THE ROLE OF THE CLINICAL ENGINEER IN HOSPITAL-BASED HEALTH TECHNOLOGY ASSESSMENT OF MEDICAL DEVICES

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Abstract: **This article provides a brief introduction to the formal process of health technology assessment (HTA), how the HTA process for pharmaceuticals is not so easily implemented for medical devices and how clinical engineering departments can play a role in implementing HTA for medical devices at the local hospital level. Examples are given where this has been done successfully at a London NHS hospital.**

Keywords *– Health Technology Assessment, Clinical Engineering and Medical Physics*

I. Introduction

The World Health Organisation (WHO) defines HTA as "the systematic evaluation of properties, effects, and/or impacts of health technology: the application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of life. It is a multidisciplinary process to evaluate the social, economic, organizational, and ethical issues of a health intervention or health technology."

However, formalised health technology assessment (HTA) is a surprisingly nascent creation. The National Institute for Health and Care Excellence (NICE) in the UK wasn't founded until 1999 and its medical devices evaluation stream - not until a few years later. In Europe it wasn't until 2005 that a group of 35 Organisations throughout Europe, led by the Danish Centre for HTA (DACEHTA), answered a call from the European Commission and Council of Ministers to make HTA a top priority, and consequently led to the creation of the EUnetHTA Project (URL).

Why is this of concern to the clinical engineering and medical physics community? By far the largest portion of HTAs are conducted on pharmaceuticals, however, there are an increasing number of new medical devices (over 100K medical devices registered in the UK versus approximately 1K pharmaceuticals)[1,2] for both treatment and diagnostics that are now being brought through the same assessment and it is becoming clear that the processes used for approving drug treatments do not map simply to medical devices (Table 1). The International Federation of Medical and Biological Engineering (IFMBE) created the Healthcare Technology Assessment Division (HTAD) and now runs HTA courses for post-graduate biomedical engineers and medical physicists, (from which this table was adapted), as well as an open access journal IFMBE International Journal of Clinical Engineering and HTA, since 2016.

The adoption of new medical devices is usually championed by a medical specialist consultant; high capital cost items such as the latest PET or MRI scanners, MRI-Linacs or robotic surgery. At the other end of the cost scale, patients will quickly adopt new medical devices in the form of smart phone apps that provide quick feedback and assurance or otherwise about chronic medical conditions such as blood pressure, insulin levels or memory. The medical specialist consultant has a deep knowledge of the health condition being managed, and the patient is increasingly becoming the end user of app based technology; the clinical engineer or medical physicist then sits squarely between these two groups. This staff group are the necessary link that can provide the technical knowledge required to fully understand both the optimal use of the medical device as well as the range of devices available to ensure context-specific efficacy and efficiency.

Published literature on approaches to medical device purchasing decisions encourage a systems-approach that incorporates local realities and interactions of "technical, financial, safety and clinical requirements" [3]. Medical physics and clinical engineering services, that can be said to be 'system-facing,' are well-placed and well-equipped to support this.

Drugs	Medical Devices
Principal action	
Pharmaco/Immunologic/Metabolic Chemical based	Physiological Mechanical/EMR/Materials
Product Life Cycle	
Long life cycle Unchanging compound	Short life cycle Constantly updated, or repaired
Clinical Evaluation	
Easy to blind One end user Short learning curve Less dependent on use setting Easy to standardise for RCTs	Difficult to blind (can't do placebo) Multiple users Long learning curve Very dependent on use setting Difficult to standardise for RCTs
Use Issues	
Efficacy is not user-dependent Usually does not require specialist training to administer Complications (adverse reactions) increase with use	User-dependent efficacy Requires specialist training Complications decrease with use.
Diversity and hetereogeneity	
Mainly large multinationals Only therapeutic	Mainly small companies but also multinationals Therapeutic and diagnostic
Costs	
High overheads with quick return on investment Lower distribution costs No maintenance or installation	Varying overheads and slow ROI Higher distribution costs Higher maintenance/installation costs

Table 1. A list of specific differences between the healthcare technology assessment process of drugs and medical devices both defined as healthcare technologies by WHO.

Driver	Hospital-based HTA questions
Efficacy	Does it work under ideal conditions?
Effectiveness	Does it work under everyday conditions?
Efficiency	Does it work at a reasonable cost?
Impact	Is it worth it for us?

Table 2. Summary of drivers that are considered during the formal HTA process.

HTA carried out by Medical Physics and Clinical Engineering hospital-based departments can be used to bridge the gap both between the medical profession and the patient but also between the medical profession and the local policy makers within the healthcare provider institutions (Table 2).

What is more, the use of *formalised* HTA can promote consistency that can make insights from HTA more robust and readily transferrable between collaborators. Formal HTA can go some way to address challenges posed by the diversity and heterogeneity (see Table 1) of medical device markets, by promoting common bases for assessment. Transferrable insights can reduce duplication in HTA efforts, as we collectively generate an understanding of which devices are best depending on the scenario.

Formal HTA at a local level to assist policy and decision making is not commonly performed, which is not surprising given the relatively recent development of HTA guidelines at international and national level. The use of Medical Physics and Clinical Engineering personnel to be involved in or even lead formal HTA of medical devices is even less common. The remainder of this article describes the successful collaboration of Medical Physics Department at Guy's and St Thomas' NHS Foundation trust (GSTT) in London, UK and the School of Biomedical Engineering and Imaging Sciences at King's College London (KCL), UK to provide formal HTA at both the local and national level of healthcare service provision.

II. KING'S TECHNOLOGY EVALUATION CENTRE (KITEC) AT KCL

The King's Technology Evaluation Centre (KiTEC) grew out of the King's Centre for Assessment of Radiological Equipment (KCARE), which was established at King's College Hospital in 1977 to evaluate the performance of new x-ray imaging equipment. These were 'hands on' evaluations by a multidisciplinary team of physicists, radiographers and radiologists and included clinical imaging of patients. Over time the methods used by KCARE moved more towards a modern HTA approach, including health economics and systematic reviews of relevant literature. In 2010, NICE issued a call for tenders for HTA centres to support its diagnostic and medical technology assessment programmes.

Under the leadership of Dr Cornelius Lewis and Prof Stephen Keevil KCARE became KiTEC, part of the part of the School of Biomedical Engineering and Imaging Sciences at KCL and incorporating medical statistics and health economics research groups also based at KCL. The KiTEC team now includes several GSTT hospital-based clinical engineers, medical experts, and academic medical statisticians and health economists. Since 2011 KiTEC has been an external assessment centre for NICE's diagnostic assessment programmes and medical technology evaluation programmes and most recently has been appointed as a Technology Specialist Evaluation Team (TSET) for the NHS-Transformation AI-Lab [4] to assist companies with building their evidence base for adoption of AI enabled medical devices by the NHS in England. Scotland, Wales and Northern Ireland have their own versions of this funding. Of the 13 "phase 4" projects funded since 2020 KiTEC is the TSET for four projects with a wide range of applications: mammography screening [5], ECG home monitoring [6], radiotherapy treatment planning [7] and incidental detection of vertebral fractures [8]. The set-up, facilitation and monitoring of these evaluations could not have been done without accessing the domain knowledge and institutional knowledge possessed by the medical physics and clinical engineering teams at all of the evaluation sites. In addition, the success of the evaluation trial designs and protocols were all heavily dependent on input from the Medical Department at Guy's and St Thomas' as to their feasibility and accuracy in obtaining the correct outcome measures. Going forward the multi-disciplinary team at KiTEC will be fundamental to the visionary MedTech Hub currently under construction at King's College London South Bank [8] providing that much needed link between medical research and health service delivery and policy making decisions. The MedTech Hub will provide a physical and creative space so that researchers, commercial entities and clinical specialist can work closely together using the framework of HTA to ensure that innovative medical technologies reach patients as quickly as possible.

III. CENTRE FOR INNOVATION, TRANSFORMATION AND IMPROVEMENT (CITI)

CITI was established at GSTT in 2021, with input from clinical engineers and medical physicists, alongside medical and nursing staff, improvement, analytics and implementation specialists, commercial innovation and legal teams.

The Centre is one example of a multidisciplinary unit, established with the purpose of delivering health service transformation. Initiatives like these have proliferated [9] due to a combination of health needs, economic challenges, emerging technologies, and learning from the Covid-19 pandemic. Medical devices and technology at large, are considered a significant vehicle for change in this space. Therefore, the role of HTA in decision-support is increasingly visible to the wider organisation—as are the clinical engineers and medical physicists involved in delivering it.

Within CITI a group clinical engineers and medical physicists, including some of the authors, led the development of a common framework for delivering innovation, transformation and improvement. Figure 1, using an analogy of London's 'circle' tube line, illustrates some of the common processes for innovation or improvement, moving from 'seeking opportunities' (on the left) through to refinement and deployment (on the bottom right).

It was identified that some form of HTA can be valuable at various points in the modelled 'innovation, transformation and improvement journey', and the framework could be used to signpost these. This includes possibilities for HTA to support decision making as practitioners "prioritise opportunities, …scan for current possibilities, …identify gaps and requirements,…evaluate solutions (in simulated environments), monitor and evaluate (post market)." By bringing medical device HTA and adoption alongside other processes for system improvement, initiatives like CITI not only showcases HTA and the work of medical physicists and clinical engineers but also exposes the role they might play in addressing challenges outside the remit of medical devices.

IV. AI CENTRE FOR VALUE-BASED HEALTHCARE AT KCL

The AI centre for value-based healthcare was established in February 2019 as part of the UK Government's Industrial Strategy Challenge Fund. The AI Centre is led by KCL and GSTT, alongside another 10 NHS Trusts, four Universities, several multi-national industry partners including Siemens Healthineers, NVIDIA, IBM, GSK, 10 UK-based SME's as well as the academic health science network (AHSN) Health Innovation Network. The centre aims to provide a "one-stop shop" for AI researchers and developers to link with front line clinicians with a goal to

speed up and improve diagnosis and care across several patient pathways including stroke, dementia, heart failure and cancer using AI enabled tools. Part of this "one-stop shop" includes the facilitation of HTA at all stages of the project development process.

The team is necessarily a multi-disciplinary consortium of leading AI, data science, research, and clinical experts. Importantly the Clinical and Scientific Computing group within the department of Medical Physics at GSTT have played an essential role in building a robust and accessible platform for testing AI solutions in a way that will satisfy the HTA process of transparency and transferability.

The AI Deployment Engine (AIDE), is an open-source platform that allows the deployment of AI models in a safe, effective, and efficient way by enabling the integration of AI models into clinical workflows without the need to integrate into the local hospital IT network. AIDE provides a comprehensive system, encompassing administrative and clinical tasks as well as regulatory compliance, all important factors in the HTA process.

The platform allows any AI product to connect to the entire patient record database without requiring additional hardware or installation each time a new product is tested within a clinical workflow. Once the clinical data has been analysed by the AI product, the results can be sent back directly to the electronic patient record database to support further clinical decision making (see Figure 2).

AIDE has been built to be compliant with Digital Imaging and Communications in Medicine (DICOM), the international standard for using medical imaging information, and Health Level Seven (HL7), a framework for using electronic health information, making it easy to integrate into existing clinical settings. AIDE's dedicated IT infrastructure allows multiple algorithms to run simultaneously through bespoke Application Programming Interfaces (APIs).

In September 2021 the first instance of AIDE went live at King's College Hospital NHS Foundation Trust, with a stroke AI tool to support NHS clinicians to help improve direct patient care. By September 2023, the aim is to have this deployed across all 10 NHS Trust partners ready to provide access to candidate AI applications [10].

V. Conclusion

HTA can be defined as research that is intended to help decision makers deal with the development, acquisition, and utilisation of medical device technologies. Hospitals are tasked with ensuring that their healthcare technology investments show substantial improvement in patient outcomes in parallel with reduced operational costs. Hospital medical physics and clinical engineering departments have the experience and skills that make them obvious leaders in the HTA process and can bridge the gap between research findings and practical implementation in hospitals. Medical physics and clinical engineering departments are the hospital centres of medical device management. They are not only responsible for basic equipment control and safety but they also provide detailed cost and service analysis and support the annual capital acquisition processes for longer term strategic planning. The extremely successful collaboration between Medical Physics Department at GSTT and the Biomedical Engineering school at KCL demonstrate how powerful these partnerships can be. Together they have brought in more than £20 million over the last 5 years specifically for the translation of research into clinical practice.

Ideally all hospital decisions involving medical devices would be reviewed by a single multi-disciplinary committee, perhaps lead by the lead consultant healthcare scientist with a clear understanding of the components of a formal HTA process and that organization's mission, values, and strategies. Of course, in order to implement this an increase in the number of medical physics and clinical engineering staff with the relevant training in formal HTA processes will be needed.

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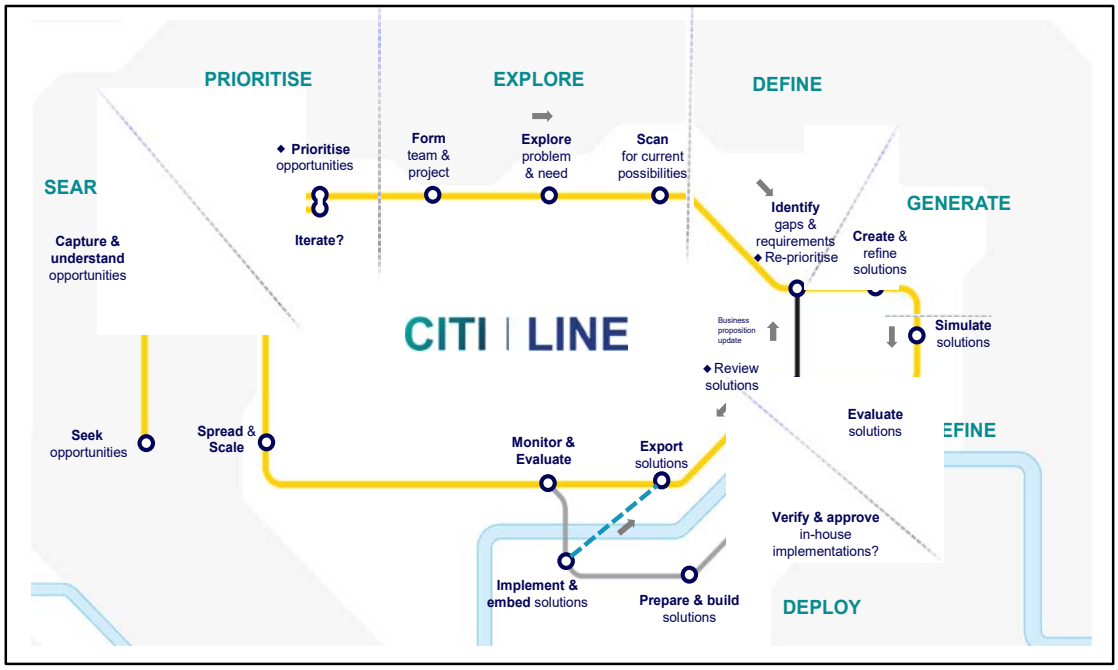

Figure 1. A cartoon version of the medical device design process from inception through to deployment viewed using the analogy of the circle tube line from the London Underground tube map.

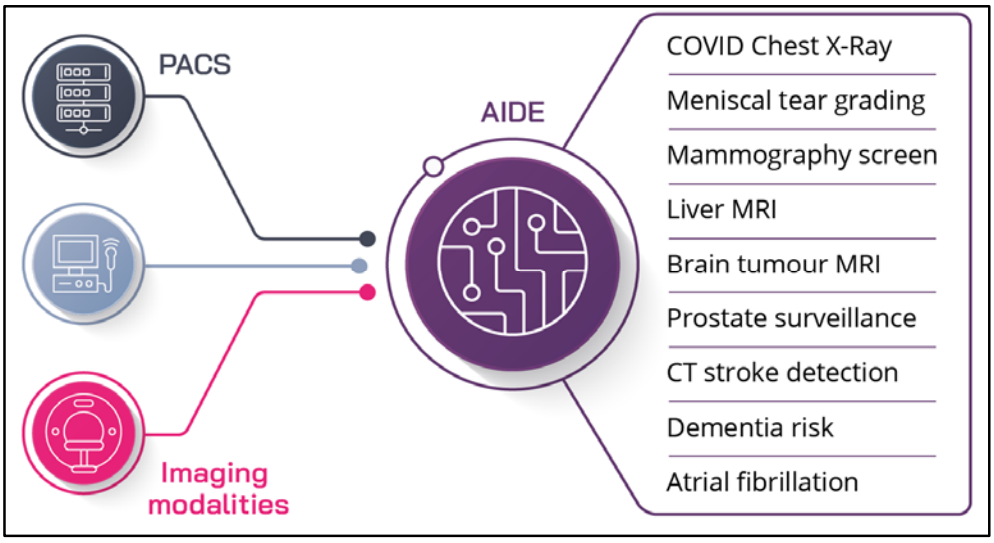

Figure 2. A schematic diagram of how the AIDE platform sits between the hospital data being analysed and the clinical services that are using the AI analysis.