

WILL POWDERED GLOVES SOON BE OBSOLETE?

A self-study monograph for continuing education for healthcare workers with an interest in occupational and patient safety and infection prevention.

ISSUE 6

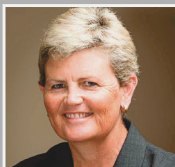
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LEARNING OBJECTIVES

After completing this continuing education activity, you should be able to:

1. Describe the history of and rationale for powdered glove use;
2. Discuss the negative outcomes for surgical patients and healthcare workers associated with powdered glove use;
3. Understand recent global directives regarding elimination of powdered examination and surgical gloves;
4. Appreciate the responses of manufacturers to powdered glove bans; and
5. Understand the need to develop or update protocols for removing and replacing all powdered examination and surgical gloves with powder-free alternatives.



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The opinions expressed in this edition are the authors' only and may not represent the official position of Ansell or Bond University.

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GUEST FACULTY

In this edition, we welcome contributions from two glove industry experts.

Anthony López is President and General Manager, Medical Solutions Global Business Unit, Ansell. Prior to his tenure at Ansell, he held key leadership positions with CareFusion and Johnson & Johnson. Tony is the author of seven leadership books (The Legacy Leader Series), and two Christian self-help books. Recently, he authored an article for the February 2017 issue of Industrial Safety and Hygiene News (ISHN) in which he discusses the implications of the United States' recent US Food and Drug Administration (FDA) ruling banning powdered glove use.

We are also grateful for the opportunity to include a summary of and excerpts from Patty Taylor's recent contribution to Asian Hospital & Healthcare Management Magazine (May 2017) in which she considers global responses to the FDA ruling. Patty is VP of Professional Education and Clinical Affairs, Ansell. Patty is a registered nurse with 20 years' international experience focusing on perioperative safety and education.

TYPES OF MEDICAL GLOVES

Medical gloves are disposable gloves used to prevent cross-contamination between healthcare providers and patients. Some medical gloves can also protect the wearer from harm caused by dangerous chemicals or pharmaceuticals. Medical gloves are made of different polymers including latex, and synthetics such as polyisoprene, polychloroprene, nitrile, and polyvinyl chloride; they come unpowdered, or powdered. Medical gloves are classified as either surgical gloves or examination gloves depending upon their intended use.

Surgical gloves are designed primarily for use in surgical procedures. They are fitted gloves with an 11-12-inch cuff, available in a precise range of sizing (half sizes 5.5 through 9.5). Surgical gloves are generally thicker and stronger so to withstand the rigorous demands of the surgical environment and the duration of longer wear time. Surgical gloves are individually wrapped and sterile. Examination gloves are designed for non-surgical medical procedures. They are ambidextrous gloves with a 9-inch cuff, generally packaged in a cardboard dispensing box (100-300 gloves/dispenser) and available in a limited range of sizes, usually XS, S, M, L, and XL.



Surgical gloves have a lower AQL (acceptable quality level) of pinholes. Generally, surgical (sterile) gloves have an AQL of 1.0 to 1.5 and examination (non-sterile) gloves have an AQL of 1.5 to 2.5. An AQL of 1 means that no more than 1% of all gloves in a sample set have pinholes. An AQL of 2.5 means that no more than 2.5% of all gloves in a sample set have pinholes.¹ (See [Ansell Cares InTouch Edition #4](#) for additional information on AQL). Because of the sterilization process, higher level of quality standard (AQL) and regulated packaging standards, surgical gloves are more expensive than examination gloves.

THE HISTORY OF AND RATIONALE FOR POWDERED GLOVE USE

Powdered surgical gloves were first used in operating rooms in the late 1800s with various lubricants used to make it easier for surgeons and operating room staff to don their gloves. One of the earliest powders was made from a pine moss which was subsequently found to be toxic. The pine moss lubricant was replaced by talcum powder until it was found that talcum powder caused several post-operative complications. Instead of talcum powder cornstarch was used as a lubricant from the 1950s onwards.² Manufacturers and powder glove users believed that cornstarch was necessary to facilitate easier donning of the gloves and also that it contributed to their comfort during use. From that time onwards it became the lubricant of choice on most surgical and examination gloves.³ Additionally, glove dusting powders had been used to prevent gloves from sticking to each other during manufacture and storage as well as to facilitate removal of gloves from their molds during manufacture.⁴



Advances in our understanding of asepsis, disease transmission routes and infection prevention and control brought with them a logical and necessary increased use of barriers to blood and body fluids including gloves. This was particularly the case from the mid to late 1980s onwards with the advent of the Acquired Immune Deficiency Syndrome (AIDS) epidemic and the rise in bloodborne hepatitis transmissions including Hepatitis B and C. From then onwards global public health experts and the infection control and operating room communities have been unrelenting in their support of universal glove use as a protective barrier.

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The emergence of additional pandemics including Severe Acute Respiratory Syndrome (SARS), Avian and Human Influenza and most recently Middle East respiratory syndrome (MERS) and Ebola have reinforced healthcare worker reliance on gloves as a critical piece of personal protective equipment (PPE).⁵⁻⁹ Availability and therefore use of medical gloves varies around the world with the World Health Organization recently acknowledging that in some low to middle income countries access to quality surgical gloves may be limited.¹⁰ In contrast in the majority of high income countries surgeons are increasingly opting to wear at least two or more pairs of surgical gloves simultaneously as a matter of routine.¹⁰

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The healthcare community's reliance on medical gloves has not been without negative consequence. Despite extensive modification to medical glove composition and improved manufacturing processes including the development of synthetic surgical and examination gloves, over time the continued use of powdered medical gloves has caused serious negative outcomes among patients and healthcare workers. These negative outcomes are discussed in detail in the next section of this issue.

NEGATIVE OUTCOMES FOR SURGICAL PATIENTS AND HEALTHCARE WORKERS ASSOCIATED WITH POWDERED GLOVE USE

NEGATIVE PATIENT OUTCOMES

Calls for the removal of cornstarch coated gloves began as early as the mid-1990s although cases of granulomatous peritonitis due to cornstarch from surgeon's gloves had been discussed as early as 1976.³ Over time, subsequent reports and research performed in both simulated and real surgical settings demonstrated that when patient tissue suffers cornstarch deposition at the time of surgery, disease associated with foreign bodies potentially manifests by causing the following harm(s) to patients:¹¹

- Promotion of wound infections;^{3,12-14}
- Delayed wound healing;¹³
- Granuloma formation in the personnel cavity resulting in adhesions and peritonitis;^{3,13-17}
- Intestinal obstruction, pelvic pain and infertility secondary to peritoneal adhesions;^{18,19}
- Endophthalmitis;¹¹
- Post-thoracotomy syndrome;¹¹
- Meningismus after craniotomy;¹¹
- Retroperitoneal fibrosis.^{11,16}

This evidence was at the heart of letters to the FDA in 1998 and again in 2011 from a consumer advocacy group petitioning for the immediate ban of the use of cornstarch powder on all surgeon and patient examination gloves.¹¹ Nationwide bans on the use of powdered gloves were actioned in both Germany in 1998²⁰ and the United Kingdom in 2000.³

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HEALTHCARE WORKERS

Powder containing high levels of airborne glove protein is suspected of triggering sensitization to NRL.²⁰ InTouch Issue 3 – Type I and Type IV Allergies discussed this mechanism in detail and can be [accessed here](#) for review. The risk of HCW sensitization from powdered gloves was first thoroughly investigated in Germany.



Allergic Contact Dermatitis

By December 1995 German experts in dermatology, allergy and occupational medicine had recognized the association between increased HCW use of powdered latex gloves and sensitization to latex. A 1999 study of dental students showed no sensitization among dental students using powder-free gloves compared to a sensitization rate of between 5%-15% among dental students using powdered gloves.²⁰ The German working group spearheaded educational and regulatory measures including a mandate banning the use of powdered NRL gloves and promoting the use of only low-allergen powder-free NRL gloves.²⁰ By 1998 Germany was able to demonstrate a significant linear reduction in latex sensitization among HCWs associated with the removal of powdered NRL gloves and their replacement with powder-free low-protein NRL gloves.²⁰ Continued compliance with this practice ensured that by 2010 NRL allergy had been eliminated in Germany.²¹

NEGATIVE OUTCOMES FOR SURGICAL PATIENTS AND HEALTHCARE WORKERS ASSOCIATED WITH POWDERED GLOVE USE

In the United States cornstarch-induced latex hypersensitivity was first reported by The National Institute for Occupational Safety and Health (NIOSH) in 1997. NIOSH recommended avoidance of latex gloves and products and avoidance of areas where you may inhale the cornstarch powder from latex gloves worn by others.³ Recommendations to use powder-free, low-protein NRL gloves or non-NRL gloves have been available from The Occupational Safety and Health Administration (OSHA) in the US and other organizations in many countries since 1998. These recommendations have been successful in those small proportion of hospitals that implemented them.²⁰ In the absence of Regulations to the contrary powdered glove use remained substantial in the US up until the FDA's eventual ban in late 2016.¹⁴

Unlike the US, the United Kingdom quickly followed Germany's lead by discontinuing the purchase of powdered gloves from 2000 onwards.³

Researchers have demonstrated that in hospitals, powdered latex gloves aerosolized more latex proteins into the air than any other medical product. As well in those hospitals where powdered gloves are used, there are typically up to 300 times more aerosolized latex proteins than in areas or hospitals where only powder-free gloves are used.¹³

Given our understanding of powder's role in sensitization, it is unsurprising that staff in those clinical areas where glove use is greatest and where non-powdered low-allergy glove use had not been mandated continued to experience sensitization. These areas include but were not limited to the Operating Rooms, Emergency Departments, Intensive Care Units, physician offices, veterinary practices, and dentistry.



The delay in governments mandating the use of powder-free NRL gloves is also frustrating when one considers that suitable alternative compositions have been available commercially from 1992.² Glove composition has continued to be refined since that time with manufacturers seeking improvements in comfort, fit, elasticity, durability again making the transition to powder-free gloves less difficult and improving HCW safety.³

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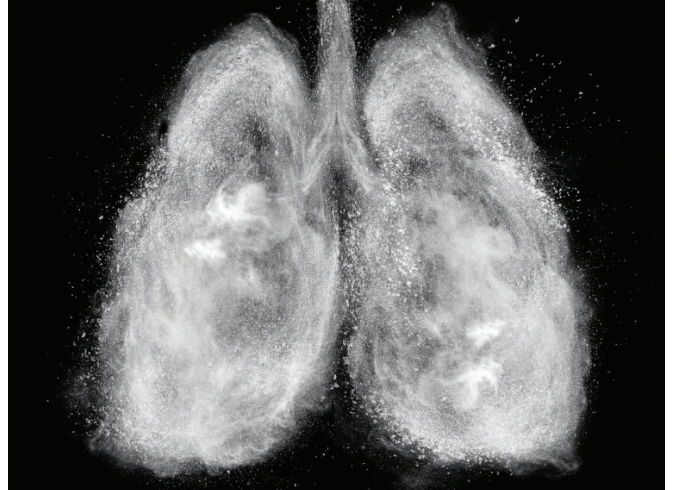
RECENT GLOBAL DIRECTIVES BANNING POWDERED MEDICAL GLOVES

PATTY TAYLOR

The 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.¹⁴

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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, 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 effective from March 27, 2017.²²



On December 27, 2016 Japan announced their intention to enact a similar ban with a two-year transition through to December 2018.²³ 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 are under the responsibility of HA. Private hospitals which are not under control of HA have also adopted the same stance.²⁴

In the wake of the FDA's decision additional countries are likely to adopt similar bans on the use of powdered gloves. The onus to provide sufficient education, to continue efforts to develop higher-quality alternatives at reasonable price points and in quantities sufficient to meet global demand rest primarily with manufacturers. The next section written by Anthony López outlines the manufacturers' response to these new but not unexpected demands.

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THE MANUFACTURERS' RESPONSE

ANTHONY LOPEZ

The recent FDA announcement banning the use of powdered surgical and patient examination gloves in the United States, as well as the absorbable powder used to lubricate these gloves, certainly comes as no surprise. But it should also come as no surprise that, despite this announcement, the users and manufacturers of medical gloves will not miss a beat, as alternative glove technologies have been proven and available for some time. Certainly, there remain many dedicated users of powdered medical gloves in the United States. And while change is never easy, it's time to change. And that's a good thing, for both professionals and patients.

Years of clinical studies, research and industry input have provided ample data about the adverse reactions to both workers and patients that may arise from the use of gloving powders. These include the potential for infection, delayed wound healing, inflammation or latex protein allergy responses. Even the practice of washing surgical gloves prior to surgical procedures has not proven to eliminate potential issues. As such, manufacturers such as Ansell have been dedicated to educating healthcare professionals about the potential risks while working with medical researchers and key opinion leaders to develop new glove technologies that provide the benefits of powdered gloves while minimizing the inherent risks.

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However surprisingly, a recent survey indicated that up to 40 percent of workers were unaware of powder safety issues. That same survey indicated that ease of donning, fit and feel were the glove attributes they rated most highly. The good news here is that new glove manufacturing technologies address both the safety issues and the attributes most highly valued.

LOOKING BACK

There is a long history associated with powdered gloves. They have been used for well over a century, initially as surgical gloves and then expanding into other areas of patient care as the onset of the AIDS epidemic and the spread of hepatitis became concerns in the late 20th century. Today, medical gloves are used beyond surgery, hospitals or medical offices. They're found in pharmacies, laboratories, emergency services and beyond.

Powder has been used in the glove manufacturing process for the following reasons:

- Powder facilitates ease of glove donning and absorbs perspiration
- It eliminates glove blocking, i.e., gloves sticking to themselves
- It functions as a mold-resistant agent
- It facilitates removal of the finished glove from a manufacturer's forming tool



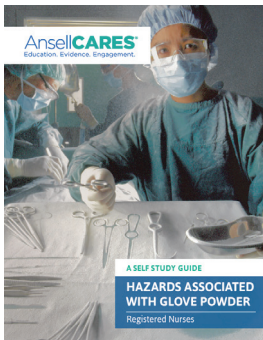
THE MANUFACTURERS' RESPONSE

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Attention to detail in the manufacturing process can produce powdered gloves with very low protein content, thus reducing the risk of latex protein allergies. And that's a good thing, since powdered medical gloves are still used in many countries around the globe.

But improved technologies and manufacturing techniques can eliminate the need for powder entirely. The application of a polymer coating to the inside film of latex or synthetic gloves enhances the donning attributes of the glove in both wet and dry conditions. A wide array of synthetic glove choices are available today such as polyisoprene, neoprene or nitrile providing excellent barrier protection. The bottom line is: there are other, better clinically relevant solutions available that have all the same fit, feel and comfort of powdered gloves.

And while many workers have already moved away from powdered gloves, many are still actively exploring the new offerings to determine which option is right for them. In fact, new allergic reactions may arise as a result of new gloves adapted after the ban due to an individual's sensitivity to some accelerators or chemicals used in the gloves' manufacture. That's where education on the part of the manufacturer critically comes in – working with



distributors and companies alike to help them select the best option that ensures performance, protection and safety for all. Moreover, when it comes to clinical education in this area, Ansell leads the way globally with a comprehensive program available for nurses and surgeons across the world.

The prices for these new technologies can be, of course, higher. But the return on investment well outweighs the initial higher cost: protection afforded to both the worker and patient, improved efficiency via less time a worker may lose with an allergic reaction and decreased risk of potential compensation or litigation from a patient affected by an allergic reaction or postoperative complication. The FDA estimates that

total annual benefits of the powdered ban are expected to range between \$26.6 million and \$29.3 million. The global impact in terms of savings will be measured potentially in the hundreds of millions.

The bottom line is: there are other, better clinically relevant solutions available that have all the same fit, feel and comfort of powdered gloves.

MOVING FORWARD

The FDA mandate eliminates, for some medical professionals, a product on which they have come to rely for decades. It's easy to say it's time to move on. After all, we HAVE to do so.

But moving on – even if we know it's for the better – isn't always an easy thing to do. Something that has become part of one's routine – such as popping a tape into a VCR or checking messages on a pink message pad slip – has gone away, replaced with better technologies. Such is the case with medical gloves.

FDA estimates that total annual benefits of the powdered ban are expected to range between \$26.6 million and \$29.3 million.

But the good news is you have a wide choice of better options. There is a broad array of medical gloves from which to choose with new, improved benefits, and it's really just a matter of finding the right fit, feel and formula that will allow you to provide the same great care you've always provided – and feel protected and comfortable while doing it.

SUGGESTIONS FOR REMOVING AND REPLACING ALL POWDERED EXAMINATION AND SURGICAL GLOVES WITH POWDER-FREE ALTERNATIVES

Healthcare workers are notoriously resistant to change. This is often associated with a perception that change is always associated with increased demands for input, expenditure or time. The implementation of new systems including new products invariably need to be accompanied by educational efforts which may include practical demonstrations or the opportunity for clinicians to have hands-on experience with the new proposed product(s). Additionally, it has been recognized that on some occasions where change has involved removal of and replacement of one type of product with a safer alternative, a small number of healthcare workers may resist the change by hoarding supplies of the original product. This has certainly been the case with the introduction of some safety engineered sharps injury prevention devices. These resistant healthcare workers cite their comfort and proficiency with the existing product as reasonable excuse for non-adoption of the newer replacements. This potentially creates an unsafe environment in which the lack of uniformity and standardization among healthcare workers facilitates their continued exposure to known occupational health and safety risks.



For this reason, it is critical that management and senior staff operating even at a ward or departmental level must always oversee the introduction and ongoing monitoring of replacement products. Overseeing this activity also requires the manager to be personally responsible for the removal and disposal of the original product. Staff may need reminding that they are expected, and in some cases, have a legal responsibility, to embrace the change including immediate and ongoing adoption and consistent use of the new product.

To facilitate the smooth transition to powder-free medical gloves hospital and clinical procurement specialists are advised to ensure that they order sufficient range, quantity and size of both powder-free examination and surgical gloves. It is likely that most glove manufacturers

will willingly provide high-quality educational material and perhaps even direct support to hospitals implementing their powder-free range.

It is critical that management and senior staff operating even at a ward or departmental level must always oversee the introduction and ongoing monitoring of replacement products.

Individual healthcare workers are also reminded of their own professional and perhaps legal obligation to assist their peers and colleagues in the adoption of new safe ways of work. In most cases this will include role modelling safe use and disposal of powder-free medical gloves. However, in the event of a healthcare worker observing continued use of powdered medical gloves by any worker in any location within the organization, the observing healthcare worker is expected to either intervene and question the use of the powdered medical glove or advise the relevant manager of this deviation.

As for all new products introduced to the clinical environment, managers should always review the success of the product's introduction soon after it is initiated and continue to monitor use up to and beyond the point of full compliance by all healthcare workers. Managers should ensure that no unpredicted harms are associated with the new product's use.

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The wide range of powder-free non-latex medical gloves will undoubtedly enable every healthcare worker the opportunity to work in environments where latex sensitization has been eliminated. This achievable goal should drive even those countries currently lacking regulatory mandates to ban powdered glove use towards their complete replacement by powder-free alternatives. Only then will healthcare workers globally be able to work in environments where the risk of sensitization to NRL has been eliminated.

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