The Case of Continuing Use of Natural Rubber Latex Gloves

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Malaysian Rubber Export Promotion Council
Washington DC, USA
Malaysia is the largest exporter with 52% of world’s market share in 2007 (28 billion pairs).
Australia’s Rubber Glove Imports (2003-2007)
(Million Pairs)

- **World**
- **Malaysia**
- **Thailand**
- **United States**
- **China**
- **Sri Lanka**

Year | World | Malaysia | Thailand | United States | China | Sri Lanka
--- | --- | --- | --- | --- | --- | ---
2002 | 581.6 | 373.5 | 156.4 | 156.4 | | |
2003 | 621.5 | 420.6 | | | | |
2004 | 889.3 | 557.6 | | | | |
2005 | 850.9 | 536.4 | | | | |
2006 | 1211.5 | | 693.0 | | | |
2007 | 1418.7 | | 754.5 | | | |

Confidential
Healthcare Professionals and Medical Gloves

- Constantly exposed to potentially harmful infectious agents, e.g. HIV, Hepatitis B & C.
- Need protection during their course of work, especially when in contact with contaminated blood and body fluids.
- One safety measure is the use of appropriate medical gloves.
Medical Glove Types

Examination
- Natural rubber latex
- Vinyl (PVC)
- Nitrile

Surgical
- Natural rubber latex
- Polychloroprene
- Co-polymer
- Nitrile
Do ALL gloves provide the same degree of safety measure that healthcare professionals need??
Different Glove Materials

Different barrier properties &

Different glove qualities
Why Natural Rubber Latex Gloves?
Aspects of Interest

- **Barrier Properties:**
  - Barrier performance
  - Comfort, fit, durability
  - Tear resistance,
  - Tactile sensitivity

- **Potential Health Risks:**
  - Latex protein allergy
  - Chemical toxicity (DEHP)

- Environmental Impact

- New Glove Certification Program
Barrier Protection

*The single most important criterion:*

Ability to provide very effective barrier protection against blood pathogens and harmful infections
Barrier Integrity of Medical Gloves – “In-use”

![Graph showing glove failure rates for different materials and studies.]

- **NR latex**
- **Vinyl**
- **Polyethylene**
- **Nitrile**
- **Neoprene**
### Barrier Effectiveness of Punctured Gloves Against Viral Penetration (Resealing Properties)

*Challenge virus - ΦX 174, diameter = 27 nm*

<table>
<thead>
<tr>
<th>Gloves</th>
<th>Needle diameter = 0.22mm</th>
<th>Virus leak (Volume, ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vinyl</td>
<td>78%</td>
<td>3 – 18</td>
</tr>
<tr>
<td>Nitrile</td>
<td>53%</td>
<td>8 – 11</td>
</tr>
<tr>
<td>NR latex</td>
<td>Zero failure</td>
<td>0.013 – 0.023</td>
</tr>
</tbody>
</table>

(Hasma & Othman 2001)
Comfort and Fit

Ability of gloves:
- to stretch
- to remain soft
- conform to hand

Latex > Nitrile, Neoprene > Vinyl
Durability of Medical Examination Gloves

NR latex > > > Vinyl Polychloroprene

Tactile Sensitivity

Latex >> Synthetics
### ASTM Glove Standards — Lower specifications for non-latex gloves

<table>
<thead>
<tr>
<th>Property</th>
<th>Surgical</th>
<th>Examination</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NR</td>
<td>SR</td>
</tr>
<tr>
<td>Min. TS (MPa)</td>
<td>24</td>
<td>17</td>
</tr>
<tr>
<td>(Strength)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min. EB (%)</td>
<td>750</td>
<td>650</td>
</tr>
<tr>
<td>(Elasticity)</td>
<td>(ASTM D3577)</td>
<td>(D3578) (D5250) (D6319) (D6977)</td>
</tr>
</tbody>
</table>

- **NR** – natural rubber latex
- **SR, Vinyl, Nitrile, Polychloroprene** – synthetic, non-latex
## ISO Glove Standards – Lower specifications for non-latex gloves

<table>
<thead>
<tr>
<th>Property</th>
<th>Surgical</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NR</td>
<td>SR</td>
</tr>
<tr>
<td>Min. Force-at-Break (Strength) - N</td>
<td>12.5</td>
<td>9.0</td>
</tr>
<tr>
<td>Min. EB (%) (Elasticity)</td>
<td>700</td>
<td>600</td>
</tr>
<tr>
<td></td>
<td>(ISO 10282)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NR</td>
<td>SR</td>
</tr>
<tr>
<td></td>
<td>7.0</td>
<td>7.0</td>
</tr>
<tr>
<td></td>
<td>650</td>
<td>500</td>
</tr>
<tr>
<td></td>
<td>(ISO 11193-1)</td>
<td>(ISO11193-1)</td>
</tr>
</tbody>
</table>

**NR** – natural rubber latex  
**SR** (*Nitrile, Polychloroprene*), **Vinyl** – synthetic, non-latex
## EN Glove Standards – Lower specifications generally for non-latex gloves

<table>
<thead>
<tr>
<th>Property</th>
<th>Surgical</th>
<th>Examination</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NR</td>
<td>SR</td>
</tr>
<tr>
<td>Min. Force-at-Break (Strength)</td>
<td>≥ 12</td>
<td>≥ 9.0</td>
</tr>
<tr>
<td>(Strength) - N</td>
<td>(EN 455-2-2000)</td>
<td></td>
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</tbody>
</table>

**NR** – natural rubber latex  
**SR** (*Nitrile, Polychloropprene*) – synthetic, non-latex  
**Others** – vinyl
### AS/NZ Glove Standards

**Lower specifications for non-latex gloves**

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<th>Examination</th>
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<tbody>
<tr>
<td></td>
<td>NR</td>
<td>SR</td>
</tr>
<tr>
<td>Min. TS (MPa) (Strength)</td>
<td>23 17</td>
<td>21</td>
</tr>
<tr>
<td>Min. EB (%) (Elasticity)</td>
<td>700 550</td>
<td>700</td>
</tr>
</tbody>
</table>

NR – natural rubber latex  
SR, Nitrile, Polychloroprene – synthetic, non-latex
Potential Health Risks

- Latex Protein Allergy
- Chemical Toxicity
  (*DEHP in Vinyl products*)
Natural rubber latex gloves, with their excellent barrier protection, are preferred.

However, latex allergy associated with their use in recent years – a concern

Given rise to various synthetic alternatives, e.g. vinyl, nitrile, chloroprene (neoprene).
Hevea Brasiliensis Latex

It contains:

- Rubber particles
- Proteins
- Carbohydrates
- Inorganic constituents
- Water
Latex gloves with:

- High residual proteins
- High powder content

Cause of allergy
Latex Glove Line (Schematic)

1. Natural Rubber Latex Harvesting
2. Collection Container with NH₃
3. Concentration From 30-60% Solid
4. Compounding
   Carbamate
   Thiram
   Mercaptobenzothiazole
   Thiourea
   Phenol
   Quinaldine
   Phenylendiamine
   Hydroxytoluene
5. Brush or Ultrasonic Former Cleaning
6. Coagulant Dip
7. Oven
8. Latex Dip
9. Oven
10. Bead Roll
11. Leaching Tanks
12. Vulcanization Ovens 100°C
13. Cornstarch Powder Application
14. Stripping

(Hamann 1993)
Protein/Antigen Reduction by Improved Processes

Protein content

Antigen level

P = Powdered
PF = Powder-free

Yeang et al. 2003
Residual Proteins with Allergens in Gloves

Primary Sensitizer

*NOT* Powder

Need to avoid High Protein gloves with excessive glove powder
Adverse Reactions (Post operational)

- Tissue adhesion
- Wound healing
- Granulomas

Cause: Presence of foreign microbodies
Foreign micro-bodies associated with human adhesions

- Gauze lint (80%)
- Starch (3%)
- Surgical sutures (2%)
- New textures (2%)
- Oil (1%)
- Others (12%)

(Duron et.al.1997)
Powder-free gloves

Low protein content –
Due to extensive washing, and chlorine treatment during processing

Powdered gloves

Can also have low protein content – using modern technologies
Glove Intervention - Use of low protein/allergen gloves in place of high protein/allergen gloves


- Dramatic drop in latex protein allergy incidence
- Latex allergic workers wearing synthetic gloves could work safely alongside their colleagues donning latex gloves
- Allergic individuals did not have to change jobs or retire because of latex allergy
- One reported no increased cost incurred, while Mayo Clinic had a saving of $200,000 per year.
Impact of Low-Protein Latex Gloves

K.Kelly, MD. Former Chair of Latex Allergy Comm., AAAAI and Assoc. Dean of Clinical Affairs, Medical College of Wisconsin (HealthLink, August 2005) –

“Latex allergy episodes in decline, prevalence drops from 8%-12% in 1990’s to about 1% today”

“Mainly due to a change in way latex gloves are manufactured – a 1000-fold drop in allergen content of gloves.”

“Many HCW’s are back to work now, with no fear of allergic reactions,….patients don’t have to be afraid to go into the hospital.”

“Latex allergic individuals wear medical bracelets, and avoid latex contact.”
Impact of Low-Protein Latex Gloves

D. Beezhold, PhD (NIOSH) & G. Sussman, MD (University of Toronto), Lessons Learned from Latex Allergies, September 2005:

- “Low-protein, powder-free gloves have drastically reduced exposure to the healthcare setting.”
- “However, it is necessary for latex-allergic healthcare workers to only wear non-latex gloves.”

J.N. Fink, Professor of Medicine, Medical College of Wisconsin; Latex Allergy in the Surgical Environment, September 2005:

- “….it appears that the epidemic has been eliminated.”
DEHP is a highly toxic plasticizer used in many vinyl gloves to make them more flexible. Often 30-50% in vinyl products.
DEHP can leach out from vinyl gloves:

🔹 when in contact with blood or body fluids of patients during medical procedures

🔹 when in contact with food during food handling
Adverse Effects of DEHP

- Toxic to liver, kidney and heart
- Causes reproductive problems:
  - Toxic to Sertoli cells (sperm production)
  - Reduced fertility
  - Ovarian dysfunction
  - Structural changes in testes
- Decrease hormone production in females
- Fetus malformation
- Listed as probable human carcinogen (EPA, NIOSH)
Infants, children, pregnant women and fetus – more sensitive to the effects of DEHP than others.

- Recent studies on human showed that prenatal exposure to phthalates lead to boys with subtle genital alternations –

  *Environ. Health Perspectives, June 2005, 113:1719-1722*
 **Warning on Use of Vinyl (PVC) Medical Devices** — *FDA on 12 July 2002*

 **Vinyl Gloves with DEHP Not to be used in Food Handling** - *Japanese Ministry of Health on 14 June 2001*

 **Ban on soft PVC toys with phthalates (DEHP) for young children** — *EU Commission 1999*
Environmental Impact

- Raw materials
- Disposal of end-products
Natural Rubber Latex

Green material – environmentally-friendly:

- Sustainable and renewable resource
- Biodegradable
Synthetic gloves

- Raw materials often toxic or carcinogenic
- Not biodegradable, disposal by burning releases harmful substances, e.g. dioxin, cyanide, HCl, etc.
Disposal by Landfill – leaching of chemicals into the soil, contaminating the ground waters, hence food supply chains
Many good reasons why Natural Rubber Latex Gloves should continue to be used

The advent of low-protein latex gloves –

❖ Alleviates latex allergy;
❖ Provides best possible barrier protection against dangerous infections.

High protein latex gloves should be avoided
NR latex gloves have many superior critical glove properties that manufacturers of many synthetic alternatives are still trying to achieve.

Indiscriminatory replacement with vinyl gloves in hospitals could expose healthcare professionals to undesirable health risks, and caution should be taken.

Hospitals should make available suitable synthetic gloves with effective barrier for individuals who are latex allergic.
New Glove Certification Program
SMG

To help identify
Quality Low-Protein Natural Rubber Latex Gloves
Standard Malaysian Glove
New Quality Certification Program

To ensure the manufacture of quality latex examination gloves that are:

- High in barrier protection
- Low in protein and powder

Powder-free  Lightly Powdered
SMG Program
for Examination Gloves developed through

R&D by RRIM*

Consultation with U.S. FDA and other relevant authorities

* RRIM – Rubber Research Institute of Malaysia
The SMG Program
(www.smg-gloves.com)

Certifies Low-Protein latex gloves that:

- Meet stringent standards
- Low protein & powder limits
# Barrier Performance

[Acceptable Quality Level for Examination Gloves]

<table>
<thead>
<tr>
<th>Standard</th>
<th>AQL requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS/NZS</td>
<td>2.5</td>
</tr>
<tr>
<td>ASTM</td>
<td>2.5</td>
</tr>
<tr>
<td>ISO</td>
<td>2.5</td>
</tr>
<tr>
<td>SMG</td>
<td>1.5</td>
</tr>
<tr>
<td>Standard</td>
<td>Requirement [maximum]</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>FDA/ISO/EN</td>
<td>Not specified</td>
</tr>
<tr>
<td>ASTM</td>
<td>200 µg/dm²</td>
</tr>
</tbody>
</table>
| SMG          | 50 µg/dm²
SMG gloves < synthetic alternatives, except for Vinyl — poor barrier properties

Certification of Quality Standard – No Additional Cost
ECRI recommends
the use of Low-Protein Gloves
with label of low Protein Content
or that SMG-Certified

Lower-Protein Latex Gloves
A Way to Reduce Allergic Reactions
in Hospital Staff

(Health Devices, May 2004, Vol.33, #5, 169-173)
Conclusion

**Latex gloves** –
These remain the **gold standard** (superior barrier performance, durability, comfort, fit, tactile sensitivity, high tear resistance.) However, only *low-protein* gloves should be used.

**Vinyl gloves** –
*Not* for medical procedures (high risks exposure to blood etc.) appropriate only for short-term low-risk tasks that involve minimal stress.

**Nitrile and other synthetics** –
More superior than vinyl gloves, but may be more costly. They are recommended for *latex allergic individuals* who have to avoid latex proteins.
For more information about NR latex medical gloves:

http://www.latengxlove.info

http://www.smg-gloves.com
Thank you for your attention