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‘Case For Quality’ Aims To Place Greater Device Purchasing Power In Hospitals’ Hands

by Shawn M. Schmitt

Hospitals should have greater assurance when buying medical devices that the products they’re purchasing are of gold-standard quality, according to a “Case for Quality” report from the Medical Device Innovation Consortium. An MDIC working group wrote the report, which gleaned its quality data from publicly available information on knee implants and ICDs. Also, a Q&A with Dwight Abouhalkah, MDIC’s program manager for Case for Quality.

A report from the Medical Device Innovation Consortium (MDIC) looks to give hospitals greater assurance when purchasing medical devices that the products they’re buying are of gold-standard quality.

Under the auspices of “Case for Quality,” MDIC’s Product Quality Analytics Working Group conducted a pilot program that reviewed publicly available information on knee implants and implantable cardioverter defibrillators. The group is made up of representatives from device manufacturers, health-care providers, US FDA and hospital value-analysis committees.

The goal of the working group was to create “dashboards” of quality and other information on particular products so hospitals could decide on the best types of devices to use to ensure patient safety and satisfaction. The working group discovered that the hospitals found the new quality-related information invaluable as they made purchasing decisions.

"This is the first step in a long journey of making sure that these hospitals use the right criteria to purchase devices," Dwight Abouhalkah, from J&J and MDIC, says.

"Most hospitals have value-analysis committees or teams that purchase medical devices, and they use certain data to purchase those devices," explained Dwight Abouhalkah, MDIC's program manager for Case for Quality, and director of quality for *Johnson & Johnson*'s medical devices unit.

Abouhalkah explained to *Medtech Insight* that the MDIC working group "set out to test a hypothesis: If hospitals' value-analysis teams actually had access to specific data about product quality outcomes, would that information help those committees make better purchasing decisions? And if they made better purchasing decisions and made the right call, would that improve patient access and outcomes?"

Launched in 2011, the Case for Quality develops best practices, standards, tools and metrics that can be used by both FDA and industry to improve product and manufacturing quality in ways that go beyond compliance with regulatory requirements. FDA's device center teamed with the agency's Office of Regulatory Affairs to create Case for Quality, which is now overseen by MDIC.

When reviewing knee implants and ICDs, the MDIC working group evaluated publicly available information about the products and matched them against seven quality indicators: safety, effectiveness, reliability, patient satisfaction, usability, availability and compatibility.

The public data was collected from several sources, including FDA's *Manufacturer and User Device Experience* (MAUDE) database, *PubMed Central*, *ClinicalTrials.gov* and the *ICD registry*. Information was also gleaned from data on medical device recalls and chatter about products in health-care user forums.

The data was then analyzed to calculate key performance indicators, which was presented to hospital value-analysis committees via four quality dashboards that contained an overview and rankings by data source, manufacturer and product. The value-analysis committees then provided feedback by way of surveys and focus groups.

"The dashboards show where certain devices fall on the quality spectrum," Abouhalkah said. "After the dashboards were provided to hospital value-analysis committees, the working group

basically surveyed the voice of the customer – in this instance, hospitals – to ask, "Is this information that we extracted across these seven quality domains useful to you? And the answer was overwhelmingly 'Yes.'"

MDIC's report offers a litany of recommendations for next steps for the initiative, including conducting a pilot in partnership with a specific registry to improve access to data, working with patient advocacy groups to develop patient-preference metrics, and using enriched data to improve the initial four dashboards.

"By the end of 2017, the goal would be to have a well-documented system for accessing and sharing device quality data," the report states. "If this goal is reached, third-party data analysis teams could use the methods developed to consistently provide accurate information about device quality."

In the meantime, Abouhalkah is aiming to get the word out to hospitals and industry. He discusses the initiative in greater detail in this *Medtech Insight* interview.

Q ***Medtech Insight*: What should the device industry do with this report, and what should hospitals do with this report? Is the report just basically saying that MDIC needs to do more work on this topic? Or is the report instructing hospitals to look at *this* device or *that* device?**

A Dwight Abouhalkah: That's a great question. You and I think hospitals have everything down and that they're buying devices based on some huge criteria that they put in some algorithms. But the answer is that they don't. Some hospitals rely on very unscientific methods of trying to buy stuff.
What this report is supposed to do is say, "If we could find information in the public domain that fit these seven domains of what we consider to be quality, would this information be useful to you?" And the answer came back a resounding "Yes, we want this information."

The report is to inform industry and hospitals that this is information that your customer wants. Let's work with FDA and all the other registries – and maybe a third party – to ensure that the publicly available information in PubMed and ClinicalTrials.gov and other sources is accurate and reliable so when we do these extractions, that hospitals' value-analysis teams will see the value. So, it kind of

informs both populations. It informs industry that, "Let's work with FDA and other registries and data sources to make sure information is accurate." And because hospitals say they want this information, then maybe the hospitals and the industry and FDA could work together to make this very seamless and very transparent.

"If this information is useful, now we need further work to make sure this data is reliable, accurate, relevant and spread across the medical device firms accurately."

Q **It seems like there's more to come, if you will – maybe another report that would require an additional study.**

A Abouhalkah: Yes. This is the first step in a long journey of making sure that these hospitals use the right criteria to purchase devices. This is not the end all/be all. It's the first step to say, "Is this information useful when we aggregate it?" If the answer had been "No," then we would probably have been done. But since the answer came back, "Yes, we like this information; we want more of it. How do we get more?" then that's what we'll do.

Again, there are challenges to getting the information. There are biases. We need to work through all of that. So, the report is saying, "Let's work together – FDA, the industry, and these value-analysis teams within hospitals – to make sure this information is accurate, and that when it's aggregated across those seven domains of quality, that the information that you get will help you make a decision to purchase these devices."

Q **How reliable is it to glean quality information from publicly available resources? For example, a lot of Medical Device Reports (MDRs) and adverse events aren't reported by manufacturers, and a lot of recalls aren't reported. How trustworthy can the results be if you're just looking at public information?**

A Abouhalkah: That's one of the things the working group said, is that there are several significant challenges related to medical device information. Is it unbiased? Is it relevant and is it available? Is it consistently applied? You mentioned MDRs. A lot of firms – or some firms – report everything, and some firms report little. So, if you have one firm that has a hundred MDRs and another firm has three, how reliable and accurate is that? So, part of this pilot is not just to say, "Hey, we've done it; we're good. We're done." Rather, it was to say, "This is a pilot to see what possible challenges there are."

Even though the working group extracted information across the seven quality domains to try and narrow down some of the biases and the challenges, the group realized that we still have challenges. That's the key: If this information is useful, now we need further work to make sure this data is reliable, accurate, relevant and spread across the medical device firms accurately. Because, like I said, some underreport and some report everything. So we went in with these assumptions that it could be biased and that it could have some issues, and we came out saying, "Yeah, it probably does." So further work needs to be done on this publicly available information to make it more accurate and available.

Q **Would this initiative make firms want to offer up information that isn't public that would maybe paint a fuller picture of the quality of its devices? Because they might say, "I'm reporting but my competitor isn't. I want to offer up some additional information ourselves so there's a fuller picture." Because what's publicly available can be skewed.**

A Abouhalkah: Well, I haven't heard the working group go in that direction. I'm not saying it's not a viable stream. But what I have heard is, for example, the MDR piece – that's actually something they've already looked at and said, "Yeah, there are manufacturers that report one another's MDRs. Maybe this is not something we want to use as a data source. Maybe the information on ClinicalTrials.gov is more important." As for recalls – obviously they either happened or they didn't. So, the working group is looking at the current data sources and asking how reliable they are, and then what can we do as a community to make them more reliable so there is as much transparency as possible.

Q **What about a manufacturer that says, "Look at what they're doing with publicly available data. This and that is what they're looking at. So let's report fewer adverse events or MDRs."**

A Abouhalkah: I think, in general, people want to report what they believe to fit the regulations and the laws. Because you're asking, "Can people break the law and not report things?" Yeah, they can. But they can do that any time. If firms think, "Well, I'm not going to do X, Y and Z because it might show up on some report two years down the road," well, hopefully that's few-and-far-between, and that those manufacturers are caught and prosecuted.

From the editors of The Gray Sheet