Prevention of Blood Exposure in the Operating Room
Primary Barriers to Safety: a Surgeon’s Perspective

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Chief of Surgery
San Francisco General Hospital
Rabbi Cindy Culpepper

Died of AIDS in 2005 approximately 10 years after an occupationally acquired parenteral exposure while working as an OR nurse at San Francisco General Hospital
Dr. Phil Trabulsy
Dr. Norman Bethune

- Died of streptococcal lymphangitis in 1939
- Occupationally acquired infection in a field hospital in China
Epidemiologic Notes and Reports Update: Human Immunodeficiency Virus Infections in Health-Care Workers Exposed to Blood of Infected Patients

Six persons who provided health care to patients with human immunodeficiency virus (HIV) infection and who denied other risk factors have previously been reported to have HIV infection. Four of these cases followed needle-stick exposures to blood from patients infected with HIV (1-4). The two additional cases involved persons who provided nursing care to persons with HIV infection. Although neither of these two persons sustained needle-stick injuries, both had extensive contact with blood or body fluids of the infected patient, and neither observed routinely recommended barrier precautions (5,6).
57 HCW’s Seroconverting After Occupational Exposure to HIV as of June 30, 2001

<table>
<thead>
<tr>
<th>Occupation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurses</td>
<td>24</td>
</tr>
<tr>
<td>Lab workers</td>
<td>19</td>
</tr>
<tr>
<td>Physicians</td>
<td>6</td>
</tr>
<tr>
<td>Surgical Technicians</td>
<td>2</td>
</tr>
<tr>
<td>Dialysis Technicians</td>
<td>1</td>
</tr>
<tr>
<td>Respiratory Therapists</td>
<td>1</td>
</tr>
<tr>
<td>Health Aids</td>
<td>1</td>
</tr>
<tr>
<td>Morgue Technicians</td>
<td>1</td>
</tr>
<tr>
<td>Housekeepers</td>
<td>2</td>
</tr>
</tbody>
</table>

26 (46%) developed AIDS
Additional unpublished data from CDC

- 2003 – 1 more case reported
- 2004 – no more cases

Personal Communication: Lisa Panlilio, MD
Possible cases of occupational HIV Infection

137 cases of HIV infection or AIDS in HCW’s without known behavioral risk factors who have a history of occupational exposure to HIV infected blood but no proven documentation of the method of HIV transmission

http://www.cdc.gov/hiv/pubs/facts/hcwsurv.htm
Occupationally Acquired HCV Infection

• The precise number of HCW’s with occupationally acquired HCV is unknown
• Average risk of HCV transmission after percutaneous exposure is 1.8%
• Multiple case reports of occupational transmission

http://www.cdc.gov/sharpsafety/toc.html
Figure 2. Work Locations where Blc Fluid Exposures Occurred NaSH 6/95 to 12/01

(n=16,855)*

- Waste/laundry/central supply (1%)
- Labs (5%)
- Other (4%)
- ER (8%)
- OR (25%)
- Inpatient (40%)
- Procedure room (8%)
- Medical/Surgical ward 21%
- Intensive care unit 13%
- Pediatrics ward 2%
- Psychiatry ward - 1%
- OB/GYN 2%
- Nursery - 1%
- Jail unit - less than 1%

*Missing values are not included in the total n.

http://www.cdc.gov/sharpsafety/wk_overview.html#overviewBloodborne
Figure 4. Devices Involved in Percutaneous Injuries
(n=13,731)

- Solid sharp (34%)
- Suture needle (19%)
- Scalpel (7%)
- Other (8%)
- Hollow-bore needle (59%)
- Glass (2%)
- Other/unknown (6%)

Hypodermic needle: 32%
Winged-steel needle: 12%
Phlebotomy needle: 6%
Other hollow-bore needle: 3%
Vacuum tube holder/phlebotomy needle assembly: 6%

*CDC*
Blood Exposure in OR at SFGH

- Observational study of 1307 consecutive cases August-October 1988
- 6.4% blood exposure rate
- 1.7% parenteral exposure rate
- Estimated HIV seroconversion due to blood exposure in OR once every 8 years

NEJM 1990;322:1788-1793
Total HCW Blood Exposures at SFGH

<table>
<thead>
<tr>
<th>Year</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>178</td>
<td>170</td>
<td>148</td>
<td>136</td>
</tr>
</tbody>
</table>
## Total HCW Blood Exposure in SFGH OR

<table>
<thead>
<tr>
<th></th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>MD/Med Student</td>
<td>19 (17 parenteral)</td>
<td>32 (30 parenteral)</td>
<td>32 (29 parenteral)</td>
<td>22 (19 parenteral)</td>
</tr>
<tr>
<td>Total</td>
<td>27</td>
<td>37</td>
<td>34</td>
<td>36</td>
</tr>
</tbody>
</table>
## Total HCW Blood Exposure in SFGH ER

<table>
<thead>
<tr>
<th></th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>33</td>
<td>31</td>
<td>36</td>
<td>28</td>
</tr>
<tr>
<td>MD/MS</td>
<td>18</td>
<td>14</td>
<td>24</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>(15 parenteral)</td>
<td>(11 parenteral)</td>
<td>(15 parenteral)</td>
<td>(7 parenteral)</td>
</tr>
</tbody>
</table>
Blood or other body fluid contact with skin and mucus membranes is unacceptable!
The technology to significantly reduce the risk of exposure to blood and body fluids already exists.
Are Surgeons using these techniques?

• 90% of intra-operative blood exposures at Grady Memorial Hospital were potentially preventable (Panlilio AL et al. JAMA 1991;265:1533-7)

• Less than 40% of surgeons surveyed at 2 Eastern Hospitals used appropriate infection control precautions (Mandelbrot et al. Surg Gynecol Obstetr 1990;171:99)
### UCSF Surgery Faculty Survey
February 2006

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of surveys sent:</td>
<td>75</td>
</tr>
<tr>
<td>Number of responses received:</td>
<td>33</td>
</tr>
<tr>
<td>Response Rate:</td>
<td>44%</td>
</tr>
<tr>
<td>Number of respondents who routinely use double gloves:</td>
<td>18</td>
</tr>
<tr>
<td>Percentage of respondents who routinely use double gloves:</td>
<td>54%</td>
</tr>
<tr>
<td>Number of respondents who routinely use blunt needles for fascial closure:</td>
<td>21</td>
</tr>
<tr>
<td>Percentage of respondents who routinely use blunt needles for fascial closure:</td>
<td>64%</td>
</tr>
<tr>
<td>Reason</td>
<td>Count</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Numbness</td>
<td>3</td>
</tr>
<tr>
<td>Don’t like feel of two gloves</td>
<td>1</td>
</tr>
<tr>
<td>Don’t double-glove for laparoscopic cases</td>
<td>1</td>
</tr>
<tr>
<td>Limits tactile feedback for pediatric cases</td>
<td>1</td>
</tr>
<tr>
<td>Not the standard when trained</td>
<td>1</td>
</tr>
<tr>
<td>Reduced sensitivity due to carpal tunnel</td>
<td>1</td>
</tr>
<tr>
<td>Single glove only</td>
<td>1</td>
</tr>
<tr>
<td>Too restrictive</td>
<td>1</td>
</tr>
<tr>
<td>Only when patient is high-risk</td>
<td>3</td>
</tr>
<tr>
<td>Lack of sensitivity</td>
<td>1</td>
</tr>
<tr>
<td>Not proven effective – why not double or triple glove?</td>
<td>1</td>
</tr>
<tr>
<td>Reason</td>
<td>Count</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Used only by housestaff</td>
<td>1</td>
</tr>
<tr>
<td>Not available</td>
<td>7</td>
</tr>
<tr>
<td>Rarely close abdomen</td>
<td>1</td>
</tr>
<tr>
<td>Never seen them in hospital</td>
<td>1</td>
</tr>
<tr>
<td>Not available for pediatric surgery</td>
<td>1</td>
</tr>
<tr>
<td>No experience with blunt needles</td>
<td>1</td>
</tr>
<tr>
<td>Never go into the habit of using them</td>
<td>2</td>
</tr>
<tr>
<td>Never considered using them but might try them</td>
<td>1</td>
</tr>
<tr>
<td>No need to use</td>
<td>1</td>
</tr>
<tr>
<td>Never heard of them</td>
<td>2</td>
</tr>
<tr>
<td>Did not know they were being used routinely</td>
<td>1</td>
</tr>
<tr>
<td>Have used them intermittently</td>
<td>1</td>
</tr>
<tr>
<td>No reason</td>
<td>3</td>
</tr>
</tbody>
</table>
Why don’t surgeons take proper precautions?

• Risk Taking Personality
• Perception that they are not at risk
• Perception of conflict between patient care and personal protection
• Reluctance to change “proven” methods of care
• Interest in “Blood-borne Infections” has declined in the past 5 years at the Annual Clinical Congress of the American College of Surgeons

www.cdc.gov/sharpssafety/workbook.html
What can be done to reduce Sharps Injuries in the Peri-operative Period?

• Education (probably diminishing returns at this point)
• Make the recommendations of the ACS re: Prevention of Sharps Injuries Joint Commission requirements
• Mandate that all procedure kits have needle protection devices
• Mandate use of safety scalpels (technology needs improvement before this is practical)
NIOSH Recommendations

• Avoid the use of needles where safe and effective alternatives are available.
• Help your employer select and evaluate devices with safety features.
• Use devices with safety features provided by your employer.
• Avoid recapping needles.
• Plan for safe handling and disposal before beginning any procedure using needles.
NIOSH Recommendations

• Report all needlestick and other sharps-related injuries promptly to ensure that you receive appropriate followup care.

• Dispose of used needles promptly in appropriate sharps disposal containers.

• Tell your employer about hazards from needles that you observe in your work environment.

• Participate in bloodborne pathogen training and follow recommended infection prevention practices, including hepatitis B vaccination.
Prevention Strategies

- Blunt Suture Needles
- Double Gloving
- Neutral Zone
- ESIP Devices
Blunt Suture Needles for Closure of Muscle and Fascia

- 59% of suture needle injuries occur during suturing of muscle and fascia
- Blunt suture needles are suitable for closure of muscle and fascia and are associated with a very low rate of percutaneous injury to HCWs
Prevention Strategies

- Blunt Suture Needles
- Double Gloving
- Neutral Zone
- ESIP Devices
The rationale for double-gloving

- Perforation rates: 40-61%
- Intra-operative glove perforation is not detected in 83% of cases
- As many as 13 - 17% of OR staff have damaged skin on their hands preoperatively
- The FDA permits a failure rate of 2.5% for unused sterile gloves, determined by the standardized “water load test”
- Data on newer glove testing methods (electrical conductance testing) indicate that older data on intraoperative glove failure (determined with the water load test) may grossly underestimate its true incidence
The rationale for double-gloving

- Double gloving may prevent prolonged occult contact with patient’s blood
- Double-gloving may protect the patient as well as the healthcare worker
- Punctures of both the inner AND and outer gloves are uncommon
- Double gloving reduces the risk of hand exposure to patient blood by as much as 87% when the outer glove is punctured
- The volume of blood on a solid suture needle is reduced when it passes through two gloves instead of one
Prevention Strategies

- Blunt Suture Needles
- Double Gloving
- Neutral Zone
- ESIP Devices
“Avoid accidents and self-wounding with sharp instruments by following these measures:

- Do not recap needles.
- Use needleless systems when possible.
- Use cautery and stapling devices when possible.
- Pass sharp instruments in metal tray during operative procedures.”

“AORN 2001 Standards, Recommended Practices, and Guidelines pg 297-298

“Surgical team members should use hands-free techniques whenever possible and practical instead of passing needles and other sharp items hand to hand….Changes in surgical practice to minimize manual manipulation of sharps (i.e., no touch techniques) can have a major impact on these injuries……Creation of a neutral zone (i.e., where instruments are put down and picked up, rather than passed hand to hand) may decrease injuries from sharp instruments.”
“Neutral Zone” or Hands-free Technique (HFT)

• A previously agreed upon location on the field where sharps are placed from which the surgeon or scrub can retrieve them. Therefore, hand-to-hand passing of sharps is limited.
HFT variations

• Can be used to pass any sharp objects

• Partial HFT:
  – Scrub hands sharps (needle driver) to surgeon
  – Surgeon returns sharps to neutral zone
Prevention Strategies

Blunt Suture Needles
Double Gloving
Neutral Zone
ESIP Devices
ESIP devices

- Safety scalpels
- Suturing devices
Interventions to consider

ACS
Evidence-based
Other suggestions
“Sharpless surgery”
American College of Surgeons

• “The ACS recommends **routinely using double glove technique**…”

• “The ACS supports **the routine use of blunt suture needles** during the closure of fascia and muscle …”

• “The ACS nevertheless recommends the use of **HFT as an adjunctive safety measure** to reduce sharps injuries during surgery except in situations where it may compromise the safe conduct of the operation.”

• “…**ESIP devices may contribute to minimizing sharps injuries in the OR.**”
Evidence-based high yield interventions to consider

- **Gloves:**
  - Always double glove.
  - Change gloves at intervals throughout the procedure, particularly during longer, high blood loss procedures.
  - Use an indicator system to determine if a perforation or other breach of the barrier has occurred.

- **Needles:**
  - Use blunt suture needles where appropriate.
  - Avoid straight suture needles.
  - Avoid directly manipulating needles with the fingers, when possible.
  - Use forceps, not fingers, to hold tissue for suturing, when possible.
  - Do not recap hollow bore needles.

- **Passing Sharps:**
  - Pass all sharps via a neutral zone when appropriate.
Other interventions to consider

- **Always** wear adequate eye protection
- Develop a standardized method for transferring sharps in your OR
- Dispose of sharps as soon as possible after use
- Use retractable or resheathing scalpels
- Remove unnecessary sharps from the surgical field.
- Avoid placing hands into surgical field without communication with team members
- Constant monitoring and evaluation of workers’ practices by supervisors may help reduce injuries
“Sharpless” Surgery

- Martin Makary, M.D., M.P.H.

- Techniques:
  - Laparoscopy, electrocautery, skin clips or glue, blunt needles, ESIP
END

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User Based Design:
Preventing occupational Exposure
to Blood in Surgery

June M. Fisher, MD
Associate Clinical Professor of Medicine, UCSF
Director, TDICT Project

UCSF Surgical Grand Rounds, March 29, 2006
Training for the Development of Innovative Control Technologies Project
The TDICT Project is a collaborative effort of health care workers, product designers and industrial hygienists dedicated to preventing exposure to blood borne pathogens through the design and evaluation of control technology.
Major Collaborating Institutions

• NIOSH
• San Francisco General Hospital
• Product Design Program, School of Engineering, Stanford University
• Industrial Hygiene Program, University of California, Berkeley
• Sharps Committee, San Francisco General Hospital
• Dental School, University of the Pacific
• Department of Surgery, UCSF
• Bay Area Visiting Nurses Homecare Agencies
• American Nurses Association
• Occupational Health Branch, California State Department of Health
• Patient Safety Center, Veterans Administration Hospital, Tampa, Fl
• Veteran’s Administration Hospital, Brooklyn, New York
• Department of Surgery, San Francisco General Hospital
Why Involve Clinicians in All Phases of Control Technology Development?

- Tap their expertise
- Assure that product’s are user-friendly and truly effective
- Develop systems that improve compliance
- Improve patient care
TDICT’s Research Methods

- Observations
- Work analysis
- Data analysis
- Product evaluation and testing
- Focus groups
- Design evaluation course for HCWs
- Brain Storming of trained users with Product Design Engineers and IHs
Outcomes Include:

• Criteria for safety feature of sharps devices
• Performance standards
• Systematic simulation methods
• Systematic user-based methods for evaluation, selection, and implementation of safer medical devices
• Task analysis instrument
Web Site / Contact

www.tdict.org

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415-641-4163
Example of a User Based Safety Criteria sheet
SAFETY FEATURE EVALUATION FORM
SAFETY SYRINGES

Date: ____________ Department: ________________________ Occupation: ________________________

Product: ________________________ Number of times used: ________________________

Please circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

DURING USE:

1. The safety feature can be activated using a one-handed technique...agree disagree 1 2 3 4 5 N/A
2. The safety feature does not obstruct vision of the tip of the sharp...agree disagree 1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature...agree disagree 1 2 3 4 5 N/A
4. This product does not require more time to use than a non-safety device...agree disagree 1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes...agree disagree 1 2 3 4 5 N/A
6. The device is easy to handle while wearing gloves...agree disagree 1 2 3 4 5 N/A
7. This device does not interfere with uses that do not require a needle...agree disagree 1 2 3 4 5 N/A
8. This device offers a good view of any aspirated fluid...agree disagree 1 2 3 4 5 N/A
9. This device will work with all required syringe and needle sizes...agree disagree 1 2 3 4 5 N/A
10. This device provides a better alternative to traditional recapping...agree disagree 1 2 3 4 5 N/A

AFTER USE:

11. There is a clear and unmistakable change (audible or visible) that occurs when the safety feature is activated...agree disagree 1 2 3 4 5 N/A
12. The safety feature operates reliably...agree disagree 1 2 3 4 5 N/A
13. The exposed sharp is permanently blunted or covered after use and prior to disposal...agree disagree 1 2 3 4 5 N/A
14. This device is no more difficult to process after use than non-safety devices...agree disagree 1 2 3 4 5 N/A

TRAINING:

15. The user does not need extensive training for correct operation...agree disagree 1 2 3 4 5 N/A
16. The design of the device suggests proper use...agree disagree 1 2 3 4 5 N/A
17. It is not easy to skip a crucial step in proper use of the device...agree disagree 1 2 3 4 5 N/A

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions which you feel should be asked regarding the safety/ utility of this product?
Safety Feature Evaluation Forms

- Tool for healthcare worker evaluation and selection of design
- Included in the OSHA 2001 compliance document for the Blood Borne Pathogen Standard
- Included in the British And Scottish NHS’s BBP websites
- Industry benchmarks
Interrelationship Between Patient and Healthcare Worker Health and Safety
• From TDICT Recommendations to NIOSH, for Research and Action
  September, 2005

• Develop a Surgical Focus
Why Focus on Surgery

• Have the highest rates of sharps injuries
• To promote patient safety - are the clinicians who have the most likelihood of transmitting BBP to patients
• Surgical teamwork exposes other HCWs
• Diversity of procedures is a challenge
• Have some legitimate reasons for not using current technology
• Limited evidence for some suggested procedural changes

• Many unmet safety device needs
Strategies to Promote Occupational Safety in the OR

Short term goals:

Develop User Based Criteria for Safety Scalpels

Identify list for other needed user based safety toolled instruments/ devices
Strategies to promote safety in the OR:

Long Term Goal:

Develop an UCSF Center to Promote occupational Safety in Surgery