Infection Control for Blood Glucose Monitoring Systems - New Regulatory Review Requirements

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Leslie Landree, Ph.D.
Division of Chemistry and Toxicology Devices
Office of in Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Background

- During the week of August 23, 2010, the FDA, CDC, and CMS issued clinical reminders and public health notifications highlighting the risk of transmission of disease from shared use of fingerstick (lancing) devices and point of care blood testing devices.

- These notifications were in response to recent outbreaks of viral hepatitis among patients where these devices were shared between users.

Background

- Accordingly, the FDA modified its regulatory review requirements for all blood glucose monitoring systems (BGMS) to ensure that validated cleaning and disinfection instructions are provided to users so that they may adequately respond to these recommendations. The FDA also stated that lancing devices should never be shared. Only single-use, auto-disabling lancing devices can be used for multiple patient use.

- Letters to BGMS manufacturers were issued (September 2010) by OIVD/DCTD. New review requirements were applied to submissions that were in house (under review or on hold) or submitted thereafter.

Overview

- Intended Use
- Device Names
- Labeling
- EPA registered disinfectant effective against Hepatitis B
- Disinfection Efficacy Testing
- Device Robustness Testing

Intended Use

- Distinct products should be created with separate intended uses (single-patient use vs. multiple-patient use).
- These products may have the same technical components (e.g., same meter and test strips and same performance data), but they will be considered separate devices.

Naming and Labeling

- Device systems should have naming schemes that tie the components (system, meter and test strips) together and differentiate the systems (single- vs. multiple-patient use) and should have separate product labeling.
- Systems differ in the type of lancing device that can be included or used.
- Categorized for CLIA separately under the two distinct names.

EPA Registered Disinfectant

- EPA registered disinfectant effective against HBV
  - Available for purchase by user
  - Acceptable disinfectant time (< 3 min)
  - No personal protective equipment
  - Follow EPA registered label instructions (pre-clean step, contact time…) for all validation testing

http://oaspub.epa.gov/pestlabl/ppls.home

Disinfection Efficacy Testing

- Diagram of device with detailed materials description (material name, texture, color, paint)
- 3 lots of each material / 1 lot of disinfectant product
- No pre-cleaning included
- DHBV (testing labs available)
- HBsAG using an FDA approved assay

Device Robustness Testing

- Minimum of 3 devices (3 meters, 3 lancing devices)
- Validate both cleaning and disinfection steps.
- Should simulate actual use (wiping). Wrapping, soaking, dunking are not acceptable methods
- Justification for both the number of cleaning and disinfection cycles - dependent on the intended use – for a typical use life of 3-5 years.

Device Robustness Testing

- Examine device exterior for signs of deterioration
  - Meter and button icons remain legible
  - Meter casing and buttons do not display any cracking.
  - Display remains clear (no cloudiness or fogging)
  - No cracking or other damage that obscures test results
  - No pixels on the display are damaged

Device Robustness Testing

- Assess performance before and after testing
  - Blood samples should be used. Control samples and simulator strips are not acceptable
  - On/off, buttons function etc…
  - Lancing device performance

Protocol Review

We recommend that disinfection and robustness Protocols be submitted for review through the pre-IDE process prior to initiating the studies.