Evidence Development and Decision Making for Medical Devices

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KEY POINTS . . .

How can early evidence on medical device safety and efficacy be generated?

How can decision makers be sure that early evidence on medical devices is of sufficient quality?

What will the medical device regulation future look like and how do we get there?

This is one of three articles in this issue on the topic of decision making on health care technologies. Dr. Marlow compares HTAs and regulation for medical devices versus the assessment and regulation policies for pharmaceuticals.

When it comes to carrying out health technology assessment (HTA) for medical devices, most people do not recognize just how different medical technologies are from pharmaceuticals in this regard. The two are very different because of a number of factors. First, medical devices do not require the same high level of evidence regarding safety and efficacy. Second, medical devices are highly disruptive to service because they are meant to be—disruption is how devices offer value.

While there are tens of thousands of devices available, many will not need to demonstrate anything other than that they are safe and effective. There may be a new version of the device on the market even before the HTA report on the older version is complete. Plus, a competitor can come along with similar device, or a new version, and need no safety or efficacy evidence at all.

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NICE and Medical Devices

The United Kingdom's National Institute for Health and Care Excellence (NICE) is an independent body—at arm's length from government—but with the role of improving outcomes for people who use the National Health Service and other public health and social care services. NICE does this by producing evidence-based guidance and advice for health, public health, and social care practitioners and by developing quality standards and performance metrics for those providing and commissioning health, public health, and social care services. NICE also provides a range of informational services for commissioners, practitioners, and managers across the spectrum of health and social care.

Figure 1. Characteristics of Medical Technologies.

Regulation does not require a high level of clinical evidence:

- Rapid iterations and new versions
- Operator learning curve
- Disruptive to services
- First-in-class and fast followers
- Lack of price transparency
- Implementation hurdles

Characteristics of Medical Technologies and their Evaluation

In 2010, NICE set up programs of activities for evaluating and supporting research in medical devices and diagnostics. What we expect from medical technologies is that they are cost effective, efficacious, and safe (Figure 1).

Safety and efficacy may be enough for most payers, and HTA may be a fairly manageable problem through evaluation. However, for the medical devices to reach the top of the "pyramid," payers may want to know more fully about both clinical effectiveness and cost effectiveness (Figure 2).
NICE oversees evaluation processes and, in doing so, partners with academic groups to carry out evaluations. Data analysis is based on registries, published evidence, and modeling.

We depend upon the hospital to carry out procedures for data submission. Most data collection is carried out in existing registries that can be modified to accept this data, or in newly created registries. Our external assessment centers are responsible for analyzing evidence by embedding HTA questions into evidence developments to give us a coherent, national approach. Questions remain, however. For example,

who owns the data? Can third parties access and evaluate the data? Who should bear the cost of evidence development? How these questions are answered may be clearer in the future.

Who Bears the Cost of Evaluation and Uncertainties?

We expect the developers of medical devices to pay in the long term, and an infrastructure is in place for data collection. Decisions makers can make the process more efficient by targeting questions about devices clearly, so that the only data collected might help to answer questions about existing uncertainties. At what stage in evaluation those uncertainties are discovered may vary depending on the nature of the technology.

Evaluation: Advantages, Disadvantages, and Real-World Evidence

How can decision makers be confident that early evidence is of sufficient quality? Commissioning through evaluation has advantages and disadvantages. Advantages include having HTA questions embedded in evidence gathering; providing incentives for data collection; having a coherent national approach; and developing a high level of stakeholder involvement. Disadvantages include the fact that that real-world evidence (RWE) may not robustly address comparative effectiveness and practical challenges, such as data governance issues.

The data must also take into account that the ultimate benefit to a given population may be larger than the target number in the scheme.

Greater Assurances Needed

Greater assurances are needed regarding the quality of observational data, especially where quality issues arise from the post-regulatory stage. Decision makers may be skeptical about the generalizability of data from health systems, and with good reason. Variations in treatment settings between countries can render some RWE outcomes irrelevant. Also, different treatment pathways or networks can lead to substantial differences (i.e., differences between the severities of disease in groups of patients in two different countries).

The future may be more efficient for a number of reasons. We may have "live monitoring" of outcomes based on rapid data linkage technologies, and decision makers and regulators may combine data from sources in such a way that expedites better answers regarding uncertainties. *EUnetHTA Joint Action 3* will help address uncertainties by giving evidence developers and users common standards on registry data quality. ■

Additional information:
This article is based on the plenary session, "Strategy in Motion: The Current and Future Lifecycle Approach to Decision Making on Health Technologies," given at the ISPOR 18th Annual European Congress 2015, Milan, Italy 9 November 2015. The preceding articles from Hans-Georg Eichler (page 10) and Finn Børlum Kristensen (page 12) were also taken from this session.

To view Dr. Marlow's presentation, go to: http://www.ispor.org/Event/ReleasedPresentations/2015Milan

For further information or to volunteer to be a reviewer for this SIG, go to: Medical Device SIG http://www.ispor.org/sigs/MedDevicesDiag/Value_assessment_MD.aspx

Figure 2. What Payers Need to Know about Innovative Technologies.