Assessment of Digital Health Technologies - Comparison of Evidence Frameworks of NICE & HAS

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BACKGROUND

- Digital health solutions as any other health technologies should prove their value to HTA bodies before they could be reimbursed by the national health insurance.
- Due to rapid growth of digital health technologies (DHTs) and their specific attributes (e.g. complexity of the solution or frequent updates), HTA bodies started developing guidelines which specify evidence that should be submitted for the assessment of DHT.

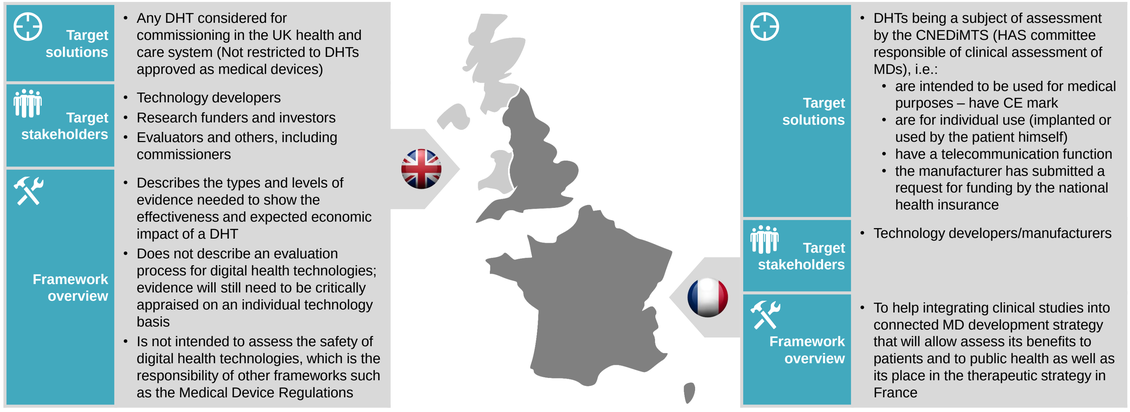
OBJECTIVES

- The aim of this study was to compare recent guidelines developed by the English (NICE) and French (HAS) HTA agencies.

METHODS

- Evidence frameworks for digital technologies defined in the following guidelines of NICE and HAS have been compared:
  - NICE: Evidence standards framework for digital health technologies (March 2019); [1]
  - HAS: Guide on the assessment of connected medical devices (MDs) (January 2019). [2]

Figure 1. Characteristics of frameworks for digital health solutions published by NICE [1] and HAS [2]



RESULTS

Target solutions

- NICE guidelines are applicable to broad range of digital solutions, which could be commissioned in the UK. They may concern not only solutions regulated as medical devices but any digital health technologies intended to be used under the NHS system. They are less relevant for solutions downloaded or purchased directly by users.
- HAS guidelines pertain only to connected MDs being the subject of the assessment by the CNEDiMTS (HAS committee responsible of clinical assessment of MDs).

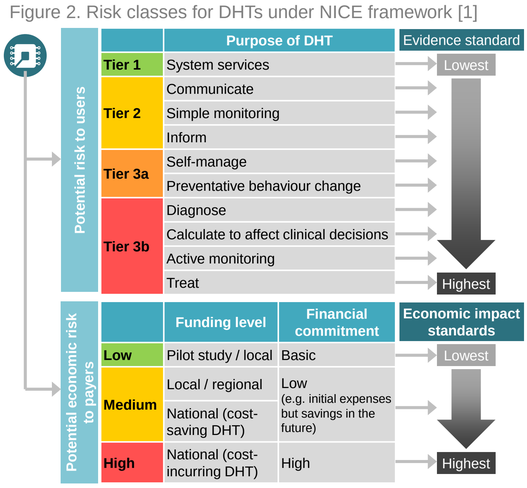
Target stakeholders

- HAS guidelines are targeting primarily the solution developers to anticipate clinical requirements for reimbursement. NICE guidelines target broader audience including solution developers, investors and assessors, including Clinical Commissioning Groups (CCG).

Framework overview and data requirements

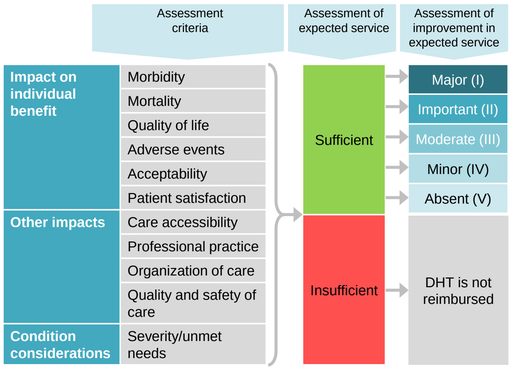
- NICE framework indicates types and levels of evidence needed to show the effectiveness and expected economic impact of a DHT, depending on the risk class to which the DHT is classified (Fig. 2), but does not describe the assessment process nor the specific criteria determining the decision.
- HAS guide indicates when new clinical studies may be required for the DHT (e.g. in case of changes in system architecture or organization of care), defines criteria for evaluation of DHT (Fig. 3) and highlights minimum data required for the recognition of additional value of the DHT.

Figure 2. Risk classes for DHTs under NICE framework [1]



- In NICE framework, each tier of risk to users indicates specific types of evidence required for the DHT. They vary from data such as user acceptability or credibility for healthcare professionals for the lowest risk DHT (Tier 1) to high quality randomized controlled trial (RCT) data or meta-analysis of RCTs for the highest risk solutions (Tier 3b). The requirements are cumulative, thus, for DHT classified on Tier 3b requirements for all lower tiers (1-3a) are also valid.
- HAS guidelines detail how it determines whether the solution provides any expected service (*service attendu*), and if so, what is the size of improvement in expected service (*amélioration du service attendu*). Robustness of trial methodology is a key criteria for the HAS, expecting preferably multicentre RCT comparing the DHT with the appropriate reference strategy. (Fig. 3)
  - The primary criteria for the assessment are impact on mortality/morbidity. QoL could be the primary criterion, if the main purpose of the DHT is to improve QoL, or if the DHT is non-inferior in terms of mortality and morbidity.
  - Other criteria (e.g. impact on care accessibility or organization) may be used to assess improvement in expected service if at least non-inferiority is shown for mortality/morbidity, safety and acceptability.

Figure 3. DHT assessment criteria and procedure according to HAS guidelines [2]



- NICE framework also provides requirements for economic evidence. HAS guidelines for connected MDs does not encompass any economic requirements as it pertains to CNEDiMTS assessment, while the economic evaluation is conducted at the level of the HAS Economic Committee (CEESP).
  - The extent of economic data required by NICE depends on the expected scale of funding (from pilot study, through local and regional funding to national funding) and the payer commitment (e.g. only initial cost of cost-saving DHT or permanent cost of cost-incurring DHT). For low risk DHTs only 2-year budget impact analysis (BIA) is required, while for high risk solutions – 5-year BIA and cost-utility analysis, both supplemented with sensitivity analyses. (Fig. 2)

CONCLUSIONS

- NICE and HAS have developed evidence frameworks to account for elements specific to DHTs and to better fit within pathways already existing in the systems – clinical commissioning in England and national funding of medical devices in France.
- They vary in terms of eligibility of DHT, target stakeholders and evidence requirements, but provide valuable, country-specific support for solution developers and fill important gap in the formal market access pathway for DHTs.

1. NICE website: https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf
2. HAS website: Guide sur les spécificités d'évaluation clinique d'un dispositif médical connecté (DMC) en vue de son accès au remboursement. January 2019. https://www.has-sante.fr/portail/upload/docs/application/pdf/2019-02/guide_sur_les_specificites_devaluation_clinique_dun_dmc_en_vue_de_son_acces_au_remboursement.pdf

ISPOR 2019, Copenhagen, Europe, November 2-6 2019. PNS235.