# Value assessment of Combination Digital Health Technologies under new NICE Evidence Standards Framework: evidence submitted and key factors for positive recommendation

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## Objectives

- Digital Health Technologies (DHT) are rapidly evolving and have the potential to provide significant benefits to patients and healthcare systems, by improving adherence, supporting with monitoring and identifying patients at risk of disease relapse/progression, etc. DHTs cover a wide range of technologies, such as mobile apps, wearable devices, telemedicine and combinations of drugs/medical devices with a digital component (cDHTs).
- Lack of regulatory frameworks and transparent evidence requirements for cDHTs means access routes remain unclear. In recent years, some Health Technology Assessment (HTA) bodies have been developing frameworks to assess DHTs' benefits for healthcare systems.
- In March 2019, the National Institute for Health and Care Excellence (NICE) published the Evidence Standards Framework (ESF)[1] for the assessment of DHTs, with the aim of ensuring that new DHTs are clinically effective and offer value to the healthcare system.
- The ESF is intended to guide local evaluations and improve consistency in the assessment of DHTs across the NHS and does not constitute a NICE evaluation process.
- The ESF is comprised of 21 non-mandated standards across 5 areas of a DHT's life cycle: design factors, describing value, demonstrating performance, delivering value and deployment considerations. It describes the type and level of evidence that different types of DHTs should be able to demonstrate.
- An analysis was conducted to determine compliance for recent cDHTs for ESF and identify key factors considered by NICE in evaluating the evidence.

**Data extracted from the HTAA for combination DHTs assessed by NICE**

| Combination DHTs assessed by NICE | | | | | |
|---|---|---|---|---|---|
| **Technology** | **Lead-I ECG (DG35)[2]** | **QAngio™ XA 3D QFR and CAAS vFFR (DG43)[3]** | **Zio™ XT (MTG52)[4]** | **DyeVert™ Systems (MTG60)[5]** | **Synergo™ (MTG61)[6]** |
| **Recommendation** | **NEGATIVE** *- 2019 -* | **NEGATIVE** *- 2021 -* | **POSITIVE W/ RESTRICTIONS** *- 2020 -* | **NEGATIVE** *- 2021 -* | **POSITIVE W/ RESTRICTIONS** *- 2021 -* |
| **Evidence standards framework criteria** | | | | | |
| The DHT should comply with relevant safety and quality standards | | | | | |
| Incorporate intended user group acceptability in the design of the DHT (patient involvement in design, development or testing) | | | | | |
| Consider environmental sustainability | | | | | |
| Consider health and care inequalities and bias mitigation | | | | | |
| Embed good data practices in the design of the DHT | N/A | N/A | | N/A | N/A |
| Define the level of professional oversight | | | | | |
| Show processes for creating reliable health information | | | | | |
| Show that the DHT is credible with UK professionals | | | | | |
| Provide safeguarding assurances for DHTs where users are considered to be in vulnerable groups or where peer-to-peer interaction is enabled | N/A | N/A | N/A | N/A | N/A |
| Describe intended purpose and target population | | | | | |
| Describe the current pathway or system process | | | | | |
| Describe the proposed pathway or system process using the DHT | | | | | |
| Describe the expected health, cost and resource impacts compared with standard or current care or system processes | | | | | |
| Provide evidence of the DHT's effectiveness to support its claimed benefit | | | | | |
| Show real-world evidence that the claimed benefits can be realised in practice (pilot in UK setting) | | | | | |
| The company and evaluator should agree a plan for measuring usage and changes in the DHT's performance over time | | | | | |
| Provide a budget impact analysis | | | | | |
| For DHTs with higher financial risk, provide a cost-effectiveness analysis | | | | | |
| Ensure transparency about requirements for deployment | | | | | |
| Describe strategies for communication, consent and training processes to allow the DHT to be understood by end users | | | | | |
| Ensure appropriate scalability (load testing) | | | | | |

**Caption:** Green, complies with ESF; Red, does not comply with ESF; Orange, unclear if it complies with ESF;
Abbreviations: DHT, digital health technology; HTAA, HTA Accelerator; N/A, not applicable; NICE, The National Institute for Health and Care Excellence.

References: [1]NICE, Evidence standards framework for digital health technologies, 09/08/2022; [2] NICE, Lead-I ECG devices for detecting symptomatic atrial fibrillation using single time point testing in primary care, 8/05/2019; [3]NICE, QAngio XA 3D QFR and CAAS vFFR imaging software for assessing coronary stenosis during invasive coronary angiography, 17/03/2021; [4]NICE, Zio XT for detecting cardiac arrhythmias, 01/12/2020; [5]NICE, DyeVert Systems for reducing the risk of acute kidney injury in coronary and peripheral angiography, 04/10/2021; [6]NICE, Synergo for non-muscle invasive bladder cancer, 30/11/2021.

## Methods

- A search of the HTA Accelerator™ (HTAA) - an IQVIA database containing information on payer assessments and evidence requirements - was conducted on 28th March 2023.
- HTAs were restricted to NICE assessments of device interventions published from 2019 - to ensure only assessments following the publication of the ESF were included - and subsequently filtered by cDHTs.
- Data extractions included submitted evidence, agency critique and recommendations. Evidence was then compared against the NICE ESF for DHTs.

## Results

- A total of 74 assessments were identified. Based on the inclusion criteria, five cDHT assessments were retrieved for analysis, amongst which only two received a positive recommendation*.
- All assessments included a systematic review of clinical evidence and head-to-head comparative data (observational or randomised controlled trial [RCT] data). Three assessments submitted RCT data (of which two were based in the UK), while one had ongoing RCTs at the time of the assessment (QAngio XA 3D QFR).
- Real world evidence (RWE) is an evidence standard under ESF; however, it was included only in two assessments, one of which received a positive recommendation, while the other received a negative recommendation.
- Four assessments included a cost-effectiveness model and one a cost minimisation model (Zio™XT). Only three assessments included a budget impact model, although this is an evidence standard under ESF. The economic models of the two assessments that did not include a budget impact model provided evidence of cost savings, although uncertainties remained.
- Patient involvement in the design of the DHT is also required but was only pursed by two sponsors.
- Other requirements (transparency about requirements for deployment, strategies for communication, consent and training processes, etc.) were sporadically provided.
- The two assessments that received a positive recommendation demonstrated promising benefits for patients and potential cost savings for the NHS. However, both recommendations were conditional to additional data collection due to observed uncertainties in either the clinical or economic evidence.
- The three assessments receiving a negative recommendation were deemed as not having sufficient evidence to support its use in the NHS, and further research was recommended.

## Conclusions

- Most of the evidence standards in ESF were met; however, specific DHT requirements were not submitted, including local RWE to demonstrate applicability to UK practice and deployment considerations.
- Main criticism from the Committee referred to lack of good quality evidence on improved efficacy, RWE and long-term data. Specific data on local use in the NHS was highlighted as a key data gap in the assessments identified, both from a clinical perspective and cost savings demonstrated.
- Key factors for positive recommendation identified were improved efficacy/non-inferiority to current practice and cost-effective use of healthcare system resources.
- While the majority of the DHTs were submitted post-publication of the ESF, it is plausible that their development did not fully incorporate the ESF requirements into account. This could potentially account for the partial fulfilment of some requirements.
- ESF outlines a high level of evidence standards for DHTs to demonstrate the benefits for the NHS and patients, and future DHTs will need to comply with a high level of evidence standards to receive a positive NICE recommendation.

*NICE decision on Lead-I ECG was published in May 2019; it is assumed the assessment would have been conducted prior to ESF publication but it is included in current analysis to align with inclusion criteria.

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