NIOSH recommends that health care facilities use safer medical devices to protect workers from needlestick and other sharps injuries.
Since the passage of the Needlestick Safety and Prevention Act in 2000 and the subsequent revision of the OSHA Bloodborne Pathogen Standard, all health care facilities are required to use safer medical devices.

Safer Medical Device Implementation in Health Care Facilities

Sharing Lessons Learned

NIOSH has asked a small number of health care facilities to share their experiences on how they implemented safer medical devices in their settings. These facilities have agreed to describe how each step was accomplished, and also to discuss the barriers they encountered and how they were resolved, and most importantly, lessons learned.

DISCLAIMER: Provision of this report by NIOSH does not constitute endorsement of the views expressed or recommendation for the use of any commercial product, commodity or service mentioned. The opinions and conclusions expressed are those of the authors and not necessarily those of NIOSH. More reports on Safer Medical Device Implementation in Health Care Settings can be found at http://www.cdc.gov/niosh/topics/bbp/safer/

Phase 3 Report – Identify and Screen Safer Medical Devices

Facility Background

We represent a small Home Health Agency, characterized by a daily average census of 25 patients. Our patient population is primarily geriatric. This agency is Medicare and Medicaid certified. Our Medicare license is for one county. We have a multi-cultural work force, consisting of 11 employees. One fulltime RN case manager, one RN on call, one Physical Therapist, two Occupational Therapists, two Home Health Aides (one does primarily office billing, referral coordination ect.). The Medical Social Worker, and Dietician are shared staff with the parent company and work out of their offices. The agency contracts for a Speech Language Pathologist staff as needed. The home health agency office is located on the administrative floor of a skilled nursing facility. The skilled nursing facility is our parent company. The home health agency utilizes the parent company for supply management and other additional support.

Our sharp injury prevention team identified and screened anticoagulation machines. This was the safer medical device prioritized in the phase 1 process. This was a two-step process. It was broken out by first identifying the manufacturers and their products and second by physically examining the devices to ensure their appropriateness for specific clinical settings.

These anticoagulation machines were fairly new on the market and not in current magazines or catalogue publications. I, the facilitator / Director of our safer devices program, sought information through varied channels. These included:

- **Internet**
  This provided information on various machines, links to manufactures, and FDA approvals. I typed in "anticoagulation machine" and ran a search.
- **DME supplier**
  The sales person was able to provide machine ordering information, and cost for 1 machine. This person also had valuable information about the one anticoagulation machine that had been pulled off the market. This machine had been mentioned to me and I had not been able to find any information on it.
- **Home Health Agency Directors**
  Very valuable information came from other Home Health Agency's who were using or considering anticoagulation machines. Professional contacts offered the name and number of staff in their agencies who were currently using the machine.
- **Coagulation clinics in the community**
  Our nurses often call in lab results to these clinics under the direction of their physicians. One of the clinics in the area was currently using an anticoagulation machine.
- **Director of Nursing from the Skilled Nursing Facility**

She had done some previous research on the machines and was able to provide a name of one.

•**National Home Care List Serve**

I was able to contact providers who had identified themselves as resources on the list serve.

•**Coagulation Manufactures**

Provided very detailed information on each machine.

There were 2 anticoagulation machines on the market. A third machine had been pulled back by the FDA and was no longer available. The sharps injury prevention team considered many factors and compared the two machines. These factors included:

- FDA approval
- Certificate of Waiver (This is lab testing approval in the home setting per the state administrative codes)
- Size, ability to carry into peoples' homes
- Able to use safety lancet
- Ease of use, maintenance; cleaning, quality checks
- Drop size of blood sample required
- Cost initial and cost to operate; strips, solutions, ect
- Availability
- Length on the market, proven reliability

The machines were quite comparable except in two categories. These categories being ease of use due to the sample size of blood required and size. The main difference was one machine required a test tube partially filled and inserted into the machine. The second machine required a large drop of blood placed on a strip. This procedure mirrored the procedure currently used in testing blood sugar levels. The second anticoagulation machine was smaller than the first

The Sharps Injury Protection Team quickly saw the benefit from the second anticoagulation machine. The size of the machine would make it portable to be carried into a patient's home for the skilled nursing visit. Secondly, training time would be minimal because the testing procedure was similar to what our staff currently used.

The sharps injury prevention team was unanimous upon selecting the second machine after analyzing the detailed information from the manufactures. The majority of the time was involved in researching products. Once all the information was collected and organized the decision was easily reached. Estimated at 5 hours of my time and less than 30 min per the other members.

Type of Staff	Time (hours)
Administrative / Management	5
Clinical	1

Lessons learned and Recommendations

This being an expensive piece of equipment (for our small agency) it is worth checking all avenues for information. The most frustrating part had been trying to track down information about a machine that had been pulled off the market. The most beneficial information getting started came from contacts in the industry.