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A SELF STUDY GUIDE

DOUBLE GLOVING – A STANDARD OF PRACTICE IN SURGERY

Registered Nurses



The issues around personal protective equipment have never been more discussed than they are today. It is no surprise given the recent Ebola crisis and the amount of information we hear daily about hospital-associated infections, surgical site infections and antimicrobial resistance. As deadly viruses such as Ebola, hepatitis and human immunodeficiency virus become more prevalent in the population, awareness is increasing that such infections may be transmitted to healthcare workers (HCWs) through contaminated blood.

Surgical gloves provide a protective barrier between HCWs' hands and infectious blood and body fluid, but research has proven that surgical gloves cannot always withstand the rigors of lengthy and strenuous surgeries, and surgical personnel do not always change their gloves frequently enough during lengthy procedures. When there is a breach, or barrier failure to a surgical glove, there is a subsequent potential for the transfer of pathogens to both the patient and the surgical team. From a risk management, infectious disease and occupational health perspective, prevention of barrier failure is key to protecting the surgical team and the patient. For members of the surgical team, the primary method of prevention is the practice of double gloving for surgical procedures. Some surgeons and nurses have eagerly adopted the practice while others have stubbornly refused, citing objections ranging from poor fit, feel and comfort of wearing two sets of gloves, to losing necessary tactile sensitivity required for intricate surgeries, all the way to administrative budget cuts that prevent the expense for extra gloves. In this education module you will explore two questions: is double gloving worth the effort and what does the evidence say?

LEARNER OBJECTIVES

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

- 1. Describe the stringent manufacturing requirements for surgical gloves.
 - 2. Discuss factors that could lead to surgical glove failure.
 - 3. Identify healthcare workers' injury and risks with single gloving.
 - 4. Identify the published advantages of double gloving.
 - 5. Discuss how to implement double gloving best practices.

INTENDED AUDIENCE

The information contained in this self-study guidebook is intended for use by healthcare

professionals who are responsible for or involved in the following activities related to this topic:

- Educating healthcare personnel.
- Working in the operating room and other surgical environments.
- Establishing institutional or departmental policies and procedures
- Decision-making responsibilities for safety and infection prevention products.
- Maintaining regulatory compliance.
- Managing employee health and infection prevention services.

INSTRUCTIONS

Ansell is a Recognized Provider of continuing education by the California Board of Registered Nursing, provider #CEP 15538 and the Australian College of Perioperative Nurses (ACORN). This course has been accredited for 2 (two) contact hours. Obtaining full credit for this offering depends on completion of the self-study materials on-line as directed below.

Approval refers to recognition of educational activities only and does not imply endorsement of any product or company displayed in any form during the educational activity.

To receive contact hours for this program, please go to the "Program Tests" area and complete the post test. You will receive your certificate via email.

AN 85% PASSING SCORE IS REQUIRED FOR SUCCESSFUL COMPLETION. Any learner who does not successfully complete the post-test will be notified and given an opportunity to resubmit for certification.

For more information about our educational programs or perioperative safety solution topics, please contact: Ansell Healthcare Educational Services by e-mail at edu@ansellhealthcare.com

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DOUBLE GLOVING -

A STANDARD

OF PRACTICE

IN SURGERY

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HISTORY OF SURGICAL GLOVES

Gloves were first introduced into the surgical arena during the 1890s when Dr. William Halstead commissioned the Goodyear Rubber Company to make the first pairs to protect the hands of the nurses and surgical assistants from the harsh disinfecting agent, carbolic acid. They were crude and cumbersome at that time, but they did protect the workers' hands from the harsh chemicals. It soon became apparent that wearing the gloves also reduced the rate of post procedure infections among patients and decreased mortality. By the early 1900s, the use of surgical gloves was routinely used during surgery in both Europe and the United States.¹



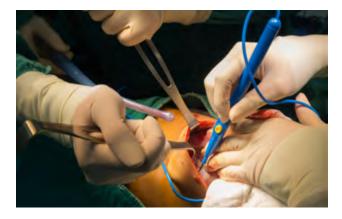
Goodyear Surgical Glove

The first mention of double gloving in the medical literature came sometime later, during World War II. An orthopedic surgeon named Dr. Marshal R. Urst, a graduate of the Johns Hopkins University School of Medicine, joined the war effort in 1943. He was Chief of Orthopaedics in the 22nd General Hospital Division in England and the 97th General Hospital Division in Germany. He explained, as they explored wounds for bullet and shell fragments, that they wore two gloves because of the risk of tearing the glove on the sharp fragment of bone.

The first disposable latex medical gloves with thinner fingers and palms were manufactured in 1964. Prior to this, surgical gloves were re-used, and had to be strong enough to withstand repeated washings and steam sterilizations. In 1966, the world's first prepackaged, sterile surgical glove became available.

MANUFACTURE OF GLOVES

The risk of exposure to bloodborne pathogens is a serious concern to healthcare providers, particularly those working in the operating room (OR). Given the serious health and cost implications related to the consequences of bloodborne infections, both OR staff and their patients need to be protected from the risk of these infections.



Surgical Procedure

SURGICAL GLOVE STANDARDS ARE GOVERNED BY NATIONAL GOVERNMENT STANDARDS

Quality specifications are written into each National Standard for a surgical glove product. They relate to physical requirements like strength, thickness, measurements, performance, and freedom from holes. Specifics include, elasticity, elongation, protein and powder levels, allergenicity or biocompatibility. These specifications require a statistical sample scheme which, if passed, mathematically ensures a maximum potential number of defined faults per 100 units. This is called an AQL (Acceptable Quality Level). Batches of product are rejected by the manufacturer if the number of faults exceeds this number. Each Standard Organization has varying requirements to be met and generally arrange factory inspections before granting a Certificate of Standards Conformity

 In Europe, medical gloves are subject to the European Standards EN 455 part 1-2-3, while the enforcement is under the responsibility of each Member State through national standards bodies and healthcare agencies. The European EN 455 standard for surgical gloves was approved by CEN (European Committee Standardization) which the members are the National standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

- The US FDA does not write standards but it does recognize standards that are written by the American Society of Testing and Materials (ASTM). Surgical gloves sold into the US must meet the ASTM standards.
- ISO (International Organization for Standardization) is an independent, non-governmental membership organization and the world's largest developer of voluntary <u>International Standards</u>. Many countries require surgical gloves entering their country to meet the ISO Standards.

HEALTHCARE PROVIDER SPECIFIC NEEDS

Manufacturers must also produce gloves that meet the customer's specific individual needs for durability, flexibility, tactile sensitivity and resiliency. The gloves need to fit like a "second skin" for the surgeons that are performing delicate microsurgical procedures and be flexible enough to touch the tiny hair-like vessels of a premature infant's heart, in addition to having the durability to withstand the rigor of the chisels and blades during a total joint replacement while providing a barrier between the healthcare worker and the patient. The material must meet stringent manufacturing standards and also stringent tactile requirements at the same time – all of this while still providing acceptable fit, feel and comfort throughout the procedure. This is no small order to fill.

Manufacturers have made great strides and improvements in gloves and have produced a large variety of quality products for HCWs to choose from including, standard, orthopedic, sensitive, radiation attenuation, and so on. Even with all the high technology in manufacturing, there are several factors that increase the likelihood of glove failure during use, including mechanical stress, type of surgery, number of instruments used in the surgical case, length of surgical procedure and the wearer's role in the surgical case.



Glove Manufacturing

FACTORS IMPACTING GLOVE FAILURE

The OR is a unique environment with inherent peculiarities that increase the chance of glove failure. Surgeons use sharp instruments and are exposed to sharp boney surfaces. Boney procedures have been associated with higher glove failure than soft-tissue surgery.^{2, 3} The operating site is confined and visibility for the OR scrub nurse may be limited. Staff use and pass sharp instruments without notifying the other person.

Hollaus (1999), found most injuries in the OR are self-inflicted, but a notable number, perhaps as many as 24% are inflicted by a coworker.² A study by Jagger et.al 2010, noted that threequarters of injuries occurred during use or passing of devices and that most sharp injuries are caused by suture needles (43.4%), scalpel blades (17%), and syringes (12%). Surgeons and residents were most often original users of the injurycausing devices; nurses and surgical technicians were typically injured by devices originally used by others.⁴ Other sources of OR exposure (Tietjen et al. 2003) include stylets, scissors, wire sutures, orthopedic equipment (drill bits, screws, pins, saws), needle point cautery tips, skin hooks, towel clips, and forceps.⁵ Quebbeman et al reported that contamination of a health care provider with blood as a result of a needle stick or other injury occurred in 50% of 234 surgical observations.⁶



Passing Scalpel

Research indicates glove perforation rates vary from 22% to 61% during various types of surgical procedures, with the highest reported in orthopedics, trauma and thoracic surgery, because in those fields the surgeon faces sharp fractured bones or bony structures in the thoracic cage.⁷ A study by Laine, indicated a 18.3% rate of glove perforation in operations.⁸ Yinusa found a glove perforation rate in nearly half of orthopedic cases, and that the operative team members

(surgeons and nurses) were at significant risk of exposure to patients' body fluid.⁹ There was a lower frequency of glove perforations in laparoscopic procedures, although the rate indicated by the study was still a remarkable 20%.⁸ The treatment of some maxillofacial fractures has an incidence of glove perforation as high as 50%, with over 80% going unnoticed at the time of operation.¹⁰

One third of devices that cause injuries come in contact with the patient after the injury to the healthcare worker, so there is also risk of disease transmission from healthcare worker to patient.² There is a trend in the literature showing that in any type of surgery, a higher percentage of instrumentation is associated with a higher glove failure rate. Injuries are most likely to occur on the non-dominant hand and involve primarily the index finger, followed by the thumb, then the second finger and finally the palm dorsa.⁷

GLOVE WEARER ROLE

Researchers have found significant differences in the glove defect rate depending on the wearer's role in the surgical procedure. Laine's study found that assistants had perforation rates of 7.7% and surgeons had perforation rates of 23.6% out of 284 surgeries.⁸ Other studies describe scrub nurses as being at the highest risk for glove failure, citing a glove perforation rate as high as 40%.² The disturbing thing about all of these statistics is that many of these study participants did not notice the glove defect until the end of the surgical procedure when the gloves were removed, and blood was seen on the hands. Berguer says that most, if not all, surgeons have encountered blood on their hands or fingers at the conclusion of a procedure without awareness of suffering an injury or the occurrence of a breach of the glove barrier by any other method.



Surgery



Surgical Team

TIME OF WEAR – LENGTH OF CASE

The rate of glove perforation appears to be related to the length of surgical time. The longer the surgical case, the greater the chance for a tear in the glove due to a bone fragment or sharp instrument. It has been documented that glove defects are as high as 56% for surgeries that last more than two hours, compared to 20% for surgeries that last less than two hours.¹¹

The risk of glove perforation increases 1.115 (95% confidence interval) times for every 10 minutes of operating time.¹² Perforations are significantly higher for emergency cases than they are for regularly scheduled cases as well. Partecke et al. found a positive correlation between the duration of wear and the incidence of micro perforations and recommended a change of gloves for surgeons, first assistants, and surgical nurses after 90 minutes of surgery.¹³

DOUBLE GLOVING RESEARCH

During surgery, intact gloves act as a protective barrier against bloodborne pathogens such as human immunodeficiency virus (HIV), hepatitis B, and hepatitis C. However, as discussed in the section above, glove perforation is frequent and often unrecognized by the surgeon or nurse. In Quebbeman's 1992 glove study of exposure in the surgical environment, he reported a 51% hand contamination rate for those who single gloved versus a 7% contamination rate for those who double gloved.⁶

The most recent 2014 Cochrane Review reported that "in 12 studies, two pairs of gloves reduced the number of perforations in gloves by 71% compared to the use of one pair of gloves. In three studies, wearing two pairs of gloves was shown to reduce blood stains on the skin of healthcare worker's by 65%." The Cochrane Review also reported further reductions in perforations when three pairs of gloves are worn compared to either wearing a double or single pair of gloves. Additionally, the use of indicator gloves, which enable a colored spot to show when the user's outer glove is perforated, reduced the number of glove perforation in two of the reviewed studies.¹⁴ Overall, the Cochrane Review authors concluded that surgeons and surgical staff wearing two pairs of gloves, rather than one, reduce their risk of being exposed to and contracting a serious viral infection occupationally.



Chapman and Duff reported data on double gloving in obstetrical procedures. Of 67 sets of double gloves studied, 66 holes were found in the outer gloves and seven holes in the inner glove. Their summary found the difference in the frequency of injury of inner and outer gloves to be highly significant. This resulted in new recommendations to double glove routinely in obstetric procedures.¹⁵ Hagen and Arntzen, conducted a study to estimate and compare the perforation risk in different categories of surgery.¹⁶ Perforations were found in 203 out of 655 operations (31%). The observed perforation frequency was 44.5% in gastrointestinal surgery, 34.7% in orthopedic surgery, 31.1% in gynecology, 18.6% in vascular surgery and 9.2% in general surgery.¹⁶

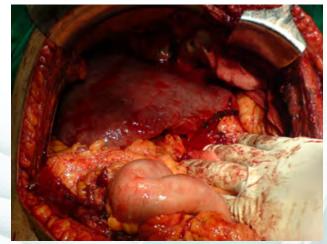
Although puncture of the outer glove is common, corresponding punctures of both the inner and outer gloves are rare. Double gloving reduces risk of exposure to patient blood by as much as 87% when the outer glove is punctured.⁸ Albin found in his studies that double gloves had leaks 25% of the time, while the single gloves had leaks 59% of the time when tested at 15-minute intervals.¹⁷ Another study done by Greco and Garza supported the double glove data, stating that operating room personnel's risk decreased by 70% in comparison with single glove use.¹⁸ All of these studies support the wearing of two pairs of surgical gloves. The practice of double gloving is supported by sound research and data.

HEALTHCARE WORKER RISK AND INJURY

SO IF THE RESEARCH IS SO IMPRESSIVE, WHY ISN'T EVERYONE DOUBLE GLOVING?

One reason could be that HCWs do not fully understand the consequences of blood and body fluid contamination in the form of post-exposure seroconversion. It is essential for wearers to understand their true risk of exposure and the probability of post-exposure seroconversion. The risk for bloodborne exposure and infection is highest in the OR.¹⁹

Many studies show that a large number, and perhaps a majority of OR injuries go unreported. One survey of over 14,000 surgeons and nurses reported in 2004 found that 73% of surgeons failed to report sharps injuries they suffered, and other HCWs did not report 52% of their injuries.²⁰ Every year, an estimated 100–200 injured HCWs die from hepatitis B. Hundreds of others contract hepatitis C, which can be fatal, as well. The risk of acquiring a virus from one percutaneous needle stick is 0.3% to 0.4% for HIV, 6% to 30% for hepatitis B (HBV), and 2.7% to 10% for hepatitis C (HCV).¹¹



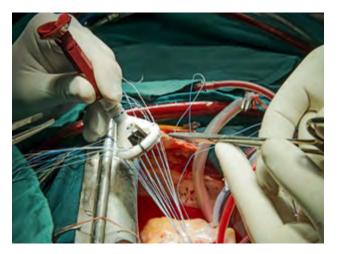
Viral Hepatitis C of the Liver

One study found that a cardiac surgeon with chronic hepatitis B (HBV) transmitted HBV to five of his patients during open-heart surgery.²¹ This surgeon reported a rate of approximately 20 percutaneous injuries per 100 procedures, which were directly related to wire closure of the sternum. He also reported 2 percutaneous injuries per 100 cases, which were associated with sharps.

The surgeon acknowledged that cases of HBV and HIV transmission from infected HCWs to patients had been documented.²¹ Another study reported an outbreak of HBV infection in 19 patients from an HBV-infected thoracic surgery resident. The resident complained of pain on the index fingers after suturing. The resident, who did not double glove, reported glove failure as evidenced by blood on his hands at the end of his cases. During a one-hour suture-tying simulation, the resident got "paper-cut-like lesions" on his fingers, and the HBV surface antigens and DNA were obtained from washings of his hands.²¹

Although double gloving increases the glove budget for a hospital, the reduction of bloodborne pathogen exposure and possible seroconversion of HCWs represents a significant savings to the hospital. "Occupationally acquired HBV infection is common among surgeons; it has been identified as having occurred in 25-30% of operating surgeons who have been in practice of surgery for more than 10 years."¹² Double gloving reduces risk of exposure to patient blood by as much as 87% when the outer glove is punctured.⁷

"Volume of blood on a solid suture needle is reduced as much as 95% when passing through two glove layers, thereby reducing viral load in the event of a contaminated percutaneous injury."⁷



Suturing

Because of the occult nature of intraoperative glove failures, double gloving may prevent occult hand contact with patient blood. Using electronic detection of glove barrier failure, one study estimates that surgeons wearing a single pair of gloves would have contact with patient blood for 42 hours for

DOUBLE GLOVING – A STANDARD OF PRACTICE IN SURGERY every 100 hours of operating time.⁷ Costs of post exposure treatment of an occupationally acquired bloodborne pathogen such as HIV are significant to a hospital. Direct costs include initial evaluation of the healthcare worker, counseling, and evaluation of the source patient, post exposure prophylactics, baseline and follow up pathology tests, clinical monitoring and follow up. In addition, there are indirect costs, which include filing workers' compensation and Occupational Health and Safety reports and other administrative paperwork, potential increase in liability premiums and legal fees. How do you put a cost to these statistics, and the cost of these infections to the future of healthcare? These statistics can be changed with double gloving.

RESEARCH ON CHANGE

Some HCWs and particularly surgeons and OR staff are disinclined to wear more than one pair of gloves. They claim that their dexterity and ability to safely handle and use instruments is compromised or in some way diminished with the addition of an outer pair of gloves.^{11, 22} Multiple studies investigating tactility and sensation both objectively and subjectively have concluded that there is no negative impact on tactility associated with use of double gloves.^{2, 6}

Quebbeman studied this and found that there was an 88% acceptance rate in the group that wore double gloves, and none of the study participants perceived any decrease in tactile sensitivity.⁶ Another study published by Webb and Pentlow looked at the effects of double gloving on tactile sensitivity and dexterity. The double glove testing was conducted several different ways, with the larger glove worn on the inside as well as the larger glove worn on the outside. Surgeons were asked to tie surgical knots and complete the Dellon's moving two-point discrimination test. The findings showed no alteration in two-point discrimination test or in the ability to tie surgical knots.

Surgeons who always or usually double-glove report that a period of 1 to 120 days (2 days in most cases) is required to fully adapt to its use and surgeons who routinely double glove report decreased hand sensation much less frequently than those who do not. It appears that a period of adaptation and retraining is required for physicians to be comfortable with the double gloving technique.²³ Most HCWs need to try several combinations of gloves before they find the right "fit" for their double gloving technique. The consensus in the aforementioned

study was that wearing the larger glove on the outside was more comfortable than wearing the larger glove on the inside.²³ A 2010 study by Fry disputes any negative impact of doublegloving on a surgeon's manual dexterity and tactile sensation. In interviews with 56 surgeons Fry found no difference in dexterity or sensation when no gloves, one pair or two pairs were worn.²⁴



Before Universal Precautions was instituted in the 1980s, nurses did not wear examination gloves for routine patient care. With the change to Universal Precautions it became necessary for nurses to begin to wear gloves to start IV lines. Everywhere across the country, in every hospital, could be heard the same lamenting nurse, "I will never be able to find the vein and start an IV with gloves on!" But guess what? Somehow, some way, it happened. Nurses everywhere around the country, and in every hospital, donned gloves and began starting IVs with gloves on, and began protecting themselves and their patients. A study published in the European Journal of Cardiothoracic Surgery had this to say about wearing gloves and making a change to double gloving. "Given a comfortable size combination, it is likely that during the accommodation period, cortical retraining will occur. The somato-sensory cortex will undergo cortical remapping when challenged with new sensory stimuli. Therefore, the perception of decreased sensation, experienced by the surgeon when first using double gloves, will likely be minimized and overcome with sensory cortical remapping...the surgeon or surgical nurse who is just beginning to use double gloves should try various combinations; when a comfortable fit is found, perceived hand sensibility will likely improve with increased experience using double gloves."2

DOUBLE GLOVING TECHNIQUE

Is there a proper technique for double gloving? Double gloving technique is as personal as the choice of your ice cream flavor. You need to try several different combinations until you find the one that works for you. Some people find that a larger glove inside with a smaller one outside works for them, others use the same size glove for both inside and outside glove. The aforementioned study published in the European Journal of Cardiothoracic Surgery found almost an equal distribution of glove sizes used by surgeons for double gloving: larger glove inside 31%, smaller glove inside 35% and both gloves the same size 31%.²

TWO-COLOR GLOVE SYSTEM

Of significant importance is the fact that glove defects are not identified at the time of the incident in the majority of the cases. Often the impaired barrier integrity is not known until the end of the case when the gloves are removed and the blood on the hand is noted. Wearing gloves of two different colors significantly increases the awareness of perforation.²⁵ When the outer glove is perforated the moisture that seeps through and allows the site of perforation to be more easily seen providing an alert for the wearer making them realize that they must immediately change their gloves. One study found that there were "fewer unnoticed perforations in the glove perforation indication group than the standard surgical glove group," 19% compared with 79%.¹⁰ Other studies have shown similar results.²⁶ As well investigators have reported that frequency of changing gloves among wearers of double gloves is significantly higher when an indicator system was used.²⁷



Should the outer glove perforate, change out both gloves as soon as possible, as the inner glove's integrity may also be lost.

ORGANIZATIONAL RECOMMENDATIONS

There are several very prestigious organizations that are involved with healthcare professionals and concerned with the protection and safety of both the healthcare worker and the patient. The following recommendations have come forth from these organizations.

- The Association of PeriOperative Registered Nurses stated, "Health care practitioners should double glove during invasive procedures."²⁸
- The American College of Surgeons states, "Double gloving does help to cut down by a factor of 10 the number of potential exposures." The ACS also acknowledges that double gloving will offer increased protection to the patient as well.²⁹
- In June 2008, the American Academy of Orthopaedic Surgeons (AAOS) revised its Information Statement on "Preventing the Transmission of Bloodborne Pathogens" and double gloving is recommended.³⁰
- The 1999 CDC Guideline for Prevention of Surgical Site Infection specified, "Wearing two pairs of gloves (doublegloving) has been shown to reduce hand contact with patients' blood and body fluids when compared to wearing only a single pair.³¹
- In 2014 the Australian College of Operating Room Nurses (ACORN) released updated Standards which represent the accepted standard of professional practice for Australian OR nurses. Standard 8 section 8.4 deals with glove use and sub-section 8.4.2 directly stipulates that nurses "comply with the recommended practice of double-gloving when scrubbed for surgical invasive procedures".³²
- The International College of Surgeons (ICS) urges all members to support and introduce whenever possible, standard double gloving with the additional benefit of a perforation indication system for all surgical intervention.³³
- The European Center for Disease and Control (ECDC) encourages the practice of double gloving to reduce hand contact to bodily fluids.³⁴
- The World Health Organization (WHO) recommends double gloving in countries with a high prevalence of HBV, HCV and HIV for long surgical procedures (>30 minutes), for procedures with contact with large amounts of blood or body fluids, for some high-risk orthopedic procedures, is considered an appropriate practice.³⁵

BEST GLOVE PRACTICES

The following points to practice are based on recommendations from Childs³⁶ and other researchers. They are offered here as further prompts and ideas to maximize the quality of infection prevention practice and guarantee patient and HCW safety:

- HCWs should routinely check their gloves for perforations even if they are not obvious.
- Double gloves should be common practice in all major cases and specifically when contamination or extended duration are expected or encountered.
- If double gloves are worn and the outer glove is perforated it is best to change both layers.
- Both viruses and bacteria have been demonstrated as being capable of passing through perforated outer gloves.
- Finding the most appropriate glove combination may require experimentation.
- Required glove resources include a color indicator system and a range of glove sizes.
- Audits should be done regularly to monitor personnel compliance with PPE and glove-wearing recommendations.
- Ensure local policies, protocols and procedures are reviewed as evidence and technology evolves.

CONCLUSION

This study module raises controversial but important questions for infection prevention teams, OR staff and all HCWs to consider in terms of their own occupational health and safety as well as that of the patient. Part of guaranteeing that safety should involve routine use of double gloves in all situations in which the foreseeable risk warrants them.



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