

Health State Utility Value Elicitation in Medical Technology and Digital Health: How Do They Compare To Pharmaceuticals? A Targeted Literature Review of Interventions in Type 2 Diabetes Mellitus



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Objective

To conduct a targeted literature review of health state utility values (HSUVs) to understand what data exist for medical technology and digital health relative to pharmaceutical interventions, using type 2 diabetes mellitus (T2DM) as a case study.

Background

- As part of the UK's National Institute for Health and Care Excellence (NICE) transformation plan, it is proposed to align health economic methods used for pharmaceuticals and medical technologies (including digital health interventions) in evidence submissions.¹
- Cost-utility analyses (CUAs) and, consequently, high quality HSUV data would therefore be required for medical technology assessments.² In addition, digital health and measuring quality of life are currently priority research areas within NICE.³
- However, it is unclear whether there is sufficient published evidence on HSUVs for medical technologies, including for digital health interventions.
- T2DM is a disease area that is well-suited for a case study comparing evidence on medical technology interventions and pharmaceuticals, since there are multiple types of devices, digital health interventions, and pharmaceuticals available to patients.⁴ Additionally, diabetes is a major health condition prioritized in the NHS long-term plan.⁵

Methods

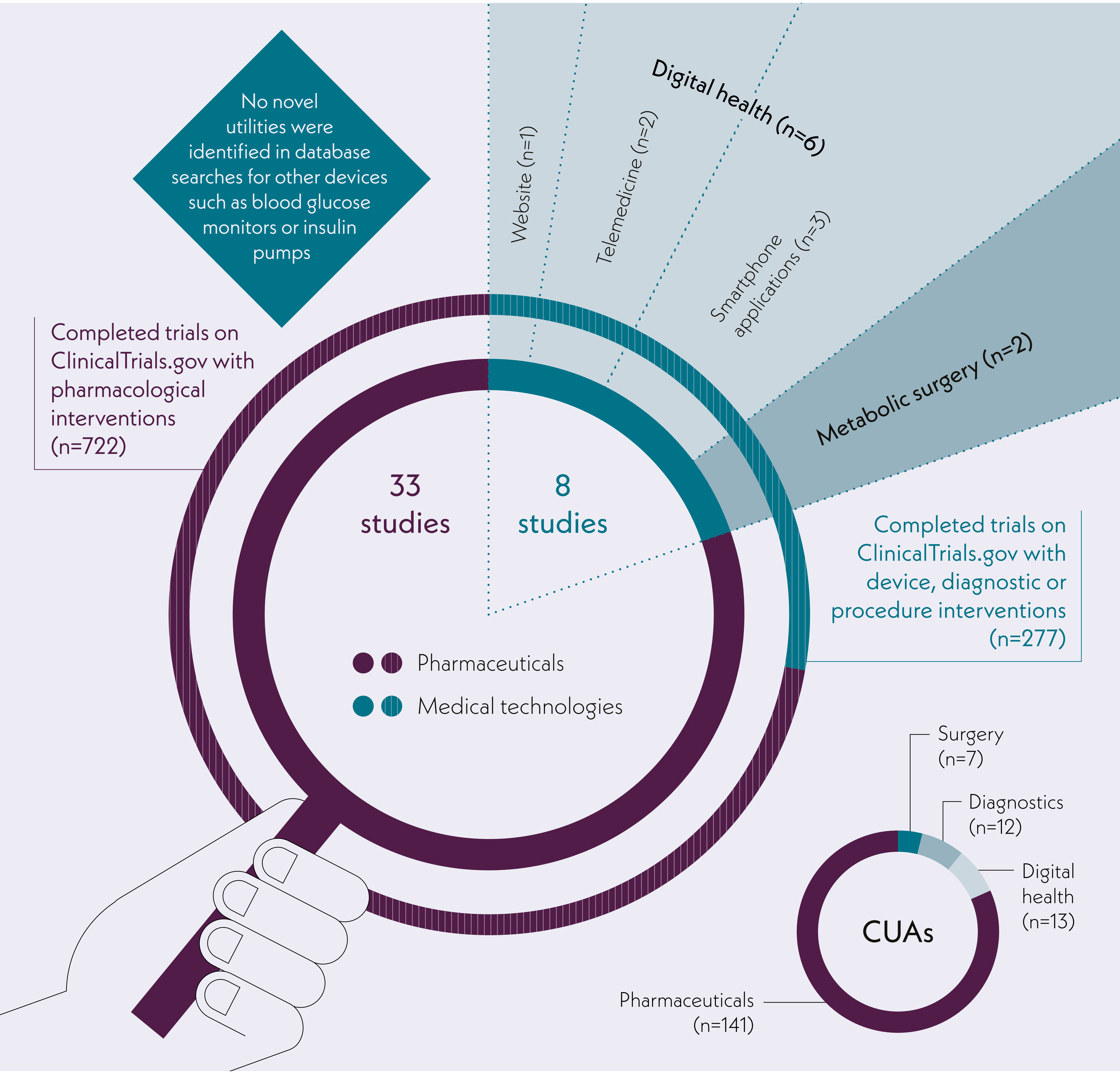
- MEDLINE, Embase, and the International Health Technology Assessment (HTA) Database were searched in October 2023 for data published since 2020, using terms for T2DM and HSUVs.
- Records were reviewed against prespecified eligibility criteria wherein all studies presenting novel HSUV data or health-related quality of life (HRQoL) data that can be used to derive utility values, such as EuroQoL-5 Dimensions (EQ-5D) scales, were included for analysis.
- CUAs were also retained to compare the volume of economic models published on medical technology interventions and pharmaceuticals.
- Supplementary ClinicalTrials.gov searches were performed for the studies completed in the same date range as the database search (2020 to October 2023), limited by condition (type 2 diabetes); number of records reporting on medical technologies was estimated by adding those that listed "Device", "Diagnostic" or "Procedure" as an intervention type.

Results

- 1,999 records identified from database searches were screened, yielding a total of 41 unique studies reporting on novel HSUVs (or HRQoL data that can be used to derive utilities) (Figure 1).
- Of the studies reporting HSUVs, 8 (20%) reported on medical technology interventions, comprising digital health (n=6) and metabolic surgery (n=2), compared with 33 (80%) studies reporting on pharmaceuticals (Figure 1).
- Digital health interventions included smartphone applications (n=3), telemedicine (n=2) and a website (n=1) (Figure 1).
- EQ-5D was the predominant metric, utilized in 37/41 (90%) studies (Table 1).
- Among the included studies on digital health interventions, 5/6 (83%) employed the randomized controlled trial (RCT) design, while 24/33 (73%) of the identified pharmaceutical studies employed prospective observational designs (Table 1).
- In comparison, a targeted search of the ClinicalTrials.gov website estimated that among the pharmacology and medical technology trials completed within the database search period, 277/999 (28%) had medical technology interventions and 722/999 (72%) had drug interventions (Figure 1).
- In addition, the database searches identified 173 publications on CUAs. These were overwhelmingly conducted in the database searches were overwhelmingly conducted in pharmaceuticals (n=141), followed by digital health (n=13), diagnostics (n=12), and surgery (n=7) (Figure 1).

FIGURE 1

Summary of findings



Abbreviations: App: application; AqoL-8D: Assessment of Quality of Life 8 Dimensions; CUA: cost-utility analysis; EQ-5D: EuroQoL-5 Dimensions; HQoL: health-related quality of life; HSUV: health state utility value; HTA: health technology assessment; NICE: National Institute for Health and Care Excellence; RCT: randomized-controlled trial; T2DM: type 2 diabetes mellitus; UK: United Kingdom; US: United States.

References: ¹Transforming NICE (2024). Available at: <https://indepth.nice.org.uk/transforming-nice/index.html> [Last accessed 13 March 2024]; ²Wolowacz S.E. et al. Value in Health 2016;19:704-719; ³NICE (2024). Methods research areas. Available at: <https://www.nice.org.uk/about/what-we-do/our-research-work/methodological-research-areas> [Last accessed 13 March 2024]; ⁴UK D. Meds & Kit (2020). Available at: <https://www.diabetes.org.uk/resources-s3/2019-11/diabetes-uk-meds-and-kit-2020.pdf> [Last accessed 13 March 2024]; ⁵NHS (2019). The NHS Long Term Plan. Available at: <https://www.longtermplan.nhs.uk/publication/nhs-long-term-plan/> [Last accessed 13 March 2024]. **Author contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: AP, HL, AV, FL; Drafting of the publication, or reviewing it critically for important intellectual content: AP, HL, AV, FL. **Acknowledgements:** The authors thank Bethan Hawkins, Costello Medical, for graphic design assistance.

TABLE 1

Characteristics of studies of medical technology interventions in T2DM reporting HSUV-related data

First author	Year	Country	Study design	Intervention	HSUV tool
Digital health					
Gong	2020	Australia	RCT	Mobile app	AQoL-8D
Iverson	2020	Norway	RCT	Telemedicine	EQ-5D
Noviani	2020	Indonesia	RCT	Mobile app	EQ-5D
Taylor	2020	UK	RCT	Web-based	EQ-5D
Kesavadev	2022	India	Interventional non-RCT	Telemedicine	EQ-5D
Heald	2023	UK	RCT	Mobile app	EQ-5D
Metabolic surgery					
Ruban	2020	UK	RCT	Bypass device	EQ-5D
Aminian	2021	US	RCT	Bypass device	EQ-5D

Conclusion

- The identified volume of HSUV-related data for medical technologies was substantially smaller than that for pharmaceuticals in T2DM (8 [20%] versus 33 [80%]), with most of the evidence for medical technologies focused in digital health.
- In comparison, among the ClinicalTrials.gov trials that were completed during the same search period, the proportion of records with medical device versus drug interventions was estimated as 28% versus 72%. This suggests that a smaller proportion of medical technology trials reported novel HSUV data compared with pharmacology.
- There was a large discrepancy in the use of RCT evidence among studies reporting HSUV-related data: while 5/6 of digital health studies in this review were RCTs, the majority of evidence for pharmaceuticals came from observational studies. This likely indicates the relatively low resources necessary for conducting RCTs in digital health compared with pharmacology.
- For the identified CUAs, the disparity between the volume of medical technology and pharmacology evaluations was as large as that for novel HSUV data, with over three-quarters of identified CUAs focusing on pharmacological interventions.
- The presented study has a number of limitations, including the targeted nature of the review, limited time frame, and one focus disease area; nevertheless the patterns identified may be useful when considering the possibility of aligning health economic methods across medical technologies and pharmaceuticals in the future.
- Paucity of HSUV-related data for medical technologies suggests potential delays in getting new technologies to patients, in particular at the HTA stage. This could be mitigated by more widespread and robust primary data collection of HSUVs by medical technology manufacturers.