

## *Natural rubber latex gloves*

No powder, low allergen, no problem?

**Evidence from Europe shows that use of good quality, low protein, powder free natural rubber latex gloves, together with monitoring and health surveillance can prevent new cases of latex protein allergy and keep already sensitized staff in the workplace.**

Two recent seminars, under the title “*Selecting the right gloves: glove selection for healthcare and personal protective equipment*” took place in London on Friday 11<sup>th</sup> March and in Edinburgh on Monday 14<sup>th</sup> March. These key events focused on how recent experience and best practice can be used to guide policy makers and users in glove selection. Experts from Germany, Finland, Malaysia and the UK examined the scientific evidence on the use of natural rubber latex gloves and latex allergy to address the important issues.

The speakers explained how other European countries have tackled latex allergy issues in hospitals, by using only powder free and low allergen examination gloves and surgeons gloves, and how these changes in glove selection policy have reduced the number of new cases of occupational asthma and dermatitis. They questioned whether a move to synthetic gloves will provide the answer to the allergy problem and explained how manufacturers have improved the quality of their gloves and how glove quality is monitored.

Altogether, more than 150 delegates, including occupational health professionals, purchasers and users, glove manufacturers and distributors, raw materials suppliers, and academic and scientific experts, participated in the discussions on this important topic.

The seminars were organized by the Malaysian Export Promotion Council (MREPC) and the UK research centre of the Malaysian Rubber Board, the Tun Abdul Razak Research Centre (TARRC), assisted by the UK’s Association of British Healthcare Industries (ABHI).

The London event, at the Landmark Hotel in Marylebone, was opened by the Malaysian Minister of Plantation Industries and Commodities, the Honourable Datuk Peter Chin Fah Kui. The MREPC’s CEO, Dato’ Teo Suat Cheng provided the welcome introduction. Mike Kreuzer OBE, Director of Regulation Priority for the ABHI, gave a short presentation on the UK’s Healthcare Industries Task Force, HITF, and illustrated how it will affect all sectors of the healthcare industry. Trudy Phelps, Standards Director of ABHI, presented this talk at the Balmoral Hotel in Edinburgh.

After the opening session, **Dr Paul Cullinan**, consultant physician at Royal Brompton Hospital and Reader at Imperial College, London set the scene in London with a talk on latex allergy, history and epidemiology in the UK. Starting with a brief history of rubber cultivation in Malaysia he followed this with a comparison between recent UK studies of the prevalence of allergy to latex proteins. He explained that it is difficult to make valid comparisons between the results of such studies because they might use the same experimental design, but different testing methods. The results show clinical latex allergy, not the level of sensitization of the population. He then

drew attention to some apparent contradictions: the published figures on occupational asthma attributed to latex show a decline in the number of cases, but a recent survey of UK allergists seems to suggest that the number of new referrals for latex-related allergy is not declining, although of course many of these patients do not in fact have latex allergy. He also explained the difficulty of proving a link between latex glove use and latex sensitization and warned that occupational asthma problems can often appear to be solved, but then reappear.

**Dr Henning Allmers**, who spoke in both London and Edinburgh, described the German experience of successfully tackling the issue of latex protein allergy, through the change from powdered to powder-free latex gloves, from his perspective as Director of the Department of Occupational Medicine, and head of the Occupational Medicine Laboratory at the Department of Dermatology, Environmental Medicine and Health Sciences at the University of Osnabrück in Germany.

The simple primary prevention approach, to protect the population, is to use only powder free latex gloves, plus some gloves of other materials. The secondary approach is also to use latex-free gloves for sensitized healthcare workers. The superior barrier properties provided by natural rubber latex gloves mean that there is no question of going 'latex-free'.

Germany's acute care hospitals have achieved dramatic reductions in the numbers of cases of both occupational asthma and skin problems attributed to latex by changing from predominantly powdered natural rubber latex gloves to powder free latex examination gloves and surgeons gloves after the mid 1990s. The change was provoked by the publication of guidelines from experts, followed by compulsory technical regulations for dangerous substances (TRGS 540 and 907) and a recommendation and publicity campaign by the BGW - German mandatory healthcare insurance company. "The NRL allergy epidemic is over in Germany", said Dr Allmers.

**Dr Kristiina Turjanmaa**, Chief Physician of the Allergy Unit at the Department of Dermatology, Tampere University Hospital in Finland, explained how Finland had already adopted a different, but equally successful, approach by using gloves with a low allergen content and monitoring and publishing the allergen levels of gloves in the marketplace. She has worked on the latex allergy problem for many years, including participating in research with Malaysian scientists.

Dr Turjanmaa told the audience in London and Edinburgh that "changing gloves, not people", has kept the allergy problem under control in Finland. From as early as 1990, the criteria for glove selection have been good barrier function, low allergenicity and low price. If particular gloves caused a problem, they were changed.

As a result of the Finnish work undertaken to identify the specific latex allergens, low allergen gloves are provided for all healthcare workers to prevent occupational sensitization, to prevent occurrence of symptoms in sensitized healthcare workers and to provide natural rubber latex allergic patients with a safe environment. Latex free gloves are used for the treatment of allergic patients and by some allergic healthcare workers. Routine skin prick testing for allergens is a common occurrence in Finland, particularly amongst children and those with food allergies are also tested for latex.

The National Agency for Medicines publishes the list of gloves according to their allergen content - *Natural rubber allergen content of latex gloves: a market surveillance study 2003* ([www.nam.fi/english/publications](http://www.nam.fi/english/publications)). A new survey will be published later in 2005. The specific tests for identifying and quantifying individual latex allergens have been developed by the Finnish company FIT Biotech ([www.fitbiotech.com/fitkit\\_brochure.pdf](http://www.fitbiotech.com/fitkit_brochure.pdf)).

**Peter Phillips**, Acting Director of the Surgical Materials Testing Laboratory (SMTL) in Wales, explored the potential risks of leaping into the unknown and switching from the long established natural rubber latex gloves to the relatively new synthetic alternatives. In Edinburgh, a talk on the same subject was presented by **John Spashett**, a member of the ABHI's Natural Rubber Latex Working Group and Technical Manager of the Enfield-based glove distributor BM Polyco.

Peter Phillips reminded the audience that UK studies of prevalence of Type 1 allergy to latex show rates well below 1%, even amongst healthcare workers. He referred to the successful work in Germany to reduce the number of new cases and raised the point that this could also be due to the use of better quality (lower allergen) gloves as well as elimination of powdered gloves. SMTL has continued to test protein levels in gloves purchased on contract for the NHS, in Wales, and found that the levels are now much lower than in the mid 1990s. He emphasized that the problem is the allergenic proteins, not the latex material itself and stressed that our current understanding of the alternative materials, such as vinyl and nitrile, is incomplete. Replacements for natural latex will not offer exactly the same properties: for example, the European standard allows vinyl gloves to be weaker than natural latex gloves. We may be introducing new risks if we rush to replace natural latex – and its unique combination of properties - with synthetic materials, so the balance of risks must be assessed.

John Spashett reiterated most of these points and, along with previous speakers, made reference to the fact that recorded cases of latex-related occupational asthma have also now fallen significantly in the UK, particularly since the NHS purchasing bodies have switched to powder free gloves in their contracts. He considered the circumstances in which NHS trusts are reassessing their glove policies and the way in which the HSE has interpreted COSHH legislation in this context. He stressed that no synthetic material can offer the same combination of strength, tactility, barrier protection and price; there is always a compromise when removing natural rubber. Synthetic alternatives do not always present a lower overall risk than natural rubber latex, so hospitals must be cautious in their approach.

**Dr Lai Pin Fah**, Senior Research Fellow and former Head of Latex Technology at the Rubber Research Institute of Malaysia, explained how Malaysia's exports of natural rubber latex examination gloves are monitored and benchmarked for quality, consistency and reliability and demonstrated how they exceed current European and US regulatory requirements.

His talk began with a brief history of latex glove production in Malaysia and the development of powder free, chlorinated and polymer coated glove technology. He described the equipment that is now available to ensure effective leaching (washing)

of gloves to remove extractable proteins, and to perform on-line chlorination or polymer coating. Even though several European countries now favour powder free gloves, he made reference to Malaysian export figures showing that much of the world is still using predominantly powdered natural latex gloves.

Dr Lai explained the limits for total extractable proteins and antigenic proteins that have been set by different bodies and how the requirements set by the Standard Malaysian Glove (SMG) programme relate to these limits. He then explained how tests performed at the ISO 17025 accredited laboratory at the Rubber Research Institute of Malaysia are used to determine the conformity of Malaysian natural latex gloves to specific benchmarks for levels of extractable proteins.

The tests show that extractable protein limits of chlorinated powder free gloves are below the recommended level of the German organization BGW (30µg/g). The majority of polymer coated gloves (which are more difficult to test using the recognized method) also fall well within the requirements of EN 455-3 and ASTM and the antigenic protein content of all the gloves is below that recommended by ASTM (10µg/g).

In both London and Edinburgh, the final talk was presented by **Dato' Dr Ong Eng Long**, Deputy CEO of the Malaysian Rubber Export Promotion Council (MREPC) and former Assistant Director of the Rubber Research Institute of Malaysia (RRIM), who summarized the key issues in glove selection and highlighted current trends in glove use, reminding the audience that the main reason for wearing gloves is to provide a barrier between the wearer and the environment, but that not all gloves provide equal performance in this respect.

He also made the point that, although the benefits of powder-free gloves have been demonstrated, most of the world is still using powdered natural latex gloves, even in surgery. Extractable protein levels have fallen, he said, both in powdered but particularly in powder free gloves, in the new generation of gloves being produced today. Dato' Ong also highlighted the specifications that Standard Malaysian Glove (SMG) must meet in terms of pinholes and extractable proteins. Shipments of Malaysian natural latex gloves (both SMG and non-SMG) are now monitored for protein content and of the powder free gloves, 91.6% have been seen to be within the limits set for the SMG.

**The question and answer sessions** provided some lively discussion on issues such as the manufacturing changes alleged to have increased allergen content; whether there may be transfer of proteins to medical devices during handling with latex gloves. Delegates also asked the speakers whether gloves should be powder free, or low protein/allergen or both and made reference to work on barrier properties of vinyl and latex gloves.

Questions were also raised about measurement of protein content vs allergen content and the identification of allergens; the use of powdered gloves worldwide; threshold limits for protein and allergen levels; how to differentiate between sensitized vs allergic persons and allergic responses to synthetic products.

Further questions were asked about how health surveillance should be undertaken (eg skin prick test vs RAST); the Finnish tests on the allergen content of gloves on the market; the recommended barrier protection for sensitized individuals and the prevalence of allergy amongst latex workers in Malaysia. Delegates enquired about chemical resistance of gloves and the availability of information from suppliers. The importance of the COSHH regulations and risk assessments was also discussed.

**The speakers reached a consensus** on the following points:

- Natural rubber latex gloves still provide the best combination of properties for gloves used in healthcare.
- ‘Powder free’ is a simple message which has been shown to work in Germany
- ‘Low allergen’ is a more sophisticated approach, which has worked in Finland, but the current test method is expensive and not yet universally accepted for this purpose.
- Nevertheless, data is available to show which gloves are likely to be lowest in protein and allergens.
- People who are not sensitized can work with good quality (low protein/low allergen, powder free gloves) and not become sensitized.
- Already sensitized staff and patients need latex-free gloves.
- Changing to synthetic gloves is not a panacea – new allergic reactions can emerge and not all gloves are suitable for all tasks. New risks can be introduced, particularly regarding barrier protection.

As a result of the interest and feedback from delegates who attended the seminars, it has been suggested that the organizers should consider making this subject matter the focus of future events. If you missed out on the opportunity to attend on this occasion, but would like to receive further information, please contact us.

## Further information

### **Seminar organizers:**

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Standard Malaysian Glove (SMG)      [www.smg-online.biz](http://www.smg-online.biz)

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MRB      [www.lgm.gov.my](http://www.lgm.gov.my)

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### **Speakers:**

#### **Chairman**

**Dr Trudy Phelps** is presently Standards Director of the Association of British Healthcare Industries (ABHI). Previous to her appointment as Standards Director, she was Technical Director of ABHI, responsible for managing all technical/regulatory/standards activities within ABHI. Trudy is the Chairman of the ABHI Natural Rubber Latex Working Group. She is also Secretary to the Eucomed Standards Focus Group (Eucomed is the European Medical Technology Industry Association). She sits on several BSI committees, including CH/100, the management committee for the Healthcare sector. Her career background has been in the field of health-care standards, with 15 years experience in project management of health-care standards for BSI, and secretariat responsibilities within BSI, ISO and CEN. Trudy's educational background is in biological sciences, having received a PhD from the Institute of Cancer Research in 1976 in Biophysics, and a BSc in Biological Sciences from the University of Sussex in 1973.

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#### **Healthcare Industries Task Force (HITF)**

[www.advisorybodies.doh.gov.uk/hitf](http://www.advisorybodies.doh.gov.uk/hitf)

more information can also be found on the ABHI website: [www.abhi.org.uk](http://www.abhi.org.uk)

**Dr Paul Cullinan** is consultant physician at Royal Brompton Hospital and Reader at Imperial College, London. His main clinical and research interests are in the occupational and other environmental causes of respiratory disease, especially allergic diseases and those involving biological allergens. He was chair of the Working Party on Latex Allergy for the British Society for Allergy and Clinical Immunology and editor of the subsequent report. He was also involved in an epidemiological study examining the sensitization to natural rubber latex of workers exposed during tapping and glove manufacture in Thailand, published in Occupational & Environmental Medicine in 2001.

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**Dr Henning Allmers** is the Director of the Department of Occupational Medicine, and heads the Occupational Medicine Laboratory at the Department of Dermatology, Environmental Medicine and Health Sciences at the University of Osnabrück in Germany. He has undertaken research and written numerous articles on latex allergy, including publications in the Journal of Allergy and Clinical Immunology looking at prevention of natural rubber latex (NRL) allergy in the German healthcare system. Dr Allmers received the degree of Master of Public Health (MPH) from Harvard University in 2002. In 2003 he became Privatdozent for Health Sciences and Preventive Medicine at the University of Osnabrück. In 2004 he was presented with the Karmann-Innovation-Award for his work on NRL allergy prevention. He received his medical training in the US and Germany and sub-specialised in allergy, occupational and environmental medicine after being an emergency physician with the German Navy.

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**Dr Kristiina Turjanmaa** is Chief Physician of the Allergy Unit at the Department of Dermatology, Tampere University Hospital in Finland. She obtained a Doctor of Medicine in 1972 from the University of Innsbruck, Austria and in 1978 became Specialist in Dermatology and Venereology at University Hospital Helsinki. From 1997 she took up a post with subspeciality in skin allergology at the University of Tampere. In 1989 she completed a thesis entitled “Latex glove contact urticaria” at Tampere University. Scientific publications include latex allergy and food allergy in small children with atopic dermatitis. She was Secretary of the Finnish Dermatological Society from 1991-94 and President of the Finnish Society for Allergy and Clinical Immunology from 1999-2001.

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**Peter Phillips** is the Acting Director of the Surgical Materials Testing Laboratory, an NHS medical devices testing laboratory funded by the Welsh Assembly Government. SMTL provide test data and technical information to the Welsh NHS, and also perform commercial testing for the International medical device industry. In particular, SMTL works very closely with Welsh Health Supplies on the various medical device contracts for the NHS in Wales, as well as carrying out numerous projects for the Department of Health and the Medicines and Healthcare Products Regulatory Agency (MHRA). Peter has been working in the medical device field for 22 years, and represents the Welsh Assembly and various Pharmaceutical organisations on numerous BSI committees including BSI committee CH/205/03 (Medical Gloves).

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**John Spashett** has worked for BM Polyco Limited, a major UK glove producer, for nine years. During this time he has performed chemical, physical and microbiological testing as well as giving lectures in Malaysia, Thailand and mainland Europe. With the formation of BM Polyco’s Medical Division he became a Technical Manager, responsible for the regulatory compliance of the entire product range. In this role he has become a UK representative to the CEN/TC205/WG3 committee responsible for the preparation of various standards including the EN455 series for medical gloves. Within the UK he was selected as one of the ABHI members (along with Trudy

Phelps) to help draft the Health and Safety Executive's 'latex toolkit' that provides advice to hospitals regarding the use of natural rubber gloves.

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**Dr Lai Pin Fah** joined the Rubber Research Institute of Malaysia (RRIM) in 1975, after graduating from Imperial College, London with a Ph.D. in Physical Chemistry. He obtained his first degree, a B.Sc. (Hons.) in Chemistry, from the University of Malaya in 1972. He was appointed the Head of Latex Technology Division in 1993, responsible for the various R & D activities on, inter alia, latex protein allergy and polymer coating of latex gloves. He was also the Chairman of the Technical Committee of the Standard Malaysian Glove (SMG) Program that was launched in Europe in 1998. He retired from the Institute in 2003 and is currently serving as its Senior Research Fellow. Dr. Lai has contributed more than 40 papers to the rubber industry and has written numerous general articles/reports on latex for the various Ministries in Malaysia.

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**Dato Dr Ong Eng Long** has been Deputy CEO of the Malaysian Rubber Export Promotion Council (MREPC) since 2001, having retired from the position of Deputy Director General (R&D) of the Malaysian Rubber Board. He joined the Rubber Research Institute of Malaysia (RRIM) in 1973 after obtaining a PhD at Queen Mary College, University of London. He became Assistant Director in 1993 and Deputy Director General in 1998. He has been involved in the rubber industry since 1973 as a researcher, R&D leader and administrator. He has published two book chapters and more than 120 technical and conference papers. Dato' Ong is also active in the standards developmental work for rubber and rubber products at national and international levels.

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