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Medical Devices

Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication: Update 11/29/2010

Original Date Issued: August 26, 2010

Date Updated: November 29, 2010

Audience:

All healthcare personnel who perform blood sampling, including point of care nurses, physicians, laboratory personnel and phlebotomists, as well as patients whose blood is routinely sampled.

Medical Specialties: All medical specialties, particularly Internal Medicine, Emergency Medicine, Family Practice, Endocrinology, Pediatrics, Intensive Care, Obstetrics/Gynecology and Geriatrics

Devices: Reusable fingerstick (blood lancing) devices and point of care (POC) blood testing devices (e.g., blood glucose meters, PT/INR anticoagulation meters, cholesterol testing devices, etc.)

Purpose: The FDA is updating its communication on the risks of using fingerstick devices on more than one person to include new FDA and other government agency activities.

Summary of Problem and Scope:

Fingerstick devices are used to puncture the skin to obtain small blood specimens for testing blood glucose, hemoglobin, and other blood components. These instruments are equipped with lancets (small, double-edged blades or needles). Some fingerstick devices have replaceable lancets and are designed to be used more than once. Others are designed for single use only.

Some fingerstick devices are packaged with POC blood testing devices, such as blood glucose meters and PT/INR anticoagulation meters. These devices are used in both home and professional healthcare settings.

Over the past 10 to 15 years, the CDC and the FDA have noted a progressive increase in reports of bloodborne infection transmission (primarily hepatitis B virus) resulting from the shared use of fingerstick and POC blood testing devices. Although the infections are occurring in a variety of health care settings, the Agencies note that these infections have increased significantly in long term care/assisted living settings. Unclear labeling and ineffective cleaning/disinfection instructions for fingerstick and POC blood testing devices may have contributed to these outbreaks.

Fingerstick and POC blood testing devices can be reused safely by a single patient in the home when the user follows device labeling for cleaning the blood testing device, for cleaning the reusable components of fingerstick devices, and for changing lancet blades.

However, fingerstick devices should **NEVER** be used for more than one person. This is not a safe practice for several reasons. Improper use or device malfunction can lead to the use of a contaminated lancet blade on more than one patient. POC blood testing devices can also be a source of bloodborne infections if used on multiple patients, because it is difficult for healthcare staff to ensure that all blood has been removed from these devices and the reusable portions of the fingerstick device. If contaminated blood is left on them, this could result in bloodborne pathogen transmission among patients. Failure of healthcare personnel to change gloves between patients could also result in bloodborne pathogen transmission.

Recommendations and FDA Action

The FDA and the CDC recommend that health care professionals and patients take the following immediate precautions:

- Never use fingerstick devices for more than one person.
- Use auto-disabling, single-use fingerstick devices for assisted monitoring of blood glucose. These devices are designed to be used only once, after which the blade is retracted, capped or otherwise made unusable. These are sometimes called "safety" lancets.
- Whenever possible, use POC blood testing devices, such as blood glucose meters and PT/INR anticoagulation meters, for one patient only. If dedicating POC blood testing devices to a single patient is not possible, the devices should be properly cleaned and disinfected after every use as described in the device labeling.
- Change gloves between patients, even when using patient-dedicated POC blood testing devices and single-use, auto-disabling fingerstick devices.

FDA and other Government Agency Activities:

UPDATED November 29, 2010

On September 20, 2010, the FDA issued a letter to manufacturers of fingerstick devices capable of being used more than once. The letter requested that manufacturers inform the FDA in writing of the following:

- models of this type of device that they manufacture or market; and
- actions they intend to take to address health risks described in this communication.

In the past, FDA cleared some multiple-use fingerstick devices for use in multiple patients, a practice that is now recognized as not safe. To correct this situation, on November 29, 2010, the FDA released [“Guidance for Industry and Food and Drug Administration Staff: Blood Lancet Labeling”](#)¹, recommending a change in the intended use and labeling of fingerstick devices to reduce the risk of bloodborne infection transmission. The FDA recommends that all fingerstick devices be labeled for use only on a single patient. The guidance also recommends manufacturers of reusable fingerstick devices to include the following information on their labeling:

- Label the reusable portion of reusable fingerstick devices with the statement “single patient use only”
- Include information in the instructions for use that the device should not be used for assisted blood draws by healthcare providers in settings such as long term care, assisted living facilities, clinics, or health fairs, and should not be shared with anyone, including family members.
- Provide validated instructions for cleaning and disinfecting the reusable portion of the device after every use by the owner of the device.

For additional information, see:

- Notice of Availability: [Guidance for Industry and Food and Drug Administration Staff: Blood Lancet Labeling; Availability](#)²
- CDC Clinical Reminder: [Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens](#)³
- Webpage: [Infection Prevention during Blood Glucose Monitoring and Insulin Administration](#)⁴

On August 27, 2010, Centers for Medicare and Medicaid Services (CMS) issued a Survey and Certification Memorandum for Point of Care Devices and Infection Control in Nursing Homes identifying the use of lancet devices for more than one patient as an infection control standards deficiency. For more information, see [CMS Survey and Certification Memorandum](#)⁵.

Report Problems to FDA:

Prompt reporting of adverse events can help FDA identify and better understand the risks associated with medical products. If you suspect problems with the use of fingerstick devices, we encourage you to file a voluntary report through [MedWatch, the FDA Safety Information and Adverse Event Reporting program](#)⁶. Healthcare personnel employed by facilities that are subject to [FDA’s device user facility reporting requirements](#)⁷ should follow the reporting procedures established by their facilities.

Contact Information:

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV or by phone at 800-638-2041 or 301-796-7100.

Additional Resources

- [Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication \(8/26/2010\)](#)⁸

Links on this page:

1. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm234577.htm>
2. <http://edocket.access.gpo.gov/2010/2010-29795.htm>
3. <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>
4. <http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>
5. http://www.cms.gov/surveycertificationgeninfo/downloads/SCLetter10_28.pdf
6. <http://www.fda.gov/Safety/MedWatch/default.htm>
7. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm>

8. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm234889.htm>