Objectives

• Clarify the origin of off label use of glucose meters
• Analyze potential options for resolving this issue
• Discuss the various ways to work with the FDA and CMS to find solutions that work for both patients and healthcare providers
Why Are We Here?

- Healthcare providers have been using blood glucose meters for many years in a variety of settings.
  - Easy to use, inexpensive, accessible
  - Used for the management of diabetes, at health fairs, in non-diabetic hospitalized patients (including critically ill patients)
  - Reliance on their use has increased over the years
- Recently, people have become aware that certain uses are off-label
  - e.g., use in critically ill patients, screening for diabetes
- Only waived if used on-label, high-complexity when used off label. Concern that:
  - Additional requirements apply under CLIA for high complexity tests
  - Many labs are not even authorized to perform high complexity testing
- Concerned about continuing patient care if cited and requirements to:
  - modify their procedures for meter use in certain settings, and/or
  - use alternate tests
Source of the problem?

• This issue has always existed, but little awareness
• Until recently there was no CMS/CAP, etc. enforcement against off label uses
• Awareness began to increase with clearance of the Roche Inform II. Labs noticed the limitation language in the label for the first time.

Why aren’t meters cleared for these uses?
Glucose Meters originally designed as consumer devices, migrated into healthcare facilities

Manufacturers began to see a market and started to make meters specifically intended to be sold in hospitals, but still sought FDA clearance as an OTC meter

Meters submitted to FDA for OTC use:
  • Are validated for use in ambulatory people with diabetes
  • Historically used study designs and performance standards developed for lay use

OTC clearance = automatically waived

Since meters are cleared for OTC use, no effort to remove/address significant interferences that lead to limitation against use in critically ill patients
Why Does this Matter to You?

• When manufacturers seek OTC clearance for meters commonly used in hospitals, they are pushing the responsibility for their use and validation off onto the labs

• Device design and manufacturing decisions do not account for risks in these settings, e.g.,:
  • The design of current meters did not consider the risks of multi patient use
  • Raises infection control issues
  • Meter materials/design do not allow for complete disinfection (e.g., strip port)
  • Decisions on design changes (e.g., new materials) do not consider the impact of the changes on off label patient populations
  • increased risk for preventable error due to interferences
  • Strip manufacturing/release criteria are not developed with your patient population in mind

Note: FDA is actively encouraging manufacturers to seek clearance for their meter for these uses
Draft Guidances

- Draft Guidance published January 7, 2014

- Shortly after, NYSDOH sent a letter to NYS labs discussing this issue, referred to FDA discussion of this issue, and referenced the draft guidances

- This, along with the coincidental timing, unfortunately linked the draft guidances with this off label issue in many people’s minds

- The draft guidance contains proposed studies that would actually fix the off label problem for labs by having manufacturers take responsibility for the design, validation and manufacture of meters/strips for the real intended uses

- If the guidances were implemented, the manufacturers would have to validate use in critically ill patients so labs would only have to verify performance

- The lack of appropriate controls, and therefore potential patient harm, remain even if FDA decides not to issue the final guidances
The draft guidance states that manufacturers of POC meters should follow the CLIA waiver process rather than get automatic waiver through OTC clearance.

Many are concerned that the guidances, if implemented, would result in non-waived glucose meters.

FDA’s intention, in writing the guidance, was that all meters be waived.

The studies and performance criteria described in the draft guidance were designed to enable companies to meet the criteria for waiver at the same time they met criteria for clearance.

CLIA waiver would not need to be delayed.
Summary

• Healthcare providers are concerned about the seemingly abrupt change in enforcement of off label glucose meter uses

• All stakeholders (FDA, CMS, Industry, Healthcare providers) want a solution that enables meters to be safely used where they are needed in healthcare

• Confusion exists about the source of this problem and realistic solutions

• We should work together toward those solutions
Thank you

Questions?