

# **Sharps Injuries among Hospital Workers in Massachusetts, 2008**

Findings from the Massachusetts Sharps Injury Surveillance System



**Deval L. Patrick, Governor**  
**Timothy P. Murray, Lieutenant Governor**  
**JudyAnn Bigby, MD, Secretary, Executive Office of Health and Human Services**  
**John Auerbach, Commissioner of Public Health**

**Letitia K. Davis, Sc.D., Director, Occupational Health Surveillance Program**  
**Alfred DeMaria, Jr., M.D., Medical Director, Bureau of Communicable Disease Control**

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To obtain additional copies of this report, contact:

Massachusetts Department of Public Health  
Bureau of Health Information, Statistics, Research and Evaluation  
Occupational Health Surveillance Program  
250 Washington Street, 6<sup>th</sup> Floor  
Boston, MA 02108

617-624-5632

[Sharps.Injury@state.ma.us](mailto:Sharps.Injury@state.ma.us)

This report is also available on line at MDPH's website:  
[www.mass.gov/dph/ohsp](http://www.mass.gov/dph/ohsp)

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## **BACKGROUND**

### Sharps Injuries

Health care worker exposures to bloodborne pathogens as a result of injuries caused by contaminated needles and other sharp devices, also known as percutaneous injuries, are a significant public health concern. Estimates by the U.S. Centers for Disease Control and Prevention (CDC) put the number of sharps injuries in healthcare as well in excess of half a million each year, with about half of those injuries, or approximately 1,000 percutaneous injuries per day, occurring in U.S. hospitals (Panlillio et al., 2000). While several studies report that injuries occur frequently to nurses, physicians and technicians, housekeeping and other support staff are also at risk (Hiransuthikul, Tanthitippong & Jiamjarasrangsi, 2006). As a measure of likelihood of injury among hospital workers, it has been estimated that 28 sharps injuries occur annually for every 100 occupied hospital beds (Perry, Parker & Jagger, 2009).

Sharps injuries have been associated with occupational transmission of hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV) as well as over 20 other pathogens (OSHA, 2001). U.S. Public Health Service guidelines provide recommendations for post-exposure management of all workers who have sustained occupational exposure to bloodborne pathogens (CDC, 2001; CDC, 2005). These guidelines provide information for determining when post-exposure prophylaxis is appropriate. Preventive medical treatment following exposure may decrease the likelihood of infection with HIV and HBV (Cardo et al., 1997; CDC, 2001). The average direct costs, including laboratory costs for tests of both source patients and exposed employees, labor costs associated with testing and counseling, and the costs of post-exposure prophylaxis, are estimated to be \$3,042 (ranging from \$1,663 to \$4,838) (O'Malley, Scott, Gayle, Dekutoski, Foltzer, Lundstrom, et al., 2007).

Sharps injuries are preventable and the overall goal should be their elimination. As a step in that direction, the U.S. Public Health Service has called for the reduction of sharps injuries among health care workers by 30% as a national health objective for 2010 (DHHS, 2006). In addition, health care facilities are required by federal regulations to implement comprehensive plans to reduce these injuries. Preventing sharps injuries requires the combined effort of government agencies, employers, and equipment manufacturers, as well as health care workers themselves. Elements of a successful sharps injury prevention program, as outlined by the CDC, include: promoting an overall culture of safety in the workplace, eliminating the unnecessary use of needles and other sharp devices, using devices with sharps injury prevention features (safety devices), employing safe workplace practices, and training health care personnel (CDC, 2008). Sharps injury surveillance is also a key component of a comprehensive program.

Prior to 2000, while some national data had been collected, little was known about the extent and distribution of sharps injuries among health care workers in Massachusetts. In 2001, pursuant to An Act Relative to Needlestick Injury Prevention (MGL Chapter 111 §53D) the Massachusetts Department of Public Health (MDPH) promulgated regulations requiring acute and non-acute care hospitals licensed by the Department to implement sharps injury prevention plans and also to report sharps injury data to MDPH. This led to the establishment of the Massachusetts Sharps Injury Surveillance System, which has collected data from all MDPH licensed hospitals for the past seven years (2002-2008).

### The Massachusetts Sharps Injury Surveillance System

MDPH regulations, mirroring the federal Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard (29 CFR 19101.1030) revised in 2001, require that hospitals licensed by MDPH use devices with sharps injury prevention technology, develop exposure control plans, and maintain logs of worker injuries with contaminated sharps. MDPH also requires that hospitals submit the data from their sharps logs annually to the Department. Data are reported to the Sharps Injury Surveillance System electronically using the Annual Summary of Sharps Injury form. The data

reported are compiled and published to guide state efforts to prevent sharps injuries and promote action at the local level. The surveillance system provides information about occupations at risk as well as devices, procedures and departments associated with sharps injuries. It also serves as a vehicle for hospitals and health care workers in Massachusetts to share information about successful prevention strategies.

The Massachusetts Sharps Injury Surveillance System is intended to provide information that can assist Massachusetts hospitals and health care workers in targeting and evaluating efforts to reduce the incidence of sharps injuries and the associated human and economic costs. Comprehensive reports of surveillance findings for 2002, 2003 and 2004 have been produced, as well as surveillance updates for 2005, 2006 and 2007.<sup>1</sup> This brief report includes findings from the Massachusetts Sharps Injury Surveillance System for the 2008 data collection period. Findings are presented by hospital bed-size categories, by teaching status as well as for all hospitals combined to allow hospitals to compare their individual experiences with those in similar facilities. Input from hospitals and health care workers regarding the surveillance activities and the content of this report is highly welcome. MDPH looks forward to continued collaboration in maintaining an effective sharps injury surveillance system to improve the health and safety of health care workers in Massachusetts.

### Underreporting of Sharps Injuries

Underreporting of sharps injuries by employees is well documented in the literature with estimates ranging from 22% to 99%, and has been found to vary by occupation and by hospital (Perry, 2000; Avarado-Ramy et al., 2003; Kotelchuck et al., 2004; Sohn et al., 2004, Au et al., 2008; Nagao et al., 2009). There are many reasons why healthcare workers may not report sharps injuries: they may perceive that the injuries or the source patients are low risk; they may fear the diseases to which they have potentially been exposed; they may have concerns about job security or the extra paperwork and time involved in follow-up. In addition, they may lack information and training about appropriate reporting procedures or the reporting procedures themselves may be inadequate (Tandberg, Stewart & Doezema, 1991). Hospitals with well established sharps injury surveillance programs and strong safety cultures may identify and report more injuries than hospitals with less well developed programs. Underreporting must be taken into account in interpreting the findings presented in this report. Hospitals, in evaluating their own data, should do so within the context of their own sharps injury surveillance and prevention programs. Assessment of underreporting should be an integral part of sharps injury prevention activities.

## **METHODS**

### Population under surveillance

All health care workers in acute and non-acute care hospitals licensed by MDPH, as well as any satellite units (e.g., community health centers, ambulatory care centers) operating under a hospital license, are included in the population under surveillance.

### Reportable exposure incident

A reportable exposure incident is defined as an exposure to blood or other potentially infectious materials as a result of an event that pierces the skin or mucous membranes during the performance of an employee's duties. A sharps injury is also considered an exposure incident if the worker is injured with a clean sharp or device (before use) through contaminated gloves or other contaminated mediums. An injury involving a clean device without any contact with infectious materials is not considered an exposure incident. See the MDPH report *Sharps Injuries among Hospital Workers in Massachusetts, 2004: Findings from the Massachusetts Sharps Injury Surveillance System*

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<sup>1</sup> "Sharps Injuries among Hospital Workers in Massachusetts" for 2002, 2003, 2004, 2005, 2006, 2007 and 2008 can be downloaded from [www.mass.gov/dph/ohsp](http://www.mass.gov/dph/ohsp) under "Needlesticks and Other Sharps Injuries" and "Data and Statistics".



([www.mass.gov/Eeohhs2/docs/dph/occupational\\_health/injuries\\_hospital\\_2004.pdf](http://www.mass.gov/Eeohhs2/docs/dph/occupational_health/injuries_hospital_2004.pdf)) for a more detailed description of the surveillance system and methods.

### Data presented

Frequencies (counts and percents) are presented for each of the data elements collected, with the exception of brand/model of device. Findings are presented for all hospitals combined (appendix A) as well as by hospital size categories (defined by number of licensed beds) (Appendix B) and by teaching status (Appendix C) to allow hospitals to compare their individual experiences with those in similar facilities. Rates using the number of licensed beds as the denominator are presented by hospital size.

## DATA HIGHLIGHTS

All 99 hospitals licensed by MDPH submitted Annual Sharps Injury Reports containing information about sharps injuries sustained by Massachusetts hospital workers in 2008. The number of sharps injuries reported by individual hospitals ranged from 0 to 329, with over half of the hospitals reporting fewer than 20 injuries. The extent to which a high number of reported injuries in a hospital reflects a true higher incidence of injuries or better sharps injury reporting practices is unknown.

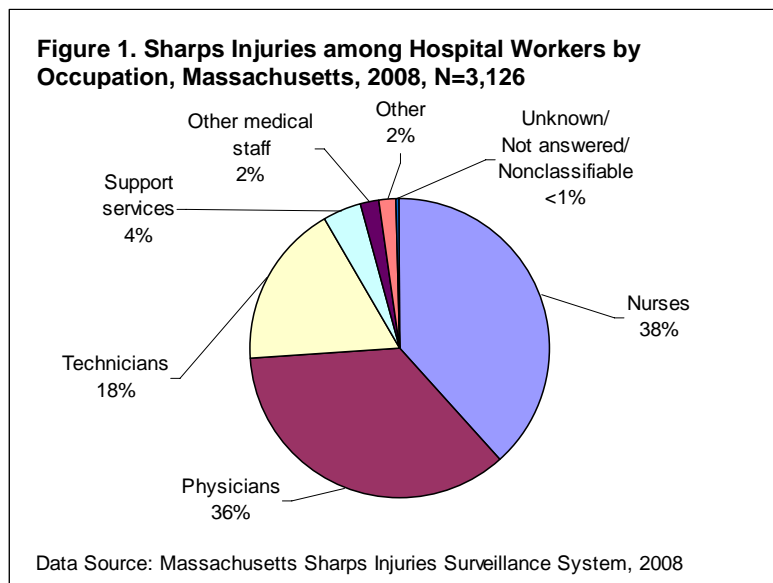
The 21 Massachusetts teaching hospitals reported 65% (2,035) of all sharps injuries. Teaching status is strongly correlated with hospital size; nearly half of the teaching hospitals (48%, 10) have over 300 beds. Detailed findings for all hospitals are presented in Appendix A. Summary tables of findings by hospital size and teaching status are provided in Appendices B and C.

### Overview

- A total of 3,126 sharps injuries among hospital-based health care workers in Massachusetts were reported for the surveillance period January 1 to December 31, 2008. This is similar to the annual number of sharps injuries reported in previous years.
- Eighty-six percent of the injured workers (2,700) were hospital employees, 9% (282) were non-employee practitioners, 3% (101) were students, and 1% (40) were temporary or contract employees.

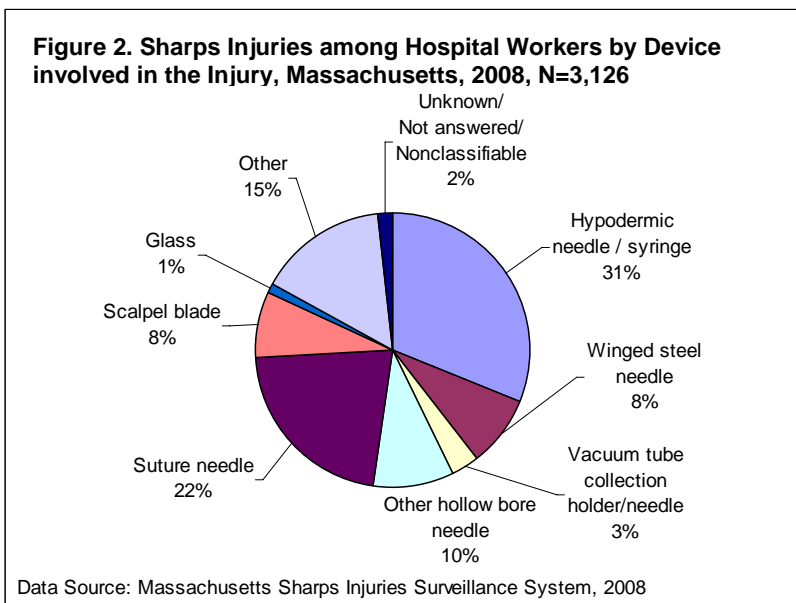
### Occupation and Department

- Nurses sustained more injuries (38%, 1,198) than any other occupational group, followed by physicians (36%, 1,115). Close to half of the injuries in the physician category were sustained by interns and residents. Physicians accounted for proportionately more injuries in large hospitals (> 300 licensed beds) (46%, 833).
- Technicians, such as surgical technicians and phlebotomists, sustained 18% (552) of the injuries. Four percent (131) of the injuries were sustained by support service workers, of whom close to a third (72) were housekeepers.



- Injuries occurred most frequently in operating rooms (32%, 1,011) followed by medical surgical wards (19%, 590). Nine percent of injuries occurred in emergency departments (281) and intensive care units (276) respectively.

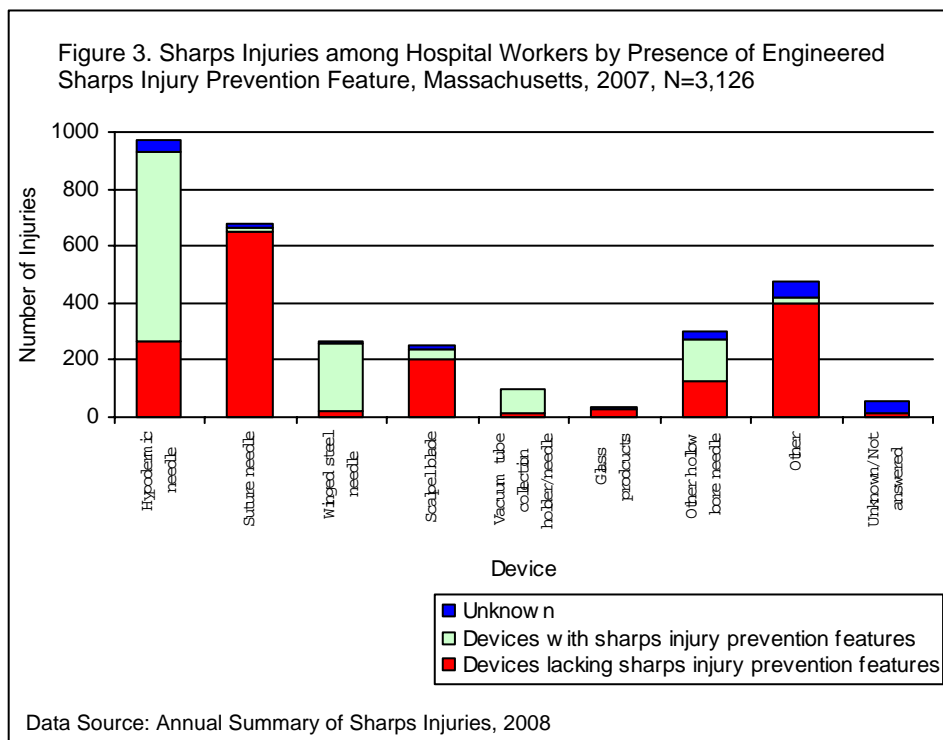
### Type of Device



- Hollow bore needles, which include hypodermic needles/syringes, winged steel needles, vacuum tube collection devices and IV stylets, as a group accounted for 52% (1,636) of all injuries reported. Hypodermic needles/syringes accounted for more injuries (31%, 972) than any other type of device. While most frequent, injuries with hypodermic needles/syringes generally involve less direct blood exposure and thus present less risk than injuries involving winged steel needles and vacuum tube

collection devices. Injuries with these two types of devices accounted for 8% (264) and 3% (99) of all injuries, respectively.

- Injuries involving solid sharp devices, including suture needles, scalpels and glass, accounted for 31% (960) of all injuries. Injuries involving suture needles accounted for 22% (679), followed by scalpel blades (8%, 249) and glass items (1%, 32).

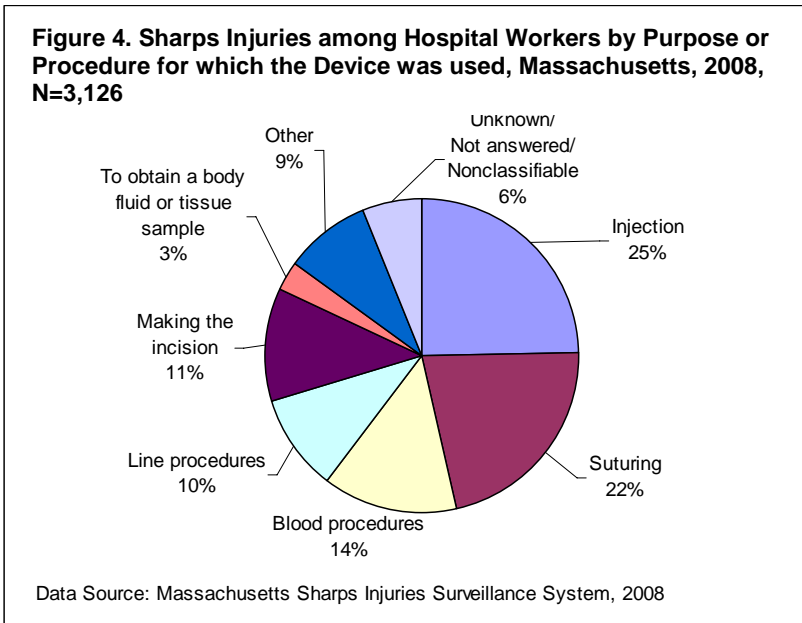


- Of the 2,917 (70%) injuries with devices for which information regarding the presence of engineered sharps injury prevention features was recorded, over half (59%, 1,712) involved devices without engineered sharps injury prevention features. However, hypodermic needles/syringes lacked these features in 27% (264) of the injuries associated with these devices, even though hypodermic needles/syringes with engineered sharps injury

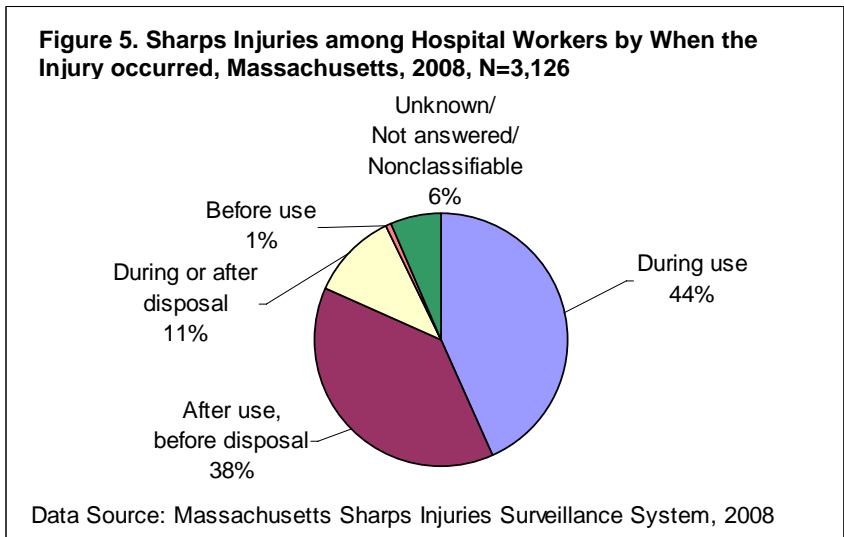
prevention features have been available on the market for the past 12 years. By contrast, only 9% (23) of winged steel needles and 11% (11) of vacuum tube collection holder/needles associated with injuries lacked these features.

### Procedure for which the Device was Used and When the Injury Occurred

- Devices involved in injuries were most frequently used for injections (25%, 771) and suturing (22%, 678) followed by blood procedures (14%, 435). In medium size hospitals injuries were most often related to injections (28%, 311), as was the case in small sized hospitals (26%, 51). Suturing accounted for 24% of injuries in large hospitals (445 injuries), in contrast to 19% and 12% in medium and small sized hospitals respectively.



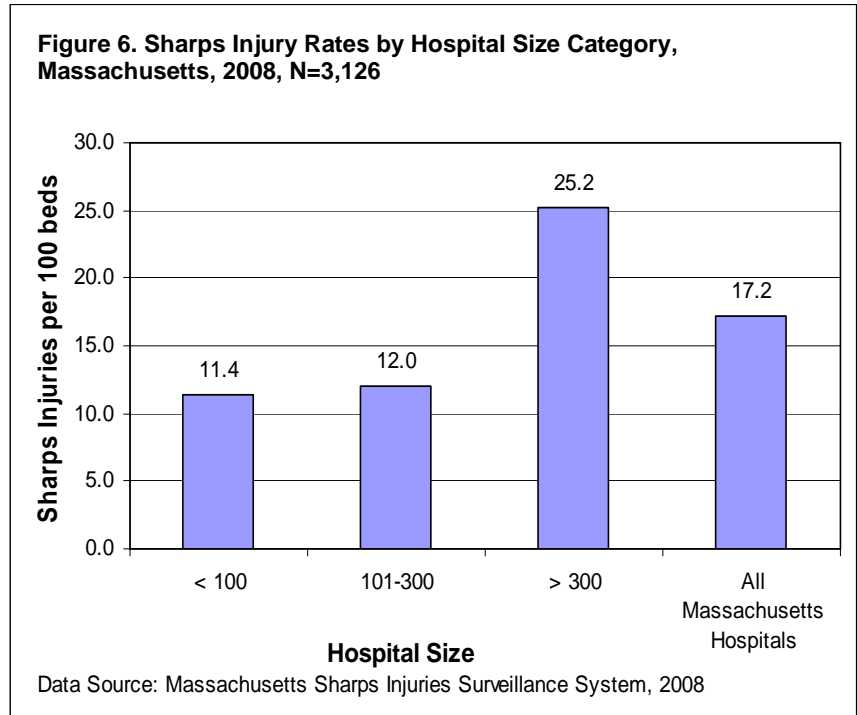
- Injuries occurred during the use of devices in 43% (1,355) of the cases. After use of the device was a more dangerous time to handle a device as compared with during use. About half (49%, 1,543) of the injuries occurred after use of the device. These included injuries sustained after use but before disposal of devices (38%, 1,199) and injuries occurring during or after disposal (11%, 344).



- Collision with sharp accounted for 18% (549) of the reported cases. MDPH continues to work with hospitals to encourage greater detail in descriptions of the incident so that these cases can be more appropriately coded. An additional 11% (334) of the cases occurred during the act of suturing.

## Rates

The statewide rate of sharps injuries among hospital workers for this twelve month surveillance period was 17.2 sharps injuries per 100 licensed beds. The annual rate of sharps injuries varied by hospital size. (Figure 6). Injury rates which include all licensed hospitals underestimate the risk for acute care hospitals, because although acute care hospitals make up only 79% of all licensed hospital beds, injuries in acute care hospitals accounted for 97% of all reported injuries. The sharps injury rate among hospital workers in acute care hospitals in 2008 was 20.6 injuries per licensed hospital beds. Large acute care hospitals had the highest annual rate of 27.7 injuries per 100 licensed beds, followed by small and medium sized acute care hospitals, which had annual sharps injury rates of 15.2 and 14.8 sharps injuries per 100 licensed hospital beds, respectively.



Given the limitations presented below of using the number of hospital beds as a denominator for assessing risks, sharps injury rates should be interpreted with caution. In comparing experience among hospitals, underreporting must be taken into consideration. The extent to which high rates of reported injuries in some hospitals reflect a true higher incidence of injuries in these hospitals or better sharps injury reporting practices compared to those with low rates is now known. Hospitals evaluating their own rates should do so within the context of their own sharps injury surveillance and prevention programs.

## LIMITATIONS

There are a number of limitations to be considered in interpreting the findings presented in this report. In order for an injury to be included on the Annual Sharps Summary, hospitals rely on health care workers to report sharps injuries. As discussed previously, there are many reasons why health care workers may choose not to report sharps injuries, and underreporting by health care workers has been well documented. Also, there is evidence that the likelihood of reporting varies by occupation and completeness of reporting varies by hospital (CDC, 2008). The surveillance findings presented in this report should be considered conservative estimates of the burden of sharps injuries among hospital workers in Massachusetts.

The rates for hospitals in Massachusetts are somewhat lower than rates reported by EPINet, which are based on occupied beds (EPINet, 2007, 2008 & 2009). In Massachusetts, the number of occupied beds and the number of licensed beds are highly correlated, and this difference in denominators does not explain the difference in Massachusetts and EPINet rates. Rates using number of beds whether licensed or occupied in the denominator have several limitations. The number of licensed beds is not an accurate reflection of patients treated nor does it provide a measure of the number of inpatient or

outpatient procedures performed or devices used, or workers at risk. For example, rates based on licensed beds may overestimate the risks of sharps injuries in facilities where a large number of outpatient procedures are performed.

For more than 90% of the records, the information about each reported injury provided by hospitals was complete. However, there was some missing information, which has been coded as “not answered”. There was also some confusion in several data elements (such as department where injury occurred and brand of device) about the type of information that should be provided. MDPH has worked collaboratively with hospitals to improve data collection and to clarify any questions about information to be reported. This has resulted in more complete and comprehensive data. MDPH will continue to work with hospitals to clarify outstanding issues.

## **DISCUSSION and METHODS FOR SHARING INFORMATION ON DEVICE MALFUNCTIONS:**

More than 3,100 sharps injuries were reported in Massachusetts hospitals in 2008, underscoring the need for continued efforts to reduce the incidence of these injuries. Findings highlight a number of continuing issues to be addressed in Massachusetts:

- The unacceptably high number of injuries with devices lacking sharps injury prevention features (55%, 1,712), most notably hypodermic needles/syringes (27%, 264) for which alternatives with sharps injury prevention features have been available for two decades;
- The need for improved disposal practices to reduce the large number of sharps injuries that occur after use of a device (49%, 1,543); and
- The need to implement safe work practices and alternative methods for wound closure to reduce the high number of injuries in the operating room (43%, 1,133).

Notably, the use of devices with sharps injury prevention features appears to be increasing as reflected in the decrease in the proportion of sharps injuries involving devices without sharps injury prevention features over time. Whereas 62% of all reported sharps injuries were due to devices lacking sharps injury prevention features in 2002, the first year of data collection, 55% involved such devices in 2008. For hypodermic needles/syringes alone, the percent of sharps injuries with devices without prevention features decreased from 57% (557) in 2002 to 28% (264) in 2008. (An in depth analysis of sharps injury rates over time is in progress and will be released later in 2010.)

While use of devices with sharps injury prevention features have been demonstrated to reduce risk of sharps injuries in numerous studies, (Rogues, 2004; Cavanaugh, 2007; Avarado-Ramy, 2003), the Massachusetts findings underscore that these devices do not *eliminate* risk. The finding that 9% of all sharps injuries and 24% of sharps injuries involving devices with sharps injury prevention features occurred while activating the sharps injury prevention feature raises critical questions about the extent to which these injuries are associated with factors such as inexperience and lack of training in the use of these devices or flaws in product design. A closer look at these devices is needed with focus on both of these factors, specifically the mechanism of the sharps injury prevention feature (e.g., retracting, sheathing, blunting). Working with purchasing departments, as well as clinical staff, to identify and evaluate devices with sharps injury prevention features is a key step to ensuring that appropriate devices are purchased and used within the hospital setting.

Hospitals are encouraged to report information about problems with devices on the Annual Summary of Sharps Injuries submitted each year to MDPH. Detailed information about problems with devices should be included in the description of how the injury occurred, along with information about the manufacturer, brand name and model number of the device. As good documentation practice, it is always better to capture as much information as possible in the Annual Summary. Starting in 2010

MDPH is also asking hospitals to report information on the Annual Summary about the mechanism of sharps injury prevention features for those injuries that occur with devices with sharps injuries prevention features.

It is also important for hospitals and individual clinicians to provide feedback to manufacturers and the FDA regarding the function of various sharps injury prevention mechanisms. Information on adverse events, such as sharps injuries, as well as device malfunction can be shared. Outlined below are methods for doing so, including means for contacting the FDA. We have outlined methods for providing feedback to individual manufacturers, although contact information for individual manufacturers is not included here.

### **Why provide feedback on devices? Why are these individual reports so critical?**

It cannot be overstated – reports from hospitals and individual clinicians provide the impetus for development of safer, more user-friendly products.

- When manufacturers develop and get approval for new products, their testing is limited and they often fail to encompass the myriad circumstances under which their products will be used. As a particular device type is used thousands and millions of times, shortcomings will become apparent. Reporting to the manufacturer is the only way that the manufacturer can know about and respond to these shortcomings.
- Points to remember:
  - The more detail provided about the shortcomings of a product, the more useful it is for the manufacturer and the more likely the device design can be improved.
  - Don't be discouraged if you don't get a welcome response from the manufacturer (or even if they suggest what you have experienced is a user failure – attributable to improper use or lack of training). As an individual, there is no way to know how many others are reporting similar complaints to the manufacturer. You may be the first or the twenty-thousandth – either way, the manufacturer is keeping track.
  - The safe use of a device should be intuitive – the sharps injury prevention feature should be so integral to the device that it works even without extensive training or focused attention to its operation. If there is an injury or near-injury with a device, the device design may be inherently inadequate for the task at hand and the manufacturer needs to know this.
- When feedback is provided (whether it is to the hospital's occupational health department, the FDA, to state or other surveillance systems, to colleagues or unions), it increases the likelihood that the information will be shared and will be useful to a larger audience. For example, voluntary reports to the FDA MedWatch program go into a searchable database. Experience with a device is then visible to others who search the database.
- This can be useful when:
  - Alternative devices are being considered and information about any "red flags" to be aware of is being researched. Searching the FDA's MAUDE database (see below) might provide comments or information about injuries from other users of the device.
  - There has been a negative experience with a device and in deciding how to respond, it's helpful to know if others are having a similar experience or if this was truly a rare event.

## How can I find out what events have been reported by others?

The FDA maintains a database of adverse events involving medical devices called MAUDE (Manufacturer and User Facility Device Experience). It is a searchable database, with monthly updates. MAUDE, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm> can be searched to find information provided by device users since 1984.

Keywords to use in the search include:

- needlestick,
- cap,
- sharps container,
- shield,
- retract, or
- any device names (e.g., butterfly, syringe).

This list of suggested terms is not exhaustive, and OHSP welcomes feedback on additional terms to include.

## What are avenues for providing feedback? (see key definitions below table)

REPORTING TO FDA\* (information can then be retrieved through MAUDE (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>))

	<i>Who should report information?</i>	<i>When should it be used?</i>	<i>System under which to report</i>	<i>Reporting method</i>
<b>FDA Medical Device Reporting (MDR)</b> <sup>1</sup> Mandatory Reporting	Hospital/User facility	A device has or may have caused or contributed to a serious injury to a patient or worker at your facility <sup>4</sup>	FDA Medical Device Reporting (MDR); using <b>Form FDA 3500A</b> or an approved electronic equivalent	<p><i>Mandatory:</i></p> <ul style="list-style-type: none"> <li>• Submit reports of device-related serious injuries<sup>4</sup> to the <u>manufacturers</u> or, if the manufacturer is unknown, submit reports to FDA.</li> <li>• Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event</li> </ul>
		A device has or may have caused or contributed to the death of a patient or worker at your facility <sup>4</sup>	FDA Medical Device Reporting (MDR); using <b>FDA form 3500A</b> or an approved electronic equivalent	<p><i>Mandatory:</i></p> <ul style="list-style-type: none"> <li>• Submit reports of device-related deaths<sup>4</sup> to <u>FDA and to the manufacturer</u>, if known;</li> <li>• Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event</li> </ul>
		This is a summary of all previous medical device reports submitted to the FDA during the year.	<b>Form FDA 3419</b> or approved electronic equivalent	<p><i>Mandatory:</i></p> <p>Submit annual report to FDA by January 1 of each year if medical device reports were submitted during the year.</p>

\*The FDA has provisions for maintaining the confidentiality of the injured party (either worker or patient).

REPORTING TO FDA\*

	<b>Who should report information?</b>	<b>When should it be used?</b>	<b>System under which to report</b>	<b>Reporting method</b>
<b>FDA Medical Device Reporting (MDR)</b> <sup>2,3</sup> Voluntary Reporting	Health Professionals and Consumers	Reporting of adverse events, product use errors and product quality problems <sup>4</sup>	FDA Medical Device Reporting (MDR); using <b>Form FDA 3500</b> or an approved electronic equivalent	<p><i>Voluntary</i></p> <ul style="list-style-type: none"> <li>This voluntary reporting program of the FDA Adverse event allows individual health professionals or consumers to report adverse events, product problems or product use errors with medications, medical devices, combination products (medication &amp; medical device), human cells, tissues, certain biological products, special nutritional product and cosmetics<sup>4</sup>.</li> <li>To report, it is not necessary to be certain of a cause/effect relationship between the adverse event and the use of the medical product(s) in question. Suspicion of an association is sufficient reason to report. You can report even if you don't have all the details<sup>2,3</sup></li> <li>Reports can be submitted online, by phone, fax, or mail.<sup>3</sup></li> </ul>

\*The FDA has provisions for maintaining the confidentiality of the injured party (either worker or patient).

REPORTING TO MANUFACTURERS

	<b>Who should report information?</b>	<b>When should it be used?</b>	<b>System under which to report</b>	<b>Reporting method</b>
<b>Informal Reporting to Manufacturer</b>	Health professionals or Hospital / User facilities and Consumers	Reporting of adverse events and product quality problems <sup>4</sup>	Contact the manufacturer and request to be put in touch with the technical support group	<ul style="list-style-type: none"> <li>Involve your procurement department and contact the local sales representative</li> <li>Make sure you keep a record of your communications with the manufacturer (date of each communication, who you spoke to, their title or department, what you discussed and follow up actions). This can be as simple as copies of emails or an electronic record (e.g. word file or excel worksheet) summarizing the communications. Having this systematic track record allows you to better see the patterns of problems you are reporting and the manufacturer's response. The longer and more informative the record, the more clout you may have with the manufacturer.</li> </ul>

<sup>1</sup> Code of Federal Regulations, Title 21, Volume 8; CHAPTER I--FOOD AND DRUG ADMINISTRATION. DEPARTMENT OF HEALTH AND HUMAN SERVICES. SUBCHAPTER H--MEDICAL DEVICES.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=803&showFR=1>

<sup>2</sup> Instructions for Completing Form FDA 3500.

<http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149236.htm>

<sup>3</sup>How to Report: <http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf>

<sup>4</sup>Key Definitions use in the Table



### Key Definitions used in the Table

**Definitions used in Mandatory reporting section of table** (please see reference for further details):

Reference: Code of Federal Regulations, Title 21, Volume 8; CHAPTER I--FOOD AND DRUG ADMINISTRATION. DEPARTMENT OF HEALTH AND HUMAN SERVICES. SUBCHAPTER H--MEDICAL DEVICES.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803&showFR=1>

*Caused or contributed* means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:

- |                                    |                  |
|------------------------------------|------------------|
| (1) Failure;                       | (4) Manufacture; |
| (2) Malfunction;                   | (5) Labeling; or |
| (3) Improper or inadequate design; | (6) User error.  |

*Malfunction* means the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in 801.4 of this chapter.

*MDR reportable event (or reportable event)* means:

- (1) An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or
- (2) An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:
  - (i) May have caused or contributed to a death or serious injury, or
  - (ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

*Patient of the facility* means any individual who is being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility. This includes employees of the facility or individuals affiliated with the facility who, in the course of their duties, suffer a device-related death or serious injury that has or may have been caused or contributed to by a device used at the facility.

*Serious injury* means an injury or illness that:

- (1) Is life-threatening,
- (2) Results in permanent impairment of a body function or permanent damage to a body structure, or
- (3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

*Permanent* means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

**Definitions used in Voluntary reporting section of table** (please see reference for further details):

Reference: Instructions for Completing Form FDA 3500.

<http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149236.htm>

*Adverse event*: Any incident where the use of a medication (drug or biologic, including HCT/P), at any dose, a medical device (including *in vitro* diagnostics) or a special nutritional product (e.g., dietary supplement, infant formula or medical food) is suspected to have resulted in an adverse outcome in a patient. To report, it is not necessary to be certain of a cause/effect relationship between the adverse event and the use of the medical product(s) in question. Suspicion of an association is sufficient reason to report. Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event. Please limit your submissions to those events that are serious. An event is classified as serious when the patient outcome is:

- |  |   |
|--|---|
| • Death                                  | • Congenital anomaly/Birth Defect   |
| • Life-threatening                       | • Required medical or surgical intervention to prevent permanent impairment or damage (Devices) |
| • Hospitalization (initial or prolonged) | • Other Serious (Important Medical Events)  |
| • Disability or Permanent Damage         |   |

*Medical Device Use Error*: Health care professionals, patients, and consumers can unintentionally cause harm to patients or to themselves when using medical devices. These problems can often arise due to problems with the design of the medical device or the manner in which the device is used. Often use-errors are caught and prevented before they can do harm (close call). Report use errors regardless of patient involvement or outcome. Also report circumstances or events that could cause use errors. Medical device use errors usually occur for one or more of the following reasons:

- |   |  |
|---|--|
| • Users expect devices to operate differently than they do  | • Devices are used in ways not anticipated by the manufacturer |
| • Product use is inconsistent with user's expectations or intuition                               | • Product labeling or packaging is confusing or inadequate     |
| • Product use requires physical, perceptual, or cognitive abilities that exceed those of the user | • The environment adversely effects or influences device use   |

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**APPENDIX A**

## Sharps Injuries among Hospital Workers in Massachusetts, 2008

<b>STATE TOTAL</b>	<b>3,126</b>	<b>100%</b>
<b>WORK STATUS OF INJURED WORKER</b>		
	<b>N</b>	<b>%</b>
Employee	2,700	86
Non-employee practitioner	282	9
Student	101	3
Temporary / Contract worker	40	1
Other	1	<1
Not answered	2	<1
<b>OCCUPATION OF INJURED WORKER</b>		
	<b>N</b>	<b>%</b>
<b>Nurse</b>	<b>1,198</b>	<b>38%</b>
RN or LPN	1,050	34
Nursing assistant	43	1
Patient care technician	42	1
Nurse practitioner	26	1
Nurse anesthetist	13	<1
Nursing student	13	<1
Home health aide	8	<1
Nurse midwife	3	<1
<b>Physician</b>	<b>1,115</b>	<b>36%</b>
Intern / Resident	515	16
MD	282	9
Medical student	51	2
Fellow	100	3
Physician assistant	56	2
Surgeon	86	3
Anesthesiologist	16	1
Radiologist	9	<1
<b>Technician</b>	<b>552</b>	<b>18%</b>
OR / Surgical technician	243	8
Phlebotomist	107	3
Clinical lab technician	67	2
Respiratory therapist / Tech	27	1
Radiologic technician	33	1
Morgue Technician	1	<1
Hemodialysis Technician	1	<1
Other technician	73	2
<b>Support Services</b>	<b>131</b>	<b>4%</b>
Housekeeper	72	2
Central supply	43	1
Attendant / Orderly	11	<1
Safety / Security	3	<1
Maintenance	1	<1
Food Service	1	<1
<b>Other Medical Staff</b>	<b>62</b>	<b>2%</b>
Medical assistant	56	2
Physical Therapist	1	<1

**APPENDIX A****Sharps Injuries among Hospital Workers in Massachusetts, 2008**

<b>OCCUPATION OF INJURED WORKER</b>	<b>N</b>	<b>%</b>
Other medical staff	5	<1
<b>Dental Staff</b>	<b>18</b>	<b>1%</b>
Dentist	5	<1
Dental Assistant / Tech	7	<1
Dental student	5	<1
Dental hygienist	1	<1
<b>Other</b>	<b>45</b>	<b>1%</b>
EMT / Paramedic	3	<1
Clerical / Administrative	5	<1
Pharmacist	1	<1
Other student	26	1
Other	10	<1
<b>Unknown / Not Answered</b>	<b>2</b>	<b>&lt;1%</b>
<b>Nonclassifiable</b>	<b>3</b>	<b>&lt;1%</b>

<b>DEPARTMENT WHERE INCIDENT OCCURRED</b>	<b>N</b>	<b>%</b>
<b>Operating and Procedure Rooms</b>	<b>1,333</b>	<b>43%</b>
Operating room	1,011	32
Labor and delivery	96	3
Radiology	101	3
Hematology / Oncology	27	1
Phlebotomy room	21	1
Cardiac catheterization laboratory	45	1
Dialysis	13	<1
Endoscopy / Bronchoscopy / Cytoscopy	12	<1
Other procedure room	5	<1
Procedure room, unspecified	2	<1
<b>Inpatient Units</b>	<b>701</b>	<b>22%</b>
Medical / Surgical ward	590	19
Obstetrics / Gynecology	52	2
Psychiatry ward	22	1
Nursery	9	<1
Pediatrics	18	1
Patient room, ward unspecified	10	<1
<b>Emergency Department</b>	<b>281</b>	<b>9%</b>
<b>Intensive Care Units</b>	<b>276</b>	<b>9%</b>
Intensive care unit	250	8
Post anesthesia care unit	26	1
<b>Outpatient Areas</b>	<b>187</b>	<b>6%</b>
Ambulatory care clinic	97	3
Home health visit	15	<1
Dental clinic	14	<1
Community health center	10	<1
Other outpatient areas	51	2

## APPENDIX A

### Sharps Injuries among Hospital Workers in Massachusetts, 2008

DEPARTMENT WHERE INCIDENT OCCURRED	N	%
<b>Laboratory</b>	<b>131</b>	<b>4%</b>
Histology / Pathology	29	1
Blood bank	5	<1
Clinical chemistry	6	<1
Morgue / Autopsy room	14	<1
Microbiology	5	<1
Other laboratory	27	1
Laboratory, unspecified	45	1
<b>Other Areas</b>	<b>197</b>	<b>6%</b>
Central sterile supply	40	1
Rehabilitation unit	38	1
Dermatology	27	1
Long term care	13	<1
Exam room	18	1
Employee health / Infection control	7	<1
Pain clinic	6	<1
Anesthesia	5	<1
Hospital grounds	3	<1
Detox unit	2	<1
Ambulance	1	<1
Central trash area	1	<1
Laundry room	1	<1
Other location	35	1
<b>Unknown / Not answered</b>	<b>1</b>	<b>&lt;1%</b>
<b>Nonclassifiable</b>	<b>19</b>	<b>1%</b>

PROCEDURE FOR WHICH DEVICE WAS USED	N	%
<b>Injection</b>	<b>771</b>	<b>25%</b>
Subcutaneous injection	591	19
Intramuscular injection	102	3
Epidural / Spinal anesthesia	17	1
Other injection	3	<1
Injection, unspecified	58	2
<b>Suturing</b>	<b>678</b>	<b>22%</b>
Suturing	670	21
Suture removal	8	<1
<b>Blood Procedures</b>	<b>435</b>	<b>14%</b>
Percutaneous venous puncture	324	10
Finger stick / Heel stick	39	1
Percutaneous arterial puncture	52	2
Draw blood from umbilical vessel	7	<1
Dialysis / AV fistula site	7	<1
Blood procedure, unspecified	5	<1
Other blood procedure	1	<1
<b>Line Procedures</b>	<b>315</b>	<b>10%</b>
To insert a peripheral IV line or set up a heparin lock	114	4
To insert a central IV line	29	1

## APPENDIX A

### Sharps Injuries among Hospital Workers in Massachusetts, 2008

PROCEDURE FOR WHICH DEVICE WAS USED	N	%
To insert an arterial line	29	1
Other injection into IV site / port	33	1
Draw blood from central or peripheral IV line or port	17	1
To flush heparin / saline	28	1
Draw blood from arterial line	12	<1
To connect IV line	5	<1
Other line procedure	42	1
Line procedure, unspecified	6	<1
<b>Making the incision</b>	<b>359</b>	<b>11%</b>
<b>To Obtain Body Fluid or Tissue sample</b>	<b>101</b>	<b>3%</b>
<b>Dental Procedures</b>	<b>12</b>	<b>&lt;1%</b>
Dental drilling	1	<1
Oral surgery	6	<1
Restorative	1	<1
Hygiene	1	<1
Dental procedure, unspecified	1	<1
Other dental	2	<1
<b>Other</b>	<b>260</b>	<b>8%</b>
To obtain lab specimens	20	1
Transferring blood / body fluid to another container	25	1
Drilling	15	<1
During disposal	6	<1
Shaving	12	<1
Other procedure	150	5
Procedure, unspecified	32	1
<b>Unknown / Not answered</b>	<b>181</b>	<b>6%</b>
<b>Nonclassifiable</b>	<b>14</b>	<b>&lt;1%</b>

DEVICE INVOLVED IN THE INJURY	N	%
<b>Hypodermic needles / syringe (hollow bore)</b>	<b>972</b>	<b>31%</b>
Hypodermic needle attached to a disposable syringe	813	26
Prefilled cartridge syringe	60	2
Hypodermic needle attached to a non-disposable syringe	30	1
Unattached hypodermic needle	34	1
Hypodermic needle attached to IV tubing	6	<1
Hypodermic needle, unspecified	29	1
<b>Suture Needle</b>	<b>679</b>	<b>22%</b>
Curved suture needle	330	11
Straight suture needle	28	1
Suture needle, unspecified	321	10
<b>Other Hollow Bore Needle</b>	<b>301</b>	<b>10%</b>
IV stylet	143	5
Huber needle	37	1
Spinal or epidural needle	20	1
Biopsy needle	24	1

## APPENDIX A

### Sharps Injuries among Hospital Workers in Massachusetts, 2008

DEVICE INVOLVED IN THE INJURY	N	%
Other type of hollow bore needle	29	1
Hollow bore needle, unspecified	48	2
<b>Winged Steel Needle (hollow bore)</b>	<b>264</b>	<b>8%</b>
Winged steel needle	126	4
Winged steel needle attached to a vacuum tube collection holder	129	4
Winged steel needle attached to IV tubing	9	<1
<b>Scalpel Blade</b>	<b>249</b>	<b>8%</b>
<b>Vacuum Tube Collection Holder / Needle (hollow bore)</b>	<b>99</b>	<b>3%</b>
Vacuum tube collection holder / needle	68	2
Phlebotomy needle (other than winged steel needle)	31	1
<b>Glass</b>	<b>32</b>	<b>1%</b>
Medication ampule / Vial / IV bottle	7	<1
Specimen / Test / Vacuum tube	10	<1
Pipette	2	<1
Capillary tube	2	<1
Other glass item	11	<1
<b>Dental Device or Item</b>	<b>12</b>	<b>&lt;1%</b>
Dental explorer	2	<1
Other dental device or item	5	<1
Dental needle	2	<1
Scaler / curette	2	<1
Dental bur	1	<1
<b>Other</b>	<b>465</b>	<b>15%</b>
Lancet	45	1
Wire	47	2
Scissors	23	1
Retractor	33	1
Electrode	22	1
Pin	24	1
Forceps	21	1
Razor	27	1
Bovie electrocautery device	25	1
Drill bit	18	1
Staple	12	<1
Bone chip / chipped tooth	8	<1
Trocar	7	<1
Histology cutting blade	5	<1
Bone cutter	4	<1
Rod	4	<1
Tenaculum	1	<1
Other needle	29	1
Needle, Unspecified	12	<1
Other type of sharp object	98	3
<b>Unknown / Not answered</b>	<b>9</b>	<b>&lt;1%</b>



## APPENDIX A

### Sharps Injuries among Hospital Workers in Massachusetts, 2008

<b>SAFETY DEVICE</b>	<b>N</b>	<b>%</b>
No	1,712	55
Yes	1,205	39
Unknown / Not answered	209	7

<b>WHEN THE INJURY OCCURRED</b>	<b>N</b>	<b>%</b>
During use of the item	1,355	43
After use and before disposal	1,199	38
During or after disposal of the item	344	11
Before use of the item **	26	1
Unknown / Not answered	43	1
Nonclassifiable	159	5

<b>HOW THE INJURY OCCURRED</b>	<b>N</b>	<b>%</b>
<b>Collision with Worker or Sharp</b>	<b>549</b>	<b>18%</b>
Collided with sharp	297	10
Collided with sharp after procedure	135	4
Collided with coworker or other person	117	4
<b>Suturing</b>	<b>334</b>	<b>11%</b>
Suturing	257	8
Manipulating suture needle in holder	58	2
Tying suture	19	1
<b>During Clean-up</b>	<b>160</b>	<b>5%</b>
During clean-up	112	4
Decontamination / Processing of used equipment	39	1
Disassembling device or equipment during clean-up	9	<1
<b>Handle / Pass Equipment</b>	<b>282</b>	<b>9%</b>
Receiving / Passing / Transferring equipment	116	4
Handling equipment on tray or stand	82	3
Disassembling device or equipment	73	2
Opening / breaking glass containers	11	<1
<b>Patient Moved and Jarred Device</b>	<b>231</b>	<b>7%</b>
<b>Activating Safety Device</b>	<b>294</b>	<b>9%</b>
Activating safety device	242	8
Incomplete activation	52	2
<b>Improper Disposal</b>	<b>218</b>	<b>7%</b>
Left on table / tray	68	2
In trash	55	2
Left in bed / mattress	22	1
On floor	17	1
In pocket / clothing	12	<1
In linen / laundry	8	<1
Other improper disposal	34	1
Improper disposal, unspecified	2	<1

## APPENDIX A

### Sharps Injuries among Hospital Workers in Massachusetts, 2008

HOW THE INJURY OCCURRED	N	%
<b>During Sharps Disposal</b>	<b>168</b>	<b>5%</b>
While placing sharp in container, injured by sharp being disposed	38	1
Collided with sharp during / after disposal	35	1
In transit to disposal	33	1
Protruding from opened container	16	1
While placing sharp in container, injured by sharp already in container	12	<1
Overfilled sharps container	10	<1
While placing sharp in container, injured by sharp (unclear if sharp in container or being disposed)	10	<1
While manipulating container	9	<1
Sharp object dropped during / after disposal	3	<1
Struck by detached IV line needle during / after disposal	1	<1
During sharps disposal, unspecified	1	<1
<b>Manipulate Needle in Patient</b>	<b>249</b>	<b>8%</b>
While withdrawing needle from patient	131	4
While inserting needle in patient	75	2
While manipulating needle in patient	43	1
<b>Recap Needle</b>	<b>78</b>	<b>2%</b>
Recapping	61	2
Cap fell off after recapping	14	<1
Removing cap after recapping	3	<1
<b>Access IV Line</b>	<b>34</b>	<b>1%</b>
While withdrawing needle from line	18	1
While inserting needle in line	10	<1
While manipulating needle in line	6	<1
<b>Failure to Activate Safety Device</b>	<b>101</b>	<b>3%</b>
<b>Device Malfunction</b>	<b>76</b>	<b>2%</b>
<b>Before Use of the Item</b>	<b>17</b>	<b>1%</b>
<b>Other</b>	<b>285</b>	<b>9%</b>
Incising	58	2
Sharp object dropped	57	2
Transferring blood / bodily fluids into specimen container	32	1
Processing specimens	19	1
Palpating / Exploring	14	<1
Sharp object dropped after procedure	21	1
Other	84	3
<b>Unknown / Not answered</b>	<b>38</b>	<b>1%</b>
<b>Nonclassifiable</b>	<b>12</b>	<b>&lt;1%</b>
<b>STATE TOTAL</b>	<b>3,126</b>	<b>100%</b>

\*\* Sharps injury is considered an exposure incident if the worker is injured with a clean sharp or device (before use) through contaminated gloves or other contaminated mediums.

## APPENDIX A

### Sharps Injuries among Hospital Workers in Massachusetts, 2008

#### Sharps Injuries among Hospital Workers by Device and Presence of Safety Features

Device	No Safety Features		Safety Features		Unknown		Total	
	N	%	N	%	N	%	N	%
Hypodermic Needle / syringe	264	27	663	68	45	5	972	100%
Suture Needle	649	96	15	2	15	2	679	100%
Winged Steel Needle	23	9	237	90	4	4	264	100%
Scalpel Blade	201	81	39	16	9	4	249	100%
Vacuum tube collection holder / needle	11	11	84	85	4	2	99	100%
Other Hollow bore needle	129	43	146	49	26	9	301	100%
Other	435	77	21	4	106	19	562	100%
<b>Total</b>	<b>1,712</b>	<b>55</b>	<b>1,205</b>	<b>39</b>	<b>209</b>	<b>7</b>	<b>3,126</b>	<b>100%</b>

#### Sharps Injuries among Hospital workers by Procedure and Devices With and Without Safety Features

Procedure	No Safety Features		Safety Features		Unknown		Total	
	N	%	N	%	N	%	N	%
<b>Injection Procedures</b>								
Subcutaneous Injection	133	23	444	75	14	2	591	100%
Intramuscular Injection	28	27	68	67	6	6	102	100%
Other Injections	43	55	29	37	6	8	78	100%
<b>Blood Procedures</b>								
Percutaneous venous puncture	32	10	289	89	3	1	324	100%
Finger stick / Heel stick	29	74	5	13	5	13	39	100%
Percutaneous arterial puncture	6	12	44	85	2	4	52	100%
Other blood procedures	9	45	9	45	2	10	20	100%
<b>Line Procedures</b>								
To insert peripheral IV or set up heparin lock	15	13	98	86	1	1	114	100%
To insert central line	17	59	8	28	4	14	29	100%
Other line procedures	78	45	86	50	8	5	172	100%
<b>Other procedures</b>	<b>1,322</b>	<b>82</b>	<b>125</b>	<b>8</b>	<b>158</b>	<b>10</b>	<b>1,605</b>	<b>100%</b>
<b>Total</b>	<b>1,712</b>	<b>55</b>	<b>1,205</b>	<b>39</b>	<b>209</b>	<b>7</b>	<b>3,126</b>	<b>100%</b>

## APPENDIX B

### Sharps Injuries among Hospital Workers by Number of Licensed Hospital Beds, Massachusetts, 2008

	Hospital size <sup>^</sup>							
	<100 beds		101-300 Beds		> 300 beds		All Hospitals	
	31 hospitals		53 hospitals		15 hospitals		99 hospitals	
	N	%	N	%	N	%	N	%
<b>STATE TOTAL</b>	<b>200</b>	<b>100%</b>	<b>1,101</b>	<b>100%</b>	<b>1,825</b>	<b>100%</b>	<b>3,126</b>	<b>100%</b>
<b>WORK STATUS OF INJURED WORKER</b>								
Employee	169	85	928	84	1,603	88	2,700	86 %
Non-Employee Practitioner	19	10	126	11	137	8	282	9
Student	8	4	29	3	64	4	101	3
Temporary / Contract Worker	4	2	17	2	19	1	40	1
Other	0	0	0	0	1	<1	1	<1
Unknown / Not answered / Nonclassifiable	0	0	1	<1	1	<1	2	<1
<b>OCCUPATION</b>								
Nurse	94	47	501	46	603	33	1,198	38 %
Physician	42	21	240	22	833	46	1,115	36
Technician	37	19	259	24	256	14	552	18
Support Services	12	6	47	4	72	4	131	4
Other Medical Staff	7	4	32	3	23	1	62	2
Dental Staff	2	1	1	<1	15	1	18	1
Other	6	3	19	2	20	1	45	1
Unknown / Not answered / Nonclassifiable	0	0	2	<1	3	<1	5	<1
<b>DEPARTMENT WHERE INJURY OCCURRED</b>								
Operating and Procedure Rooms	83	42	409	37	841	46	1,333	43 %
Inpatient Units	49	25	285	26	367	20	701	22
Emergency Department	19	10	124	11	138	8	281	9
Intensive Care Units	6	3	85	8	185	10	276	9
Outpatient areas	10	5	65	6	112	6	187	6
Laboratories	7	4	48	4	76	4	131	4
Other areas	25	13	76	7	96	5	197	6
Unknown / Not answered / Nonclassifiable	1	1	9	1	10	1	20	1
<b>PROCEDURE FOR WHICH DEVICE WAS USED</b>								
Injection	51	26	311	28	409	22	771	25 %
Suturing	23	12	210	19	445	24	678	22
Blood Procedures	35	18	212	19	188	10	435	14
Line Procedures	20	10	93	8	202	11	315	10
Making the Incision	28	14	99	9	232	13	359	11
To Obtain Body Fluid or Tissue Sample	4	2	36	3	61	3	101	3
Dental Procedures	0	0	2	<1	10	1	12	<1
Other	26	13	76	7	158	9	260	8
Unknown / Not answered / Nonclassifiable	13	7	62	6	120	7	195	6

<sup>^</sup> Information on the number of licensed beds is obtained from the MDPH Division of Health Care Quality.

## APPENDIX B

### Sharps Injuries among Hospital Workers by Number of Licensed Hospital Beds, Massachusetts, 2008

	Hospital size <sup>^</sup>							
	<100 beds		101-300 Beds		> 300 beds		All Hospitals	
	31 hospitals		53 hospitals		15 hospitals		99 hospitals	
	N	%	N	%	N	%	N	%
<b>STATE TOTAL</b>	<b>200</b>	<b>100%</b>	<b>1,101</b>	<b>100%</b>	<b>1,825</b>	<b>100%</b>	<b>3,126</b>	<b>100%</b>
<b>DEVICE INVOLVED IN THE INJURY</b>								
Hypodermic needles / syringe	67	34	371	34	534	29	972	31 %
Suture Needle	23	12	214	19	442	24	679	22
Winged Steel Needle	23	12	127	12	114	6	264	8
Scalpel Blade	16	8	63	6	170	9	249	8
Vacuum Tube Collection Holder / Needle	11	6	46	4	42	2	99	3
Glass	0	0	12	1	20	1	32	1
Dental Device or Item	1	1	4	<1	7	<1	12	<1
Other Hollow Bore Needle	21	11	107	10	173	9	301	10
Other	35	18	140	13	290	16	465	15
Unknown / Not answered / Nonclassifiable	3	2	17	2	33	2	53	2
<b>SAFETY DEVICE</b>								
No	99	50	493	45	1,120	61	1,712	55 %
Yes	94	47	520	47	591	32	1,205	39
Unknown / Not answered	7	4	88	8	114	6	209	7
<b>WHEN THE INJURY OCCURRED</b>								
During Use of the Item	83	42	452	41	820	45	1,355	43 %
After Use / Before Disposal	89	45	447	41	663	36	1,199	38
During or After Disposal of the Item	15	8	133	12	196	11	344	11
Before Use of the Item	2	1	8	1	16	1	26	1
Unknown / Not answered / Nonclassifiable	11	6	61	6	130	7	202	6
<b>HOW THE INJURY OCCURRED</b>								
Collision with Worker or Sharp	28	14	165	15	356	20	549	18 %
Suturing	15	8	105	10	214	12	334	11
Handle / Pass Equipment	16	8	92	8	174	10	282	9
Activate Safety Device	23	12	128	12	143	8	294	9
Manipulate Needle in Patient	17	9	86	8	146	8	249	8
Patient Moved / Jarred Device	14	7	100	9	117	6	231	7
Improper Disposal	8	4	79	7	131	7	218	7
During Sharps Disposal	9	5	69	6	90	5	168	5
During Clean-up	15	8	55	5	90	5	160	5
Failure to Activate Safety Device	18	9	43	4	40	2	101	3
Recap Needle	7	4	27	2	44	2	78	2
Device Malfunctioned	2	1	38	3	36	2	76	2
Access IV Line	3	2	4	<1	27	1	34	1
Before Use of Item	1	1	6	1	10	1	17	1
Other	18	9	86	8	181	10	285	9
Unknown / Not answered / Nonclassifiable	6	3	18	2	26	1	50	2

<sup>^</sup> Information on the number of licensed beds is obtained from the MDPH Division of Health Care Quality.

## APPENDIX C

### Sharps Injuries among Hospital Workers by Hospital Teaching Status, Massachusetts, 2008

	Teaching Status <sup>^</sup>					
	Teaching		Non-teaching		All Hospitals	
	21 hospitals		78 hospitals		99 hospitals	
	N	%	N	%	N	%
<b>STATE TOTAL</b>	<b>2,035</b>	<b>100%</b>	<b>1,091</b>	<b>100%</b>	<b>3,126</b>	<b>100%</b>
<b>WORK STATUS OF INJURED WORKER</b>						
Employee	1,777	87	923	85	2,700	86 %
Non-Employee Practitioner	155	8	127	12	282	9
Student	78	4	23	2	101	3
Temp / Contract	23	1	17	2	40	1
Other	1	<1	0	0	1	<1
Unknown / Not answered / Nonclassifiable	1	<1	1	<1	2	<1
<b>OCCUPATION</b>						
Nurse	665	33	533	49	1,198	38 %
Physician	913	45	202	19	1,115	36
Technician	300	15	252	23	552	18
Support Services	76	4	55	5	131	4
Other Medical Staff	36	2	26	2	62	2
Dental Staff	14	1	4	<1	18	1
Other	29	1	16	1	45	1
Unknown / Not answered / Nonclassifiable	2	<1	3	<1	5	<1
<b>DEPARTMENT WHERE INJURY OCCURRED</b>						
Operating and Procedure Rooms	927	46	406	37	1,333	43%
Inpatient Units	422	21	279	26	701	22
Emergency Department	156	8	125	11	281	9
Intensive Care Units	201	10	75	7	276	9
Outpatient areas	130	6	57	5	187	6
Laboratories	88	4	43	4	131	4
Other areas	102	5	95	9	197	6
Unknown / Not answered / Nonclassifiable	9	<1	11	1	20	1
<b>PROCEDURE FOR WHICH DEVICE WAS USED</b>						
Injection	449	22	322	30	771	25%
Suturing	486	24	192	18	678	22
Blood Procedures	229	11	206	19	435	14
Line Procedures	209	10	106	10	315	10
Making the Incision	260	13	99	9	359	11
To Obtain Body Fluid or Tissue Sample	70	3	31	3	101	3
Dental Procedures	9	<1	3	<1	12	<1
Other	185	9	75	7	260	8
Unknown / Not answered / Nonclassifiable	138	7	57	5	195	6

<sup>^</sup> Information on hospitals' teaching status is obtained from the Massachusetts Division of Health Care Finance and Policy.

## APPENDIX C

### Sharps Injuries among Hospital Workers by Hospital Teaching Status, Massachusetts, 2008

	Teaching Status <sup>^</sup>					
	Teaching		Non-teaching		All Hospitals	
	21 hospitals		78 hospitals		99 hospitals	
	N	%	N	%	N	%
<b>STATE TOTAL</b>	<b>2,035</b>	<b>100%</b>	<b>1,091</b>	<b>100%</b>	<b>3,126</b>	<b>100%</b>
<b>DEVICE INVOLVED IN THE INJURY</b>						
Hypodermic needles / syringe	588	29	384	35	972	31
Suture Needle	488	24	191	18	679	22
Winged Steel Needle	143	7	121	11	264	8
Scalpel Blade	190	9	59	5	249	8
Vacuum Tube Collection Holder / Needle	42	2	57	5	99	3
Glass	23	1	9	1	32	1
Dental Device or Item	7	<1	5	<1	12	<1
Other Hollow Bore Needle	181	9	120	11	301	10
Other	333	16	132	12	465	15
Unknown / Not answered / Nonclassifiable	40	2	13	1	53	2
<b>SAFETY DEVICE</b>						
No	1,226	60	486	45	1,712	55%
Yes	654	32	551	51	1,205	39
Unknown / Not answered	155	8	54	5	209	7
<b>WHEN THE INJURY OCCURRED</b>						
During Use of the Item	929	46	426	39	1,355	43%
After Use / Before Disposal	721	35	478	44	1,199	38
During or After Disposal of the Item	209	10	135	12	344	11
Before Use of the Item	19	1	7	1	26	1
Unknown / Not answered / Nonclassifiable	157	8	45	4	202	6
<b>HOW THE INJURY OCCURRED</b>						
Collision with Worker or Sharp	393	19	156	14	549	18%
Suturing	256	13	78	7	334	11
Activate Safety Device	155	8	139	13	294	9
Handle / Pass Equipment	196	10	86	8	282	9
Manipulate Needle in Patient	156	8	93	9	249	8
Patient Moved / Jarred Device	135	7	96	9	231	7
Improper Disposal	130	6	88	8	218	7
During Sharps Disposal	104	5	64	6	168	5
During Clean-up	96	5	64	6	160	5
Failure to Activate Safety Device	38	2	63	6	101	3
Recap Needle	48	2	30	3	78	2
Device Malfunctioned	37	2	39	4	76	2
Before Use of Item	12	1	5	<1	17	1
Access IV Line	30	1	4	<1	34	1
Other	212	10	73	7	285	9
Unknown / Not answered / Nonclassifiable	37	2	13	1	50	2

<sup>^</sup> Information on hospitals' teaching status is obtained from the Massachusetts Division of Health Care Finance and Policy.

## **APPENDIX D**

### Resources

#### Sharps Injury Surveillance and Prevention

MDPH Occupational Health Surveillance Program

<http://www.mass.gov/dph/ohsp>

Sharps Injury Surveillance and Prevention Project - e-mail: [Sharps.Injury@state.ma.us](mailto:Sharps.Injury@state.ma.us)

OSHA Subject Page for Needle Sticks

Includes Bloodborne Pathogens Standard and compliance directive

<http://www.osha.gov/SLTC/bloodbornepathogens/index.html>

CDC-MMWR September 30, 2005 / Vol. 54 / RR-9

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Post Exposure Prophylaxis

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5409a1.htm>

CDC-MMWR June 29, 2001 / Vol. 50 / RR-11

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV and Recommendations for Post Exposure Prophylaxis

<http://www.cdc.gov/mmwr/PDF/rr/rr5011.pdf>

CDC Division of Healthcare Quality Promotion

Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program

<http://www.cdc.gov/sharpssafety/>

CDC Division of Healthcare Quality Promotion, Issues in Healthcare

Information related to bloodborne pathogens

<http://www.cdc.gov/ncidod/hip/Blood/blood.htm>

CDC Division of Healthcare Quality Promotion, National Surveillance System for Health care Workers

<http://www.cdc.gov/ncidod/hip/SURVEILL/nash.HTM>

National Surveillance System for Health care Workers,

Summary report for data collected from June 1995 through July 1999

<http://www.cdc.gov/ncidod/hip/NASH/report99.PDF>

NIOSH Alert – Preventing Needlestick Injuries in Health care settings

<http://www.cdc.gov/niosh/2000-108.html>

JCAHO Sentinel Event Alert, Issue 22 August 2001

Preventing Needlestick and Sharps Injuries

[http://www.jcaho.org/edu\\_pub/sealert/sea22.html](http://www.jcaho.org/edu_pub/sealert/sea22.html)

EPINet, International Health Care Worker Safety Center, University of Virginia

<http://www.med.virginia.edu/medcntr/centers/epinet/>

Training for Development of Innovative Control Technologies (TDICT) Project, San Francisco General Hospital

<http://www.tdict.org/>

Sustainable Hospitals Project, Lowell Center for Sustainable Production, University of Massachusetts Lowell

<http://sustainablehospitals.org>