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CLINICAL PERSPECTIVE

Hazards of Glove Powder

Rose Moss, MN, RN, CNOR
Perioperative Nurse Consultant/Medical Writer
C & R Moss LLC
Casa Grande, AZ

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Medical gloves are used on a daily basis to reduce the risk of disease transmission for both patients and healthcare workers. However, as the use of gloves continues to evolve, so do concerns related to the risks associated with glove powder; these concerns provide the impetus for the transition to the use of powder free latex or synthetic gloves as the new standard of care.

The Use of Powder in Medical Gloves

Historically, glove powder has been used as a lubricant to facilitate donning of medical gloves. Early generations of reusable gloves were thick and very difficult to don and remove and required laborious procedures to prepare them for reuse. With the advent of single use gloves, various glove powders were used in manufacturing both to facilitate donning and also to prevent gloves from sticking to the forming molds or to each other. However, none of these powders proved to be as inert as initially thought and exposure to glove powder has been associate with a number of harmful effects, risks, and complications for both patients and healthcare workers.

Powder is used in the manufacture of medical gloves for the following reasons:[i]

- It functions as a mold-releasing agent and facilitates removal of the finished gloves from the manufacturer's form. A powder is incorporated in the mixture that coats the glove former at the beginning of production.
- It lubricates the gloves, which eases glove donning. Powder applied to the inside of the finished glove allows the wearer to put the glove on easily and smoothly.
- It absorbs perspiration when the gloves are being worn.
- It eliminates glove blocking (ie, gloves sticking to themselves or to the glove packaging) when a powder is used on the surface of the finished glove.

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Ansell Limited
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Hazards Associated with Glove Powder

There is considerable scientific evidence documenting the hazards associated with cornstarch powder in medical gloves and its disease-causing capabilities.[ii] The hazards associated with glove powder, for both patients and healthcare workers, are outlined below.

- Vehicle for latex antigens. Today, natural rubber latex (NRL) allergy remains a concern for both healthcare workers as well as patients, since latex is composed of various potentially irritating proteins.[iii] In addition, airborne latex allergen is produced during use of powdered latex gloves; this usage may provoke respiratory and anaphylactic response to latex in sensitized individuals.[iv]
  Sensitivity to NRL affects approximately 8% to 17% of healthcare workers,[v] but repeated exposure may increase this condition.

  - *Types and Stages of Latex Allergy*

    A latex allergy, or hypersensitivity, occurs when the body's immune system reacts to NRL proteins.[vi] A Type I systemic reaction is an immediate hypersensitivity reaction mediated by the development of IgE antibodies to specific proteins in latex; this causes a serious and potentially fatal event.
    The following five stages are characteristic of Type I conditions:[vii]
      - Stage 1 – Local urticaria in the contact area.
      - Stage 2 – Generalized urticaria with angioedema.
      - Stage 3 – Urticaria with asthma, itching of the eyes or nose, and gastrointestinal symptoms.
      - Stage 4 – Urticaria, anaphylaxis, and shock.
      - Stage 5 – Chronic asthma and permanent lung damage.

    The United States Food and Drug Administration's (FDA's) 1997 Medical Glove Powder Report concluded that the primary adverse impact of glove powder appears to be its role in contributing to the development of NRL allergies, since the powder serves as an airborne carrier of natural latex proteins.[viii]

- Vehicle for transfer of pathogenic microorganisms. An early report of air sampling studies noted that high levels of airborne starch powder contamination were found in areas where powdered latex gloves were used; moreover, cultures of collected samples showed a clear association between the starch particles and bacterial colonies, suggesting that airborne particles could act as a vector for pathogens – either harmless environmental bacteria or infectious pathogens - in the hospital environment.[ix]

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- Patient complications. Glove powder is also a concern for surgical patients. The extensive number of peer-reviewed studies cited in a petition to the United States FDA clearly show that when cornstarch is deposited in tissues at the time of surgery, it can result in foreign-body disease, eliciting an escalation of the inflammatory process and result in the following harms to patients:[x]
    - Promotion of wound infections;
    - Delay in wound healing;
    - Granuloma formation within the peritoneal cavity, leading to the development of adhesions and peritonitis;
    - Intestinal obstruction, pelvic pain, and infertility due to peritoneal adhesions;
    - Endophthalmalitis;
    - Post-thoracotomy syndrome;
    - Retroperitoneal fibrosis; and
    - Synovial inflammation.

  Since the early 1970s, many international standards have required manufacturers to label their sterile powdered glove packages with a specific warning statement to remove the powder from the outside surface of the glove, thus eliminating any cornstarch-induced surgical complications.[xi,xii] Poor compliance with printed instructions has been cited in the literature, and unfortunately, studies have shown that washing of powdered gloves prior to use is inefficient in totally removing glove powder.[xiii,xiv] It has also been reported that the cost of washing powdered gloves can be at least seven times higher than the cost of using powder free gloves.[xv]

  Powder contamination can also interfere with important biological diagnostic procedures, resulting in laboratory misdiagnoses, which can lead to inappropriate treatment or unnecessary surgery.[xvi]

Ban on Glove Powder

As a result of the well-documented risks associated with the use of powdered surgical gloves for both patients and staff members, several countries have banned the use of glove powder.

- United States. In the United States**,** the US Food and Drug Administration (FDA) has enacted a rule banning the use and marketing 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 becomes effective on January 18, 2017.[xvii] 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.[xviii]

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- Germany and Europe. Germany reported a positive linear correlation between reductions in both new onset skin allergy cases (87% reduction from 1998 to 2005) and occupational asthma cases (95% reduction from 1997 to 2005) and the declining purchase of powdered NRL gloves.[xix] This report also noted that available data from other European countries also demonstrated that NRL allergies in healthcare workers have decreased as a result of a reduction in the use of powdered NRL gloves.[xx,xxi]

  Germany has banned the use of powdered gloves since 1998;[xxii] the National Health Services of the United Kingdom has not purchased powdered medical and surgical gloves since 2000.[xxiii]

- Australia. A 2014 report by Safe Work Australia, noting the need for better worker training in regards to occupational contact dermatitis and occupational contact urticaria, includes reducing the availability of powdered disposable latex gloves in Australia as one initiative.[xxiv]

- United States Hospitals. Prior to the FDA ban on powdered surgical and exam gloves and absorbable powder lubricant hospitals across the United States were transitioning to the use of powder free gloves; several of these are noted below.

  - The University of Virginia Healthcare System, Charlottesville, Virginia.[xxv]

    The University of Virginia was the first health care system in the United States to ban cornstarch from all examination and surgical gloves.

  - The Mayo Clinic.

    The Mayo Clinic has been addressing problems associated with latex since the late 1980's and early 1990's; while latex gloves are still used, they have a very low or unmeasurable allergen content. In addition, the gloves purchased by the Mayo Clinic are also either nonpowdered or have a minimal amount of powder.[xxvi]

    The use of only gloves with low or undetectable allergen content has allowed the Mayo Clinic to successfully control occupational allergy to NRL; this practice significantly decreased the concentration of allergen in the work site, reduced the number of new cases of occupational NRL allergy, and also permitted healthcare workers with latex allergy to continue working at their usual jobs.[xxvii]

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- The John Hopkins Hospital, Baltimore, Maryland.[xxviii]

  As of January 2008, in an effort to make medical care safer for both patients as well as healthcare workers, The Johns Hopkins Hospital became the first major medical institution to become "latex safe" by ending all use of latex gloves and almost all medical latex products. The replacement gloves, at that time, were made one of three synthetic products (neoprene, polyisoprene, or vinyl), none of which contain natural plant proteins. Sterile neoprene and polyisoprene gloves were used in the operating room because of their more sensitive feel.

- The Cleveland Clinic, Cleveland, Ohio.[xxix]

  The Cleveland Clinic's network of 9 hospitals have converted their hospitals and clinics to powder free, nonlatex surgical, and examination gloves.

- University of Kentucky (UK), Lexington, Kentucky – Latex/powder free environment.[xxx]

  UK HealthCare, recognizing that the incidence of reactions to NRL in healthcare settings has risen due to frequent exposure to latex and latex proteins, seeks to reduce the exposure to latex and to create a latex-safe environment that minimizes exposure to latex whenever possible. In regards to gloves, the policy states:

  - General use/exam gloves are powder free vinyl.
  - Powder free latex and synthetic sterile gloves will be available for use in surgery.
  - Special use (eg, chemotherapy, glutaraldehyde, other) gloves are powder free nitrile.

  In all cases, if an employee is known to have a latex sensitivity or allergy, UK HealthCare will provide latex-free gloves.

- Brodstone Memorial Hospital, Superior, Nebraska – Latex safe environment.[xxxi]

  Brodstone Memorial Hospital provides information to its patients and visitors regarding its latex safe environment, ie, their buildings are free of latex powder in order to provide the highest quality patient care.

- Shriners Hospital for Children, Galveston, Texas – Latex safe environment.[xxxii]

  Shriners Galveston Hospital has adopted a latex-safe environment policy, meaning that the standard for jobs requiring barrier protection is the use of reduced protein, powder free gloves. For caregivers who are latex sensitive and require barrier protection, the hospital provides non-latex supplies for both caregivers and patients who are latex sensitive.

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Rationale for and Benefits of Switching To Power Free Latex or Synthetic Gloves

There are several reasons for and benefits of switching to powder free latex or synthetic gloves; these include that:

1. Powder can cause the development of adhesions and granulomas.
2. Powder increases the risk factor for post-operative wound infections.
3. Powdered gloves can increase latex allergens sensitization and provoke hypersensitivity Type I reactions.
4. Powder contaminates the hospital environment and increase exposure to latex allergens through air inhalation.
5. Powder can increase the risk of cross contamination of microorganisms.
6. Powder can interfere in laboratory testing causing false results.
7. Powder has an abrasive action on the skin.
8. Powder unbalances skin pH.
9. Powder interacts with alcohol-based hand solutions.
10. Powder increases time and costs

Switching to powder free latex or synthetic gloves is also cost effective. The costs associated with latex allergies occur in three areas: to defend litigation; the financial judgment after a patient injury due to latex exposure; and compensation of healthcare workers who have developed latex hypersensitivity because of repeated exposure to latex products during their employment.[xxxiii] While implementing a latex powder free environment is estimated to cost between $75,000 and $200,000 per year; worker-related costs associated with latex allergy may be substantial.[xxxiv] For a registered nurse in Canada who has to stop work because of NRL, allergy costs has been reported to be more the $200,000; in Germany, it is estimated to cost $83,000 for each individual with a disease related to latex allergy.[xxxv] Further, powder-related surgical site infections (SSIs) could offset gloves costs as studies have shown individual SSI costs ranging from $11,000 to $30,000 in the US,[xxxvi] $6,624 to $28,534 in Japan,[xxxvii] and a 60.6% increase in hospital costs in Switzerland per SSI.[xxxviii]

Reducing exposure to latex is both a safer and more economical option than removing a latex-sensitized individual from the workplace; the use of low-allergen, powder free NRL gloves significantly reduces airborne exposure to latex in most healthcare practice settings.[xxxix] Healthcare facilities, regardless of size, are likely to realize financial benefits from becoming latex-safe, even if latex-related disability levels are extremely low.[xl] The Mayo Clinic reported an annual cost savings of $200,000 with a switch to low-allergen powder free gloves and similarly, a teaching hospital in Ontario, Canada reported no increase in cost for powder free gloves as a result of consolidated glove purchasing.[xli]

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