This document is a compilation of notes from five conference sessions, provided by volunteer “scribes” Amber Hogan (day 1, session 4), Gina Pugliese (day 1, session 5), Cathie Gosnell (day 1, session 6), Dionne Williams (day 1, session 7), and Elise Handelman (day 2, session 2). The conference organizers hoped to recruit a scribe for each of the 11 conference sessions, but this proved overly ambitious. We are grateful to our five volunteers for their efforts in writing up and sending in these notes.

Further resources are available on the conference website, including a video of the keynote address by John Howard and each speaker’s Powerpoint presentation. Visit http://www.healthsystem.virginia.edu/pub/safetycenter/safetycenter/internetsafetycenterweb pages/nspaconference/nspaconference.html.

Session 4: “OSHA’s Bloodborne Pathogens Standard: Challenges of Effective Enforcement” -- notes by Amber Hogan

Elise Handelman:
- Kudos to Elise Handelman from Janine Jagger for being a strong advocate for healthcare worker (HCW) safety. Much early work was initiated through interactions between International Healthcare Worker Safety Center (IHWSC) and OSHA.
- 1927 - re-publication of NEJM article of research areas for nursing profession. “There is the matter of the hypodermic…” As then, today there is the need for safe, simple, quick devices… we are still on the quest.
- Washington Post – the “well-armed medic” - #16 on list is needle disposal container.
- Introduction of panel on OSHA policy, enforcement, and labor/union perspective
- Jordan Barab – DOL OSHA, Deputy Assistant Secretary. Seen issue from all angles, union, Hill staffer, blogger, leading OSHA strategic planner. Lifelong worker advocate.
- Katherine Cox – safety and health for AFSCME. Has worked on behalf of HCWs. Will address challenges of NSPA on behalf of workers.

Dionne Williams:
- OSHA Bloodborne Pathogens Standard (BPS) is the most frequently cited OSHA standard. Gets the most questions, emails, and phone calls than any other standard; even during the BP Gulf Coast oil spill.
Setting priorities – unprogrammed inspections are highest inspection driver, of which compliants drive the most. Prior to NSPA, 70% were unprogrammed; post NSPA 51%. The 805- SIC has the highest numbers of inspections (nursing and long-term care).

BPS timeline: 1991 initial rule promulgated. Engineering controls required, but difficult to enforce as little specific guidance published. 2001 revised rule didn’t change requirements for engineering controls, rather incorporated specificity, including annual review of SESIPs.


2001-2010: #1 review and update ECP (annual review), #2 engineering controls, #4 soliciting input from frontline HCWs

Willingness on part of the employer really determines how much work on enforcement OSHA needs to do.

Reusable blood tube holders (2002-2009); large labs are reusing tube holders for blood collection; standard prohibits needle removal; OSHA developed compliance guidance that single-use tube holders must be used without removing needle. Citations were issued and contested. Example of changing nature of enforcement based on standard and technology (availability of SESIPs).

Important lesson learned – OSHA enforcement operates efficiently because of support from professionals in field, research, surveillance, etc. from professionals in field.

Ahead… still gaps, still much to be done in enforcement. More discussion of HCW and patient safety hand-in-hand.

**Jordan Barab:**

- Working on HCW issues for a long time. 1982 AFSCME, first issues were HCW safety related. HIV workshop in 1983.
- Hazards include – infectious diseases, workplace violence, antineoplastics, musculoskeletal disorders (MSDs), etc. All they have in common = no OSHA hazard-specific standard
- Early barriers -- Physicians said in early days that PPE would inhibit practice of medicine.
- BPS → AFSCME and SEIU petitioned OSHA in 1980s to develop infectious disease standard. Also first standard specific to healthcare.
- 1991 BPS standard did deal with engineering controls. Took stigma away from blaming healthcare workers for being stuck because they were careless.
- NSPA through regulation – bringing employees into the fold. Setting up excellent model that employees provide best knowledge of hazards and controls.
- Role of regulations → prime example that regulation works. Might be better suited to be called “Legal Protections for Workers”. Beneficial worker protection also saves money.
- No progress comes without organizing. Science is essential with organizing and union petitions.
- NSPA wouldn’t have gone anywhere without organizing. Kudos to Borwegen and SEIU.
- Congress passed NSPA unanimously.
- BBP still only standard that deals with infectious disease. Now on to SARS, MRSA, flu, etc. These hazard areas need more attention. Infectious disease standard is on OSHA regulatory agenda – potential to have OSHA enforce CDC guidelines (per BPS model).
- Ahead… much more to do related to science and organizing.

**Katherine Cox:**

- Previous work; trying to increase HBV vaccine among HCWs.
• Will be exploring as Dr. Howard mentioned… the “wild west” of healthcare… home health.
• Would be nice to look back and say we made the same progress in home health that we did in acute care. Need to elevate home health on radar.
• 7.6million people receive care in home.
• Who? Elderly, chronic, those with disabilities, patients monitored short-term after hospital discharge
• Providers? Formal: nurses, nurses aides, personal care Informal: >1 in 5 households provides care to someone older than 18
• Who pays? Largest % is Medicare, then Medicaid, state/local government, private insurance
• Will be more people receiving care in homes in future. Huge incentives to reduce costs; movement to care in centers other than acute care.
• Lack of good data re: home health, lack of reporting mechanisms, geographical isolation if exposure, gaps in training
• Home care per OSHA inspection data is least inspected healthcare sector
• Other hazards – MSDs, latex, violence, stress, secondhand smoke. Overall, a dangerous place to work.
• Exposures: nurses – needles from injection, iv, blood collection. Aides – improperly disposed sharps, diabetes devices, waste, wound care
• Challenges – difficult to control home environment; potentially given unrealistic recommendations that suite acute care and not home care (e.g. immediately seek post-exposure followup after an sharp incident)
• Need protocols in place that make sense given the environment/setting of care
• What needs to be done? Increase use of safety devices, increase training to use devices, increase training to identify hazards.

Q&A:
• Comment – applause to OSHA for being proactive partner in HCW safety
• Comment – incorporate CMS and Joint Commission standards on sharps safety
• Comment – many non-safety sharps enter homes through patient prescriptions because CMS does not reimburse for safety injection devices.

Session 5: Gaps in Safety-Engineered Medical Devices- Improving Uptake, Seeking Innovation – notes by Gina Pugliese

Moderator: June Fisher, MD; Training for Development of Innovative Control Technologies (TDICT) Project and Trauma Foundation, San Francisco

June Fisher, MD: Task Analysis: A User-Based System to Identify Unmet Needs
• To achieve zero needlesticks will require frontline HCW collaboration with material scientists, product design engineers and industry
• A frontline healthcare worker (HCW) evaluation and selection and institutionalization of safety devices requires a task analysis that includes usability testing and evaluation of efficacy. Components include:
  • Screening of the devices using specific criteria
• Failure analysis
• Testing of device using scenarios
• Repeat of failure analysis
• Pilot testing in the workplace
• Evaluation of worker and patient outcomes and acceptability

• A task analysis can provide an inventory of sharps and clinical procedures using sharps, changes in clinical procedures; use of unprotected sharps use; a means to compare units; identification of needs for new devices.

• Additional strategies for success:
  • Frequent and multiple training is necessary
  • Network with other facilities
  • Organizational commitment for a culture of safety
  • Remove old technologies
  • Work with resistant team members
  • Review current research with the team members

• Visit www.TDICT.org for sample documents/forms, including clinical procedure forms, task analysis procedures, forms for tasks analysis of kits and trays

**Bruce Cunha** RN, MS, COHN-S, Manager of Employee Health and Safety, Marshfield Clinic, Marshfield WI

• Observed a drop in needlestick injuries in their facility, but most reported needlesticks are occurring in ambulatory care.

• Continued challenges: Still finding sharps hidden in drawers; sometimes difficult to determine if lack of compliance with use is related to a poorly designed product or they just don’t like it.

• Gaps in availability of safety devices include:
  • bone marrow needles
  • spinal needles
  • Needles for bariatric patients, e.g., those with 30 inch knee joint (sometimes need to use a spinal needle)
  • Needle extenders for cervical injections
  • Accupuncture

**Angela K. Laramie**, MPH, Project Coordinator/Epidemiologist, Massachusetts Sharps Injury Surveillance Program, Massachusetts Department of Public Health (MDPH)

• All hospitals licensed by MDPH are required to maintain a log of sharps injuries for each calendar year, and submit that log annually to MDPH. All licensed hospitals have complied and more than 3,000 sharps injuries have been submitted to MDPH.

• More than half of all injuries occur with devices lacking sharps injury prevention features. In 2008, when that figure was adjusted to exclude suture needles, more than 40% of injuries occurred with devices lacking sharps injury prevention features. Over time, the proportion of injuries involved devices with sharps injury prevention features has increased, likely reflecting greater use of such devices.

• Sharps injury rates have decreased over time since 2002, when evaluated using the number of licensed beds as the denominator. (In Massachusetts, occupancy is highly correlated with the number of licensed beds.)
  • 2002: 19.1 sharps injuries / 100 licensed beds
  • 2008: 17.2 sharps injuries / 100 licensed beds
• average annual decline of 2.5% (p<0.001)
• overall decline of 12.5%
• Device specific analysis was conducted for hypodermic needles/syringes, winged steel needles, IV stylets, and suture needles. Alternatives with sharps injury prevention features are widely available for all but suture needles.
• For both hypodermic needle/syringes and winged steel needles, as the proportion of injuries with devices with sharps injury prevention features increased (which can be seen as a proxy for use), the rate of sharps injuries decreased. (However, this was statistically significant only for winged steel needles)
• Approximately 20% of injuries between 2006 and 2008 occurred with devices from pre-packaged kits; 56% of those involved devices lacking sharps injury prevention features (when suture needles were excluded, that percentage dropped only to 48%).
• Main messages:
  • While the count of sharps injuries has remained relatively constant since 2002, the rate has decreased significantly over time.
  • There is much room for improvement in reducing the number of devices in use which lack sharps injury prevention features.
  • Prepackaged kits continue to be a source of devices lacking sharps injury prevention features.
  • The increase in the proportion of injuries involving devices with sharps injury prevention features raises questions about the need for additional training in the use of those devices or the need for better design of the sharps injury prevention mechanisms.

Cathie Gosnell, RN MS MBA, Clinical Consultant, Premier Safety Institute, Premier Healthcare alliance.

• Challenges to achieving 100% compliance with Safety-engineered medical devices (SMDs) and zero needlesticks include: gaps in devices and consistent utilization and implementation in some settings
• Gaps in device types, designs and uptake include
  • Arterial line catheters; Huber needles; epidural and spinal needles, biopsy needles, safety ophthalmic blades, acupuncture needles
  • More safety devices needed for nuclear medicine, dental procedures and home care
  • Safety procedure trays – available, but typically do not include a safety version of the procedure needle
• Need to evaluate whether gaps in devices are institution specific vs. market availability
• Move toward passive, automatic or semi-automatic designs that have been shown to be more effective in reducing risk of needlestick
• Challenges with implementation:
  • Lack of awareness (eg blunt suture needles – multi-center study on efficacy done in 1997 (CDC/MMWR, 1997)
  • Significant education required to use some devices
  • Need to enforce compliance
  • Need front-line worker input to select preferred devices to increase compliance
• Strategies to improve selection and use:
  • Organizational safety culture – for patients and workers
• Annual and on-going review of devices in use and on the market
• Product fairs so all frontline workers have the opportunity to survey the market
• May need different devices for different procedures / clinical settings
• Conduct a root cause analysis for every needlestick to gather information on issues/barriers (e.g. change product, more education, or management.


- There has been a steady increase in U.S. market share for safety-engineered sharp devices compared to non-safety devices for IV catheters, phlebotomy devices and needles & syringes from 1998 – 2009 (market share being a proxy for conversion from conventional to safety devices). These three categories of safety devices have a market share of 80% or more. Conversion to safety devices continues to be slower in alternate site facilities compared to acute care facilities. For example, for peripheral IV safety catheters, adoption in acute care is approximately 96% compared to only 89% in alternate sites.

- A recent study by Tosini and colleagues published in Infection Control and Hospital Epidemiology evaluated the efficacy of various types of safety-engineered sharps injury prevention (SESIP) devices in 61 French hospitals. This is one of the first large scale studies comparing one SESIP device to another. Results indicated that devices with automatically activated safety features (also known as passive) and semi-automatic devices were ten times more effective in preventing sharps injuries compared to devices that require active engagement of the safety feature.

- OSHA requires front line workers to evaluate and select safety devices. A variety of factors and performance considerations influence the preferences of workers. In a study conducted by the Premier Safety Institute®, 875 clinicians in 30 hospitals assessed the performance considerations of 10 different types of syringe and phlebotomy devices (34,075 devices). The top 10 performance considerations identified by study participants follow. It was noted that for syringes, the ability of syringe to deliver an accurate dose was identified as more important than the safety feature.

- Top ten performance considerations for phlebotomy devices
  1. Reliable safety feature
  2. Easy to use - simple
  3. Easily disposed in sharps container
  4. Does not interfere with blood draw
  5. No risk of spray or drip
  6. Satisfactory for standard procedures
  7. One handed
  8. Visualize procedures
  9. Range of sizes available
  10. Use on heavy, thin, fragile veins

- Top ten performance considerations syringes
  1. Accuracy of dose
  2. Reliable safety feature
  3. Hands remain behind needle
  4. Visibility of medicine
  5. Exposed sharp covered after use
  6. One-handed
  7. Does not interfere with procedure
  8. Simple and self evident
  9. Range of syringe and gauge size
  10. Does not take more time to activate
Free and publicly available resources from the Premier Safety Institute include a comprehensive web site on sharps injury prevention, a 12-page needlestick prevention brochure for worker education, and the revised CDC sharps injury prevention workbook (in CD and pdf) download at www.premierinc.com/needlestick.

Session 7 - Surgical Sharps Safety panel - notes by Dionne Williams

Dr. Ramon Berguer:
- 1980’s – HIV/AIDs awareness sparked a shift from considering it a badge of honor to be covered with blood.
- Where are we? We need to combine effort from: Needlestick data; 2) professional societies; 3) industry; and 4) government
- Data: NaSH data shows an estimated 50-80,000 suture needle injuries; approx. 25% of all sticks in hospitals occurring in the operating room. Hopkins data shows that up to half of all OR patients are infected with bloodborne illnesses.
- Sharps risks: there’s shared risk by all members of the surgical team.
- If we could eliminate suture needles we would decrease approx. 40% of sticks particularly to nurses and OR techs who are more often stuck by devices used by others (77.2% and 85.1% respectively).
- Professional Societies: Safer surgery promoted by associations such as AORN, ACS, AST, AANA etc. The ACS usually is not in favor of telling its members what to do and yet has made several statements available on the ACS website promoting safer practices including double gloving.
- National strategies recommended – (ACGME, AORN, ACS, AST, CSPS) – professional society leadership in crafting a “bundle” and providing training; should make it a policy for all ORs to use safety devices and require doctors to comply if they want to work in a particular facility.
- Local hospital enforcement is important in implementation of OR sharps policies
- Government: We need regulatory pressure
- Industry: We need to improve market penetration of safety devices; need industry support and marketing innovation.

Speaker 2 - Charlotte Guglielmi:
- AORN and Sharps Safety: Upcoming perioperative nurse week – training nurses on how to speak up when unsafe actions are done in OR
- Ways of overcoming obstacles: a) having frequent and multiple training methods; b) multidisciplinary sharps injury prevention plan; c) educating new employees and residents on sharps safety; d) create a culture of safety; e) collaborate with personnel.
- Tools to help develop the business case for implementation include a) rapid learning education tools; b) resources for evaluating sharps – templates for sutures and scalpels; c) CSPS safe surgery principles.

Speaker 3 - Brett Sarnoff – Ethicon:
- Available devices: sutures; dermabond (eliminates the need for suturing skin); blunt suture needles; other needless closures; Plus A antibacterial sutures.

**Speaker 4 - Dr. Mark Davis:**

- 1990’s heightened awareness of HIV & HCV. Sentinel event – deep scalpel blade injury and exposure to possible HIV and blood; delayed testing and no safety devices available at the time. Improvement with adopted use of blunt sutures and other options available for procedures for which blunt sutures are not appropriate (e.g., staples – bowels; dermabond – skin)
- *Spectrum of Awareness:* goes from those already on board through to those that miss the safety meetings altogether. Use of blunt sutures among US surgeons - approximately 5% vs. approximately 65% in Japan – this suggests a fundamental difference in safety culture.
- *Drivers to change with surgeons:* 1) lowering complications; 2) saving time; 3) reducing costs; 4) procedures, techniques, devices; 5) linking safety device use to getting paid.
- *Occupational safety risk is not a change agent for surgeons.*
- Obstacles to change include denial of occupational risk.
- *Surgical personality:* surgeons are highly trained, independent thinkers and not especially subject to peer pressure.
- What’s needed: (A) *soft solutions* (e.g., frequent random inspections by OR managers; sign displaying number of days without injuries; publishing quarterly data on injuries; sharing personal stories).
- Also, need (B) *hard solutions* (e.g., written OR personnel safety policy; detailed list of required safety devices, neutral zone, PPE etc; require that any deviations from policy must be explained; suspension of privileges; training of new hires and annual review in a sit-down classroom). Need to hold surgeons accountable somehow e.g., through a letter from the CEO communicating that OR safety devices are required for OR privileges. Future of Medicare/Medicaid – payment incentives, where payments are linked to value; should link Medicare/Medicaid payments to hospital compliance with OSHA.

**Comments:**
- Recommend removing the idea about posting signs for the number of days without needlestick injuries as this might encourage underreporting
- Since blunt sutures are the only devices with cost benefits that can be documented, it is recommended that more be done to increase use of these devices.
- Recommend using alternate terminology for “blunt” sutures

**Day 2:**

**Session 2 – Sharps injuries in the EU/Gabriella – Elise Handelman, note-taker**

- The goal of the Italian surveillance is to define the problem.
- HBV:
  - The prevalence of HBV is significantly higher in Europe than in the U.S.
  - Mandatory vaccination is rare, usually only for nurses and physicians.
  - Where vaccination is mandatory, the compliance rate is only ~ 65%. Hopefully, this will increase with the birth vaccinations now in place.
• HCV:
  o Also widespread throughout Europe.
  o Italy is a prime area with prevalence in some areas as high as 25%. The highest prevalence is in Germany where immigration has affected the rates.
  o There has been no decrease in sero-conversions post exposure (question of treatment?).
  o The highest risk continues to be blood filled syringes.
  o The highest prevalence is in those over age 65 years.
  o 30% of those exposed sustained psychological outcomes following exposure/sero-conversions.

• HIV:
  o Prevalence is also high throughout Europe.
  o Sero-conversion following exposures have decreased as a result of post-exposure treatment. This was particularly evident between 1994-2006.

• Needlesticks:
  o Between 1994- Dec 2009, Italy recorded 86,552 exposures. Nearly 75% were percutaneous.
  o 410,000 were nurses; 213,000 were physicians; 590,000 were other workers (housekeeping, etc.).
  o Dr. DeCarli projects over 5 million needlestick injures in Europe.
  o Under-reporting by nurses in estimated at 28%.
  o Both Italy and Spain began awareness campaigns to encourage reporting.

• Legislation:
  o The existing legislation in Europe has had mixed results.
  o New legislation (“Framework”) for EU is unique: workers, nurses, trade representatives, administrators and managers met to identify ways to reduce injuries BEFORE the regulations were written, then presented them for legislative action which occurred rapidly.
  o Spain was able to demonstrate a significant cost saving with use of safer devices. Spain documented a 65% reduction in NSI.
  o Many countries still do not participate in the Framework. Most “High Level Isolation Units” in Europe (N= 41) do use the Framework.

The new “Framework” document includes students and contractors. Key components include:

  o “No blame” culture – workers are not fired for reporting.
  o Risk assessment – including work organization
  o Practice changes (SESIPS and banning recapping)
  o Use of sharps containers
  o Training
  o Open communication
  o Reporting mechanism
  o Injured workers to receive follow up and treatment

Comments from participants during the Q & A:

• Surgeons in the UK are REQUIRED to be immune to HBV.
• Italy is not using safety (blunt) suture needles.
Scandinavian countries are using SESIPS less because their rates of BBP in the population are relatively low; but HCW travel throughout Europe and immigration continues, so a law is needed to protect HCWs. Sweden has low levels of vaccination among immigrants.

ARTISTIC DRAWING SHOWN WAS VERY MOVING AND MANY ASKED FOR A COPY.

There are still some needs for conventional needles.

Some discussion about optimal treatment for HCV—“wait and see” may not be needed if genotype is identified. 12 weeks of medications are now thought to be effective in some cases.