BIOMEDICAL & SCIENTIFIC RESEARCH ETHICS COMMITTEE (BSREC)

Protocol/Proposal Guidance

Title:

Health Technology Assessment of Medical Devices: Gaps in current guidelines and training programmes.

Lay Summary:

Health Technology Assessment (HTA) is a multidisciplinary field of policy analysis that uses a systematic process to evaluate the properties and effects of a health technology to support informed decision-making. The assessment of a health technology is guided by similar underpinnings that include clinical effectiveness, safety, cost-effectiveness, patient perspectives and experience, and ethical and legal considerations. Historically, medical doctors and health economists have been the main experts of HTA. When the costs for drugs become prominent in NHS, pharma specialist become to be more and more involved in HTA. Now days, medical devices are becoming one of the main costs for NHS and therefore, biomedical engineers are becoming more and more involved in HTA.

However, the distinction in the assessment of drugs versus medical devices (e.g., drugs are only therapeutic while devices can be diagnostic) is unlikely to be addressed in most general HTA guidelines. As such, some HTA agencies or networks have developed guidelines specific to medical devices. It remains uncertain, though, if these guidelines consider all the unique features of medical devices that do not exist with drug therapies.

Therefore, this study aims to elicit biomedical and clinical engineers opinion regarding the extent of which current HTA guidelines, methods and tool are capturing technical characteristics, usability, safety, user setting dependences and maintenance of devices throughout their lifecycle via an online survey.

Background:

The European Parliament and Council of the European Union defines a medical device as “any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings. (1) Moreover, the US Food and Drug Administration specifies that medical devices are used to diagnose, treat or prevent a medical condition without any chemical action in the body.(2) The

World Health Organization (WHO) extend those definitions including the role of medical devices for the end of life and the fact that medical devices can be used alone or in combination.

There are important differences between medical devices and drugs that can impact the assessment of their effectiveness.(3-5) Unlike drugs, the permission to market medical devices may not be based only on the evaluation of efficacy and safety data from randomized controlled trials. Further, manufacturers must perform studies on human subjects for high-risk devices, but there are no explicit standards on the sample size, design, or follow-up period required.

Post-market surveillance and observational data, therefore, are complementary to the pre-market process because they can identify durability and rare serious adverse events from long-term use of the device.(6) As there are important methodological issues and contextual considerations that require attention when assessing the effectiveness and safety of medical devices, new research initiatives are in development intended to address them.(7,8)

The adoption of a medical device will likely have a more significant impact in an organization compared with the introduction of a new drug therapy. Further, a medical device can have numerous applications and a shorter lifecycle, and its effectiveness can also be impacted by the user interaction, setting and the learning curve to operate it.(3-5)

Health Technology Assessment (HTA) is a multidisciplinary field of policy analysis that uses a systematic process to evaluate the properties and effects of a health technology to support informed decision-making. The assessment of a health technology is guided by similar underpinnings that include clinical effectiveness, safety, cost-effectiveness, patient perspectives and experience, and ethical and legal considerations.(9)

The differences between devices and drugs highlighted by Pecchia and Craven that can impact HTA methods and processes were grouped into five categories. They include the product lifecycle, clinical evaluation, user issues, costs, and intellectual property.(10) The distinction in the assessment of drugs versus medical devices is unlikely to be addressed in most general HTA guidelines.(11) As such, some HTA agencies or networks have developed guidelines specific to medical devices.(CADTH reference to be added)(12-16) It remains uncertain, though, if these guidelines consider all the unique features of medical devices that do not exist with drug therapies.

The involvement of biomedical and clinical engineers in HTA can provide insights on the technical characteristics, usability, safety, user setting dependences and maintenance of devices throughout their lifecycle.(17-19) In a 2013 study, Margotti et al. interviewed clinical engineers, health care providers and managers in four public hospitals in Brazil to inquire about their perspectives on the decision making process in acquiring new medical equipment, HTA, and the identification of aspects to guide HTA in their institutions. Based on the participants' responses, the authors concluded that the decision making process to introduce a new medical equipment was not based on evidence, and recommended that the hospitals establish a formal HTA process that would involve clinical engineers to integrate medical equipment in the hospitals.(20)

In November 2016, the School of Engineering, in cooperation with the International Federation of Medical and Biological Engineers (IFMBE)-HTA Division and the World Health Organization (WHO), held a focus group to review the main guidelines on HTA of medical devices and to

contextualize the differences between medical devices and drugs. To describe how differences between devices and drugs impact HTA methods and processes.

Aims/Objectives:

This study aims:

- to elicit experts' opinion regarding which important aspect of medical devices lifecycle is currently not captured by HTA standard methods and tools;
- starting from the work done in Warwick in November 2016, define a set of recommendations on how HTA can capture medical devices peculiarities and achieve consensus among the most representative BMEs;
- Identify and recommendations methods and tools that can help capturing those aspects.

Design/Methodology:

We will invite a purposive sample of a minimum of 20 biomedical and clinical engineers through asking representative scientific societies to provide a list of representative and knowledgeable biomedical and clinical engineers. For instance, organizations as the UK Institute of physic and Engineering in Medicine (IPEM), the European Alliance of Medical and Biological Engineers and Scientists (EAMBES), the International Federation of Medical and Biological Engineering (IFMBE) and WHO Medical Device Unit have been already consulted, and will circulate an invitation mail containing the link to or our survey among their associates.

The potential responders will be required to have experience with conducting HTAs or understand the concept of HTA, and experience with health technologies, including design, development, testing, implementation, and maintenance, and from various areas in the health care sector.

The survey will be developed on a web-page using the online survey tool: LimeSurvey. The web-page will be only visible through the link send via email. Our invitation will be sent via email and it will include the information leaflet with the description of the study objectives, a letter inviting the individual to participate, an overview of the Delphi methods, expected time to complete survey, and a link to the survey. A consent form is presented at the beginning of the online survey in which we will ask to verify that:

- The potential responders understood all the information provided about the study,
- their participation is voluntarily
- they authorise us to use the responses provided for our study, and
- they explicitly agree to participate.

The invitation will also indicate that anonymised responses will be used to write scientific papers for relevant journals and conferences and that personal data will be stored separately to the research data to keep responses confidential. None of the personal information will be published at any point and they will only be available to the Chief investigator. Any information about the responder's professional experience in the area of HTA will be used for statistical purposes only.

If the participants will be unable to participate in Delphi process, we will invite them to suggest alternates, whom they felt would be appropriate for the study.

A 5-point Likert scale will be applied, where “1” will be strongly agree and “5” will strongly disagree. Median scores will be calculated per recommendation and methods/tools in order to characterise the answer category above and below which 50% of the answers fall. Interquartile ranges (IQRs) will be used represent the spread of the data and to assess the level of consensus per recommendation and per method and tool. Ratings with a median of ≤ 2 (i.e., high level of agreement with the proposed recommendation and methods/tools) and a narrow IQR were considered to have reached consensus. Those with a median ≥ 4 with a narrow IQR will be considered to have reached consensus on a strong disagreement with the recommendation and proposed methods/tools.

Prior to a wider distribution, the survey will be pilot-tested among the members of the HTA Division of the IFMBE.

Data will be anonymised and analysed using a variety of statistical methods to assess intragroup variation in responses and in order to provide preliminary estimates of uncertainty around point estimates provided by such a sample of experts. This survey will be carried out in one wave with no follow-up. Answers of all respondents will be stored on a SSL server and accessible only via user name and password and anonymized before the statistical analysis.

Ethical Considerations:

Participant Confidentiality and Data Security: limited personal information will be stored (e.g. email, name, years of experience, training path) separately to the research data to keep responses confidential. Participant names will be stored in order to give them the opportunity to withdraw from the study at any point (e.g., after giving their answers, for any reason, they may do not want their answers to be included in the final pooling). Responders will be invited via email, which will contain the link to the survey. When the responder starts the surveys, the system records her/his email. From that, we know the name (as we have invited them). Once downloaded, the results will be stored on a CD in a protected locked store in the office of Dr Pecchia in the School of Engineering of the University of Warwick. The answers to the survey will be anonymized before being analysed and responders will not be identifiable from the answers given. All the information acquired will be stored on an encrypted server using the SSL technology. Responses will be accessible using user name and password to the research staff. Once downloaded from the server, online data will be cancelled and study information will be stored for 10 years as a CD in a protected locked store in the office of Dr Pecchia in the School of Engineering of the University of Warwick. The data from the survey will be stored as an excel file protected with a password.

Right of Withdrawal: responders can leave the questionnaire at any point. Non-completed questionnaires will not be included in the study and will be permanently erased from the server. Responders who have already submitted their response can contact the Chief investigator through the contact info in the leaflet and express their will to withdraw, their response will be not included in the study and immediately erase from the server.

Benefits and risks: during the survey participants can opt to receive via email a copy of the final report of the study and a copy of any publication deriving from this study . There will be no additional risks due to the participation to this study.

Financing:

No additional financing support will be required for this study.

Dissemination and Implementation:

The results of this study will be published in relevant scientific journals and will be presented at relevant conferences, including forthcoming IFMBE meetings.

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Appendices:

The following documents are attached:

- Application form for research ethics approval;
- Questionnaire (paper version)