Editor's Corner

Many readers of this Journal will be familiar with the field of Health Technology Assessment (HTA), at least in principle if not in detail. They may also be aware of the three main pillars of HTA: evaluating comparative effectiveness; cost-effectiveness, and organizational impact, and that HTA serves to inform decision-making in order to promote an equitable, efficient, and high-quality health system.

HTA activities often fall within the domain of specialized units or agencies – be these in the public or private health sectors - with health economists as lead practitioners. The questions posed relate primarily to allocative efficiency issues and related affordability of new medicines, drugs, and procedures for various target populations or groups. As such, HTA is downstream to assurance of regulatory compliance and upstream of technology dissemination and related life-cycle management.

HTA has recently been redefined by an international joint task group as a "multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its life cycle".[1]

It's useful to spend a minute unpacking that definition. What disciplines are involved and who are the primary drivers of the process? Health economists play an important role, as do health clinical professionals. For so-called hospital-based or 'mini-HTA', a broader mix of stakeholders – including clinical engineering (CE), or CE&HTM (Health Technology Management) professionals – would be involved. In all cases, it is the HT-related questions posed that are the crucial determinant of what the process entails and who is involved.

At this point, it's worth remembering that the first technology assessment in the healthcare space was that of the artificial human heart, and the second of the CT scanner – both conducted by the (then) Office of Technology Assessment of the US Congress and hence the birthplace of HTA. One can surmise the key questions posed in each case: does the technology work and is it safe in the first instance, and can the health system afford the proliferation of this new and expensive medical imaging system in the second.

What are the 'explicit methods' and who gets to define these? There are several formal methodology frameworks, the most recent being the European collaboration of HTA (EUnetHTA) HTA Core Model.[2] The 'value of a technology' is a loaded term, since the needs and value systems of the different stakeholders in the outcome of the HTA process may not always be aligned. Lastly – and perhaps most importantly in our context – is to establish the 'different points in a technology's life-cycle'.

Current HTA practice commonly sees the technology life-cycle in the generic sense, from embryonic to early adoption to market acceptance to mature and eventual replacement and/or abandonment. Interestingly, a recent publication[4] refers to 6 stages for Life-Cycle HTA: preassessment; safety and efficacy assessment; HTA; adoption; de-adoption, and reassessment.

What has all this got to do with CE&HTM? Everything! CE&HTM practitioners are key stakeholders in – and overseers of - the operational Life-Cycle Management (LCM) of medical devices, with decision-making an integral component of all phases, from needs assessment, planning, and budgeting to procurement, commissioning, maintenance, user support, and training, and eventual decommissioning and disposal. Numerous decisions are made by CE&HTM practitioners in consultation with other stakeholders along the device's journey from cradle to grave. All of this can be done without mention of HTA.

Should this not be addressed - for both operational and strategic reasons - since the HTA 'toolkit' can be used to select the most appropriate approach in providing the evidence needed for specific decisions while also serving to support the standardization of institutional processes? In addition, by using the language of HTA,

CE&HTM practitioners can align themselves with existing HTA processes where these exist.

There are also broader benefits. As readers may well be aware, GCEA and the IFMBE's Clinical Engineering Division are engaged in the important exercise of defining the CE/HTM Bodies of Knowledge and Practice at the global level, both of which would benefit from the addition of HTA concepts and principles as being core to both CE/HTM knowledge and practice. On a related note, the IFMBE's Health Technology Assessment Division has recently suggested greater involvement of biomedical and clinical engineers in current HTA activities - and further explored related gaps and opportunities - in a recent publication.[3] Another European-based in the HTA domain – EuroScan also known as the International HealthTechScan (i-HTS) has joined Global Clinical Engineering Alliance on a couple of World Health Organization projects.

Another benefit is linked to the challenges many colleagues are facing in raising the importance of CE/HTM in their respective countries, needing CE/HTM roles and contributions to be recognized in national policy and related support of professional recognition, capacity development, and appropriate resourcing.

A different perspective on HTA and related issues is informed by the reality that many lesser-resourced settings are well familiar with: "*...inefficiency (that) signifies the denial of additional citizens of opportunities to realise health improvements at zero extra cost. This makes inefficiency both immoral and unethical.*"[4]

This begs the question: Are the resources currently invested (allocative efficiency) in the regulation, assessment, and management - individually and collectively - of health technologies in general and medical devices, in particular, achieving the highest return on investment when their actual impact is juxtaposed with their potential impact given the same levels of investment? There is anecdotal evidence that regulatory and assessment agencies in some countries are pursuing the implementation of best global practices in upstream LCM activities, thereby consuming significant resources that could be better utilized in addressing proverbial orchards of low-hanging fruit associated with the downstream operational life-cycles of health technologies and medical devices, and related *technical efficiency*.

This in turn leads us to ask: Why not do an HTA on HTA, i.e. consider the cost-effectiveness of current HTA-related activities and their resourcing and impact, relative to their potential if their scope was broadened and a larger set of stakeholders were gathered at the decision-making table? Incidentally, the same question could be asked of Health Technology Regulation and CE/HTM activities and related resourcing.

Yours thoughts? Let me know at mladen.poluta@up.ac.za

REFERENCES

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