Hot Topic:
Hospital-Based Glucose Meters

CMS Partner’s Meeting
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Glucose Meters

- Available for more than 3 decades
- Revolutionized diabetes management
- Allow for better glycemic control by diabetics
- Have gotten smaller, faster, and more accurate over the years
Glucose Meters

• FDA clears glucose meters for the following intended uses:
  • For quantitative measurement of glucose in whole blood (e.g., capillary, venous, arterial)
  • For use by healthcare professionals or lay users
  • A few are cleared for use on neonates

  For the following indications:
  • As aid in monitoring the effectiveness of diabetes control program
  • Not intended for the diagnosis of or screening for diabetes

Other ways they are also used (off-label):
• Glycemic control protocols in hospitals (diabetics and non-diabetics)
• Critically ill patients
• Anything they are needed for in the hospital
Glucose Meters

• Manufacturers submit the meters to FDA with home use claims even when they intend to sell them as hospital use meters

• They submit validation data suitable for home use capillary self testing, and minimal validation in arterial and venous blood (if claimed)

• This submission strategy allows the hospital meters to be waived (due to OTC status) without the need for CLIA waiver studies
Glucose Meters

• In recent years concerns have been raised citing the inability of currently cleared glucose meters, if not adequately validated and controlled by the hospital, to perform effectively in critical care settings, given that these devices were not originally designed or evaluated for this type of use.

• Patients in critical care settings can be more acutely ill and medically fragile, and are more likely to present physiological, pathological and pre-analytical factors that could interfere with glucose measurements as compared to other types of users.

• For critically ill patients who by their very nature tend to be more seriously ill, any inaccuracies in the meters could further increase the risk to these patients.
Glucose Meters

• For many years, FDA has requested that all labeling for glucose meters include a statement in their device labeling indicating that the system is not intended to be used in the critically ill patient population.

• We requested this statement because the device has not been designed for use in, or studied in this population.

• By including the statement in the Limitation section, FDA hoped to clarify that use in the critically ill population is an off label use and hospitals need to validate that use and place appropriate controls to assure the accurate and appropriate use of the device.
Off Label Use

- Hospitals are recently becoming more aware of these limitation statements

- FDA has been receiving more questions about these limitations, including whether use of meters in the ICU would be off label use

- Because off-label use would void the waived status, facilities would technically need high complexity certification to use these meters:
  - In critically ill patients
  - In people without diabetes

- **Challenge** – abrupt disruption of glucose meter use in hospital settings may adversely affect patient safety
Discussion

• Has this issue been raised in your programs?

• What should be done to improve the situation for hospitals and patients?

• FDA tools
  • Regulatory authorities
  • Manufacturer actions/responsibilities

• CMS/Partners tools