I've been thinking...

Final Unique Device Identification Rule. Finally.
November 2013

I've been thinking about Harry Potter, Cheerios, smoke detectors, and the FDA's final Unique Device Identification (UDI) rule.

In the *Goblet of Fire*, Professor Dumbledore informs Harry Potter of the evil Lord Voldemort's eminent return, then warns: "Dark and difficult times lie ahead, Harry. **Soon we must all face the choice between what is right and what is easy."**

In 1999 the Institute of Medicine's (IOM) report, *To Err Is Human,* warned America of an unseen enemy—a medical problem *darker* and more *difficult* than most had imagined. The report estimated that between 44,000 and 98,000 patients die each year as a result of medical errors. As many as 7,000 of these were lost to preventable medication errors, while another 1.5 million patients were needlessly suffering from adverse drug events. We don't know the number of patients whose suffering and deaths involve medical device mishaps but it's multiples of the number impacted by medication errors. And, all these statistics say nothing of the commensurate toll on caregivers who are unintentionally and unwittingly compromising their commitment to *do no harm*.

Buried in its pages, the report prophetically noted that bar-code point-of-care technology might prevent many of these errors. Nearly fifteen years later, around two-thirds of our nation's hospitals are scanning bar-coded patients and most medications to ensure they match. Subsequently, studies have revealed dramatic (65 to 86 percent) reductions in medication-administration errors in hospitals utilizing the technology.

This could not have been accomplished without the FDA.

Well before the IOM report, a number of forward-thinking hospitals wanted to utilize bar-code medication administration (BCMA). Unfortunately, since only a handful of drug labels included bar codes back then, implementing was unrealistic.

In retrospect, the IOM report motivated healthcare systems, professional organizations, and concerned individuals to persuade FDA to require that manufacturers include linear bar codes containing NDC numbers on all immediate drug packages.

Earliest discussions on potential regulations leaned toward including bar-coded labels on medical devices as well as on medications. Weighing the multitude of challenges, FDA leaders quickly discerned that completing bar-code rule for drugs would be more complex than initially imagined. They also felt that simultaneously crafting a rule for labeling medical devices would be impossible. Prudently, the administration tackled drug packaging immediately and postponed medical-device labeling for a later date—three to

five years, as I recall.

While FDA's bar-code medication rule (issued February 26, 2004) took about two years to finalize, its medical device rule (issued September 24, 2013) required *nine* years to formulate.

I'm flying today in some not-so-friendly skies. Consider some of the turbulence through which the FDA had to fly to arrive at its pretty good rule:

> Q. Exactly what is a medical device? (The list includes hundreds of thousands of products, ranging from tongue depressors, gauze pads, and surgical sponges to hip joints, defibrillators, and infusion pumps.)
>
> Q. Do tongue depressors really need to be labeled? Individually packaged?
>
> Q. Would linear bar codes required for medications be too limiting for devices? Would 2-D and DataMatrix bar codes be more suitable? What about RFID?
>
> Q. Must auto-identifiers be applied to actual devices, packaging, or both?

Add to this the serial debate, which makes me think of cereal, like the two single-servings I just inhaled for breakfast over Wyoming. I don't know how many boxes of "heart-healthy" Cheerios United goes through each year, but I do know that all are labeled with the same UPC bar code.

Shortly before arriving in Kansas, I visited the lavatory and scratched my head upon seeing the ashtray in the door just above the no-smoking sticker. Having involuntarily memorized the lines from the safety demonstration about federal regulation prohibiting tampering, disabling, or destroying smoke detectors, I looked up. It was there.

Thousands of airplane ashtrays share one bar-code identifier like those Cheerio boxes. But all smoke detectors in the sky (like many critical airplane components) are required by federal regulation to be imprinted with unique serialized bar codes. When Boeing must issue recalls on parts, a unique-part-identification database assists the company in promptly pinpointing each plane possessing the part in question, all in the interest of maintaining their *friendly* skies.

So what about medical devices?

Early consensus discerned that while there may be little value in serializing cotton balls, serializing heart parts could prove invaluable when hospitals must identify individual patients whose specific parts are being recalled.

Here is FDA's flyover of its *Unique device identification system. Final rule.*

> The Food and Drug Administration's (FDA) final rule establishes a system to identify devices through distribution and use. With certain exemptions, the rule requires that labels on medical devices include unique device identifiers (UDI).
>
> Labelers must submit product information concerning devices to FDA's Global Unique Device Identification Database (GUDID).

> The rule requires the label and device package of each medical device include the UDI in plain-text and in a form that uses automatic identification and data capture (AIDC) technology (bar codes) directly marked on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use.

Still have questions? Me too. Lots. But I've also got good news: on November 21 at 1 pm EST, The unSUMMIT University will offer a Webinar UDI Update Straight from the FDA Horse's Mouth**,** in which I will be interviewing and putting your questions to Jay Crowley, Senior Patient Safety Advisor at the FDA's Center for Devices and Radiological Health. Not incidentally, the UDI System would not have happened without FDA's workhorse Crowley and his perceptive, pleasant, patient, and persistent leadership.

So, take a break, grab a sandwich or a bowl of Cheerios if need be, and listen in. It will do your heart good.

As we have learned with bar-coded medications, the value of uniquely identified devices will only be realized if and when they are actually scanned. Achieving what we have with BCMA has not been easy. Scanning medical devices at the point-of-use promises to be even more difficult.

With Harry Potter, healthcare providers continue to **face the choice between what is right and what is easy.**

What do you think?

Mark Neuenschwander aka Noosh

BTW. I'm curious if UDI calling for multidimensional bar codes is a good omen that FDA may soon amend its drug bar-code rule to allow multidimensional bar codes for medications. I hope so. I'm flying to Silver Spring, MD this week (more Cheerios) to meet with some FDA peeps to learn what I can as to where things are following it's announced intent in July of 2011, to retrospectively review the drug rule. FYI, here is what I had to say back then.

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