



OVERVIEW

Latex allergy is a term that describes the range of allergic reactions to substances in natural rubber latex (NRL). An allergy is a hypersensitivity disorder of the immune system. Allergic reactions appear when a person's immune system reacts to nontoxic substances in the environment, in this case natural rubber latex (NRL). NRL gloves are the main source of allergic reactions. NRL is also used in a wide range of products, such as condoms and some medical devices. Latex is used in over 40,000 products with many different uses. The exact cause of latex allergies is unknown. It appears that repeated and frequent exposure to NRL products may bring on symptoms in some people.

Since the late 1980s there has been a dramatic rise worldwide in allergy to latex. A logical explanation is the use of universal precautions for preventing the spread of infectious diseases such as the AIDS virus. As a result, the use of latex gloves is nowadays widespread. Frequent exposures to latex and rubber products are common. Healthcare workers (HCWs) are at particular risk for latex allergy.

LEARNER OBJECTIVES

Upon completion of this educational activity, the learner should be able to:

- 1. Discuss historical events in the development of latex allergy among HCWs.
- 2. Explain three adverse reactions associated with the use of NRL.
- 3. List populations at risk for developing latex allergies.
- 4. Identify methods of testing available to diagnose latex allergy
- 5. Describe the problems encountered by individuals exposed to glove powder.

INTENDED AUDIENCE

The information contained in this self-study guidebook is intended for use by healthcare professionals who are responsible for or involved in the following activities related to this topic:

- Educating healthcare personnel.
- Establishing institutional or departmental policies and procedures
- Decision-making responsibilities for safety and infection prevention products.
- Maintaining regulatory compliance
- Managing employee health and infection prevention services.

INSTRUCTIONS

Ansell is a Recognized Provider of continuing education by the California Board of Registered Nursing, provider #CEP 15538 and the Australian College of Perioperative Nurses (ACORN). This course has been accredited for 2 (two) contact hours. Obtaining full credit for this offering depends on completion of the self-study materials on-line as directed below.

Approval refers to recognition of educational activities only and does not imply endorsement of any product or company displayed in any form during the educational activity

To receive contact hours for this program, please go to the "Program Tests" area and complete the post-test. You will receive your certificate via email.

AN 85% PASSING SCORE IS REQUIRED FOR SUCCESSFUL COMPLETION.

Any learner who does not successfully complete the post-test will be notified and given an opportunity to resubmit for certification.

For more information about our educational programs or perioperative safety solution topics, please contact Ansell Healthcare Educational Services by e-mail at edu@ansellhealthcare.com

Planning Committee Members: Luce Ouellet, BSN, RN Latisha Richardson, MSN, BSN, RN Patty Taylor, BA, RN Pamela Werner, MBA, BSN, RN, CNOR

As employees of Ansell Mrs. Ouellet, Mrs. Richardson, Mrs. Taylor and Ms. Werner have declared an affiliation that could be perceived as posing a potential conflict of interest with development of this self-study module. This module will include discussion of commercial products referenced in generic terms only.

TABLE OF CONTENTS

OVERVIEW	2
INTRODUCTION	4
PHYSIOLOGY OF THE IMMUNE RESPONSE	5
COMPLICATIONS ASSOCIATED WITH GLOVE POWDER	9
POPULATION AT RISK	11
PREVALENCE OF LATEX ALLERGY	12
DIAGNOSTIC SCREENING FOR LATEX ALLERGY	13
ASSESSING ALLERGENICITY OF NRL PRODUCTS	14
MANAGING LATEX ALLERGY	15
RESTRICTIONS AND BANS ON POWDERED GLOVES	15
GLOSSARY	
REFERENCES	19



INTRODUCTION

Gloves containing Natural Rubber Latex (NRL) represent an important hand barrier and their use is an integral part of healthcare practice. Although they provide excellent protection against the transmission of infectious agents, they have been associated with adverse skin reactions in some users.

Since the introduction of universal glove precautions (now known as 'standard precautions') in the 1980s, medical glove use has grown considerably. This increased frequency of exposure to medical gloves for both HCWs and patients has led to a number of reported adverse reactions. Fortunately, the advent of improved technologies, powder-free latex gloves, synthetic gloves and superior modern manufacturing processes has since reduced the incidence of latex reactions.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 medical gloves and many other healthcare and consumer products. Most people are regularly exposed to NRL as it exists in items such as clothing, toys, tires, door and window seals and elastic bands. The majority of medical 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. NRL is also a natural, biodegradable product, containing no petroleum by-products or dioxins.

As not all adverse reactions to medical gloves are latex allergies, it is important to be aware of other sources of irritation. Other adverse reactions include allergic delayed contact dermatitis (ACD), irritant contact dermatitis (ICD) and responses to glove powder and other sensitizing 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 glove irritations.

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

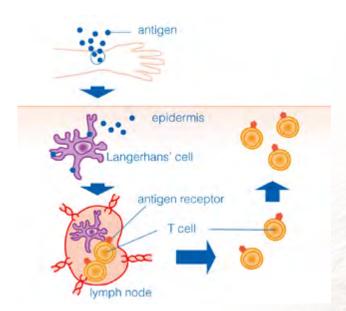


Figure 1: The immune response.

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 recognize 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

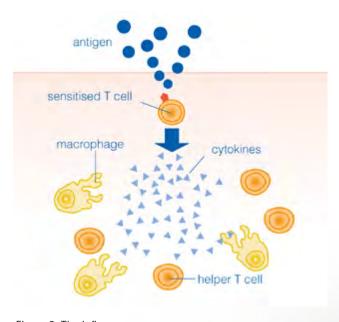


Figure 2: The inflammatory response.

ADVERSE SKIN REACTIONS

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 ACD), ICD 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; and
- 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:

- urticaria
- conjunctivitis;
- · rhinitis; and
- 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

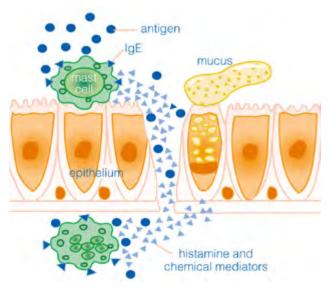


Figure 3: The type 1 allergic response (early phase)

In the late phase, symptoms become active again several hours later when there is an influx of basophils, eosinophils and neutrophils. 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).

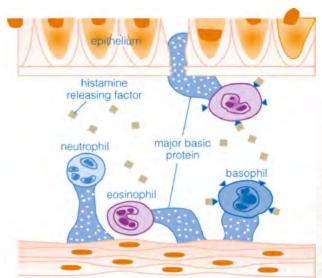


Figure 4: The type 1 allergic response (late phase)

DELAYED TYPE IV RESPONSE – DELAYED OR ALLERGIC CONTACT DERMATITIS (ACD)

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 16 of this clinical guide). 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; and
- dryness of the skin at the site, although dermatitis may extend beyond the area of contact.

The type IV response begins when the allergens (such as residual chemicals leached from the glove) penetrate the skin, triggering the formation of T cells sensitized to the specific antigens.⁵ (see figure1).



Repeated exposure to the antigen in allergic individuals results in the re-activation of sensitized T cells and the production of an inflammatory response, causing type IV symptoms.⁵ (see figure 2).



OTHER CAUSES OF SENSITIVITY

Some individuals may also be sensitive to other substances associated with 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);
- · coloring pigments, either organic or inorganic;
- · quaternary ammonium compounds;
- antioxidants which are used to prevent the degradation of NRL products; and
- · preservatives.

Irritant contact dermatitis (ICD)

ICD is a non-immune reaction affecting a number of glove users. This type of contact dermatitis is more frequently encountered than delayed contact dermatitis.

It may be a local reaction to:

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



ICD in web space

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; and
- · scaling and cracking.

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

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



In the event of a persistent dermatitis, it is recommended to always consult a medical practitioner. This is due to the fact that the clinical manifestations of ACD and ICD, the most frequent type of dermatitis suffered by healthcare professionals, are very similar and it is not always possible to visually differentiate between these two types of dermatitis.

COMPLICATIONS ASSOCIATED WITH GLOVE POWDER

Glove powders are modified corn starches 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

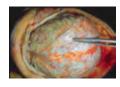
The introduction of glove powder into the body can impair normal physiological functions, causing complications associated with the introduction of a foreign body such as:

- · liver 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; and
- 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 ICD, adhesions and granulomas.

ICD may be 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 metabolize 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. Surgery may be required to remove adhesions and granulomas before inflammatory reactions such as swelling, tenderness and fever subside.







Above images in order left to right:

- 1. Starch Meningitis
- 2. Starch Peritonitis
- 3. Powder Contamination after eye surgery

Complications associated with glove powder can be reduced by wearing powder-free gloves.

If powdered gloves are used, the following best practices should be followed:

- 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; and
- always washing hands thoroughly after removing gloves.



	Type 1: latex allergy	Type IV: allergic contact dermatitis (ACD)	Irritant contact dermatitis (ICD)
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, sensitized to 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. Localized or generalized 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. Thickness 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.	Minimize contact with the causative agent. Institute a regular skin care regimen. Avoid oil-/fat-based hand creams. Wear power-free gloves.

POPULATION AT RISK

Although the majority of healthcare professionals are not at risk of NRL allergy, their increased level of exposure to NRL means HCWs 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; and
- » 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; and
- » 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; and
- » atopic individuals or individuals with existing plant or food allergies such as bananas, avocados, other fruits or nuts.



HEALTHCARE WORKERS AT RISK

It is important for all healthcare professionals to assess their own level of NRL sensitivity. HCWs should take notice of any reactions to substances such as food, chemicals, offensive vapors, 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 the following:

- redness and swelling of the involved area;
- · itching;
- · rash;
- · weal;
- · excessive tearing;
- sneezing, itching and watery discharge from the nose;
- · swelling of the eyelids; and
- 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; and
- seeking prompt medical care for skin problems.

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, catheterization 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 catheterization, barium enemas, dental work, use of condoms, blowing up toy balloons or contact with household products such as utility gloves; and
- episodes of unexplained adverse reactions from anesthesia.



PREVALENCE OF LATEX ALLERGY

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. It is believed that demand often exceeded supply, allowing gloves from sub-standard manufacturers and highly allergenic gloves to infiltrate the market.

Studies analyzing the prevalence of NRL allergies amongst HCWs have produced varying results, with estimates of NRL allergy ranging from 0.6 to 17% of the healthcare population, 6.8 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, the use of powder-free gloves, latex allergy education and the development of latex-free alternatives.

DIAGNOSTIC SCREENING FOR 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 hypersensitivity to both chemical and protein allergens.	A drop of elutable glove extract or piece of rubber glove is placed in 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 hypersensitivity 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 form 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 the 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).



ASSESSING ALLERGENICITY OF NRL PRODUCTS

Test	Indication	Methodology	Advantages	Disadvantages
Modified Lowry Assay	Determines the total amount of aqueous 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 substance 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 polypeptides in the latex. No certified standard reference material is current 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. ASTM D7427.	Specific monoclonal antibodies are coated onto a microtiter 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) labeled specific monoclonal antibodies, which bind to microtiter platesbound monoclonal antibodies. After washing, HRP substrate is added and the intensity of the color produced is directly proportional to the specific allergen concentration of the sample.	Guaranteed sensitivity and specificity irrespective of the presence of any other proteins of 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 adverse response in sensitized individuals.
Latex ELISA for Antigenic Proteins (LEAP) – Enzyme-linked immunosorbent Assay (ELISA) RAST Inhibition Assay	ASTM D6499 since 2000. Quantifies latex allergens in a latex extract.	Latex proteins are immobilized by adsorption 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 color change. The spectrophotometric absorbance of the orange-colored reaction product is then measured. Soluble allergens in latex product extracts compete for binding to latex-specific IgE,	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. Very sensitive technique for quantifying latex allergens.	Uses latex proteins extract from non-compounded ammoniated latex films. Uses rabbit rather than human sera. Has not been validated against specific allergenmeasuring methods, such at the skin prick test or RAST inhibition assay. Requires a large pool of individual sera from NRL-sensitized humans to ensure
•	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.		that all relevant antibodies are included. • Lack of standardized NRL allergens and standardized serum pool, limits its use worldwide. • Time consuming and expensive. • Not widely available.	

MANAGING LATEX ALLERGY

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 nonlatex items;
- · a pro-active occupational health program; and
- correct latex product identification.

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

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; and
- obtaining a latex-safe care cart.

RESTRICTIONS AND BANS ON POWDERED GLOVES

The documented adverse effects caused by the use of powdered gloves are the reason for a global decrease in powdered gloves usage, and a shift towards powder free gloves. Realizing the dangers of cornstarch on examination and surgical gloves, hospitals around the world starting moving to powder free gloving alternatives. Germany's regulations of personal protective equipment banned the use of powdered medical gloves in 1997. In 2000, the Purchasing and Supply agency for

the United Kingdom ceased to purchase any gloves lubricated with cornstarch.¹¹

The US Food and Drug Administration (FDA) enacted a rule banning the use of powdered surgical gloves, powdered exam gloves, and absorbable powder for lubricating surgical gloves. The ban, first proposed in March 2016, was announced by the FDA on December 19, 2016 and became effective on January 18, 2017. FDA's rationale for the ban is based on the risk of illness or injury to patients and healthcare providers exposed to the powdered gloves, when internal body tissue is exposed to the powder, which may include severe airway inflammation and hypersensitivity reactions. Powder particles may also trigger the body's immune response, which can lead to an array of conditions from allergic reactions to surgical complications. Alternatively, there are other medical gloves available that are powder free and provide the same degree of protection, hand dexterity, and performance without posing the same risks to individuals.¹²

In addition, on January 8, 2017, the Saudi Food and Drug Authority (SFDA) banned the manufacture, import, sale and distribution of powdered surgical and patient examination gloves as well as the absorbable powder used to facilitate wearing of medical gloves. In a statement on its website HYPERLINK "http://www.sfda.gov.sa/"www.sfda.gov.sa, the Authority explained that the reason for the ban is the probable link of using such gloves with many health risks, including acute respiratory infections; anaphylaxis; allergic asthma; inflammation and damage of lungs' airways (bronchial tubes); skin rash and adhesions of abdominal membranes. The ban is to go into effect March 27, 2017.¹³

On December 27, 2016 Japan announced their intention to enact a similar ban with a two-year transition through to December 2018.¹⁴ The Ministry of Food and Drug Safety Korea in a January 24th 2017 meeting announced they too are considering a powdered glove ban transition through to December 2018.

Hospital Authority (HA) of Hong Kong implemented a ban to local hospitals effective 19th January 2017, following the ruling of US FDA. This applies to government hospitals which is under the responsibilities of HA. Private hospitals which are not under control of HA have also adopted the same stance.¹⁵



GLOSSARY

ADVERSE

Acting against or in a contrary direction

ADHESION

Fibrous bands that form between tissues and organs, often as a result of injury during surgery

ALLERGIC REACTIONS

In an allergic reaction, the immune system starts fighting substances that are usually harmless (such as dust mites, pollen, or a medicine) as though these substances were trying to attack the body

ALLERGENICITY

Antigens that cause allergic reactions, such as pollens, industrial chemicals, certain foods and dander

ANAPHYLAXIS

A severe hypersensitivity reaction resulting from exposure to a substance to which an individual is sensitized; 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

ATOPIC

The tendency to acquire certain forms of allergic familial conditions such as hay fever, asthma, eczema and urticaria

BIODEGRADABLE

A type of waste which can be broken down, in a reasonable amount of time, into its base compounds by microorganisms and other living things, regardless of compound type

BRONCHIAL OBSTRUCTION

Airway obstruction is a blockage of respiration in the airway; it can be broadly classified into being either in the upper airway or lower airway

CHEMICAL ACCELERATORS

A substance that increases the rate of a chemical reaction

CHEMICAL MEDIATORS

Histamines, leukotrienes, and cytokines that limit the amount of exudate (or stuff your body doesn't want) causing the muscle to swell after injury

COAGULANT

A substance that causes coagulation; to cause transformation of (a liquid or solid, for example) into or as if into a soft, semisolid, or solid mass

CONGENITAL

A condition existing at birth and often before birth or that develops during the first month of life (neonatal disease).

CONJUNCTIVITIS

Conjunctivitis, also known as pinkeye, is an inflammation of the conjunctiva; the conjunctiva is the thin clear tissue that lies over the white part of the eye and lines the inside of the eyelid

CROSS-LINK

Bridging of individual molecules

CYTOKINE

Hormone-like proteins secreted by many different cell types; cytokines regulate the intensity and duration of immune responses

DELAYED ALLERGIC CONTACT DERMATITIS (ACD)

Inflammation of the skin occurring at the area of contact with an irritant evidenced by redness, itching and various skin lesions; generally caused by a chemical irritant and appears hours to days after exposure

DELAYED HYPERSENSITIVITY

Type IV hypersensitivity is often called delayed type hypersensitivity as the reaction takes two to three days to develop

ERYTHEMA

An abnormal redness of the skin due to local congestion, as in inflammation

GRANULOMA

A small area of inflammation in tissue; granulomas are most often the result of an infection and associated with foreign bodies left in the wound such as glove powder

HEVEA BRASILIENSIS

Latex rubber tree

HISTAMINE

A chemical found in some of the body's cells which causes many of the symptoms of allergies, such as a runny nose or sneezing

INFECTIOUS AGENTS

Infections are caused by infectious agents such as viruses, viroids, and prions, and microorganisms such as bacteria

IMMEDIATE HYPERSENSITIVITY

Type I hypersensitivity (or immediate hypersensitivity) is an allergic reaction provoked by re-exposure to a specific type of antigen referred to as an allergen such as NLR

IMMUNE RESPONSE

The immune system is a system of biological structures and processes within an organism that protects against disease

IMMUNOGLOBULIN E

A type of antibody associated with allergic reactions; IgE antibodies

IMMUNOGLOBULIN IGE RECEPTORS

Found on the surface of mast cells and basophils

IRRITANT CONTACT DERMATITIS (ICD)

The development of dry, itchy, irritated areas on the skin, usually the hands; this type of reaction is not an actual allergy to latex, but is the irritation from frequent glove use and also from hand/skin washing, sweating, and/or irritation from powder lubricants due to persistent contact with the irritant

LANGERHANS CELLS

Antigen-presenting immune cells of the skin and mucosa

LYMPH NODE

An oval-shaped organ of the lymphatic system, distributed widely throughout the body including the armpit and stomach and linked by lymphatic vessels; a response to illness that includes inflammation of the lymph nodes specifically indicates a biological factor

MACROPHAGES

Large-sized 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

METABOLIZE

All chemical reactions that occur in living organisms, including digestion and the transport of substances into and between different cells, in which case the set of reactions within the cells is called intermediary metabolism or intermediate metabolism

NON-IMMUNE

Not having immunity; susceptible; likely to be affected with, if exposed

OCULAR

Relating to the eye

PREVALENCE

The proportion of a population found to have a condition (typically a disease or a risk factor)

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

RETICULOENDOTHELIAL SYSTEM

Also called macrophage system or mononuclear phagocyte system; class of cells that occur in widely separated parts of the human body and that take up particular substances; these cells are part of the body's defense mechanisms

RHINITIS

Inflammation of the nasal mucosa

SENSITIZING SUBSTANCES

Hypersensitive or reactive to an antigen, such as pollen, especially by a second or repeated exposure

SPINA BIFIDA

A developmental congenital disorder caused by the incomplete closing of the embryonic neural tube

STANDARD PRECAUTIONS

The primary strategy for successful infection control and reduction of HCWs exposure; standard precautions are used for care of all patients, regardless of their diagnosis or presumed infectious status

SYNOVIAL

The soft tissue found between the articular capsule (joint capsule) and the joint cavity

T CELLS

White blood cells primarily produced in the lymph nodes and transported through the circulatory system providing a rapid and potent defense against infectious agents; also called T lymphocyte

URTICARIA

An allergic reaction of the skin with eruption of smooth, itchy patches, weals or hives

VULCANIZATION

An irreversible process in which polymer chains are crosslinked 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.

REFERENCES

- 1. Nutter A. Contact urticaria to rubber. Br J Dermatol 1979; 101(5): 597-8.
- Granady LSJ. The history and diagnosis of latex allergy. Immunol Allergy Clin North Am 1995: 22.
- Yip ES. Comments to the Maine legislature on proposed prohibition of sale of non-sterile latex gloves. 2003.
- O'Gilvie, W. Latex sensitisation in the healthcare setting. Device Bulletin 9601 April 1996, The Medical Devices Agency of the Department of Health.
- Guyton AC, Hall JE. Textbook of medical physiology. 10th ed. Philadelphia: WB Saunders, 2000.
- Susman E. AAAAI: Latex sensitivity infrequent in HCWs. In: Doctor's guide global edition. 2003.
- Robbins SL, Cotran RS, Kumar V (eds). Robbins basic pathology. 7th ed. Philadelphia: WB Saunders, 2003.
- 8. Sussman G. The effects of interventions and glove changes in HCWs with latex allergy. Ann Allergy Asthma Immunol 2003; 90: 179–80.
- Rosemary Nixon. Occupational contact dermatitis in HCWs. Ansell Cares 2004. www.professional.ansell.com.au. Accessed July 2008.
- 10.Edlich RF, Long WB, Gubler DK, et al. Dangers of cornstarch powder on medical gloves - seeking a solution. Ann Plast Surg. 2009; 63(1):822-826.
- 11. Edlich RF, Long WB 3rd, Gubler KD, et al. Citizen's Petition to Food and Drug Administration to ban cornstarch powder on medical gloves: Maltese cross birefringence. American Journal of Emergency Medicine. 2009;27(2):227-235.
- 12.US Food and Drug Administration. https://www.federalregister.gov/documents/2016/12/19/2016-30382/banned-devices-powdered-surgeons-gloves-powdered-patient-examination-gloves-and-absorbable-powder Accessed January 31, 2017.
- 13. Saudi Food and Drug Authority Prohibits Manufacturing, Importing, Selling, Distributing of Powdered Gloves. http://www.spa.gov.sa/viewstory. php?lang=en&newsid=1578447 Accessed January 31, 2017.
- 14.https://www.pmda.go.jp/files/000216103.pdf Accessed March 2, 2017.
- 15.http://www.ha.org.hk/haho/ho/cico/cicobiweeklyvol6no19.pdf Accessed March2, 2017



Ansell Healthcare Products LLC 111 Wood Avenue, Suite 210 Iselin, NJ 08830 USA Ansell Healthcare Europe NV Riverside Business Park Blvd International, 55, 1070 Brussels, Belgium Ansell Limited Level 3, 678 Victoria Street, Richmond, Vic, 3121 Australia Ansell Services (Asia) Sdn. Bhd. Prima 6, Prima Avenue, Block 3512, Jalan Teknokrat 6 63000 Cyberjaya, Malaysia