FDA Perspectives on Hospital Glucose Sensors

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Glycemic Control Protocols

- In the past 10 years, the practice of managing glycemic levels in hospitalized, critically ill patients has been implemented in many institutions.

- Published and observational studies demonstrate the potential for improved outcomes in a broad range of hospitalized patients.

- While there may be significant benefits, there is a risk of inappropriate treatment if the glucose measurement device used as part of the protocol malfunctions.

- A variety of glucose measurement devices are currently being used in these hospital settings for this purpose and many more are in development.
Measurement of glucose is not novel...

Strip based glucose test systems ("glucose meters")
- Indicated for use by diabetics or healthcare professionals as an aid in monitoring the effectiveness of a diabetes control program
- Used widely for many other purposes, even in healthcare settings
- Detection and quantification of glucose uses enzyme (glucose oxidase, glucose dehydrogenase) and amperimetric technology
- They are contra-indicated for use with individuals who are critically ill and have other limitations
- Questions raised...are they accurate enough?
Measurement of glucose is not novel…

**Point-of-care (POC) non-stripe based devices**
- Fewer limitations in use (such as interferences)
- Performance similar to lab analyzers
- Perceived as being less convenient than glucose meters
  - Storage of reagents versus test strips
  - Cost of reagents

**Laboratory glucose analyzers**
- Advantage of robust performance (precision, accuracy)
- Not as fast/convenient as strips or POC devices
- Venipuncture specimen
What is different about these innovative devices?

Hospital Glucose Sensors
- Indicated for the continuous (or near-continuous) measurement of blood glucose in hospitalized patients to better enable glycemic control protocols
  - Provide near real time data
  - Can give trend information
  - Can be designed with alarms for crisis avoidance
- They are intended for hospitalized patients, many of whom may be critically ill
  - Specimen may be ISF, venous whole blood from catheter, and others
  - Some use novel detection technologies
The Indications for Use is Quite Different
Indications for use

This is a key consideration when FDA considers if a device is safe and effective

- Who is the population of patients for which these devices will be used?
- Who are the intended users and can they operate the device appropriately on a day to day basis?
- What clinical setting (surgical ICU, general floors, emergency care, etc.)?
Indications for use continued

• How will the results of the device be used?

  ✓ In real time to replace discrete blood glucose measurements?

  ✓ To monitor trends over time?

  ✓ To alert clinicians of hypoglycemic and hyperglycemic events?
Why does indications for use matter?

If a device is studied in one population but used in a different population...

- Performance may be different
- Benefits and risks may differ
- Potential interferences may differ due to patient physiology or therapies administered
Considering the end user

- Benefits (how can it help patients) and limitations (keeping patients safe)
- Understanding of how to use the device and how not to use it
- Devices should be well characterized device with respect to performance and accuracy
Overview of this session
Discussion of…

**Study Design:**
- Evaluation in the intended use population in the intended use setting
  - Medical surgical? Critically ill? General floors? Pediatric?
- Incorporation of pre-analytic factors (insertion of device into patient, handling reference specimen)

**Performance:**
- Do the performance needs depend on the intended population or on how it will be used?
- What factors should be considered to validate and demonstrate a safe and effective device?
  - *Sufficient* accuracy? What metrics?
  - *Sufficient* reliability
- “*Sufficient*” may not mean “Perfect”!
Summary

- Glucose sensors are being developed for use in hospitalized patients
- Safe and effective devices for this purpose show great promise in improving patient care
- Need for devices with sufficient accuracy and reliability
- FDA is committed to working with all stakeholders to facilitate development of these innovative devices
Thank you!!