HTAi HEALTH TECHNOLOGY ASSESSMENT iNTERNATIONAL

Medical Devices Interest Group Newsletter

Issue 1, November 2020

From the Chairs

Welcome to the inaugural edition of the Medical Devices Interest Group Newsletter! It has been a challenging year for all of us. We hoped to see you all this year in Beijing and to really get the group's activities off the ground. However, despite all of the disruption, we have managed to host several webinars and have many plans for content over the coming year. We hope that you find something useful or interesting in this newsletter and are looking forward to making this a regular publication. We would also love to hear from you, so please feel free to get in touch if you have anything you'd like to add to the next issue (including news, publications, upcoming activities or other announcements) or if you have any feedback for us.

All the best,

Richard Charter and Rabia Kahveci

Co-chairs

News

Covid-19 Response Webinar

The Medical Devices Interest Group hosted the 4th installment in HTAi's Webinar series on Covid-19 response. The webinar, which was titled Intensive Care = Expensive Care: How HTA can Support Cost-effective Digitization in Hospital Settings took place on July 16 and can be viewed by clicking the link above.

Collaboration with the Hospital-Based HTA Interest Group

We are very pleased to announce that the Hospital-Based HTA Interest Group and the Medical Device interest group have agreed to start cooperating on future activities: such as webinars, discussion sessions and developing reports. We hope that this will provide you the opportunity to be updated on the activities of both groups and for those activities to be aligned in the interest of both groups.

Manchester Annual Meeting 2021

We were incredibly disappointed not to be able to deliver the programme we wanted to in Beijing this summer, but we aim to make up for that next year in Manchester. We are hoping to put on a workshop and a panel and have already heard about many interesting events from our members.

Ukraine Regional Meeting

The HTAi Regional Meeting in Ukraine took place remotely between 8-11 September this year. The Medical Devices Interest group was well represented at the meeting. More information on the program can be found by clicking the link above.

NOTE: Newsletter issues will be available for access on the Medical Device Interest Group page on the HTAi website.

HTAi News

- As of **January 1st 2021**, all members of Interest Groups will require to be paid members of HTAi. You can renew your membership or find out more information on the HTAi website.
- The deadline for Oral, Poster & Vignette presentation submissions is **November 26, 2020** (23.59 Mountain Standard Time). Abstracts can be submitted on the Manchester 2021 website.

The Medical Devices Interest Group

The Medical Devices Interest Group (MDIG) was established at the Cologne 2019 Annual Meeting. Since its inception, MDIG has appointed Jamie Erskine as Technical Officer for 2020 and 2021, and begun to develop the mission and goals of the group. Our Mission is:

> "To promote the role of MedTech in interdisciplinary and multi-stakeholder health technology assessments to enable the holistic shift of healthcare systems toward the key principals of value-based healthcare: improving health outcomes and lowering total system costs".

The group also has 3 primary goals:

1. to produce **relevant, objective research to inform, and improve policy making** that is intended to **improve population health**.
2. **advance the dialogue on Medical Device HTA** methods and evidence based policy making to develop the way we evaluate a **rapidly evolving technology sector**.
3. **reflect all stakeholder groups** and ensure the unique role of HTAi is considered in policy discussion.

To this end, a major priority for the group is to generate research output and we have identified five key themes that we wish to address for HTA in MedTech:

1. Moving beyond the differences in the evaluation of MedTech and pharmaceuticals.
2. The challenges & opportunities associated with digitally enabled, artificial intelligence driven medical devices.
3. Ensuring sustainability and environmental considerations are factored into the value assessment of medical devices.
4. Implementing value based access programs (managed entry agreements) for medical technologies.
5. Distinguishing between the roles of HTA and value based healthcare (VBHC) in the evaluation and implementation of medical technologies.

We have been awarded a small amount of funding from HTAi to help support this research and hope to update you on its progress soon. We also hope to cover one of these five topics over the coming issues of the Newsletter. Many thanks to Dr Sally Lewis, a member of MDIG's Advisory Board who provided the following article on Value-Based Healthcare.

Is Value-Based Healthcare a Help or a Hindrance?

Any innovative intervention in healthcare should demand us to ask of ourselves the problem we are trying to solve, the desired outcome for this individual, and the associated costs and ramifications for the wider healthcare system. Nowhere is this more true than in the development and adoption of diagnostic, monitoring and therapeutic medical devices.

An evidence-based path to adoption of novel devices which may be of very high value to patients has been problematic, as highlighted by the recent excellent article by Campbell et al., 'Generating evidence for new high-risk medical devices'. Additionally there are differences between the type of data collection required and evidence needed to support HTA decision making between diagnostic and therapeutic devices.

What we are seeking to do is achieve value for patients (in terms of the outcomes that matter to them) and healthcare providers and governments who are under pressure to balance resource allocation to meet multiple needs of patients across the population they serve.

Therefore, we want to adopt novel devices quickly when they show a lot of promise but also subsequently ensure that they deliver on that promise in the lives of real people. We can and should back up that decision making with ongoing outcome data capture including patient-reported outcomes as part of real world evidence generation. The push towards value-based healthcare is helpful in this regard as it encourages the embedding of patient-reported outcome data capture into direct care, thereby making it a more sustainable endeavour with the ability to create more robust data sets. The implementation of patient-reported outcome measurement should never be set up as a data collection exercise alone. Patient -reported outcomes can enhance the communication between patients and their clinical teams and therefore, have a range of uses in supporting shared decision making, acting as triggers for key conversations and as a needs assessment long before we have acquired larger datasets for value analysis.

Much has already been said about the need for a new relationship between industry and healthcare systems, particularly in considering new contracting models based on patient outcomes. This should not be misunderstood, as this new relationship with industry is not about driving the medical industrial complex in isolation without taking account of the impact of an intervention on the whole system of care for patients. We accept that industry has to be profitable. However, to achieve maximum value for patients we need to also ensure that we undertake two additional activities.

The first of these is, of course, to minimise unnecessary costs by adopting the most cost effective product on the market. Careful attention to outcomes is necessary in order to make this judgment.

The second is to ensure optimal positioning of devices in the patient pathway. Does evidence based medicine not achieve this? If we look at any atlas of variation on device utilisation it would appear not. For example, the use of implantable devices for patients with advanced heart failure often correlates only with the proximity of the patient's home to the tertiary centre. Unwarranted variation, both over- and under-treatment exist and we must tackle both. If we look at the definition of evidence-based medicine as outlined by Sackett et al., we may be able to guess at the answer why.

- 'Evidence-based practice is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research.'

• 'The patient brings to the encounter his or her own personal preferences and unique concerns, expectations, and values.'

Crucially, evidence-based guidelines tend to miss out the second part about the patient's context and the shared understanding of their situation with their clinician. This in turn may subsequently influence choices made about the appropriateness of an intervention for that individual including whether to receive a medical device. This problem impacts on monitoring devices, for example CGM in diabetes or telemetry in heart failure; and therapeutic devices, for example implantable defibrillators or resynchronisation devices in heart failure patients.

Condition-specific patent-reported outcome data are essentially structured communications about symptoms and health status between an individual and their clinician. It therefore provides information both about need and about impact of an intervention on quality of life in a very specific way. Unlike generic measures of quality of life such as the EQ5D, it is generally harder to generate QALYs (quality adjusted life years), the comparable measure of cost effectiveness usually employed by health economists as part of the bases for a health technology assessment. However, I would argue that these measures give us much more information about the impact of an intervention.

If we can embed patient-reported outcome measures as a useful activity in the direct care of patients, and find ways to use this data including in the generation of QALYs from condition-specific tools, then we will enhance our ability to assess the value of medical devices and their true impact on the lives of patients.

Dr Sally Lewis, National Clinical Lead for Value-Based and Prudent Healthcare and Honorary Professor at Swansea School of Medicine

References

Campbell B, Wilkinson J, Marlow M, Sheldon M. Generating evidence for new high-risk medical devices BMJ Surgery, Interventions, & Health Technologies 2019;1:e000022. doi: 10.1136/bmjsit-2019-000022

Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ 1996; 312 (7023): 71–2. doi: 10.1136/bmj.312.7023.71

Twitter: twitter.com/HTAiOrg @HTAiOrg
Facebook: www.facebook.com/HTAiOrg @HTAiOrg
LinkedIn: www.linkedin.com/company/htai

Co-chairs: Richard Charter Richard.charter@alirahealth.com ; Rabia Kahveci rkahveci@safemedua.org

Technical Officer: Jamie Erskine Jamie.erskine@kcl.ac.uk
