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INTEGRATE-HTA: THE PERSPECTIVE OF EUnetHTA

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The HTA Core Model (HTACM) of EUnetHTA and the INTEGRATE-HTA Model (IHTAM) both provide HTA experts with advanced guidance on how to assess health technologies. In this study, we examine the similarities and differences of the two models, identifying synergies and opportunities for future collaboration. We also consider how such an alignment of the HTACM and IHTAM might be done in practice and present some alternative practical approaches. Overall the two models share several similarities, primarily the perception of HTA as a multidisciplinary analysis that needs to be adjusted according to the properties of the technology under assessment.

Keywords: Research methodology, Models, HTA core model, Integrate HTA model, Health technology assessment

In this study, we examine the INTEGRATE HTA Model (IHTAM) (1) in the light of our experience within the European Network for Health Technology Assessment (EUnetHTA). Our focus is on identifying synergies and opportunities for future collaboration, primarily from the viewpoint of the HTA Core Model®. Some other EUnetHTA tools and methods are considered too, but with less emphasis.

THE HTA CORE MODEL®

The HTA Core Model (HTACM) is a methodological framework for producing and sharing HTA information (2–4). The Model aims at increasing the usability of HTAs beyond their original production location as well as at reducing unnecessary duplication of work within HTA agencies. The Model consists of three main components: (i) the HTA Ontology contains potential questions (assessment elements) to be asked within HTA projects and identifies relations of these questions. The generic questions need to be translated into specific research questions within projects; (ii) methodological guidance provides HTA projects with overviews on how to answer the research questions; (iii) common reporting structure defines a standardized output format for HTA projects, intended to enable effective searching, retrieval, and sharing of information.

Separate applications of the Model each contain a subset of contents tailored for the assessment of different types of technologies (e.g., medical/surgical interventions or pharmaceuticals) or of technologies used for specific purposes (e.g., diagnostics or screening), or when choosing between a comprehensive ("full") assessment and rapid relative effectiveness (Table 1). The different applications have all been tested in several pilot HTAs (5;6).

THE HTA CORE MODEL MAKING BENEFIT OF OTHER METHODOLOGICAL DEVELOPMENTS: THE EXAMPLE OF MedtecHTA

The "Methods for Health Technology Assessment of Medical Devices: a European Perspective" MedtecHTA (www.medtechta.eu) was another FP7 EU-project. Between 2013 and 2015 it developed methodological guidance for performing HTA of a specific type of technology. The objective of MedtecHTA project was to investigate improvements in HTA methods to allow for more comprehensive economic evaluation of medical devices (7). The leading partner of the work package on methods for comparative effectiveness research, UMIT (the University of Health Sciences, Medical Informatics and Technology), was also a collaborating partner of EUnetHTA Joint Action 2 at that time and offered in agreement with the whole MedtecHTA consortium to make the results available to EUnetHTA. The EUnetHTA Work package 7 decided to develop a methodological guideline for therapeutic medical devices. The work was led by UMIT using mainly the findings of MedtecHTA. This guideline built on the MedtecHTA guidance for the evaluation of clinical effectiveness of medical devices, but the recommendations were derived independently and reflect also the work of guideline authors and EUnetHTA's internal and external review process (8).

Writing a methodological guideline can be considered an efficient, relatively quick possibility for a team of experts to make their findings available to EUnetHTA, particularly when no specific resources are on hand to develop a new HTACM application that requires more consideration of compatibility with the existing applications. Such a guideline could then later be developed into an HTACM application, when resources

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Table 1. Domains of HTA According to the HTA Core Model

- Health problem and current use of technology (CUR)
- Description and technical characteristics of technology (TEC)
- Safety (SAF)
- Clinical effectiveness (EFF)
- Costs and economic evaluation (ECO)
- Ethical analysis (ETH)
- Organizational aspects (ORG)
- Patient and social aspects (SOC)
- Legal aspects (LEG)

HTA, health technology assessment.

and some practical experience of using the guideline are available.

SIMILARITIES AND DIFFERENCES BETWEEN THE HTA CORE MODEL AND THE INTEGRATE HTA MODEL

Although no explicit HTACM application for complex technologies exists, several similarities or parallels can be identified between the HTACM and the IHTAM. First, both models are *multidisciplinary* by nature and suggest the need for assessing health technologies from multiple perspectives. Even the rapid relative effectiveness assessment (REA) application of the HTACM, which focuses on effectiveness and safety, contains a checklist for considering the nonclinical domains.

Both models also recognize that the different *domains are intertwined* in many ways and often evidence or other findings from one domain affect the analysis and results of another. In the IHTAM these themes are considered for example within the first of the six guidance documents (9), whereas in the HTACM the relations are identified in the ontology (sequential and content relations) and within the methodological guidance.

The main theme of the model, that is, complexity of some health technologies, is a fundamental part of the IHTAM. In the HTACM, such aspects have been considered in particular during the development of the *organizational aspects* (ORG) as well as the *patient and social aspects* (SOC) domains that rely mostly on the translation model as a technology implementation framework, recognizing the complexity of many health technologies (10).

Also the careful definition of the health technology under assessment and of the assessment context is common for both models. In the HTACM, this is addressed in the Introduction/Ethics chapter, in the scoping of projects, including the analysis within *description and technical characteristics of technology* domain (TEC) and *health problem and current use of technology* (CUR) domain, as well as in relevant guidance documents (Methodological Standards and Procedures, HTA Core Model Online), and in the IHTAM, for example, in Therapeutic Medical Devices – EUnetHTA Guideline (8).

Some important differences between the two models also exist. To begin with, it should be acknowledged that none of the current HTACM applications has been developed *explicitly for addressing complexity*. Therefore, and by definition, the IHTAM covers such themes more extensively and in much more detail. This is also because the HTACM aims at providing only overviews of methodologies, referring to more detailed guidance, such as the EUnetHTA Guidelines, whenever appropriate. Therefore, parts of the IHTAM, for example the guidance on treatment moderation and patient's preferences, resemble more the EUnetHTA Guidelines than the HTACM content.

The two models differ also in the way they relate to HTA processes. The IHTAM takes at times very clear stand to the HTA process itself, which is displayed for example in the "five-step process" incorporated in the model. The HTA Core Model, on the other hand, mostly refrains from providing too detailed process guidance. This is to allow use of the model in various local (national or regional) contexts, where the mandatory processes may vary considerably. Instead, the HTACM focuses on bringing clarity to the structure and presentation of HTAs. One further clear difference is also the extent of analysis enabled by the two models, with the HTACM covering a wider spectrum of aspects through the *safety* (SAF) and ORG domains, which are not included in the IHTAM.

Finally, while the IHTAM considers also the actual decision-making process (Step 5), the HTACM does not cover such aspects. The inclusion of themes such as, for example, multi-criteria decision analysis (MCDA) was considered by the developers, but it was regarded as being a process that takes place after the actual HTA project.

POTENTIAL FOR SYNERGIES

Considering the aforementioned similarities and differences, it is evident that there are significant synergistic opportunities between the IHTAM and the HTACM, but that some further work to accomplish interoperability in practice would be required. Building the various HTACM applications, the specific subsets for different purposes, allows not only further development of existing applications but also expansion of themes covered by the model. Actually, the current HTACM is a result of developing first the applications for interventions and diagnostics and then later amending those with the applications for screening and pharmaceuticals (both rapid and full).

From the viewpoint of the HTA Core Model®, there would be three theoretically possible ways of aligning efforts with the IHTAM. The first method would be to expand the model with a *new application* to cover complexity. Such "HTA Core Model application for complex health technologies" could act as an interface between the two models, and it would entail that the IHTAM and HTACM exist as separate entities also in the future. The key contents of the IHTAM would need to

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be summarized within the application's methodological guidance and the remaining, more detailed guidance of the IHTAM could be connected through hyperlinks. Also HTA ontology within the HTACM would need to be screened against the advice within IHTAM and, where appropriate, amended by either adding new assessment elements or through revising the data in the existing elements, particularly the "clarification" texts of the questions (see domain-specific assessment elements in EUnetHTA Joint Action 2) (11). Such new or revised assessment elements could benefit the other applications, too. Finally, the fitting of the common reporting structure for purposes addressed by IHTAM should be considered and amended if needed.

The second option would also use a specific HTACM application for complex technologies; but unlike in the previous method, this option would aim at incorporating all of the IHTAM contents into the HTACM as an application and discontinuing the IHTAM as a separate entity. Due to the high level of methodological detail within the IHTAM, this approach would, however, create a somewhat disparate (i.e., much more detailed) application compared with the already existing ones. If such an approach would be preferred, a more feasible solution would probably be to include some materials of the IHTAM as EUnetHTA Guideline(s) to keep the HTACM application leaner.

In the third option, the IHTAM principles and findings regarding assessment of complexity would be applied across the whole existing HTACM, covering all existing applications. No new HTACM application would be constructed and the IHTAM would remain as a separate entity. This approach might be justified as an alternative, considering that the current applications of the HTACM all stem from either the *type* or *purpose of use* of health technologies, whereas *complexity* does not refer to any specific type or purpose. It is rather a property (using continuum simple-complex). As with the previous options, this would require review and revision of all components of the HTACM, in particular the ontology and the methodological guidance. In this case, the revisions and amendments would be made to the existing HTACM contents (whether general or technology-specific). Including all contents of the IHTAM within the HTACM in this manner would probably be unfeasible, as it would expand the methodological contents of the HTACM beyond the original concept of providing overviews.

Whatever option would be used to align the two models, it should happen in a coordinated manner and as a result of mutual decisions. Respecting relevant intellectual property rights and attributing work to original authors are integral parts of such a process. Of all these three options, the first and the third are closest to the original idea of the HTA Core Model, that is, to standardize the contents (question–answer pairs) of HTA and to provide overviews of state-of-the-art methodologies within different domains, linking to more detailed guidance elsewhere. It would also allow specific, focused expert groups to develop either the HTACM or the IHTAM using various funding mechanisms. Selecting which of these two options would be more feasible would require a more thorough analysis of each method. Complete merging of the two models (the second option) would require a substantial amount of work and inclusion of several EUnetHTA tools in the considerations. Perhaps the strongest argument for such an undertaking would be a desire to include the IHTAM (as a whole) within the official EUnetHTA methods and tools, and relevant development resources.

Specific attention to the HTA *process* as a whole and in some cases to *detailed scientific advice* provides common ground to examine the IHTAM in relation to some other EUnetHTA products as well. Detailed scientific guidance is included within EUnetHTA in fourteen *EUnetHTA Guidelines* and one reflection paper (12). Guidance on the HTA process exists both for full assessments and rapid REAs through the HTA Core Model Handbook (13). Exploring potential synergies and hyperlinking of these documents with the IHTAM materials and vice–versa would probably benefit both entities.

POPULATION SCREENING AS AN EXAMPLE OF SYNERGIES

Population screening is a technology that entails complexity and has a specific HTACM application. In addition to the actual screening test, the whole screening process involves several components that may affect the final outcomes, such as inviting and informing citizens, educating professionals, arranging and selecting further investigations for those who are screening-positive, and finally the medical treatment if the disease was found. Such a technology could be used as a practical example in potential future efforts to align the HTACM and the IHTAM.

CONCLUSIONS

The IHTAM is an impressive work that sheds light on a challenging area of HTA, adjusting the research methods to match the complexity available in many settings. The approach has been tested in assessing a pertinent theme, palliative care. Further assessments using the IHTAM will provide more evidence of its usefulness in practice and identify areas for development.

Several health technologies embody at least some level of complexity. Hence, the principles and methods incorporated in the IHTAM bear good potential to also benefit EUnetHTA's products. Important synergies could be achieved through further joint development and integration of the IHTAM and EUnetHTA's products, primarily the HTA Core Model®, the Guidelines, and the process guidance. Such efforts would require adequate financial and intellectual resources to ensure results of high quality.

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CONFLICTS OF INTEREST

Dr. Lampe reports personal fees from F. Hoffmann - La Roche Ltd, on consultancy services outside the submitted work. Dr. Schnell-Inderst has nothing to disclose.

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