NKDEP Laboratory Working Group
Conference Call
May 22, 2006

Call Notes

Participants

Joris Delanghe	Chandra Jain
John Eckfeldt	Harvey Kaufman
Jim Fleming	Andy Levey
Elisa Gladstone	Leigh Ann Milburn
Neil Greenberg	Gary Miller
Ethan Hausman	Gary Myers
Tom Hostetter	Mauro Panteghini

The majority of this meeting was spent discussing additions, deletions, and enhancements of the NKDEP's *Suggestions for Labs*. The revision, which will be posted on the NKDEP website (Rev. June 2006), serves as documentation of the discussion.

Below is a list of items that warrant additional documentation, including those slated for discussion during the July LWG meeting in Chicago, IL.

- Andy Levey will work with Ethan Hausman, Leigh Ann Milburn, and the FDA to address implications for use/adoption of the MDRD equation in pharmacy practice and necessary changes in product labeling. Andy will keep Greg Miller and the LWG informed of their discussions.
- Before the call Greg and Andy discussed *Suggestions* text changes related to the applicability and limitations of the MDRD equation. Changes are documented in the revised version of *Suggestions*.
- The NKDEP is adopting use of the term "eGFR" (versus GFRest).
- Sixty needs to be "covered" in item three related to the NKDEP's recommendation to report values above 60 as ">60." The resolution was: "Quantification of eGFR values of *60 mL/min/1.73 m^2 or below* have more clinical implications for classification of kidney function than above these levels."
- The term "minimal bias" is no longer being used. The resolution was to direct the reader to the *Clinical Chemistry* article's discussion of "acceptable bias."
- Use of the term "reference ranges" when identifying CKD stage intervals can be misconstrued. The LWG favors use of "decision limits."

- Revised creatinine standardization language includes: "*Original* MDRD Study Equation," "IDMS-Traceable MDRD *Study* Equation," and "*traditionally* calibrated creatinine methods."
- The LWG discussed the uncertainty of estimating kidney function in children and the possible need to consult with a pediatric nephrologist to confirm recommended practice.
- *Suggestions for Labs* will now use the term "kidney function" (versus "renal function").
- Update on SRM 967: The value assignment for SRM 967 is complete. Measurements using the isotope dilution-GC/MS-based method and the new ID-LC/MS-based method were in good agreement. The assigned values for the two levels will be:

	mmol/L	*mg/dL*
Level 1	0.0665 ∀ 0.0019	0.753 ∀ 0.021
Level 2	0.3462 ∀ 0.0073	3.916 ∀ 0.083

The Certificate of Analysis is complete except for the section on commutability. Once the commutability study is complete and documented, NIST will draft wording to briefly describe the study and provide a link or reference to a more detailed description of the study and its findings. NIST has had several inquiries about the material, so they are anxious to complete the process and make the reference material available.

Agenda Items for July LWG Meeting

- Pharmaceutical labeling changes (FDA approval)
- Need for the development of a standard comment/recommendation for use on lab reports (e.g., when eGFR should not be used)
- Finalization of recommendation on (not) reporting multiple values when a patient's age or gender are unknown
- Children and use of cystatin C to assess kidney function
- Next round of revisions to Suggestions for Labs