



Mayo Clinic

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

William F. Marshall, M.D.

Infectious Diseases
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Dear Sir or Madam:

The response to the FDA's request for information is as follows:

I. Introduction

Since June 2000 our institution has actively worked to uniformly comply with the updated OSHA Bloodborne Pathogen directive and the subsequent National Needlestick Safety and Prevention Act (Public Law 106-430) signed into law 11/6/2000. Various departments have worked aggressively to track and prevent needlesticks even before this institutional program was established.

Data from our various departments show the most dramatic decline in needlesticks to healthcare workers occurred when the needleless IV system was adopted and when safety equipment was mandated for blood collections. The **needleless IV** system was introduced in 1994. After the introduction of this safety equipment, the needlestick rate for hollowcore punctures **fell 42%** for our hospital floor staff. Safety devices for **drawing blood** were introduced in September of 1999. After training of employees, mandating the use of safety devices and removal of all old, non-safety devices, the needlestick rate **dropped 74%** in this workgroup.

Work areas continue to analyze injuries annually from contaminated medical sharps, evaluate current and new safety equipment, scrutinize work practices and strive to prevent such injuries. As the data above demonstrates, engineering controls are very effective measures for prevention of needlestick/sharp injuries.

While efforts to reduce needlestick injuries continue, the institution is targeting high-risk tasks that currently involve hollowcore, blood-filled needles for possible safety devices. This includes starting IVs and keeping IV lines needle-free.

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II. Specific Actions Called for in the March 2001 Petition to the FDA

A. Banning certain medical devices

We would support the ban of these devices:

Non-safety IV catheters

Blood collection devices that do not meet the FDA's safety criteria

Glass capillary tubes

IV infusion equipment that does not use needleless technology (this would include prepared syringes of medications coming from pharmaceutical companies with non-detachable, non-safety needles)

We make these recommendations for reasons similar to those written in the petition:

Their use creates a high risk of exposure and transmission of bloodborne pathogens, Hepatitis B, Hepatitis C and HIV

Their use is common by healthcare workers

There is currently available FDA-cleared technology to minimize exposure

Manufacturers of medical devices should be held to the same standards for safety equipment for use with blood and body fluids as healthcare employers.

Supporting Data

Safety IV catheters

As literature supports (see references 1,2,3), **safety devices for starting IVs** dramatically reduce the number of punctures experienced by healthcare workers and the waste handlers downstream. Our experience confirms this. Over the last 4 years in areas starting hundreds of IVs yearly, a decline in such high-risk exposures has occurred when using safety equipment meeting the recommended safety criteria. Four years ago these areas experienced significant numbers of needlesticks involved with starting IVs. In 2002, safety devices were mandated. All the old equipment not complying with OSHA's and FDA's safety criteria was removed. To date, these areas have had **no exposures** utilizing the safety catheters.

Blood Collection Devices

As mentioned above, safety devices have replaced all non-safety devices for blood collections. This has resulted in a **74% decline** these high-risk exposures.

Glass capillary tubes

Since the National Committee for Clinical Laboratory Standards (WCCLS) banned the use of glass capillary tubes several years ago, these have not been used in our institution.

IV infusion equipment

Medications that come from pharmaceutical companies in syringes with non-safety needles attached still account for **20-40% of needlesticks** occurring with our hospital floor staff. Such devices defeat needleless IV mandates, utilizing needles in IV ports when none are needed. Syringes without needles attached are preferred but are not always available from the pharmaceutical companies. (Even when these medications are to be given subcutaneously or intramuscularly, the syringes without needles are preferred for needlestick prevention.) Such non-safety forms of medications pose dangers during disposal, since the contaminated needle is not covered immediately after administration. Often such devices have to be unscrewed from

holder, creating a clear danger for the healthcare worker with a contaminated needle uncovered. Examples include:

- Narcotics
- Antibiotics
- Heparin
- Vaccines
- Anti-inflammatories

Such devices come from various pharmaceutical companies such as Abbott, Aventis, Merck, et

B. Performance Standard

Consideration should be given to writing a performance standard based on the five design criteria to protect all healthcare workers. The **most effective control of the needlestick/sharp hazard is safety equipment**. When it is mandated, and old equipment is removed from supply our data shows that behavior changes, practices change and bloodborne pathogen exposures are reduced.

C. Labeling

Labeling conventional syringes, "To prevent possible exposure to HIV and hepatitis, do not use for standard blood draws," may be helpful. Conventional syringes should not be used for that purpose unless a safety needle is attached.

III. Conclusion

Prevention of transmission of Hepatitis B, Hepatitis C and HIV to Healthcare workers is the reason the Needlestick Safety and Prevention Act was passed. Healthcare workers, healthcare employers and manufacturers of medical devices all need to work together to provide a safe work environment for such prevention. OSHA and JCAHO regulate healthcare workers and employers. Their mandates are in place and work is moving forward for compliance in the healthcare field. FDA regulates medical devices. Equal attention and work in regulation and compliance of **new and old medical devices** must be accomplished to provide a safe work environment for healthcare workers.

References

1. Gershon RR. Pearse L. Grimes M. Flanagan PA. Vlahov D. The impact of multifocused interventions on sharps injury rates at an acute-care hospital. [Journal Article] *Infection Control & Hospital Epidemiology*. 20(12):806-11, 1999 Dec.
UI: 10614603
2. Jagger J. Bentley MB. Injuries from vascular access devices: high risk and preventable. Collaborative EPINet Surveillance Group. [Journal Article] *Journal of Intravenous Nursing*. 20(6 Suppl):S33-9, 1997 Nov-Dec.
UI: 9423399
3. Connor RE. Krall SP. Megargel RE. Tan LE. Bouzoukis JK. Reducing the rate of paramedic needlesticks in emergency medical services: the role of self-capping intravenous catheters. [see comments.]. [Journal Article] *Academic Emergency Medicine*. 3(7):668-74, 1996 Jul.
UI: 8816182

Sincerely,

William Marshall

William F. Marshall, M.D.

Chair, Bloodborne Pathogen Exposure Reduction Subcommittee

WFM:ljh

Members of the Bloodborne Pathogen Exposure Reduction Subcommittee

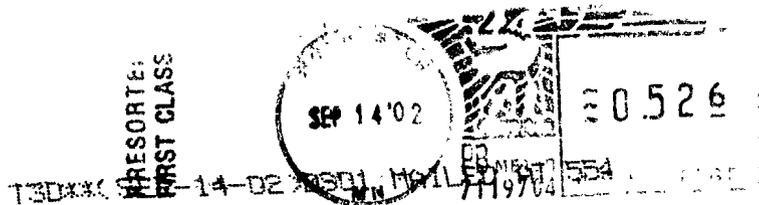
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