Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication

U.S. Food & Drug Administration

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Audience:
All staff who perform blood testing such as, point of care nurses, physicians, laboratory personnel, phlebotomists, and primary care personnel in long-term care and assisted living facilities, hospitals, private physician offices, labs, clinics, schools, public health fairs; and patients.

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.)

Summary of Problem and Scope:

CDC and FDA have noted a progressive increase in the reports of bloodborne infection transmission over the past 10 to 15 years (primarily hepatitis B virus), resulting from the shared use of fingerstick and POC blood testing devices. The infections are occurring in a variety of health care settings; however, the Agencies note a significant increase in hepatitis B virus infection outbreaks related to the shared use of multiuse fingerstick devices and POC blood testing devices 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 devices are instruments equipped with a lancet (a small, double-edged blade or needle). These devices are used for making skin punctures to obtain small blood specimens which are tested for blood glucose, hemoglobin, and other blood components.

Some fingerstick devices are packaged with POC blood testing devices, such as blood glucose meters and PT/INR anticoagulation meters, while other fingerstick devices and lancet blades are sold separately.

Fingerstick devices are designed for either multiple use or single use. POC blood testing devices designed for over-the-counter use are used in both home and professional healthcare settings. Fingerstick and POC blood testing devices can be

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

Fingerstick and POC blood testing devices used on more than one patient may not be safe for several reasons. Improper use or device malfunction can lead to the use of the contaminated lancet blade on more than one patient. Furthermore, it is difficult for healthcare staff to ensure that all blood has been removed from POC blood testing devices and the reusable portions of the fingerstick device. If POC blood testing devices are used on multiple patients and are not cleaned and disinfected correctly and thoroughly between each patient, contaminated blood left on them could result in bloodborne pathogen transmission among patients. Fingerstick devices should **NEVER** be used for more than one person. Failure of healthcare personnel to change gloves between patients could also result in bloodborne pathogen transmission.

In the past, FDA has cleared multiple-use fingerstick devices both for use in multiple patients, and in single patients. However, multiple-use fingerstick devices cleared for use in more than one patient increase the risk of bloodborne infection transmission between patients. Also, labeling of some multiple-use fingerstick devices made for single patients may not clearly state that the device is intended for use **only** for single patients. In addition, labeling of fingerstick devices made for single patients do not clearly state that the device is intended for use for single patients. This may result in the use of these devices in multiple patients.

Recommendations and FDA Action

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

1. Fingerstick devices should **NEVER** be used for more than one person.
2. Auto-disabling, single-use fingerstick devices should be used 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 may also be called "safety" lancets.
3. Whenever possible, POC blood testing devices, such as blood glucose meters and PT/INR anticoagulation meters, should be used only on one patient and not shared. 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.
4. Change gloves between patients, even when patient-dedicated POC blood testing devices and single-use, self-disabling fingerstick devices are used by healthcare personnel.

Some legally marketed fingerstick devices have been cleared for use on more than one patient. Shortly, FDA will issue a separate communication describing the actions the Agency will take to assure that these devices are labeled for use on only one patient to reduce the risk of bloodborne infection transmission.

For additional information from CDC, see:

- CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens [1]
- Webpage: Infection Prevention during Blood Glucose Monitoring and Insulin Administration [2]

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 [3]. Healthcare personnel employed by facilities that are subject to FDA's device user facility reporting requirements [4] 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 [5] or 800-638-2041.

SOURCE [6]

Source URL (retrieved on *03/10/2014 - 5:48pm*):
http://www.mdtmag.com/news/2010/08/use-fingerstick-devices-more-one-person-poses-risk-transmitting-bloodborne-pathogens-initial-communication?qt-recent_content=0

Links:
[1] http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html
[2] http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html
[3] http://www.fda.gov/Safety/MedWatch/default.htm
[4] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm
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