

**Testimony to the
Clinical Operations Working Group, Health IT Standards Committee
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Medical Device Hearing**

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<http://www.nlm.nih.gov/healthit.html>

Thank you for the opportunity to provide testimony on this important topic. NLM has experience with a broad set of medical device interoperability and data integration issues, but our testimony is focused on two major goals, for which our standards and vocabulary experience may be particularly relevant.

- Standardized output from devices that perform tests, measurements, and imaging studies at the source - so that exact test results can be delivered to EHRs, public health information systems, and clinical research information systems.

Standard tagging, including standard identifiers for the device involved and standard codes and vocabulary for the results would increase data quality and reduce data creation burden for health care, public health and research. This would provide substantial benefits for quality and safety, surveillance, research efficiency, and translation of research into practice.

- Publicly available electronic structured product labels (SPLs) for medical devices and equipment available in the marketplace. Device SPLs should include unique device identifiers (analogous to NDCs for medications), standard nomenclature (analogous to RxNorm for medications), brand names, and product details. SPLs should be produced for all types of medical devices and equipment used in health care, e.g., laboratory test devices, implantable devices, surgical equipment, wheelchairs, etc.

An up-to-date, comprehensive freely available public database of device/equipment SPLs – with both unique identifiers and standard names that link to a useful class structure - would provide a more efficient basis for decision support, alerts and recalls, inventory control, and disaster response activities involving medical devices and equipment.

General Questions

(2) Are there areas where standards are more mature or less mature?

- a. LOINC can be used to specifically identify tests/measurements performed by many medical devices. For some types of tests, SNOMED CT can represent the valid values for results. Coverage in both is good today and can easily be expanded.
- b. There are viable potential candidates for a US standard for device nomenclature, which is necessary to allow decision rules/retrieval based on types of devices. Rulemaking for SPLs for devices (FDA) and/or stage II certification criteria for EHRs may provide an opportunity to obtain public input on this issue, move to a decision on the target device nomenclature standard for the US in 2012, and establish a viable transition strategy for stakeholders.

(3) What standards or standards-related capabilities are most relevant and important to the meaningful use of EHR technology?

- a. Standard electronic test results generated by devices **AND** transmission of these precise tagged results by laboratories (including hospital and public health laboratories) to clinicians (**IN ADDITION** to any clinical interpretation of the results that may be desired or required)
- b. Robust unique identification system, medical device nomenclature that supports retrieval by device classes, and SPL infrastructure for devices

(5*) If you could wave a magic wand to effect one change to enable more effective and widespread use of health care devices, what would that be?

For use of health care devices, it would be a robust unique identification system with a publicly available database that includes ALL assigned identifiers linked to data about the devices they identify, including standard names. (In other words, we need to learn from experience with drugs and avoid problems caused by (a) the lack of a comprehensive, authoritative public source of all NDCs and (b) the current slight delay in the assignment of RxNorm names and identifiers to newly approved drugs.)

Interoperability/Data Integration Panel

8. What data about devices is needed in EHRs?

- a. **Devices that are prescribed, implanted, or become part of the care record**
Unique identifier, brand name, standard nomenclature that links to useful classification structure – UI should link to public SPL database with additional device details from manufacturer.

b. Devices that transmit or record data used in the EHR

Unique identifier for the device attached to standardized data generated/recorded by the device

9. Questions related to Meaningful Use

a. How would device data in EHRs affect Stage 1 measures?

Currently there are three Stage 1 quality measures for eligible hospitals and Critical Access Hospitals that require information about use of prophylaxis for Venous thromboembolism (VTE). As presently specified, the measures use SNOMED CT to capture “Application of a (particular class of item used for mechanical prophylaxis)” such as “Application of intermittent pneumatic compression device (procedure).”

This approach may be sufficient for basic tracking of therapeutic interventions, but is not sufficient for other important hospital responsibilities that would require more granular information: hospital management (monitoring of stocks and flows); safety/adverse event reporting and analysis (assessing whether problems are with individual devices or with lots); therapeutic monitoring of slightly different alternatives within a single class. UIs for devices would enable data capture and recording through the EHR to support all these uses.

b. What device-related patient safety and/or quality issues should be measured or reported?

Patient notification and appropriate action following alerts about safety problems with implanted devices or devices used in procedures.

10. What is the impact of the recent FDA MDDS rule on device integration with EHRs?

Viewed just from the perspective of the goals outlined above, it should make it easier for FDA to require submission of SPLs for this category of devices.

Data Accuracy & Integrity Panel

14. What are the data accuracy and data integrity requirements for device data in EHRs?

- a. Product metadata – EHRs should retain a UI that provides a direct link to product details and a standard name that provides a direct connection to a vocabulary structure that supports decision rules/retrieval based on classes of devices.