Fingerstick Devices to Obtain Blood Specimens: Initial Communication - Risk of Transmitting Bloodborne Pathogens

U.S. Food & Drug Administration

ISSUE: FDA and CDC 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 point-of-care [POC] blood testing devices.

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. 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.

BACKGROUND: Fingerstick devices are instruments equipped with a lancet. 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.

RECOMMENDATION: Fingerstick devices should never be used for more than one person. 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[08/26/2010 - Initial Communication [3] - FDA]
[08/26/2010 - Infection Prevention during Blood Glucose Monitoring and Insulin Administration [4] - CDC]
[08/26/2010 - Clinical Reminder: Use of Fingerstick Devices [5] - CDC]

SOURCE [6]

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Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
[4] http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html
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