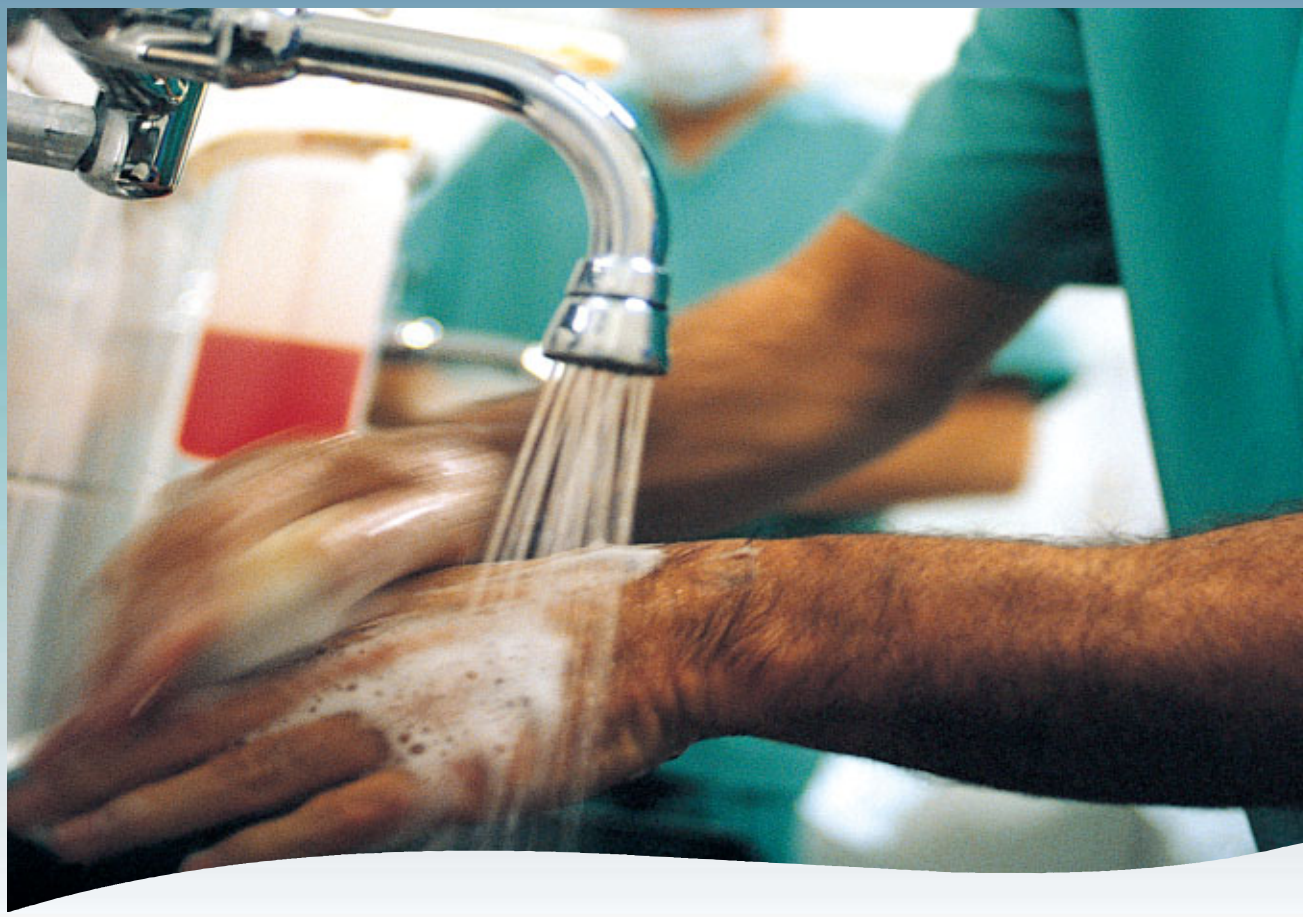
Latex Allergy Management



Understanding natural rubber latex, chemical allergies and powder-related problems associated with glove barriers

An information and educational program for
the hospital and medical community

Ansell Cares

Latex Allergy Management

Understanding natural rubber latex, chemical allergies and powder-related problems associated with glove barriers

This clinical reference manual is one in a series of continuing education services provided by Ansell Healthcare as part of an ongoing commitment to the development of quality hand barrier products and services for the healthcare industry.

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Abstract

Gloves containing natural rubber latex (NRL) provide excellent protection against the transmission of infectious agents and are an integral part of healthcare practice. However, NRL gloves have been associated with skin irritation in some users. Adverse skin reactions to NRL gloves include delayed contact dermatitis (Type IV reaction), latex allergy (Type I reaction) and general skin irritations.

The earliest report of latex allergy was published in the *British Journal of Dermatology* in 1979.[1] Immunoglobulin antibodies specific to the allergens found in NRL were detected in some of the individuals affected by allergic reactions. In the USA, the first case of latex allergy was reported in 1989.[2]

Symptoms of latex allergy usually occur within 30 minutes or earlier after exposure and may include erythema, pruritus or local urticaria. In rare cases, symptoms of anaphylaxis may occur.

The introduction of universal glove precautions has increased the exposure of healthcare workers and patients to NRL gloves, leading to a rise in the number of people experiencing adverse reactions. Although NRL gloves are a potential source of sensitivity, individuals can also become sensitised to NRL through many other medical and household items. Most people are regularly exposed to NRL as it is a component of thousands of everyday products.

Correct recognition and management is the key to successfully managing NRL allergies and other skin irritations. The information provided in this guide is designed to assist healthcare professionals in identifying and managing potential risks associated with NRL glove use. Healthcare professionals should consult their individual institution and qualified physicians for specific recommendations, policies, diagnosis and treatment related to NRL and chemical allergies.

Intended audience

This clinical guide is intended for use by healthcare professionals who are responsible for, or are involved in, the following activities relating to hand barrier protection:

- educating healthcare personnel
- establishing institutional or departmental policies and procedures
- making decisions about hand barrier products
- maintaining regulatory compliance
- managing employee health and infection control services.

This clinical guide has been compiled and updated with input and assistance from key opinion leaders in medical and nursing practice, scientific research and the manufacturing industry.

Contents

Section 1
Overview

Understanding natural rubber latex allergy management

Gloves containing NRL represent an important hand barrier and their use is an integral part of healthcare practice.[3] Although they provide excellent protection against the transmission of infectious agents, surgical gloves in particular have been associated with adverse skin reactions in some users. This clinical guide is an information resource intended for healthcare professionals who use surgical gloves, or are involved in educating healthcare personnel and establishing institutional policies and procedures. It contains information that may help reduce the risks of glove-related skin irritations and allergies and provides recommendations to assist in identifying and managing adverse reactions without compromising barrier protection.

Since the introduction of universal glove precautions (now known as 'standard precautions') in the 1980s, surgical glove use has grown considerably. This increased frequency of exposure to surgical gloves for both healthcare workers and patients has led to a number of people experiencing adverse reactions. However, the advent of improved technologies, powder-free gloves and superior modern manufacturing processes has since reduced the incidence of latex reaction.[3] For the majority of healthcare professionals and the patient population, the risk of latex allergy is low.[3]

Adverse reactions to NRL gloves can range from general skin irritations to a serious allergic response.[4] Allergic reactions may be a response to the NRL from which the glove is made or to other chemicals used in the manufacturing process.[5]

NRL is a particular kind of rubber derived from the milky sap of the *Hevea brasiliensis* tree. It is used to manufacture surgical gloves and many other healthcare and consumer products. Most people are regularly exposed to NRL as it exists in items such as clothing, toys, tyres, door and window seals and elastic bands.

The majority of surgical gloves are still manufactured from NRL because it is difficult to replicate the benefits of elasticity, comfort, strength, barrier performance, alcohol resistance and economy that NRL can offer.[3] NRL is also a natural, biodegradable product, containing no petroleum by-products or dioxins.[3]

As not all adverse reactions to surgical gloves are latex allergies, it is important to be aware of other sources of irritation.[6] Other adverse reactions include delayed contact dermatitis, irritant contact dermatitis and responses to glove powder and other sensitising substances used in glove manufacture. In addition, an adverse reaction may actually be in response to the use of soaps, hand scrubs and abrasive hand towels. Correct recognition and management are the keys to successfully managing allergies and other surgical glove irritations.

Section 2
Physiology of the immune response

The immune response is activated whenever the body comes into contact with an antigen, which is most commonly a protein.[4] The antigen is initially detected by Langerhans' cells in the dermis, which stimulate the lymph nodes and reticuloendothelial system to produce specific antibodies and T cells against the antigen (Figure 1).[5]

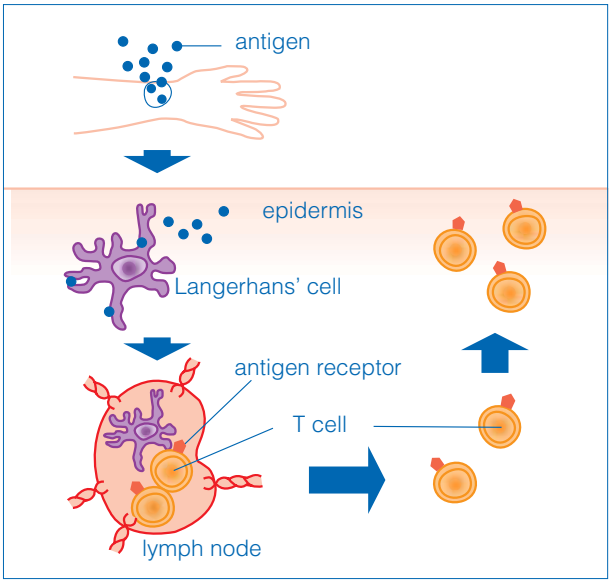

Figure 1: The immune response

In addition to antibody-mediated responses, when an individual is re-exposed to the same antigen, the cell-mediated response is re-initiated. Specialist T cells produced in response to the initial contact with the antigen recognise the antigen as 'foreign'. With each repeat exposure, T cells stimulate the local release of cytokines and macrophages, resulting in an inflammatory response (Figure 2).[5]

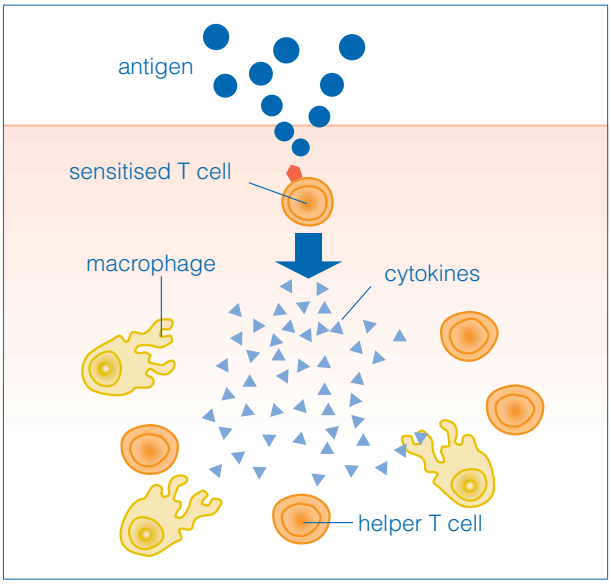

Figure 2: The inflammatory response

Adverse skin reactions associated with glove use

Adverse reactions to NRL gloves can range from mild irritation to a serious allergic response.[4] The four major types of adverse skin reactions associated with NRL glove use are: immediate hypersensitivity (Type I or latex allergy), delayed hypersensitivity (Type IV or contact dermatitis), irritant contact dermatitis and glove powder irritations.

Immediate Type I response: latex allergy

A Type I response is a reaction to residual proteins found in latex.[4] While there are more than 250 different types of latex proteins, approximately 20% are allergenic.

The reaction is immediate, typically occurring 5–30 minutes after initial contact. The symptoms are commonly:

- swelling and redness, local to the site of exposure
- non-specific symptoms such as itching and burning.

The symptoms can spread to areas remote to the site of contact with the glove, and can be accompanied by:

- conjunctivitis
- rhinitis
- bronchial obstruction.

In **rare** cases, symptoms of anaphylaxis can occur.

A Type I allergic response is mediated by IgE antibodies.[7] IgE-mediated hypersensitivity to latex involves a rapidly developing early phase and a late phase. In the early phase, circulating latex antigens cross-link with IgE receptors on mast cells, activating the cells to release histamine and other chemical mediators in the respiratory tract.[5] Mediator release occurs within minutes of exposure to the antigen and correlates with the onset of allergic symptoms (Figure 3).[7]

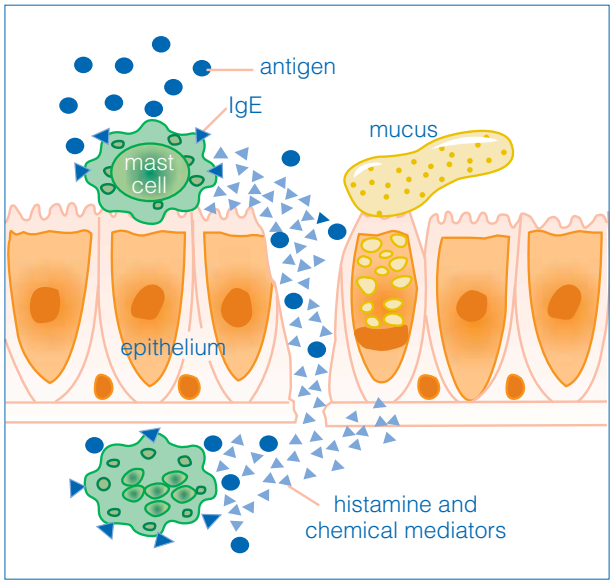

Figure 3: The Type I allergic response (early phase)

Section 2
Physiology of the immune response (cont.)

In the late phase, symptoms become active again several hours later when there is an influx of basophils, eosinophils and neutrophils.[7] This is followed by the production of histamine-releasing factors, some of which cross-link basophil-bound IgE and stimulate inflammatory cell release mediators (Figure 4).

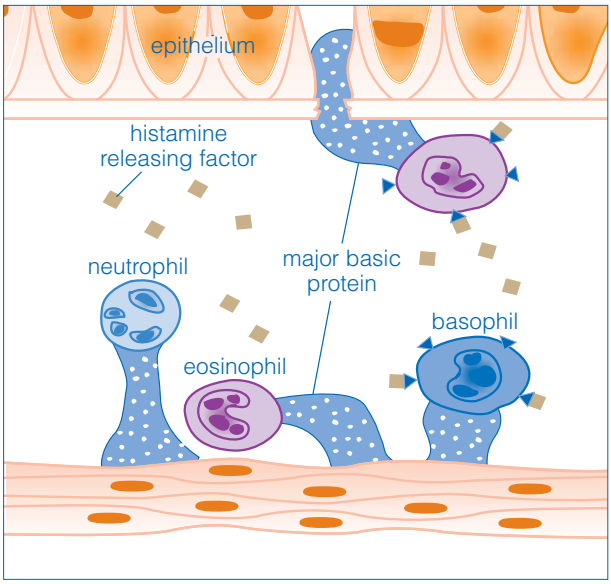

Figure 4: The Type I allergic response (late phase)

Delayed Type IV response – delayed contact dermatitis

A Type IV allergy is a reaction to specific allergens such as chemical residues from the glove manufacturing process (commonly chemical accelerators, covered on page 15 of this clinical guide).[8] The response is delayed rather than immediate, usually occurring 6–48 hours after initial contact, although symptoms can last for up to 4 days.

The symptoms include:

- erythema
- swelling
- cracking
- itching
- weeping
- dryness of the skin at the site, although dermatitis may extend beyond the area of contact.

The Type IV response begins when the antigens (such as residual chemicals leached from the glove) penetrate the skin, triggering the formation of T cells sensitised to the specific antigens.[5]

Repeated exposure to the antigen in allergic individuals results in the re-activation of sensitised T cells and the production of an inflammatory response, causing Type IV symptoms.[5]

Other causes of sensitivity

Some individuals may also be sensitive to other substances associated with surgical glove use. Other causes of sensitivity besides latex and chemical accelerators include some or all of:

- lanolin, which is used as a glove softener by some other manufacturers (not used in Ansell products)
- polyoxypropyleneglycol, a coagulant used in the glove manufacture process (not used in Ansell products)
- colouring pigments, either organic or inorganic
- quaternary ammonium compounds
- antioxidants which are used to prevent the degradation of NRL products
- preservatives.

Irritant contact dermatitis

Irritant contact dermatitis is a non-immune reaction affecting a number of surgical glove users.

It may be a local reaction to:

- detergents
- frequent hand washing
- inadequate drying
- climate extremes
- pre-existing dermatitis
- aggressive scrubbing techniques
- glove powder.

The typical time of onset is within minutes to hours of glove contact.

Symptoms are limited to the site of glove exposure and include:

- redness
- chapping
- chafing
- dryness
- scaling and cracking.

Irritant contact dermatitis is a condition affecting the skin, and should not be confused with an allergy. Glove users can help reduce the risk of irritation by:

- minimising contact with the causative agent
- instituting a regular skin care regimen
- avoiding oil/fat-based hand creams
- wearing powder-free gloves.

Complications associated with glove powder

Glove powders are modified cornstarches used to assist in the donning of the glove. Powder in the manufacturing process is primarily used to prevent blocking or adherence of the NRL surfaces.

Although some individuals may experience irritations associated with glove powder, it is not causative of allergic reactions. Glove powder is, however, a possible carrier of latex proteins and chemical accelerators used in the manufacturing process. Studies have demonstrated that glove powder is probably a contaminant which transports latex proteins throughout the medical environment.[4]

The introduction of glove powder into the body can impair normal physiological functions, causing complications associated with the introduction of a foreign body such as:

- kidney failure due to blockage of hepatic vessels
- contamination of implants or transplant organs
- damage to synovial joints
- impairment of ocular function
- blockage of reconstructed fallopian tubes after surgery
- interference with diagnostic tests
- contamination of drug preparation during chemotherapy admixture procedures.

Skin irritations associated with glove powder are mainly related to its potentially abrasive effects. Such complications include irritant contact dermatitis, adhesions and granulomas.

Irritant contact dermatitis is caused by the abrasive effects of glove powder, coupled with the irritation caused by frequent hand washing, strong surgical scrub agents, soaps and detergents. It results in dry, crusty, hard bumps and horizontal cracks on the skin, which may manifest as itchy dermatitis on the back of the hands under the gloves.

Adhesions and granulomas may form when an individual is unable to absorb and metabolise cornstarch. Adhesions are bands of fibrous tissue found on the surface of serous membranes, causing the tissue to connect with tissues of opposing surfaces or organs. Granulomas are a large group of distinctive focal lesions that are formed as a result of inflammatory reactions caused by biological, chemical or physical agents.[7] Surgery may be required to remove adhesions and granulomas before inflammatory reactions such as swelling, tenderness and fever subside.

Recommendations for reducing glove-powder complications

Complications associated with glove powder can be reduced by:

- washing the outside of the gloves thoroughly after donning
- removing gloves slowly and placing them in an appropriate container
- never snapping, flicking or tossing gloves into a disposal container
- always washing hands thoroughly after removing gloves
- wearing powder-free gloves.

Section 2
Physiology of the immune response (cont.)

Summary: Adverse skin reactions

	Type I: latex allergy	Type IV: delayed contact dermatitis	Irritant contact dermatitis
CAUSE OF ADVERSE RESPONSE	Direct or airborne exposure to a specific latex allergen.	Direct contact with a specific allergen (often a chemical such as a chemical accelerator).	• Frequent hand washing and inadequate drying • Aggressive scrubbing techniques and detergents • Climate extremes • Pre-existing eczema or dermatitis • Mechanical abrasive action of glove powders • Skin maceration from prolonged glove use • Individual skin differences
ALLERGIC MECHANISM	Circulating latex antigens cross-link with IgE receptors on mast cells to release histamine and other chemical mediators.	Invading antigens cause the formation of T cells, sensitised to the specific antigen.	No allergic mechanism.
PHYSIOLOGICAL RESPONSE	Chemical mediator release results in vasodilation, increased capillary permeability, blood and tissue leukocytosis.	Local release of inflammatory agents, such as cytokines and macrophages.	Local inflammation.
CLINICAL SIGNS AND SYMPTOMS	Cutaneous effects: • Itchy rash • Localised or generalised urticaria Systemic effects: • Oedema • Rhinoconjunctivitis and asthma or swelling and itching of the exposed skin, especially the face • Itchy, watery eyes; runny, itchy nose • Sneezing and shortness of breath, coughing and wheezing • Feeling faint or light-headed due to hypotension *In rare cases, in allergic individuals, systemic effects may progress to anaphylactic reactions.*	Acute: • Erythema • Pruritis or itching • Vesicle or blister formation with cracking, crusting and peeling skin. Chronic: • Chronic dryness • Fissuring of the skin • Thickening and darkening of the skin • Eczema or dermatitis. *Clinical signs may occur beyond the site of contact.*	• Erythema • Chapping and chafing • Dryness and scaling • Cracking and fissuring • Excessive itching and burning • Occasional vesicle or blister formation *Clinical signs are sharply defined and limited to the area of glove contact.*
TYPICAL TIME OF ONSET	Usually 5–30 minutes after initial contact, but can occur immediately.	6–48 hours.	Minutes to hours (dependant on individuals).
RECOMMENDATIONS	• Seek definitive diagnosis and recommendations from a qualified physician • Wear a medical alert bracelet • Avoid contact with NRL • Switch to a synthetic (non-NRL) glove	• Use a glove brand which has been washed or leached during manufacture to reduce residual chemicals which may cause the allergy • Avoid products which contain the specific chemicals which cause the allergy • Seek definitive diagnosis and recommendations from a qualified physician	• Minimise contact with the causative agent • Institute a regular skin care regimen • Avoid oil/fat-based hand creams • Wear powder-free gloves

Section 3
Natural rubber latex allergies

Who is at risk of adverse reactions to natural rubber latex?

Although the majority of healthcare professionals are not at risk of NRL allergy, their increased level of exposure to NRL means healthcare workers may be more susceptible than the general population.[4] Other groups potentially at risk include spina bifida or spinal injury patients, patients with a history of multiple invasive procedures, latex workers and atopic individuals.

Factors that may contribute to the incidence and risk of developing a NRL allergy include:

- Frequency and duration of NRL exposure
  - multiple latex exposure for extended periods
  - skin breakdown or pre-existing skin condition caused by frequent hand washing, scrubs and glove powder abrasion
  - failure to wash the hands after wearing gloves
  - perspiring under gloves
- Route of exposure
  - compromised natural skin barrier, such as cuts or lesions on the hands
  - contact of the allergen with mucous membranes, such as the mouth, nose or other parts of the respiratory tract
  - entry of the allergen into the circulatory system
- Predisposing factors
  - history of frequent exposure to latex
  - history of multiple invasive surgical procedures
  - individuals with chronic conditions such as spina bifida or congenital urological anomalies
  - atopic individuals or individuals with existing plant or food allergies such as bananas, avocados, other fruits or nuts.

Assessment of individual risk

It is important for all healthcare professionals to assess their own level of NRL sensitivity. Healthcare workers should take notice of any reactions to substances such as food, chemicals, offensive vapours, clothing or other frequently used items. Recurrent episodes of the symptoms are an indication that you should see your physician. Signs of sensitivity may include some or all of:

- redness and swelling of the involved area
- itching
- rash
- weal
- excessive tearing
- sneezing, itching and watery discharge from the nose
- swelling of the eyelids
- respiratory distress.

Preventative measures to reduce the risk of NRL reaction include:

- identifying the specific allergy by consulting with a physician if necessary
- wearing an allergy identification band
- reporting recurring signs and symptoms of any allergies
- checking the household for articles containing NRL components
- understanding employer policies for protecting NRL sensitive employees in the workplace
- taking meticulous care of the skin, as it serves as a natural immune barrier
- avoiding contact with the agents which cause the specific allergy, both direct and airborne
- seeking prompt medical care for skin problems.

Section 3
Natural rubber latex allergies (cont.)

Assessment of patients at risk

A standard questionnaire should be used to identify the risk of latex allergy in patients. A patient questionnaire may ask if the patient has a history of:

- adverse reactions to NRL
- allergies to bananas, avocados or other fruits or nuts
- major or multiple surgical procedures as an infant or child
- frequent dental work, catheterisation or enemas
- asthma or hay fever
- hand eczema or dermatitis
- episodes of local or systemic swelling, rash, inflammation or respiratory distress during or following urinary catheterisation, barium enemas, dental work, use of condoms, blowing up toy balloons or contact with household products such as utility gloves
- episodes of unexplained adverse reactions from anaesthesia.

The prevalence of natural rubber latex allergies

The introduction of universal glove precautions (commonly referred to as 'standard precautions') to prevent the transmission of disease has increased the exposure of healthcare professionals to NRL gloves.[4] This increased level of exposure resulted in an apparent initial rise in the prevalence of NRL allergies, particularly in the 1980s when glove precautions were first implemented. Mandatory glove policies also meant that gloves were in greater demand. This demand often exceeded supply, allowing gloves from sub-standard manufacturers and highly allergenic gloves to infiltrate the market.

Studies analysing the prevalence of NRL allergies amongst healthcare workers have produced varying results, with estimates of NRL allergy ranging from 0.6 to 10% of the healthcare population.[6,8] In the UK, no conclusive evidence has indicated that the prevalence has significantly increased.[4] The prevalence in the general population is estimated to be even lower than 1%. The incidence of NRL allergy is now decreasing due to a steady improvement in manufacturing technologies, latex allergy education and the development of latex alternatives.[3]

Assessing the risk of natural rubber latex allergy

A number of diagnostic procedures for allergy screening are available to evaluate suspected NRL or chemical allergy. These tests should be conducted under the direction and supervision of a qualified allergist.

Test	Indication	Methodology	Risk to individual
Patch test	Assessment for hyper-sensitivity to both chemical and protein allergens.	A drop of elutable glove extract or a piece of rubber glove is placed on the forearm. The area is checked in a specified length of time (typically 20 minutes) for a skin response.	Low to high.
Skin prick test	Assessment for hyper-sensitivity to protein allergens. Would not be used for routine diagnosis of latex hypersensitivity.	Elutable proteins are extracted from a piece of glove and made into solution. A drop of this solution is placed on the forearm, which is then pierced by a lancet. The resulting reaction is compared with saline as a negative control and histamine or codeine as a positive control.	High (resuscitation equipment must be available).
Radio-allergosorbent test (RAST)	Quantitative measurement of allergen-specific IgE antibodies in the test individual's serum.	This method uses a blood sample from a suspected NRL sensitive individual. It measures specific IgE antibodies against NRL allergens. RAST is reported to have an 80% sensitivity and 100% specificity in non-atopic individuals.	Level of risk is reduced because it involves a blood test without actually exposing the individual to the allergen.
In-use provocation test	This test is used when the skin prick test result is not in agreement with the case history. Individuals with slightly positive skin prick test or RAST results should always be given the in-use test to verify allergy existence.	The individual is required either to wear a finger of the NRL glove or a whole NRL glove on one hand while using a PVC glove on the other hand as a negative control. The individual is then examined over 15 minutes to see if any symptoms develop.	High (resuscitation equipment must be available).

Section 3
Natural rubber latex allergies (cont.)

Assessing allergenicity of natural rubber latex products

The following table outlines methods used for assessing protein content and/or allergenicity of NRL products.

Test	Indication	Methodology	Advantages	Disadvantages
Modified Lowry Assay	Determines the total amount of water-extractable protein associated with NRL products. Tests for residual protein content in NRL materials. The FDA has mandated this measurement technique to determine total protein content.	Residual water-soluble proteins are extracted from a latex glove piece, and then precipitated to remove interfering water-soluble substances. The protein content is then quantified by blue colourimetric reaction measured by a spectrophotometer.	An inexpensive test that is rapidly and easily performed.	• A large number of substances often added to NRL during compounding can cause interference in these assays • Limited sensitivity • Lack of specificity • Erroneous results can occur due to the complex mixture of polypeptides in the latex • No certified standard reference material is currently available to assess the accuracy of this test method
FIT Kit testing	Determines the total amount of water extractable allergen from NRL products. There are four separate kit tests available. Each one is specific for a particular allergen. This test method is currently undergoing validation as a certified ASTM test method.	Specific monoclonal antibodies are coated onto a microtitre well, binding the specific allergens from the NRL sample. After incubation, unbound material is removed by washing. The sample is incubated a second time with horse-radish peroxidase (HRP) labelled specific monoclonal antibodies, which bind to the microtitre plate-bound monoclonal antibodies. After washing, HRP substrate is added and the intensity of the colour produced is directly proportional to the specific allergen concentration of the sample.	• Guaranteed sensitivity and specificity irrespective of the presence of any other proteins or chemical substances used in the manufacturing process • Easy to perform • Highly sensitive	• Required to perform four separate tests to obtain the allergenic potential of the sample • Measures the four major allergens found in NRL products but does not measure other allergens which could potentially elicit an adverse response in sensitised individuals

Assessing allergenicity of natural rubber latex products (cont.)

Test	Indication	Methodology	Advantages	Disadvantages
Latex Elisa for Antigenic Proteins (LEAP) – Enzyme-linked Immuno-sorbent Assay (ELISA)	Measures not only the total latex proteins present, but also the levels of immunologically reactive latex protein.	Latex proteins are immobilised by adsorbtion to plastic and reacted with rabbit anti-latex antisera. After washing, the plate is reacted with a second anti-rabbit IgG and finally a substrate is added which results in a colour change. The spectrophotometric absorbance of the orange-coloured reaction product is then measured.	• Test is very sensitive and provides easily reproducible results • Discriminates between immune-response-inducing and non-inducing proteins • Test is easy to perform as it does not use radio-isotopes	• Uses latex proteins extracted from non-compounded ammoniated latex films • Uses rabbit rather than human sera • Has not been validated against specific allergen-measuring methods, such as the skin prick test or RAST inhibition assay
RAST Inhibition Assay	Quantifies latex allergens in a latex extract.	Soluble allergens in latex product extracts compete for binding to latex-specific IgE in pooled sera from latex-allergic individuals. When soluble allergens react with the IgE, the IgE antibody is inhibited from binding to a solid phase latex allergen preparation. The amount of inhibition is proportional to the quantity of soluble allergens in the extract.	Very sensitive technique for quantifying latex allergens.	• Requires a large pool of individual sera from NRL-sensitised humans to ensure that all relevant antibodies are included • Lack of standardised NRL allergens and standardised serum pool limits its use worldwide • Time consuming and expensive • Not widely available

Section 4
Glove manufacture

How are gloves manufactured?

The production of NRL gloves begins with the harvesting of raw latex, which is tapped from the *Hevea brasiliensis* tree. Stabilisers such as ammonia and other vulcanising chemicals are then added to the latex in a process known as compounding. Next, the mixture is stored in holding tanks where it is allowed to mature. The compounded latex then undergoes a variety of tests prior to being released for dipping.

Continuous batch machines perform the dipping process. This procedure produces powdered, chlorinated, powder-free or coated powder-free gloves.

After being dipped and cleaned in sodium hypochlorite and nitric acid, coagulant is applied to the clean glove former. Coagulant induces latex to deposit on the former, and is critical for even film formation.

The glove former, which is now coated with a thin layer of coagulant, is then dipped into chilled latex. The latex is chilled to delay any further pre-vulcanisation.

The former is then coated with a film of coagulated NRL. Next, the NRL film undergoes the first series of leaching to remove any residual coagulant.

After leaching, the film is vulcanised in ovens at temperatures ranging from 120°C to 140°C. The vulcanisation process irreversibly cross-links the polymer chains with sulfur. The accelerators which were added during the compounding phase increase the speed and efficiency of the cross-linking process.

Latex proteins present in the glove are then reduced in a process exclusive to Ansell known as PEARL (Protein and Endogenous Allergen Reduction Leaching). This process involves washing the gloves in three cycles: a 20-minute hot water and detergent wash, followed by two 20-minute hot water rinses. This reduces effective residual protein levels from 150 µg/dm^2 to less than 50 µg/dm^2. Gloves are then tested further for quality control before packing.

The role of chemical accelerators in glove production

The use of chemicals in the manufacture of NRL gloves transforms latex from its original liquid state to a very thin, strong and elastic film. Accelerators are chemicals used in the manufacturing process to increase the binding speed between sulfur and the glove material. Sulfur is used to assist bonding of the glove material to form a product with superior stretch and recoil. It also adds strength to the glove, gives integrity to the latex during use, and stabilises the latex for long-term storage.

Three main classes of chemical compounds are used as accelerators: thiurams, dithiocarbamates and mercaptobenzothiazoles (MBTs). Some residual accelerators can be a source of skin irritation.

Thiurams

Thiurams are most commonly regarded as a cause of Type IV delayed contact dermatitis. Thiurams decompose during vulcanisation, liberating the sulfur and carbamates.

Mercaptobenzothiazoles

MBTs were initially implicated as relatively potent sensitisers, however, the incidence of sensitisation to this group of compounds is lower than other accelerator compounds. This is most likely due to their less frequent use in glove production. MBTs are an important accelerator because of their solubility in natural rubber.

Dithiocarbamates

Dithiocarbamates facilitate cross-linking and curing by absorbing sulfur and carrying it into the glove material. There are more than 34 types of dithiocarbamates, and they are even less sensitising than thiurams and MBTs. These compounds contain zinc, which is important to the solubility of the accelerator in NRL and its ability to react with sulfur.

Figure 5: The dipping process

Figure 6: Manual stripping

Chemical accelerators in Ansell gloves

Brand	Thiurams	Carbamates	Mercaptobenzothiazoles	Other
Surgical gloves				
Gammex® PF		ND		PV100
DermaPrene® Ultra				
MicroThin NuTex®	✓	✓		
NuTex® DermaShield		ND		PV100
NuTex®	✓	✓		
Encore® Orthopedic	✓	✓		
SensiTouch® Powdered	✓	✓		
Conform® Powdered	✓	✓		
Gammex® Powdered	✓	✓		
Examination gloves				
No Powder Exam SensiClean®		✓	✓	
ExamTex®		✓		
NitraTex®		✓	✓	
Laboratory gloves				
LabTex® Light Powder		✓		
LabTex® Plus		✓		
LabTex® Nitrile		✓	✓	
Dental gloves				
Denta-Glove™ Light Powder		✓		
Denta-Glove™ PF		✓		

ND = Levels Not Detectable

Section 4
Glove manufacture (cont.)

How is Ansell working to reduce glove allergenicity?

Ansell is committed to reducing glove allergenicity at every stage of the manufacturing process. High quality procedures ensure that residual protein levels are reduced at each step of production, from the initial preparation of the raw latex to the use of PEARL (Protein and Endogenous Allergen Reduction Leaching) technology when necessary.

Ansell is also working to reduce glove allergenicity by continually refining its use of chemical accelerators. Different accelerator types, concentrations and processes are being used in manufacture to develop the best glove product possible.

Ansell also offers a variety of alternatives within its glove range. These include powder-free gloves (using DermaShield finishing processes) and DermaPrene Ultra gloves (latex and accelerator free). For more information on glove alternatives, see page 15 (accelerator chart).

To assist users with latex sensitivity, all Ansell Healthcare products carry the warning: *This product contains natural rubber latex which may cause allergic reactions*.

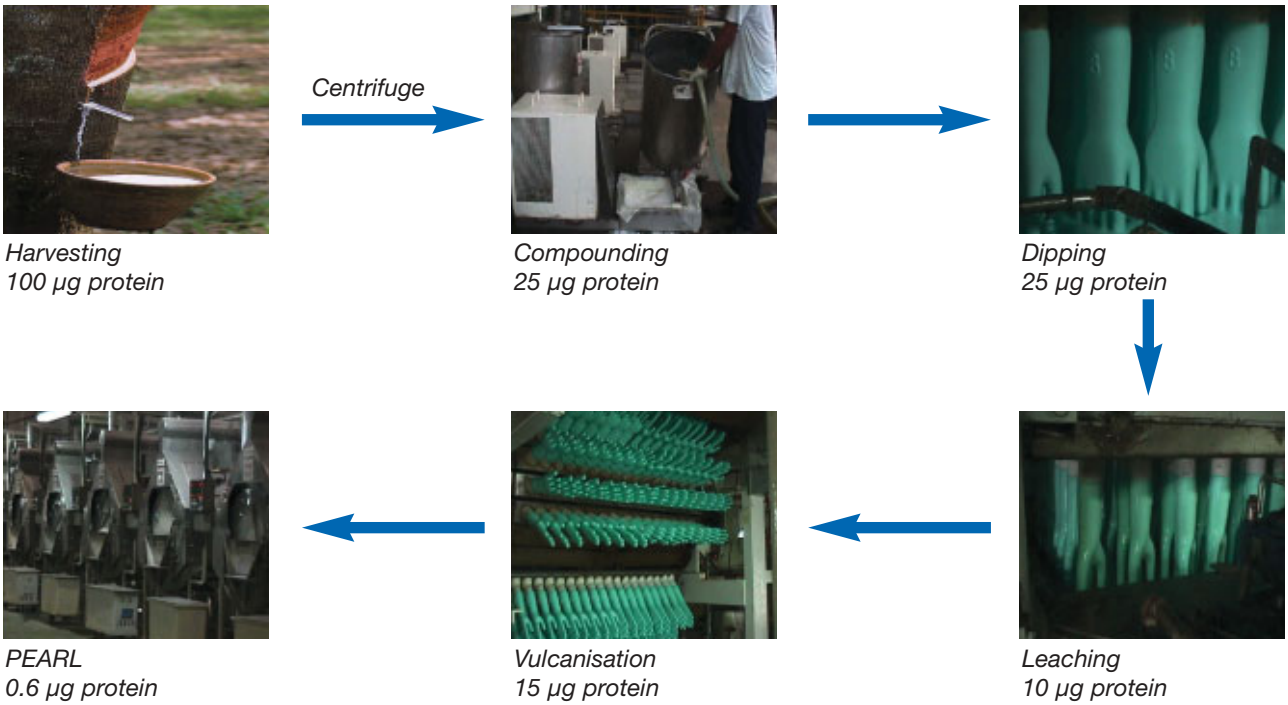

Figure 7: Reducing glove allergenicity

µg = micrograms

Standards for glove manufacture

All gloves are tested to determine the Acceptable Quality Level (AQL) of the product. This involves the sample testing of each batch of gloves to determine the number of nonconformities per 100 units, which is the process average. The process average relates to the acceptable level of nonconformities from a very large batch or series of batches. The risk of receiving two or more defects in a box of 100 gloves is virtually nil at an AQL of 0.065.

AQL testing involves two stages. The first is an air test, which tests the batch of gloves with air to expand the glove material to expose obvious holes or defects between fingers. Next, water testing is performed. To test glove integrity, gloves are filled with 1.5 L of water for 2 minutes to check for leaks under sustained pressure.

International AQL standards for surgical gloves are set at a minimum AQL 1.5, while the Australian and New Zealand standard for examination gloves is AQL 2.5. Ansell's minimum standards are much higher, with a minimum AQL of 0.065 required for surgical gloves before packaging, and a minimum AQL of 1.5 for examination gloves.

Before packing, all gloves are visually inspected. Packed boxes are then sterilised before being checked for seal integrity and that the inner pack is not infringing the seal. Random samples are also selected from finished packs to check for defects and packaging faults.

New developments in glove manufacture from Ansell

Ansell is committed to offering alternatives for individuals affected by adverse glove reactions by using the latest innovations in manufacture technology. New developments from Ansell include:

- **Powder-free latex**, providing reduced abrasion and allergen carrier risk
- **Synthetic alternatives**, such as polychloroprene, nitrile and other materials currently in development
- **PV100 as a chemical accelerator**, which breaks down to CO_2, N_2 and H_2O
- **Thiuram-free formulations**
- **Continual latex formulation improvements**
- **Research into gamma irradiation cross-linking in the vulcanisation process.**

Figure 9: Water testing

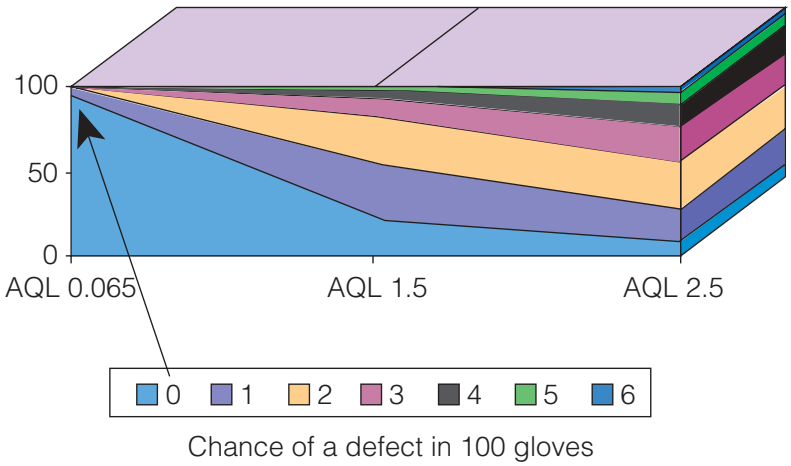

Figure 8: Acceptable quality levels

Section 5

Managing latex allergies in healthcare staff and patients

The key to managing latex allergies and adverse glove reactions in healthcare professionals and patients lies in correct recognition and appropriate action. Establishing NRL-free or powder-free policies and procedures is an important preventative measure to reduce the risk of adverse glove reaction.[3]

This can be done by forming a multidisciplinary committee responsible for developing uniform policies and procedures to protect both patients and healthcare professionals. The committee should be responsible for developing and maintaining:

- a latex-safe standard operating procedure manual
- a latex-safe allergy cart or means for staff to access non-latex items
- a pro-active occupational health program
- correct latex product identification.

Latex allergy awareness can also be established through a uniform education program involving information aids such as brochures and videos.

Healthcare workers should be encouraged to report any symptoms and complete a questionnaire to determine their personal risk of latex allergy.

A standard questionnaire should also be used to identify the risk of latex allergy in patients. For a sample patient questionnaire, please refer to section 3.

If latex allergy is suspected, it may indicate a need for further testing. For patients affected by latex allergy, immediate precautions should be enforced including:

- latex allergy ID band
- documentation on patient chart
- precaution sign outside patient care areas
- alerting of appropriate departments
- removal of latex items from patient care area
- obtaining a latex-safe care cart.

Glossary

Accelerators – chemical catalysts that speed the cross-linking process during natural rubber latex glove manufacture.

Acute – rapid onset with severe symptoms but of short duration in contrast to chronic.

Allergen – antigens that cause allergic reactions, such as pollens, industrial chemicals, certain foods and dander.

Anaphylactic shock – severe hypersensitivity reaction resulting from exposure to a substance to which an individual is sensitised. It occurs within minutes and is life-threatening. It involves difficulty breathing, cyanosis, cough, pulse variations, fever, convulsion and collapse ending in death if immediate treatment is not given.

Antibody – the specific protein the body generates to interact with the antigen and destroy it or render it harmless.

Antigen – an agent invading the body, most frequently a protein.

Antioxidants – chemicals used to prevent oxidation (for example, degradation of rubber products).

Atopic – the tendency to acquire certain forms of allergic familial conditions such as hay fever, asthma, eczema and urticaria.

Chronic – a term used to describe an extended course of symptoms/illness, in contrast to acute.

Colourimetric test – a test which measures the intensity of colour in a substance or fluid.

Conjunctivitis – inflammation of the conjunctiva of the eye.

Cross-link – bridging of individual molecules.

Curing – see vulcanisation.

Cyanosis – a bluish colouration of the skin and mucous membranes which develops as a result of reduced haemoglobin.

Cytokines – hormone-like proteins secreted by many different cell types. Cytokines regulate the intensity and duration of immune responses.

Dermatitis – inflammation of the skin occurring at the area of contact with an irritant evidenced by redness, itching and various skin lesions.

Eczema – an acute or chronic cutaneous inflammatory condition with redness, eruptions of the skin, itching and/or burning.

Erythema – an area of the skin that shows diffused redness, usually caused by capillary congestion.

Histamine – a potent substance stored in mast cells and basophil granules. This substance is released during an allergic reaction.

Immune system – a group of tissues and leukocytes that constantly combat any infectious agent that tries to invade the body and neutralises, destroys and/or eliminates it from the body.

Immunoglobulin – another term for antibody.

Immunoglobulin E (IgE) – a type of antibody associated with allergic reactions.

Leukocyte – white blood cell.

Local reaction – a reaction limited to a definite area, such as the area of contact with the irritating substance.

Macrophages – large size phagocytes that ingest infectious agents and/or dead tissue and cells.

Mast cells – specific cells that release toxic substances such as histamine from damaged tissues following an allergic reaction.

Proteins – organic molecules which are the building blocks of living organisms. Naturally occurring proteins are components of natural rubber latex and some act as allergens.

Rhinitis – inflammation of the nasal mucosa.

Sensitise – to make sensitive by exposure to an allergen which results in stimulating the body's immune system to produce antibodies specific to that allergen.

Systemic reaction – a reaction which involves all the body systems in contrast to a local reaction. Sometimes referred to as a 'generalised reaction'.

T cells – white blood cells primarily produced in the lymph nodes and transported through the circulatory system providing a rapid and potent defence against infectious agents.

Urticaria – an allergic reaction of the skin with eruption of smooth, itchy patches, weals or hives.

Vulcanisation – an irreversible process in which polymer chains are cross-linked and the material becomes elastic. It increases strength, resistance and elasticity of the glove by combining with sulfur or other additives in the presence of heat and pressure.

Weal – small raised itching elevation of the skin as from an insect bite.

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