Infection prevention strategies for procedures performed outside operating rooms: A conceptual integrated model

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Classification

Evidence-based practice is possible only when sufficient evidence exists. When there are evidence gaps, practice must be guided by expert opinion, which in turn is often extrapolated from basic principles, prior (ie, historical) practices, and common sense. This was perhaps best illustrated (sarcastically) by Smith and Pell’s 2005 systematic review of randomized controlled trials of parachute use. An overly strict and blind reliance on high-quality evidence often falls short when faced with the quandaries of clinical practice. Ironically, even the Grades of Recommendation, Assessment, Development and Evaluation system, now widely used to rate clinical guideline recommendations, was developed by expert opinion.

Background scientific information and expert opinion form the bottom layer of the evidence-based medicine pyramid and thus should not be dismissed when climbing up the levels of evidence. Some authors also have criticized the evidence-based medicine model for its rigid, unidimensional approach to complex problems.

We were recently faced with a simple question from a provider at our institution (Why must I wear a mask and a surgical hat to perform fine needle aspirations?) that illustrated such a gap. Not only were we unable to provide evidence to support this practice, but we also had no comprehensive policy regarding infection prevention practices for medical procedures performed outside an operating room.

INITIAL SURVEY OF EXISTING LITERATURE

A survey of textbooks, technical notes, and practice guides was unhelpful: Most of these sources referred, at some point, to “your local policy.”

Guidance exists for several specific procedures. For instance, since 2007, Standard Precautions have included the use of a mask when performing a lumbar puncture with injection of material or catheter placement:1 We have strong data2 and guidelines3 advocating full barrier precautions for central venous catheter placement. The catheter-associated urinary tract infection4 and intravascular catheter-related infection prevention guidelines5 also address key elements of infection prevention for these procedures.

For most procedures—from skin biopsy to chest tube insertion—no authoritative guidance exists, and published evidence is lacking. Healthcare personnel do as they were trained, and pass the details along when they train someone new. This is true for the technical elements and the type of personal protective equipment used.

An important problem is that the language used to describe practices can be misleading. Some procedures are described interchangeably as aseptic or sterile. Some reference sources use words like surgical asepsis.6 To paraphrase Inigo Montoya,1 “We keep using these words. Do they mean what we think they mean?”
<table>
<thead>
<tr>
<th>Nonsterile</th>
<th>Sterile superficial</th>
<th>Sterile invasive</th>
<th>Surgical-like</th>
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</thead>
<tbody>
<tr>
<td><strong>Aim</strong></td>
<td></td>
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<tr>
<td>Standard Precautions' Gloves</td>
<td>Reduce contamination of procedure body site</td>
<td>Protect procedure body site from pathogenic microorganisms</td>
<td>Protect procedure body site from all microorganisms</td>
</tr>
<tr>
<td>Skin preparation</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Surgical drape(s)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td><strong>Examples of procedures</strong></td>
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<td>Bladder catheterization (in and out)</td>
<td>Paracentesis</td>
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<td>Percutaneous catheter insertion</td>
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<td>Laceration repair</td>
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<td>Cardiovascular procedures</td>
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</tbody>
</table>

'Standard Precautions include hand hygiene, the use of appropriate personal protective equipment if risk of exposure for the healthcare worker, safe injection practices and cough etiquette.

'Do not use skin preparation directly on wounds. Alcohol-based product preferred.

'Available guideline or reference.
The bottom line is that there is no consensus regarding how to classify medical procedures as to their risk for contamination or infection. As such, the safeguards (eg, type of gloves, mask, and surgical drapes) needed to prevent infectious complications are not uniform and are often not explicitly addressed. For many (if not most) procedures, there is no guideline or consensus as to what the infection prevention measures should be. In the era of mandatory reporting and diligent efforts to curb health care-associated infections, the absence of a consensus or standardization on this issue is both concerning and counterintuitive.

OUR PROPOSED MODEL

We surveyed the available literature and published materials in different areas of medicine associated with procedures (eg, surgery, emergency medicine, interventional radiology, and critical care) and reviewed 10 years of The New England Journal of Medicine clinical practice videos. These video tutorials demonstrate common medical procedures in a step-by-step approach. They are reviewed by experts before online posting and are very popular among medical trainees. It therefore seemed logical to include them as resource.

We used this background research to develop a 5-tiered, progressive classification of procedures performed outside operating rooms. We opted to title our categories “clean,” “aseptic,” “sterile-superficial,” “sterile-invasive,” and “surgical-like.” The classification, along with examples, is summarized in Table 1.

Clean means free of dust, soil, and debris. The aim of such procedures is to reduce the risk of contamination at the body site where the procedure is performed. Standard Precautions (including hand hygiene and the use of appropriate personal protective equipment if there are risks of splashing) apply, and examination gloves are used. Clean procedures do not require skin preparation (ie, disinfection of the skin) or the use of surgical drapes. Examples of clean procedures include endotracheal intubation, nasogastric tube insertion, bedside gynecologic procedures (eg, intrauterine device placement/removal and endometrial biopsy), and chronic wound care without sharp debridement.

Aseptic technique should be used when the procedure body site should be free of pathogenic microorganisms. Standard Precautions apply as always and skin preparation is performed. Products containing alcohol are generally preferred. Most of the time these procedures are no-touch techniques (the provider does not touch the critical area; that is, the exact place where the breach in normal physiologic barrier will happen or has happened) and examination gloves are worn, but if the provider is to touch the critical area of the procedure, surgical gloves should be worn. Examples of procedures include venipuncture and peripheral intravenous line placement, arterial blood gas measurements, skin biopsies, and fine needle aspirations.

Sterile means free of all microorganisms. We divide sterile procedures into 3 categories: sterile superficial procedures require the use of Standard Precautions, skin preparation, and surgical gloves and surgical drapes tailored to the local procedure body site. Urinary catheter insertion and bone marrow biopsies fall into this category.

Sterile invasive procedures add a procedure or surgical mask to sterile superficial procedures. Examples include lumbar puncture, thoracentesis, paracentesis, laceration repair, and chronic wound care when sharp debridement is performed.

Surgical-like procedures require full surgical attire (ie, sterile gown and gloves, surgical mask, and hat) and wide- to full-body coverage by surgical drapes. These procedures include central venous catheter and arterial line placement, chest tube insertion, percutaneous endoscopic feeding tubes insertion, and vascular interventional radiology procedures.

OUR OBJECTIVES AND LIMITATIONS

We realize that this classification is not evidence-based, but was instead developed using our clinical experience and available published materials. We believe it helps to fill a gap by providing a rational and simple framework to present infection prevention requirements for procedures. We intend it as a starting point for future discussion and research.

We wish to share our model so that it can be improved with input from different perspectives. We thus welcome any new (or overlooked) studies or guidelines and constructive comments from experts of various perspectives. A logical next step would be surveys to understand the variability of practices locally, nationally, and beyond. Then, focused research questions could challenge the model and its recommendations for specific procedures. These efforts will lead to a better, stronger framework to standardize practices and decrease the number of hospital-acquired infections associated with these procedures, a goal that will also need to be evaluated.

References