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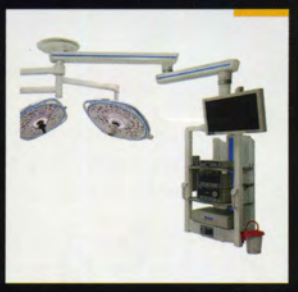

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Device Management Goes Global

By Matt Skoufalos

Big data has been more than a trend in medical device management for years, driving everything from cost analyses, patient outcomes, and product recalls to purchasing decisions and maintenance schedules. But with the creation of the FDA's Global Unique Device Identification Database (GUDID) by the U.S. Food and Drug Administration (FDA), and the subsequently rolled out mandates to label medical devices with unique device identification (UDI) codes, medical equipment manufacturers in the original and aftermarkets are being folded into a greater, national inventory control process than has ever existed in the United States.

September 24, 2015 represents the second of five benchmark deadlines in the GUDID and UDI process: the date by which "the labels and packages of implantable, life-supporting, and


Bob Hankin

life-sustaining devices must bear a UDI," according to the FDA. Although many manufacturers have already been labeling their products with FDA-specified standards, the process of complying with the UDI program requires them to do so in both human- and machine-readable formats. Shepherding manufacturers and remanufacturers through the process are three UDI-issuing agencies: the Health Industry Business Communications Council (HIBCC), GS1, and International Council for Commonality in Blood Banking Automation(ICCBBA).

Among manufacturers in the health care industry, the most commonly used bar code standards are those devised by HIBCC and GS1, said Robert Hankin, PhD., President and CEO of HIBCC of Phoenix, Arizona. Both standards are UDI-compliant, but with different technical characteristics.

HIBCC UDI codes are based on an alphanumeric standard with an 18-character variable-length product code, Hankin said. These typically serve device manufacturers — such as those of orthopedic equipment — who manage large numbers of small parts. Such manufacturers "need a large data set to identify each of them uniquely, and never use the same ID twice," Hankin said.

In comparison, said Siobhan O'Bara, Senior Vice President of Industry Engagement for GS1 US, GS1 Global Trade Items Numbers, or UPCs, provide numeric product identifiers of a fixed length. They are typically used in retail and health care environments.

ICCBBA codes are also alphanumeric, but require unique identifiers that tie human tissue products to their donors, according to Pat Distler, Technical Expert at ICCBBA in San Bernardino, California. These are the least commonly used among the three standards.

Many device manufacturers were already compliant with the new FDA regulation before it was passed, Hankin said; conversely, some weren't labeling at all. But as the federal government "is trying to build what would amount to a giant medical device catalog," with the GUDID, what's really happening is that the FDA is coordinating with similar standardization initiatives of other countries, he said. Similar legislation is being considered by the European Commission, and Turkey has had such regulations in place since 2006.

Because of the FDA regulations, Hankin said, “we’re getting new registrations every day,” as foreign companies that export their products register them with HIBCC. In fact, he said, the entire process will have benefits for importers of foreign-made medical devices, as the FDA can better identify “counterfeit devices that sneak into the United States” as much as it can manage “patient safety issues, medical error issues, [and] logistical warehouse issues.”

“It’s an exciting time,” Hankin said. “It makes good sense. Barcoding’s been around a long time, but typically, when it was issued in the ’70s and ’80s in health care, once it moved past the loading dock, the barcode wasn’t really used.”

Today, barcode scanners are far more omnipresent, and far more integrated into inventory management practices. HIBCC, for example, offers a free, downloadable app that allows users to scan a medical device and get the UDI.

“It has to have a HIBCC code on it for our app to read it, but it’s that kind of simplicity,” Hankin said. “A nurse or a physician or a hospital administrator, if they’re jotting down information or need information about a device, they can scan it.”

Niche Cases

Aftermarket medical device manufacturers must also secure UDIs for their products, and they should be brand-consistent to the original equipment manufacturer, said Siobhan O’Bara. Refurbishing a product and relabeling it would require the generation of a new UDI under the FDA statute — which does not cover questions of liability or financial responsibility for doing so.

Most of all, the entire process, like all FDA actions, is designed with patient safety in mind, she said.

“The patient is the focus of this,” O’Bara said. “The FDA vision is that you or I as a patient could go in, pre-care, post-care [and] look up a device to which we have insider access from our electronic health record or implant registry information; the same information that is being demanded in the consumer space.”

Most capital equipment will bear a direct mark from its original manufacturer as well as having a DI (device identifier) and PI (production identifier) etched into them, O’Bara said, providing a “direct link from the original manufacturer,” especially in the cases of devices that go through sterilization or even re-processing. Devices with a longevity beyond that package will have markings that must be managed during a reprocessing or remanufacturing, she said.

“When you reprocess a device or an item and you call it something else, because you don’t resell it under the manufacturer’s original part number, that counts as a separate device, and you need to identify that device,” O’Bara said.

“You are responsible for that identification record from the time that device moves out of your facility into another location or a provider setting,” she said.

An even more specialized segment of the device identification market than the aftermarket is human tissue that is regulated as a medical device. It’s a niche market, Distler said, comprising such exotic products as corneal lenticules, umbilical cord vein grafts, human collagen, and femoral veins used as arteriovenous shunts. FDA already determines on a case-by-case basis whether products of human origin are regulated as biologic or as medical devices.

“There’s not a lot of tissue devices compared to the medical device world, which has thousands of products,” she said. “They have lot numbers; they produce a hundred identical items. With tissues, they’re all unique.”

The function of unique identifiers on products made with human tissue is to create a traceable path from the donor of a product to its recipient. Most typically, donor tissue comes from a cadaver, Distler said, and if information about the deceased is revealed that could have a potential impact on patients, every single recipient of tissue from that donor must be identified for the purposes of follow-up.
“They may later learn that a patient had been exposed to hepatitis, let’s say, and therefore, they want to recall all those products,” Distler said. “They need to find out where they all went, bring them all back, quarantine them, and destroy them.”

ICCBBA is an organization as distinct and equally specialized as the challenges of identifying human tissue-based products. The council employs just a dozen people, and is “not even considering branching out” beyond its focus of serving organizations like tissue banks that deal with medical products of human origin, Distler said. In observing the challenges related to managing that niche clientele, the takeaway is that those FDA policies that work for 99 percent of product labeling systems don’t work for all of them.

“Ours is a little more complicated because we have standardized product coding,” Distler said. “The other systems don’t require that, but that’s part of our system. We have a donation

identification number; that too, is new for them. [Vendors are] having to learn a new way of identifying products and that's kind of an educational process. We talk with them, we work with them, we help them select the codes they're going to need."

In implementing a changeover to a system that is compliant with the FDA regulations, Distler said pitfalls include the time that it takes to implement widespread changes to software, proving their stability, and doing so rapidly, and without error.

"It has to be right," she said. "It is a challenge. I respect the people doing it. They didn't have a huge amount of time."

After the September deadline, Distler said, "the ball will pass to the receiving organization" — in other words, the hospital systems that have to read those bar codes. Just as in its regulation of blood banks, in which "the FDA required bar coding on blood bags before they required anyone to be able to read them," Distler said, the onus falls on the labelers first.

"We're moving in the right direction," she said. "There will be bumps along the way. It's a first step; a huge first step."

Global considerations

With the exception of those products that do not fall under the guidance of Good Manufacturing Practices, everything that is constituted as a medical device in the United States is bound by the FDA regulations. The UDI statutes were drafted with input from "organizations that supported a global vision of patient safety," O'Bara said, including the International Medical Device Regulators Forum (IMDRF), inviting collaboration that allowed "the best opportunity to understand what the other regulations meant for a country" and seeking "as much commonality as possible for a global regulation."

"There's always going to be a level of locality in your regulation, but if your base identifier has global uniqueness and global interoperability, then your end-to-end supply chain visibility has the best opportunity for a good outcome," O'Bara said. "The visibility doesn't stop and start at borders only."

O'Bara also believes that, in the longer term, the Big Data payoff for the information yielded by unique device identifiers could prove to be significant, revealing "an empowerment of [analytical] information previously unavailable to patients and clinicians" about medical equipment.

"Is a higher-priced item performing better than a lower-priced item?" she said. "Is a reprocessed unit clinically different from an OEM one? It provides a level of analytics previously unavailable."

“The vision is that with this identifier, which is both machine-readable and human-readable, on your inner pack and outer pack, you now are moving into an entirely different realm of inventory management [and] inventory traceability,” O’Bara said.

O’Bara also believes that the analytics upside of the device identifier question “actually folds quite cleanly into the Affordable Care Act and the 21st Century Cures Act,” linking device information with patients’ electronic health records, and creating a timeline of health care decision-making that is transparent to patients and caregivers. Such data could be used by patients to request a certain type or condition of product at some point in the future, perhaps within a decade or more.

“Between 2018 and 2020 you’re going to catch the net of all the [FDA labeling mandate] implementation and all the markings,” O’Bara said.

Many device companies that never had to consider labeling before will now have to take on that challenge, Hankin added; so, too, he said, will health care workers who never had to consider the impact of device labeling.

“Physicians right now will have to know a lot more about this,” Hankin said. “We see that bedside nurses don’t usually think about things like scanning product codes, but they may begin to when these things become required information in patient medical records.”

He also believes the UDI initiative will offer “next-level impacts” that he regarded as “positive.”

“In a good database, it acts almost like a product pedigree,” Hankin said. “If you can trace a device to its original owner, you have a greater likelihood of identifying manuals, specs. UDIs are never retired, deleted, or removed. They might be deactivated, but they’ll always be there.”

By Matthew N. Skoufalos on August 31, 2015