of latex allergy in the German healthcare system through education and interventions. Researchers measured NLR in the air in healthcare in hospital settings, and evaluated NRL sensitisation in healthcare workers. By switching to powder-free NRL gloves, detectable aeroallergens were eliminated. Sensitised healthcare workers were able to work using latex-free gloves without experiencing adverse reactions[10].

Following this study, the German government brought in a law in 1997/98 banning the use of all powdered latex gloves in German healthcare facilities. New cases of NRL-caused occupational asthma fell by 86% between 1997 and 2001, and there was a 69% drop in new suspected cases of NRL-caused skin allergy between 1998 and 2000[6]. Dentistry, however, remained a problem area.

In the UK, trade unions and professional bodies (including UNISON, AMICUS/MSF and the Royal College of Nursing) campaigned for preventive measures as more and more of their members were affected, and have supported personal injury claims by individuals sensitised through their workplace.

The Latex Allergy Support Group (LASG) is a self-help group led by sensitised individuals. It has campaigned tirelessly to raise public awareness of the issues, promote latex-safe environments and provide advice and support to sensitised people and others with an interest in the field of latex allergy. LASG has recently set up an international expert Medical Advisory Panel to provide guidance to the Group on medical, scientific and technological NRL issues.

In 2002, the Trades Union Congress, National Association of Theatre Nurses and LASG jointly organised two important international conferences on latex allergy, with industry support. They brought together a wide range of interest groups, including manufacturers, sensitised people, enforcing authorities, researchers and clinicians, to discuss the issues and develop collaborative approaches to preventing and managing latex allergy.

Prevention of occupational allergy is a priority area for the Health and Safety Commission, which has set up the National Asthma Project Group to work strategically with others towards a target of a 30% reduction in occupational asthma cases by the year 2010, including a latex-specific target of zero for latex gloves related asthma by 2005. The top eight causes of occupational asthma in the UK, of which latex comes fifth, account for half of all new cases. With up to 3,000 new cases of occupational asthma each year, and more than 12,600 recorded asthma-related deaths in the UK during 2001[11], the need for action to prevent and control the risks of hazardous exposures is an urgent issue for all concerned.

In October 2003, Des Browne MP, the Minister for Work at the Department of Work and Pensions, launched the HSE-led latex educational toolkit for healthcare on the HSE website and pledged government support for measures to help prevent occupational allergy, including latex allergy.

At industry level, manufacturers, suppliers and trade associations are working with others to reduce risks through product research and development and improved standards where action is required. Examples include the development of the Malaysian Standard Rubber Glove, elimination of powder in latex gloves, reduced NRL-protein content and reduced use of allergenic chemical additives.

Increasingly, suppliers (including retail outlets and brand names) are identifying and reviewing their supply of latex products and offering latex-free alternatives. The NHS Purchasing and Supply Agency has withdrawn powdered latex gloves and products with high NRL-protein content from its catalogue and NHS trusts are beginning to withdraw from use of latex examination gloves, switching to latex-free alternatives that are becoming more cost-competitive. However, procurement and supply chain arrangements remain a problem even within the NHS.

Recent surveys have shown patchy response to the DMA's advice on availability of latex-free equipment. For example, an LASG survey in 2000 revealed that 80% of ambulance trusts surveyed had no latex-free equipment for sensitised patients, and over 50% had no latex-free gloves.

■ The second part of this feature will look at risk assessment, workplace prevention and the resources available to help reduce the risks and raise awareness about latex allergy at work.

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