**Designing medical technology for resilience: integrating health economics and human factors approaches.**

**Borsci S, Uchegbu I, Buckle P, Ni Z, Walne S, Hanna GB.**


The adoption of innovations in medical care is still slow and faces many barriers. Limited data or information on the impact on clinical practice or perceived value perception of new technology may negatively effect the decision making process for implementation and use of a new device or diagnostic. There is a need for shared understanding of the purpose, value, and benefits provided by medical technologies to facilitate implementation.

In this study, the authors define the term resilience as “the art of managing the unexpected” or at the organizational level, “the ability to anticipate, prepare, respond and adapt.” They argue that designing for resilience means designing usable and secure devices that require a minimal amount of service adaptation to allow for adoption and diffusion into various health systems, regardless of context.

To this end, the authors believe that the development of medical devices should be user-centered, which would include:

- Device design requirements and specifications;
- Stakeholder needs analysis;
- Development and assessment of user guidelines and user manuals;
- Specification of intended and abnormal use definitions;
- Risk and safety assessments;
- Interaction performance analysis (ie, understanding and predicting the learning curve and usability factors.)

The authors note that 5 health technology assessment (HTA) institutions have developed specific guidelines for evaluating medical devices, and of the 9 documents identified, 5 are specifically focused on diagnostic devices.

EUnetHTA recommends the use of cost-effectiveness or cost-utility to increase the usability of the economic evaluation, but the authors suggest another type of approach (known as HERD MedTech [Human and Economic Resilience Design for Medical Technology]) to perform these evaluations in stages prior to the development of the device.

Within the health economics and outcomes research field, the evaluation of medical and diagnostic devices still presents a challenge, mainly for the institutions that need this data to establish a rational process of decision making. In this way, formally establishing adequate parameters for the evaluation of medical devices and diagnostics is mandatory within the economic reality of health around the world; Without setting fundamental parameters, we cannot evolve into value-based healthcare.

**Analysis of duplication and timing of health technology assessments on medical devices in Europe.**

**Hawlik K, Rummel P, Wild C.**


In this article, the authors discuss the methodological obstacles to performing health technology assessments (HTAs) of medical devices. Here, the EUnetHTA 2015 initiative is highlighted as a milestone in the establishment of a joint methodological framework, the HTA Core Model®, which includes a methodological guideline for the evaluation of therapeutic medical devices.

The question that motivated the authors to conduct this study was: How many evaluations of medical devices are being duplicated in Europe? To answer this question, the authors conducted a survey in the ADVANCE HTA database (HTA reports conducted by European HTA institutions as of 2004) for reports of 10 medical devices (high or medium risk) that were frequently evaluated in 2014. The study sought to estimate the level of duplication and the duration of the analysis, starting from the authorization for the medical device from January 2003 to July 2016. The study analyzed 3 primary items:

- the number of annual and global reports by technology;
- the number of evaluations per institution in the 13-year period;
- the commercialization authorization date versus the institution schedule/reporting.

The 10 medical devices analyzed in the study generated a total of 120 evaluations, and half (5) of the devices were evaluated two or more times in this period.

The authors conclude that the number of repeated analyses found in the study shows that cooperation between European HTA institutions could optimize assessments and align the used methodologies.

From the HTA technical point of view, certainly not all data is transferable from one country to another, but there is a good deal of information that can be shared. The authors’ suggestion is that the adoption of a core model, such as the HTA Core Model®, could facilitate this collaboration, allowing institutions to take advantage of the exchange of valuable information.
Pathology and laboratory medicine in low-income and middle-income countries.

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This series of 7 articles published by The Lancet broadly addresses access to high-quality and timely pathology and laboratory medicine (PALM) services in low-income and middle-income countries. One of the main points addressed is that sustainable development goals and universal health coverage cannot be achieved without PALM services and 4 elements were identified as barriers to the expansion of PALM access: (1) insufficient human resources and workforce capacity, (2) inadequate education and training, (3) inadequate infrastructure, and (4) insufficient quality, standards, and accreditation.

The articles also point out that information technology and point-of-care testing cannot compensate for weak healthcare systems and that there is an urgent need for more research to map the challenges of access solutions to PALM more accurately, and that if analyzed and negotiated in high volumes, diagnostic tests could be more accessible to the population.

The economic evaluations of the diagnostic devices are unique, since the diagnoses do not treat the patients directly but rather guide their treatments. Considering the therapeutic and diagnostic advances and their combination, such as personalized medicine, the challenge of extending this benefit and providing diagnosis that adds value to the health environment not only of the low-income and middle-income countries, but also of the wealthier countries represents an intellectual challenge for health economics and outcomes researchers and health technology assessment worldwide.

For those interested in evaluations that involve the use of diagnostic devices and / or focus on low-income and middle-income countries markets, we recommend reading the articles in this series online at http://www.thelancet.com/series/pathology-and-laboratory-medicine?dgclid=etoc-edchoice_email_Mar&utm_campaign=twglobalpath18.