Value of Unique Device Identification in the Digital Health Infrastructure

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In recent years, high-profile cases of medical device failure resulting in patient harm—such as implantable cardioverter-defibrillator leads and metal-on-metal hip implants—have received substantial attention both in the medical literature and popular press. These examples illustrate the need for a more effective system of monitoring device performance and protecting patient safety.

The first action in the Food and Drug Administration’s (FDA’s) report on strengthening postmarket device surveillance, “establish a Unique Device Identification (UDI) System and promote its incorporation into electronic health information,” was addressed with publication of the UDI Proposed Rule. The Final Rule, expected in June 2013, will mandate that manufacturers assign unique identifiers to their marketed devices. In addition to enhancing postmarket surveillance, use of UDI should ensure the ability to track a device across health care settings; support safe and accurate device use; create a standard for device documentation in health information technology (HIT) systems; enhance recall management; improve efficiency; and support health care cost savings. A human-readable and automated identification and data capture form of UDI will be required per the proposed rule, the latter to allow automated capture of UDI in HIT systems. The rule will pertain to all 3 classes of medical devices.

Automated capture of UDI is a digital infrastructure improvement that additionally supports the recent Institute of Medicine recommendation: “Improve the capacity to capture clinical, care delivery process, and financial data for better care, system improvement, and the generation of new knowledge.” With efforts toward developing and using full capabilities of HIT to support optimal patient care, quality, efficiencies, and reduced costs, UDI integrated with HIT should be recognized as an important initiative.

Devices typically pass through many hands and places before being used in a patient. UDI establishes a standard identifier across these settings and a means to track the device. A study by Poon et al on barcode e-MAR (electronic medication administration record) found statistically significant reductions in medication error after barcode e-MAR institution. An analogous scanning system for devices should also support error reduction. Hospital systems, incentivized by meaningful use, have been adopting electronic health records (EHRs), but a standard format and location for device documentation are lacking, particularly important for implantable devices.

UDI in EHRs would provide this standard and clear link of device to patient. Ability to access UDI in EHRs would support improved implantable device identification prior to revision surgery or an emergency procedure. This could help minimize inability to identify a device, the need for multiple devices available at the point of care for the procedure, possible lack of needed equipment or devices at the point of care, a patient needing additional imaging or more extensive surgery, and associated health care costs. As EHR and personal health records advance, UDI would establish a standard for device data transferred to patient portals or between patient care settings.

In addition to the discussed clinical use of UDI in EHRs, there is expected value for use in postmarket surveillance. Areas include UDI use in clinical registries, adverse event reports, postmarket studies, extended databases, and the FDA Sentinel system. UDI would provide a standard format and means to link device information between registries, data sets, and IT systems to support more robust postmarket surveillance. Capturing UDI electronically in the patient care setting is necessary to capitalize on this value and support postmarket surveillance initiatives through FDA and others to monitor device performance and protect patient safety. The current process for the recall of devices is fraught with inefficiency. Capturing UDI in hospital IT systems should help to improve the ability to query EHRs via UDI and enhance identifying affected patients.

Clinical and operational efficiencies stemming from use of UDI are important considerations in the current health care climate, despite financial implications of UDI implementation. Replacing manual entry with scanning UDI should free up time for patient care. Costs associated with error should be minimized. Use of UDI in procurement, inventory, and recall management supports efficiency, error reduction, and related cost savings. UDI in HIT systems pro-

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vides a standard for aggregation and analysis of device data for clinical and business decision making. Use of UDI could help reduce some labor intensity of device data submission to registries. Aggregation of postmarket surveillance data using UDI could allow earlier knowledge of device failure and need to recall, potentially leading to fewer affected patients and lower costs. Additionally, UDI use in postmarket surveillance data could support more thoughtful future device iteration to mitigate detected device shortcomings.

UDI integrated with HIT is an important initiative in advancement of the digital health infrastructure. The FDA’s UDI rule will mandate manufacturers to label devices with UDI, but does not mandate others to use UDI. Current work supported by FDA’s Medical Device Epidemiology Network Initiative (MDEpiNet) includes a Brookings Institution UDI implementation initiative and a UDI implementation demonstration project. The Brookings initiative is focused on assessment of value and challenges, education of multiple stakeholders, and development of an implementation roadmap. The UDI demonstration project is aimed at proving the feasibility and utility of incorporating UDI into the EHR, using it to capture key device attributes from reference databases, and creating a data set containing patient and device information for postmarket surveillance. The project’s scope is inclusive of cost and workflow considerations. Research under separate funding has investigated implant identification prior to revision surgery in the context of UDI.

In many ways, barcode scanning of UDI and integration into HIT is following a similar path to barcode e-MAR, computerized physician order entry, and EHR dissemination. Research in these areas indicated benefits and barriers, including cost, and recommended development of incentives and mandates. The HITECH Act supported creation of Medicare and Medicaid EHR incentive programs with computerized physician order entry and e-MAR becoming Meaningful Use core objectives within these programs. Ongoing research studies on UDI are also focused on assessment of benefits and barriers, quantification of clinical and operational impact, and building an evidence base. Integration of UDI into HIT systems and use across health care also hold promise with value for patient safety, postmarket surveillance, and clinical and operational efficiency. Achieving this will require education of multiple stakeholders, continued research, as well as support similar to that given e-MAR and computerized physician order entry through regulation or meaningful incentives.

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REFERENCES