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FactFinders

# FactFinders for patient safety: Use of sterile gloves for interventional pain procedures

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Myth: Sterile gloves must be worn for all interventional pain procedures.

Fact: The decision to wear sterile vs. non-sterile gloves for interventional pain procedures involves consideration of the potential risk of infection unique to each procedure and patient.

Among the many dire repercussions of the COVID-19 pandemic, supply chain disruption has adversely affected the availability of a variety of goods including medical personal protective equipment (PPE). Resulting shortages of medical gloves have been significant [1]. It has become obvious that sterile and non-sterile medical grade gloves must be used rationally to preserve critical items for appropriate indications. The American demand for medical gloves is now estimated at 8.7 billion gloves per month, roughly double the usage compared to three years ago, with 99% of production located in China and Malaysia [1]. The Spine Intervention Society (SIS) has previously published a FactFinder describing the value of handwashing and hand hygiene prior to performing procedures [2]. This FactFinder investigates the data concerning the circumstances in which sterile vs. non-sterile gloves are required for injections.

The World Health Organization (WHO) "Best Practices for Injections and Related Procedures Toolkit" states that there are situations in which it is acceptable to perform intradermal, subcutaneous, or intramuscular injections without gloves and other times when it is acceptable to perform these procedures with non-sterile gloves. This Toolkit does not advocate for the routine use of sterile gloves, specifically based upon the potential exposure to bodily fluids and/or skin breaks in physicians administering injections [3]. However, the Food and Drug Administration (FDA) recommends the use of medical gloves at all times when in contact with bodily fluids, hazardous drugs, or contaminated items, but does not distinguish between sterile and non-sterile gloves [4]. Neither of these guidelines specifically discusses neuraxial, paraspinal, or intra-articular injections.

The use of gloves for interventional pain procedures is considered standard of care; however, it is not clear when it is acceptable to use non-sterile as opposed to sterile gloves. In a study of 25 volunteers who wore either sterile gloves or clean gloves, cultures were obtained from the palmar surface of the gloves. There was a significant increase in colony-forming units (CFUs) on clean, non-sterile gloves as compared to self-donned sterile gloves. The lowest rate of CFU growth was after technician-assisted sterile glove donning [5]. While these data have not been replicated in clinical practice, they suggest that the use of sterile gloves decreases the amount of bacteria on the interventionalist's hands during a specific procedure and that assisted-donning provides the most sterility.

A systematic review and meta-analysis of 13 studies (11,071 subjects) of cutaneous surgical procedures (Mohs micrographic surgery, laceration repair, standard excisions, and tooth extractions) demonstrated no difference in the rates of surgical site infections when comparing sterile glove use (2.0%) to non-sterile glove use (2.1%) [6]. Details of handwashing or scrubbing prior to putting on gloves were not evaluated as a component of this meta-analysis. The relative risk for surgical site infection with non-sterile glove use was 1.06 (95% Confidence Interval: 0.81–1.39).

## Neuraxial procedures

The Spine Intervention Society's (SIS) 2nd Edition Practice Guidelines for Spinal Diagnostic and Treatment Procedures recommends the use of sterile gloves for all neuraxial and paraspinal procedures and "at least two pairs" of gloves for intradiscal procedures [7]. A 2017 joint practice

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advisory from the American Society of Anesthesiologists (ASA) and American Society of Regional Anesthesia & Pain Medicine (ASRA-PM) includes an advisory statement supporting the use of sterile gloves during the placement of neuraxial needles and catheters in order to decrease the risk of infection [8]. One hundred percent of "consultants who were selected based on their knowledge or expertise in neuraxial techniques" and 94.6% of active ASA members "strongly agreed" with this assertion. The authors of the practice advisory noted that the literature is "insufficient" to confirm that infection risk is mitigated by the use of sterile gloves. In fact, all available published cases of epidural or intrathecal infection following neuraxial procedures were performed by practitioners who were wearing sterile gloves. This is likely due to the fact that sterile glove use for these procedures is ubiquitous. No randomized controlled trials or case-control studies on infection risk mitigation with the use of sterile as compared to non-sterile gloves have been published.

## Extra-axial injections

There have been only two published case reports of infection following lumbar medial branch blocks and five cases of infection following intraarticular facet joint injections [9–15]. In all seven of these cases, aseptic technique was utilized, and, importantly, glove usage was not discussed. While the data are sparse regarding the use of sterile gloves for paraspinal procedures, the infection rate for these procedures appears to be exceedingly low given the paucity of published case reports of infection following cervical, thoracic, or lumbar medial branch blocks and/or radiofrequency neurotomy. This does not account for infections that may have occurred but were not reported (*e.g.,* due to medicolegal reasons).

## Peripheral joint injections

A 2003 survey study reported that 32.5% of physicians who perform intraarticular steroid injections of the knee routinely used sterile gloves, 46.6% used either sterile or non-sterile gloves, and 53.4% did not wear gloves [16]. The only available consensus statement that includes glove usage to mitigate infection risk comes from the Italian Society of Rheumatology (SIR). The SIR advocates for the routine use of non-sterile, disposable gloves during arthrocentesis [17]. Other groups have agreed and recommended the routine use of non-sterile gloves during joint aspiration and injection procedures [18–20]. However, there is at least one publication with a recommendation for routine use of sterile gloves for aspiration and injection of joints; although there is no evidence to support this within the associated publication [21].

A 1999 retrospective study of 69 rheumatologists and over 1.1 million injections identified a 0.0013% incidence of sepsis following intra-articular corticosteroid injections over a 21-year period [22]. The authors did not report any results of the difference in infection rates between procedures that were performed with sterile and non-sterile gloves, but rather stated that "no relationship with the incidence of sepsis after local corticosteroid injection was found." It is important to note that the study specifically evaluated the outcome of sepsis and did not investigate the incidence of other infections.

## Recommendations

It is recommended that all providers follow applicable guidelines for the use of gloves published by professional medical societies and regulatory bodies such as the Centers for Disease Control & Prevention (CDC), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Healthcare Facilities Accreditation Program (HFAP), Centers for Medicare and Medicaid Services (CMS), hospital risk management, and other local healthcare regulatory agencies. The guidelines may differ depending upon whether the procedure is performed in a hospital operating room, an ambulatory surgery center, an outpatient office, or other location. Individual institutions may also have their own policies and guidelines for glove use.

The nature of interventional pain procedures involves handling the shaft of the needle that is inserted into the patient. These procedures are quite different from those on which evidence or guidelines exist in which only the hub of the needle is touched or there is no contact with the needle at all (syringe attached to the needle) by the physician. When established guidelines do not provide sufficient clarity, decisions are best guided by published evidence viewed in the context of best medical judgment.

- It is likely that the lack of evidence for, or against, the use of sterile gloves in the performance of neuraxial procedures is based upon the *a priori* assumption that sterile gloves should always be worn when accessing the epidural or intrathecal space to best mitigate the potential catastrophic consequences of epidural or intrathecal infection. For these reasons, SIS recommends using sterile gloves for all neuraxial procedures.
- There is a paucity of high-quality comparative evidence related to the use of sterile vs. non-sterile gloves for paraspinal procedures. Comparative evidence related to cutaneous surgical procedures suggests that there may be no added benefit to using sterile gloves to minimize infections. In the absence of direct evidence, SIS recommends that sterile gloves be used for all paraspinal procedures. If sterile gloves are not available due to a national shortage, it may be acceptable to proceed with a paraspinal injection with careful consideration given to the true urgency of the procedure and whether it can reasonably be delayed without the potential for greater morbidity. This decision should also be considered within the context of potential risk of infection unique to each procedure and patient (*e.g.,* medical comorbidities, adjacent hardware).
- High quality data suggest that there may be no added benefit in using sterile gloves to minimize the incidence of sepsis when performing peripheral joint injections. There is a paucity of high-quality, comparative evidence related to the use of sterile vs. non-sterile gloves for minimizing the risk of skin or joint infections. In the absence of direct evidence, SIS recommends that sterile gloves be used for all joint injections, unless sterile gloves are not available. In these instances, it may be reasonable to perform these procedures with single-use non-sterile gloves. The decision regarding whether to proceed with single-use non-sterile gloves should be based upon the potential risk of infection unique to each procedure and patient (*e.g.,* medical comorbidities, adjacent hardware).
  - For any injection procedure in which the physician bends the needle tip to facilitate directional control, it is recommended that sterile gauze be used to prevent direct contact with the physician's gloved fingers.

## Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Ameet Nagpal, MD, MS, MEd, MBA reports a relationship with Various Law Firms that includes: paid expert testimony. Mathew Saffarian reports a relationship with Independent Medical Evaluations that includes: consulting or advisory. Mathew Saffarian reports a relationship with Various law firms that includes: paid expert testimony. Jaymin Patel reports a relationship with Professional Disability Associates that includes: consulting or advisory.

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