SHIELD Scientific
compliance comfort protection

A SAFE PAIR OF HANDS

University of Nottingham, April 17th 2009

A SHIELD Scientific Education Programme

Learning Objectives

- **Describe differences between gloves**
- **Distinguish three common reactions to wearing latex and synthetic gloves**
- **List the four components of gloves that can trigger reactions and sensitivities**

Increased Reactions

- Dry chapped hands
- Cracking
- Eczema (reddening of the skin)
- Dermatitis (inflammation)

New Symptoms

- Hives
- Rhinitis
- Asthma
- Conjunctivitis
- Anaphylaxis

Glove Components

- Chemicals
- Proteins
- Powder
- Endotoxins

Chemicals provide:

- Strength
- Stretchability
- Storage preservation

Latex Being Tapped from Rubber Tree – source of latex proteins

Manufacturing Process – use of powder as a release agent

Use of Powder as a donning agent – residues on hand

Endotoxins (Pyrogens)

- Originate from raw latex materials or result from poor manufacturing practices
- Not destroyed by the sterilization process
- May be present on sterile surgical or cleanroom gloves

Dermal Reactions

- Irritant Contact Dermatitis (also known as irritation, irritant dermatitis or dermatitis)
- Allergic Contact Dermatitis (also known as Type IV, Delayed Hypersensitivity or Chemical Allergy)
- Natural Rubber Latex Allergy (also known as Immediate Type Hypersensitivity, Protein Allergy or Type I)

Irritant contact dermatitis

- Non-allergic condition
- Can effect everyone (i.e. latex and synthetic glove wearers)
- Both non-glove-associated and glove-associated irritant contact dermatitis

Glove Related Irritant Contact Dermatitis

- Chemicals
- Powder
- Endotoxins
- Friction
- Air occlusion

Non-Glove Related Irritant Contact Dermatitis

- Soaps
- Detergents
- Disinfectants
- Degreasing agents
- Ethylene Oxide
- Alcohol

Acute Irritant Contact Dermatitis

Irritant Contact Dermatitis – the Symptoms

- Itching
- Redness
- Inflammation
- Scaly appearance
- Burning sensation
- Thickened skin
- Blisters
- Small hard bumps
- Cracks
- Line of demarcation with glove induced irritation

Corrective Action for Irritant Contact Dermatitis

- Consult Occupational Health
- Switch to gloves low in chemical residues (refer to data sheet for evidence of low irritant potential)
- Powder free
- Use caution around infectious agents
- Consult a dermatologist if symptoms persist

Allergic Contact Dermatitis

- Also known as Type IV, Delayed Hypersensitivity or Chemical Allergy
- More than 2800 substances known to be contact sensitizers
- Allergic condition affecting genetically predisposed individuals
- Dose and rate dependent
- Glove-related allergic contact dermatitis can occur with latex and synthetic gloves
- Non glove-associated causes are fragrances (e.g. in shampoos, soaps etc), disinfectants and nickel
- Typically occurs 6-48 hours after allergen exposure
- More than 80% of diagnosed cases can be traced to accelerators

Symptoms of Chronic Allergic Contact Dermatitis

- Dryness
- Scaling
- Peeling
- Pimples
- Reaction extends beyond the area of glove contact
- Cracking
- Inflammation
- Skin blisters

Chronic form of Allergic Contact Dermatitis

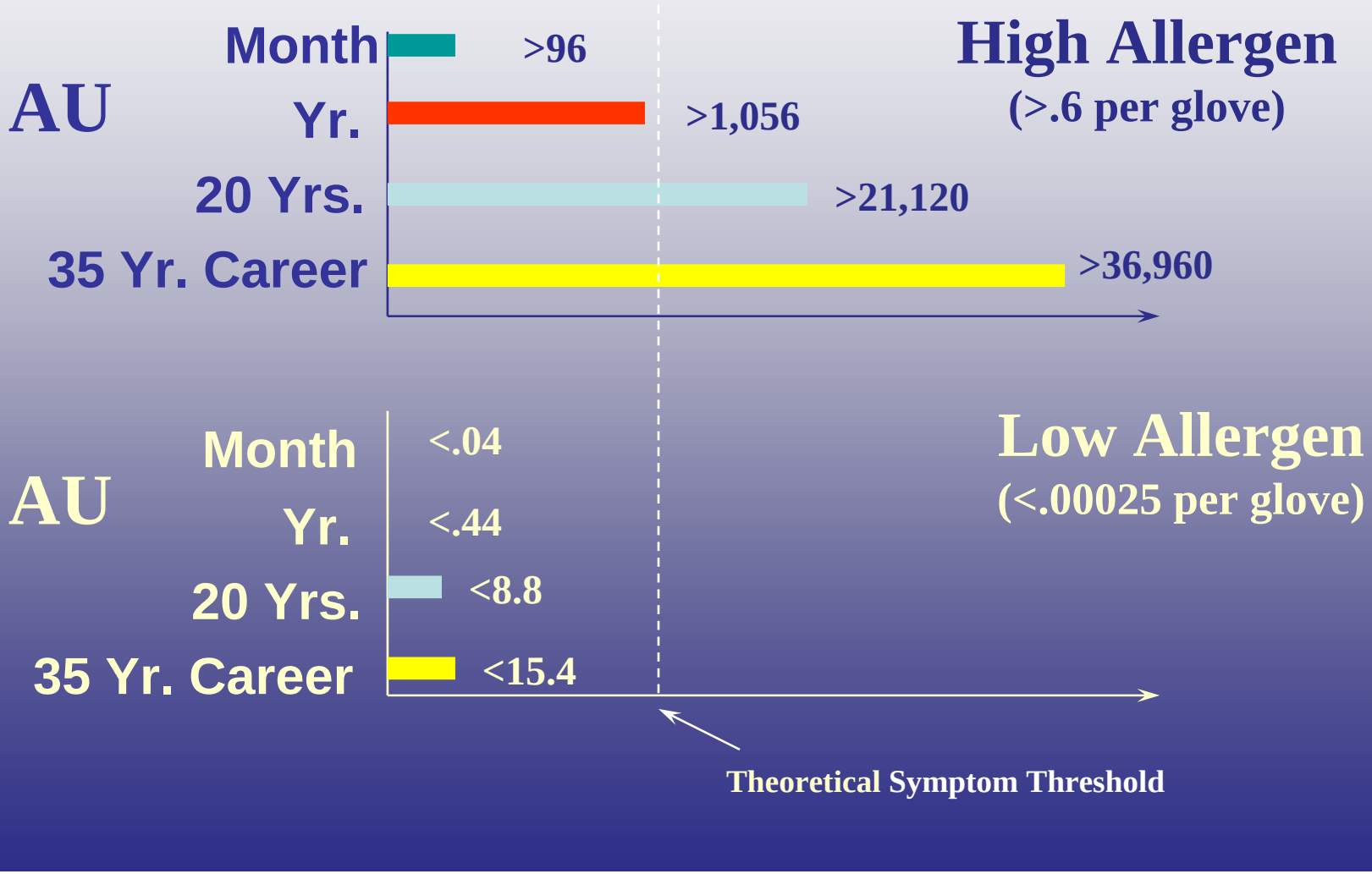
Corrective Action for Allergic Contact Dermatitis

- Consult Occupational Health
- Switch to gloves that are low in chemical allergens (refer to data sheet for evidence that gloves are low in chemical sensitizers)
- If specific chemical allergen has been identified, select a glove not containing this chemical

Gloves -Allergen Exposure (Millions)

for Allergic Contact Dermatitis

8 Changes/Day



Natural Rubber Latex Allergy

- **Also known as also known as Immediate Type Hypersensitivity, Protein Allergy or Type I**
- **Allergic condition affecting genetically predisposed individuals**
- **Dose and rate dependent**
- **Can occur within one minute to an hour of exposure to allergen**
- **Potential for cross-reactivity with many common foodstuffs (e.g. apples, potatoes, tomatoes etc)**

Symptoms of Natural Rubber Latex Allergy

- Urticaria
- Hives
- Asthma
- Anaphylaxis
- Hay fever symptoms

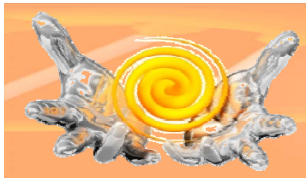
Cross-Reactive Allergens

- Apples
- Avocados
- Bananas
- Celery
- Cherries
- Chestnuts
- Ficus
- Figs
- Grapes
- Kiwis
- Mangos
- Melons
- Passion Fruit
- Peaches
- Celery
- Pears
- Pistachios
- Potatoes
- Ragweed
- Strawberries
- Tomatoes
- Latex

Natural Rubber Latex Allergy - Staff Must:

- Notify their supervisor and Occupational Health
- See an allergy specialist
- Wear synthetic gloves
- Work in a powder free environment
- Notify colleagues, dentist or GP
- Wear a medic alert bracelet
- Carry a source of adrenaline if prescribed

TRIAGE FORMAT:
GUIDE to DIFFERENTIATION of GLOVE REACTIONS



EMPLOYEE COMPLAINS OF REACTION TO GLOVES

Report to Occupational or Employee Health

This triage is only a guideline. Employer protocols regarding glove-associated reactions should be reviewed by your staff allergist and dermatologist.

Location: Hands or Arms Only

NO

Symptoms in addition to (or in lieu of) those on the hand/arm :

- Abdominal cramping, nausea
- Anaphylaxis
- Angioedema, pharyngeal swelling
- Blood pressure drop, tachycardia
- Diarrhea
- Dyspnea*
- Headaches, disorientation
- Itching, burning eyes*
- Respiratory distress, asthma*
- Rhinitis*

* Note: If symptoms persist, but diagnositic test for immediate type hypersensitivity (Type I) to latex are negative, consider airborne irritants and chemical sensitizers (Type IV) of glove and non-glove origin

→ IMMEDIATE TYPE HYPERSENSITIVITY (TYPE I)

YES

Urticaria (Hives)

YES → IMMEDIATE TYPE HYPERSENSITIVITY (TYPE I)

NO

How long have symptoms occurred?

Recent (Acute)

Symptom onset after glove removal

Rapid

Itching, swelling, blisters, sores, cracking, redness or dry appearance

→ IRRITATION

Delayed (6 to 72 hours)

Clustered bumps, itching (but upon scratching, painful), peeling, scales, blisters, red or dry appearance

→ DELAYED TYPE HYPERSENSITIVITY (TYPE IV)

Long-term (Chronic)

Symptoms

Appear beyond border of the glove

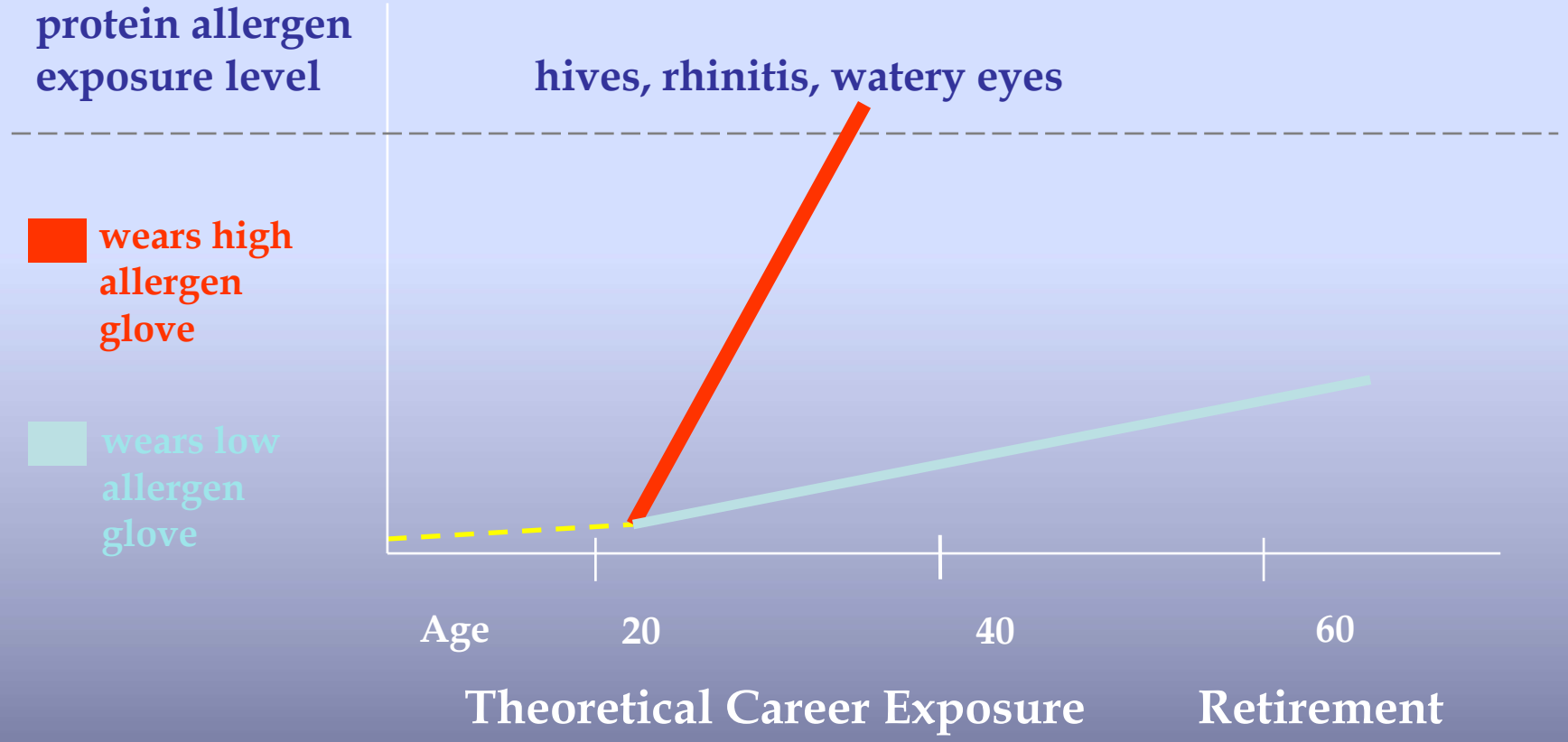
YES → DELAYED TYPE HYPERSENSITIVITY (TYPE IV)

Delayed onset

NO

→ IRRITANT CONTACT DERMATITIS

Threshold for Clinical Symptoms – Natural Rubber Latex Allergy



Natural Rubber Latex Products

Employee OH review

Glove barrier issues – Focus on vinyl

- Up to 60% in-use failure rate (Rego & Roley,1999)
- Poor chemical resistance properties
- DEHP is a reprotoxin
  - Carcinogenic
  - Mutagenic
  - Reduces reproduction
  - PVC medical devices must be labelled “Containing phthalates”

Glove Selection

To reduce:	*Choose gloves:*
Irritant Contact Dermatitis	➢Low in chemicals ➢Low in endotoxins ➢Powder free
Allergic Contact Dermatitis	➢Low in chemical contact sensitizers & powder free
Natural Rubber Latex Allergy	➢Low in protein ➢Powder free
Occupational Asthma	➢Powder free
In-use barrier failure	➢Quality material appropriate to task

Dermal Reactions

TYPE OF DERMAL REACTION	INCIDENCE OF OCCURRENCE
Irritant contact dermatitis	40%-60%* *Owenby, 1998
Allergic contact dermatitis	12%* *Gibbon, 2001
Natural rubber latex allergy	0.8%-7%* * Lebenbom-Mansour, 1997

Disposable Glove Directives -which Directives are relevant?

- Workplace Directive 89/654/EEC
  - Employer obligations → Protect the employee
- PPE at Work Directive 89/656/EEC
  - Employers obliged to undertake risk assessment of hazards to employees
- Personal Protective Equipment Directive (PPE) 89/686/EEC
  - Manufacturer's obligations → Protect the wearer.
- Directive 93/42/EEC on Medical Devices (MDD).
  - Manufacturer obligations → Protect the patient.

THIS SUGGESTS THAT GLOVES FOR USE IN THE LABORATORY SHOULD BE « PPE » REGISTERED

How to identify MDD Gloves?

- Underneath the CE mark, EN455 will usually feature providing easy identification.
- Non-sterile MDD Gloves are also often called Exam, Examination or Medical Gloves.
  - Highlighting their role in patient care.
- Non-sterile exam gloves are considered Class 1 Medical Devices.
  - This means gloves undergo a self certification process conducted by the manufacturer.
  - No independent validation of the test data by an external organization.

CE

EN455

PPE Directive 89/686/EEC (cont) – summary of categorization

PPE CATEGORY	RISK	CERTIFICATION / INSPECTION	CE MARKING
PPE Category I: Simple Design	Minimal	Self-certification	CE
PPE Category II. Intermediate Design	Intermediate	Notified Body (product testing)	CE
PPE Category III. Complex Design	Irreversible or mortal	Notified Body (product testing+ quality audit)	CE 0321

INTERPRETATION OF EU REGULATIONS

PROTECTION AGAINST VIRUSES

- EN374-2:2003 is the reference standard
  - Based on the water leak or air leak procedure to demonstrate that gloves offer an effective barrier to micro-biological hazards
  - NB: EN374-1:2003 Article 3.2 Explains that the micro-organism resistance definition extends only to bacteria and fungi. The test does NOT apply to protection against viruses.

THE VIRAL PENETRATION TEST
(ASTM F1671)
COULD BE THE RIGHT SOLUTION

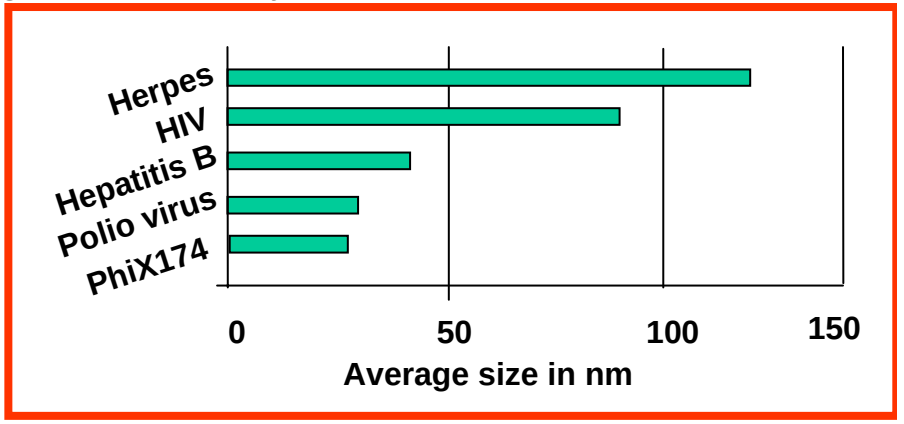
SHIELDskin™ ORANGE NITRILE™ Gloves

WATER LEAK ASSAY

- **Impact:** Leaks and defects on gloves impact *personal safety* and *process integrity* from human-borne contamination
- **Test Method:** **EN374-2:2003** *"Protective Gloves Against Chemicals and Micro-organisms – Part 2: Determination of Resistance to Penetration"* is suitable for demonstrating that gloves form an effective barrier to bacteria and fungi but *does not apply to viruses*
- **Limits:** To be considered micro-organism resistant gloves must achieve at least an AQL of <1.5. All SHIELDskin™ gloves must achieve an AQL of <0.65 *making them more than twice as effective*
- **Testing:** is conducted for every manufactured batch of gloves. Additionally regular external auditing is carried out by a *Notified Body (*indicated by the 4 digits under the CE mark) as part of the PPE Cat III certification. CE 0123

VIRAL PENETRATION TEST

- **Impact:** Users handling live viruses need to know if their glove can protect them from accidental spills as well as provide a suitable barrier to protect process integrity. This test evaluates the quality of the glove film that cannot be detected using Water Leak Assay
- **Test Method:** **ASTM F1671-07** "Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens" using the non-hazardous Phi-X174 Bacteriophage as a penetration test system
- **Limits:** No viruses should go through
- **Industry standard method:** Yes
- **Testing:** Required for every new glove or glove formulation, and tests are done on as needed basis. Performed at an outside laboratory such as Nelson Laboratories



Choosing the right glove

- 1) What is the principal intended purpose:
  - Personal Protection
  - Process Protection
  - Patient Protection
- 2) What is the risk
  - Minimal Risk => PPE Cat I i.e. easily reversible
  - Irreversible / mortal risk => PPE CATEGORY III

- 3) How do I protect my hand from the wearing of gloves
  - Glove associated irritation
    - Powder free
    - Low in chemical residues (viz. primary skin irritation test)
  - Glove associated Type IV reactions
    - Powder free
    - Low in chemical contact sensitizers (viz. Buehler sensitization test, Modified Draize test & specific chemical sensitizer test)
  - Glove associated Type I reactions
    - latex-free gloves
- 4) Which material do I select – vinyl, nitrile or latex?
  - Long cuff Nitrile preferred
  - Ensure proper fit