

#### GLOVE CHANGE — WHEN AND WHY?

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

#### LEARNING OBJECTIVES

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

1. Understand the incidence, risks, and prevention of surgical site infections (SSIs) and how surgical gloves contribute to these;
2. Summarize current critical thinking about surgical glove integrity;
3. Identify the gloving recommendations contained in some of the key policy and practice directives that guide perioperative care; and
4. Appreciate innovation in medical glove manufacturing including the role of antimicrobial gloves in reducing SSI risk.

#### ISSUE 8

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## BACKGROUND

Surgical care is currently one of the world's most frequent healthcare interventions with the World Health Organization (WHO) estimating that in 2012, 312.9 million operations were performed globally.<sup>1</sup> As the current world population ages and chronic conditions proliferate, WHO also estimates that both the number of surgeries and range of surgical options will grow by at least the 38% reported over the eight years prior to this most recent data.<sup>1</sup>

While unable to estimate the actual burden of surgical site infection (SSI) due to the absence of reliable global data, WHO suggests that in low to middle income (LMI) countries, one third of surgical patients develop an SSI. In high-income countries reports suggest that depending on the type of surgery, the proportion of patients who develop an SSI ranges between 0.75%-9.5%.<sup>2</sup> For some patients a SSI may be minor, however for many it may have catastrophic, life-long consequences including increased morbidity and even mortality.<sup>3</sup>

For the healthcare system, SSIs are costly with some countries including the USA and more recently Australia, adopting pay-for-performance systems whereby additional costs associated with specific SSIs are either not covered by insurance or where a hospital is penalized for each SSI by the denial of government funding.<sup>4</sup>

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Equally alarming is the global issue of antimicrobial resistance (AMR) whereby antimicrobial agents are no longer effective against pathogens.<sup>5</sup> Prevention of SSI makes an important contribution to the reduction of AMR by promoting judicious use of prophylactic antibiotics and reducing additional, avoidable use of antimicrobials for SSI treatment.<sup>5,6</sup>

Despite appreciating the critical need to prevent SSIs experts have recently questioned long held beliefs regarding SSI cause(s), the relationship between patient-specific and procedural SSI risks and subsequently, the real value of implementing novel technologies and interventions to prevent SSIs.<sup>6</sup>

Traditionally surgeons have believed that intraoperative airborne contamination was the primary cause of SSI however they also acknowledge that "impeccable surgical technique and operating room behavior" including maintaining proper asepsis of the sterile field and at the surgical site by avoiding breaches are critical.<sup>6</sup>

"impeccable surgical technique and operating room behavior" including maintaining proper asepsis of the sterile field and at the surgical site by avoiding breaches are critical."<sup>6</sup>

This edition of InTouch is therefore dedicated to interrogation and discussion of the evidence relating to the contribution of intact gloves to SSI prevention and conversely, how non-intact surgical gloves increase the risk of SSI.



# HOW SURGICAL GLOVES PREVENT SSI

Since the mid-1800s surgeons and their assisting personnel have appreciated and tried to better understand and counteract activities, methods, circumstances and interventions that increase a surgical patient's risk of developing a SSI.<sup>3</sup>

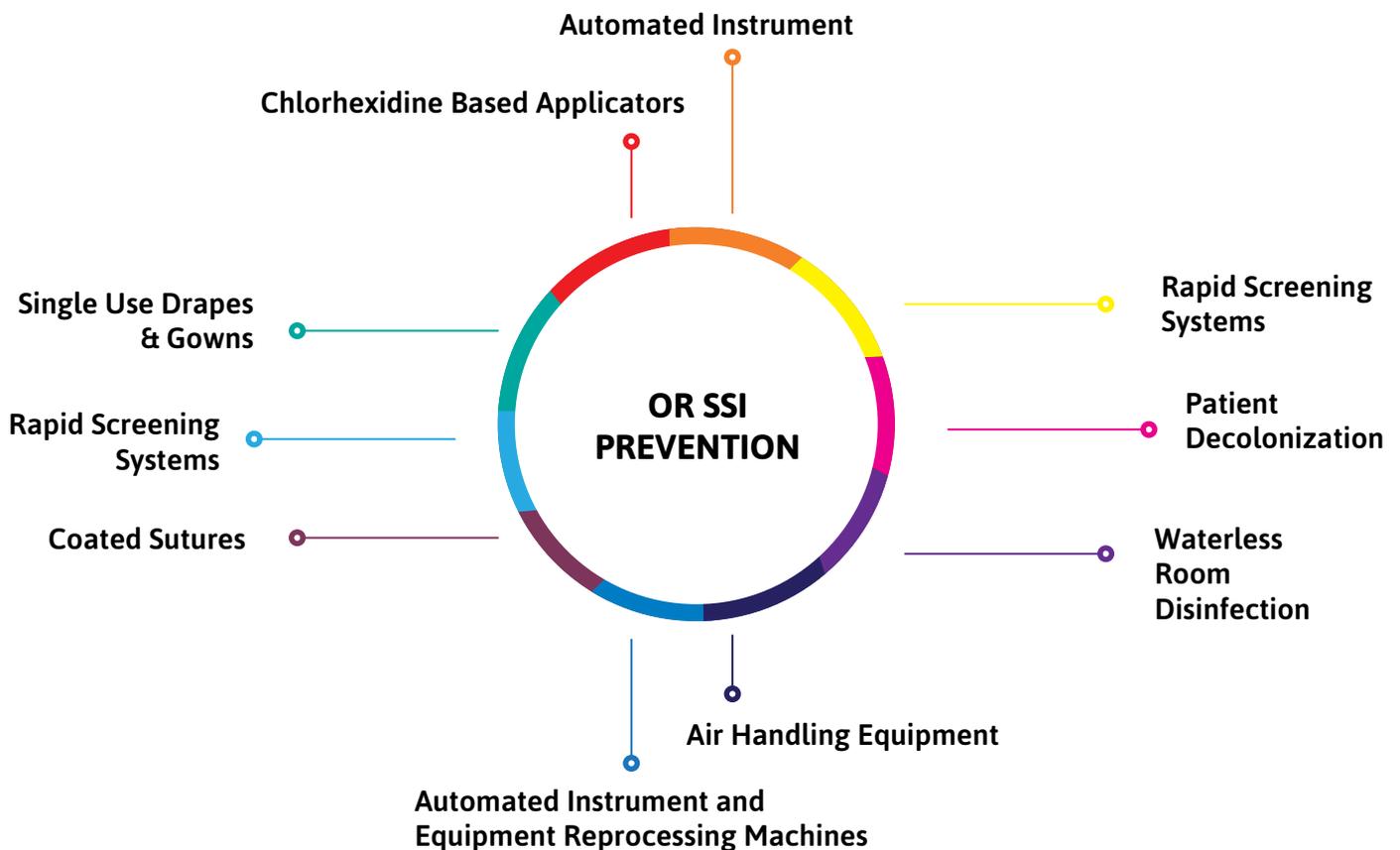
These have included management of the operating environment as well as a strict suite of measures and behaviors designed to employ and maintain sterile technique.<sup>3</sup>

While various local, national and even global guidelines<sup>2,7,11</sup> for SSI prevention vary in their specific recommendations and thus promote unhelpful ambiguity and non-standardized practice,<sup>12</sup> the significance of infection control and prevention<sup>13</sup> measures such as cleaning of the operating room, surgical hand preparation, donning of protective, sterile gowns and gloves, disinfection of the surgical site, use of sterile instruments and equipment and in particular establishment and maintenance of sterile technique<sup>14</sup> to reduce the transmission of microbes to surgical patients are unquestioned.<sup>13,14</sup>

Additional and alternative measures, technological innovations and formulations such as rapid screening systems, patient decolonization, waterless room disinfection, air handling equipment, coated sutures, impregnated, single use drapes and gowns, chlorhexidine based applicators, automated instrument and equipment reprocessing machines and wound protection and irrigation systems may offer additional infection prevention options.<sup>3,6,13-17</sup>

However, the importance of protective barriers to prevent contamination of the surgical site and transmission of microbes between the patient, touched sterile surfaces and members of the operating team remain unquestioned.<sup>2,7-11</sup>

Gloves are one of the most, if not the most, important of these barriers and according to Beldame,<sup>18</sup> "...surgical gloving is a showpiece of asepsis, ensuring the prevention of cutaneous bacteria from the wearer in the surgical field as well as protecting the surgical team from the patient's biological fluids."



## HOW SURGICAL GLOVES PREVENT SSI

Surgical gloves are typically sterile and used routinely by operating room personnel, anesthetic and intensive care staff and other clinicians as a barrier to prevent contact with blood and body fluids and also to stop contamination of a surgical wound, a critical aseptic field (such as that used for urinary or long-term vascular catheterization), a key part or a key site.<sup>19-21</sup>

The use of surgical gloves does not excuse their wearer from the requirement to perform appropriate surgical hand preparation using either a suitable antimicrobial soap and water or a suitable alcohol-based handrub and adequately drying their hands prior to donning sterile, surgical gloves.<sup>2,6</sup>

Intraoperative surgical glove perforation is common and always classifies as a breach of sterile technique. Breaks in sterile technique provide an opportunity for microbial contamination.

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Hospital Acquired Infection *Staphylococcus aureus*

A four stage classification has been proposed for such breaches based on the speed with which the breach is recognized and remediated.<sup>3</sup> Gaines reports that:

<b>Type 1</b>	The break is recognized immediately
<b>Type 2</b>	The break is recognized shortly after it occurs
<b>Type 3</b>	The break is recognized later
<b>Type 4</b>	The break is not recognized at all

Each type of break involving compromised glove integrity is serious, as potentially pathogenic organisms can travel through holes in the glove(s). This pathogenic transfer inevitably increases contamination of the operative site.<sup>22</sup>

The volume and virulence of pathogens and the ability of the host’s immune system to resist this invasion effect whether a SSI<sup>22</sup>, or in the case of contaminated device insertion, a device-related, healthcare acquired infection (HAI) develops.<sup>23-26</sup>

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## CURRENT CRITICAL THINKING ABOUT SURGICAL GLOVE INTEGRITY

As surgeons, especially orthopaedic specialists,<sup>24,27,18</sup> grapple with complex issues such as antimicrobial resistance, ever increasing demand for complex procedures such as total joint arthroplasty, long-term safety of implants and the impact of SSI on patient outcomes, it is common to see further interrogation and investigation of well-established infection prevention and control measures including use of surgical gloves.<sup>28</sup> Researchers and users are particularly interested in better understanding the frequency of surgical glove perforation, how use of more than a single layer of gloves impacts surgical glove perforation, methods for facilitating earlier recognition of glove perforations and how novel glove formulations impact SSI.

Perforation of surgical gloves is common with reports ranging from 3.58%<sup>18</sup> to 78%.<sup>29</sup> The risk of a surgical glove's integrity varies according to factors such as the nature of the task at hand, the type of surgery, the surgical and aseptic skill of the wearer and their dominant hand, the type and particularly the sharpness of surfaces coming into contact with the glove(s) and the length of continuous time for which a glove or pair of gloves are worn and the mechanical stress to which they are subjected.<sup>24</sup>

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Typically the risks of potential exposure of either the operator or the patient are greatest for complex open surgery compared to minimally invasive procedures and aseptic, non-surgical procedures.<sup>3</sup> Recent research has compared perforation rates according to the number of pairs worn and by type of surgery performed finding perforation rates of 15.2% in single gloves, 14.4% in double gloves, 15.5% in emergency operations, and 14.3% in elective surgery.<sup>25</sup>

Other studies have focused on glove perforation specialties, and/or procedures and how this may impact the risk of SSI. One such study undertaken in Hong Kong investigated risk factors for glove perforation in primary total knee replacement and the risk of subsequent superficial surgical site infection and periprosthetic joint infection. The researchers found that the rate of superficial surgical site infection was

significantly higher in the group of patients who had been operated on by surgeons with inadvertent visibly perforated gloves (9.1%) compared to those where surgeons' gloves were free of perforation(s) (0.5%). All surgeons had worn double gloves which were routinely changed at various stages of the procedures including after draping, before cementation and if there was any visible perforation.



Research into the causes and prevention of glove perforation is common with many investigators including Mistelli and colleagues,<sup>26</sup> recommending that routine use of double gloves and systematic changing of the outer gloves at designated times, or stages intraoperatively would reduce the incidence of perforations. They believe that this protocol would also simultaneously protect the wearer and reduce any bacterial load on the glove surface, thereby reducing the potential of surgical site contamination.<sup>18</sup>

It is feasible that some operating room personnel under appreciate the risks associated with glove perforation because many,<sup>30-32</sup> if not most,<sup>22</sup> glove perforations remain either undetected,<sup>18,23,29</sup> or are detected only at, or close to, the conclusion of a surgical procedure.<sup>22,23</sup> Glove perforations can be either macro or microscopic, again limiting their early detection.<sup>24</sup>

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## CURRENT CRITICAL THINKING ABOUT SURGICAL GLOVE INTEGRITY

The high numbers of undetected glove perforations are also concerning because they provide an unrecognized opportunity for the bacterial regrowth of microorganisms on the hands of glove wearers to contaminate the surgical site<sup>32</sup> or for the HCW to be exposed to potentially pathogenic organisms sourced from the patient.<sup>22</sup>

Equally important is the need for the glove wearer to immediately replace torn or perforated gloves. Research has demonstrated that when perforated gloves are recognized, 66.7% of glove wearers immediately replace the perforated glove.<sup>22</sup>

The high numbers of undetected glove perforations are also concerning because they provide an unrecognized opportunity for the bacterial regrowth of microorganisms on the hands of glove wearers to contaminate the surgical site<sup>32</sup>

As the majority of glove wearers do not perceive perforation of their glove(s), some experts have recommended routine use of double gloves and also adoption of a glove perforation or breach indicator system.<sup>22</sup> Such a system has the potential to facilitate timely recognition and replacement of defective gloves. Early replacement of the defective glove eliminates the risk of pathogen transfer via glove perforation.

Evidence cited in a 2014 Cochrane review shows that double indicator gloves compared to standard gloves (single and double gloves) reduce the number of perforations in one glove on average by 90%.<sup>33</sup> Other studies have shown that double gloving may reduce the risk of intraoperative blood exposure to the healthcare worker by 6-fold to 13-fold.<sup>19</sup> These are compelling reasons for double gloving to become universally recommended routine practice.<sup>19</sup>

Given that almost half the perforations of an outer glove also involve perforation of the inner glove at the corresponding site, changing only the outer glove is insufficient to protect staff.<sup>29</sup> Regardless of whether the user believes a perforation is present, the inner and outer gloves should be changed when the outer glove on either hand is changed.<sup>24</sup>

Very recent glove options include pre-donned pairs of double gloves which provide an additional layer of protection as well as facilitate fast, easy donning and include a darker colored inner glove for early detection of perforation. Pre-donned double gloves may also potentially increase double gloving compliance. By eliminating the additional inner-wrap packaging associated with the traditional second glove pair, pre-donned double gloves will also produce less packaging waste than two singularly packaged pairs of glove.

Regardless of whether the user believes a perforation is present, the inner and outer gloves should be changed when the outer glove on either hand is changed.<sup>24</sup>



## CURRENT GLOVING RECOMMENDATIONS

While all guidelines recommend at least one pair of intact surgical gloves be worn during every surgical procedure, recommendations regarding routine glove change and/or use of double gloves during surgery vary greatly.<sup>2,7-11,14,34,25</sup> SSI Guidelines developed by the WHO and the Centers For Disease Control and Prevention (CDC), arguably the world's two most significant public health agencies, are both silent on the issues of double gloving and routine, recommended surgical glove change.<sup>2,11</sup> WHO's position is not entirely surprising given the opinion of some of their key advisors during a 2015 European meeting that "...available evidence to assess the effect of wearing additional gloves, intraoperative glove change or type of gloves on SSI rates is very limited and of low-quality..."<sup>36</sup> and the need for guidelines which are achievable in LMI countries rather than high-income countries alone.

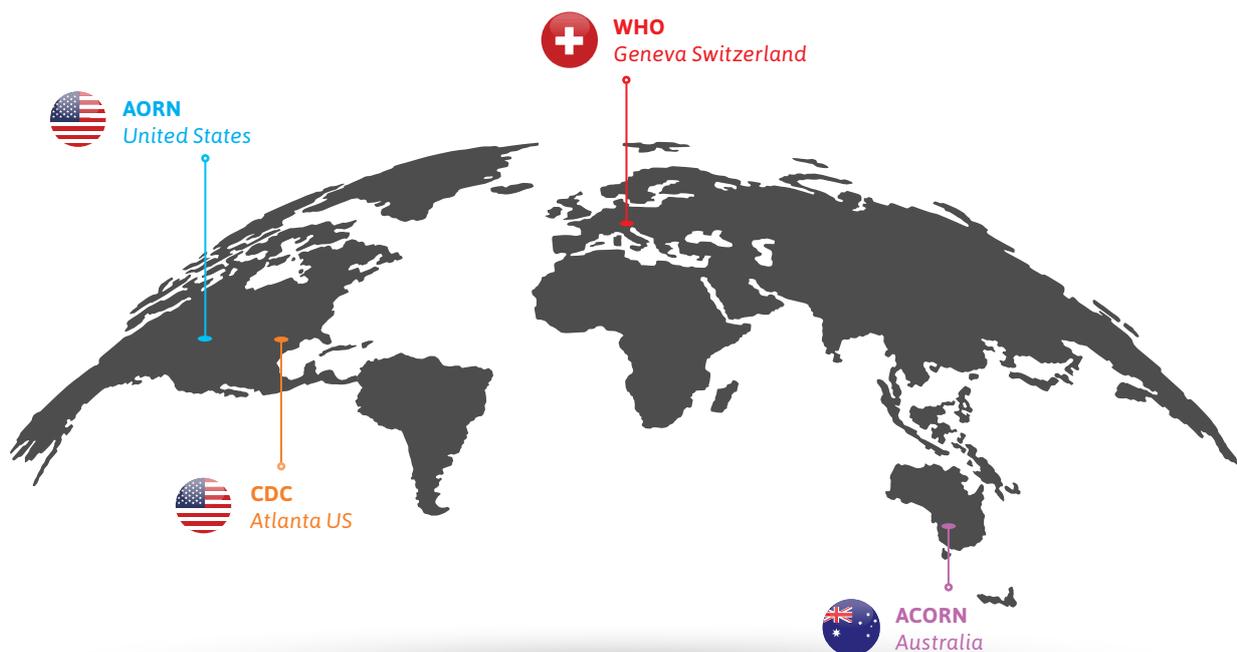
In contrast, shown in table 1 on page 8, guidelines written specifically by active members of operating teams i.e. the American Academy of Orthopaedic Surgeons, the Association of Operating Room Nurses (AORN) and the Australian College of Perioperative Room Nurses (ACORN)<sup>7,8,14,34,35</sup> clearly state a preference for routine use of double gloves and also specify occasions or events which routinely require changing of gloves.

Like much of surgical practice, randomized control trials are needed to better understand these issues and until more well-designed research is undertaken practices, including glove use, will remain non-standardized according to either specialty, procedure-specific or surgeon-specific norms and preference.

The lack of standardization in various guidelines' recommendations regarding glove use and glove change may be due to most of the in-vivo and invitro studies undertaken being underpowered and therefore limiting the generalizability of their findings and uptake of their recommendations. It is also worth considering the ethical or practical constraints that limit surgical research.

Unfortunately, the absence of specific recommendations in many surgical guidelines supports non-standardized practice which in many surgical specialties and sub-specialties may be guided by surgeon-preference rather than outcomes, logic or science.<sup>37</sup>

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## CURRENT GLOVING RECOMMENDATIONS

	Recommended Glove Changes	Use of Double Gloves	Other
<b>WHO<sup>2</sup></b>	No recommendation	No recommendation	
<b>CDC<sup>11</sup></b>	No recommendation	No recommendation	Wear sterile gloves if a member of the scrubbed surgical team.
<b>EPIC/NICE<sup>10</sup></b>	No recommendation	Consider wearing two pairs of sterile gloves when there is a considerable risk of glove perforation and the consequences of contamination may be serious.	
<b>SHEA<sup>9</sup></b>	All members of the operative team should double glove and change gloves when perforation is noted.	All members of the operative team should double glove and change gloves when perforation is noted.	
<b>AORN<sup>8,14</sup></b>	<p>Scrubbed team members should change their surgical gloves</p> <ul style="list-style-type: none"> <li>• after each procedure,</li> <li>• when actual or suspected contamination occurs,</li> <li>• after touching a helmet or visor worn in the surgical setting,</li> <li>• after adjusting a microscope or optic eyepieces,</li> <li>• immediately after direct contact with methylmethacrylate,</li> <li>• when gloves begin to loosen from swelling or expanding as a result of the absorption of fats and fluids,</li> <li>• when there is a visible defect or perforation or suspected perforation, and</li> <li>• every 90 to 150 minutes</li> </ul>	Scrubbed perioperative team members should wear two pairs of gloves, one over the other, to help prevent exposure of the hand in the event of a glove perforation.	The Centers for Disease Control and Prevention, the American College of Surgeons, and the American Academy of Orthopaedic Surgeons all support double gloving during invasive procedures.
<b>ACORN<sup>7,35</sup></b>	Sterile gloves are changed after 1.5–2 hours of wear time and at other critical points during surgery (handling implants and prostheses).	Double gloving continues to be the recommended practice, with use of an indicator glove of a different colour underneath, when available.	
<b>Other<sup>34</sup></b>	When a surgical case is completed the surgeon should change their outer layer of gloves and apply the dressing while the outer pair of gloves is clean and taking care not to inadvertently soil the gloves by having contact with contaminated drapes or equipment.		

**Table 1:** Summary of gloving recommendations in a sample of global SSI prevention guidelines.

## INNOVATION IN MEDICAL GLOVE MANUFACTURING INCLUDING THE ROLE OF ANTIMICROBIAL GLOVES IN REDUCING SSI RISK.

Developing innovative solutions to overcome the high frequency of glove perforation and the lack of prompt recognition by glove wearers has been a major goal of glove manufacturers over the past few years. Glove manufacturers have also benefitted from the increased understanding of bacterial regrowth on glove users' hands even after surgical hand washing.

Coupled with new knowledge about microbial passage through single and double surgical gloves some glove manufacturers have introduced antimicrobial-treated (AMT) examination and/or surgical gloves.<sup>19,31,32,38-40</sup>

In essence AMT medical gloves are designed to overcome some aspects of glove misuse including excessive and extended glove wearing,<sup>38</sup> failure to recognize perforations, failure to change gloves in a timely fashion and inadvertent contamination of environmental surfaces<sup>38</sup> and operative sites.<sup>32</sup>

As with all novel infection prevention devices, additional research is needed to determine the long-term impact of AMT gloves on surgical technique and outcomes, patient and HCW safety, microbial adaptation, antimicrobial resistance and their relationship and impact on co-existing measures such as surgical site skin preparation, surgical hand antisepsis, impregnated or coated devices and equipment and wound irrigation systems.

It may also be the case that AMT gloves provide benefit and infection prevention in areas of healthcare other than surgery where patients are at greatest risk of developing an HAI. Possible sites could include ICUs, neonatal, renal, hematology, solid organ transplant and oncology units. Conversely, future challenges in HAI and SSI prevention may require new interventions and innovations currently either beyond our thinking or for existing measures used in alternate social, occupational or professional settings other than healthcare.

### Early research into the efficacy of AMT gloves is promising having showed that they may:

- prevent contamination of near-patient environments during routine care by suppressing bacterial survival and growth on their outer surface;<sup>38-40</sup>
- reduce the risk of surgical site contamination in the event of an intra-operative glove breach by suppressing re-growth of flora on the wearer's hands;<sup>32</sup> and
- reduce bacterial passage through perforated surgical gloves;<sup>19,31</sup>

## WHERE TO FROM HERE?

In this issue of InTouch, we have reviewed current practice, research, guideline recommendations and innovations relating to glove use and SSI risk and prevention. This review has highlighted that despite understanding the key role surgical gloves play in SSI prevention, improvements are needed to provide for the

safety of patients and clinicians.

In future issues of InTouch, we look forward to sharing more information and insights into making healthcare and in particular, surgical care safer for patients and their caregiver.

### Initial focus areas for quality improvements should include:

**acceptance** that gloves are always an adjunct to hand hygiene and not an alternative, and that sterile, surgical gloves are only effective if they are intact;

**adoption** of routine double-gloving for complex surgeries including those where glove perforation is most likely and/or surgical site infection is potentially catastrophic;

**introduction** of routine double glove changing (both top and under glove) at critical stages within every complex surgical procedure;

**consideration** of using AMT gloves for care and procedures where there is any likelihood of glove perforation and subsequent contamination of the environment, the patient, or the healthcare worker; and

**clarifying** and standardizing guidelines and recommendations to reflect the above practices.

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