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Recent US and French access frameworks could pave the way to the reimbursement of digital health technologies

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OBJECTIVES

- Despite rapid growth, access and reimbursement of digital health technologies (DHTs) has proven difficult due to lack of clear access guidance or strict evidence generation requirements (e.g., clinical trials).
- Two recently published assessment frameworks have been adopted in France and the United States (US) in 2023, with corresponding assessments allowing for the use of real-world evidence (RWE).
- In France, PECAN (*Prise en charge anticipée des dispositifs médicaux numériques*) framework grants temporary reimbursement (1 year) for innovative DHTs, while companies develop supporting evidence demonstrating clinical and/or organisational benefits, which will be used in the application for permanent reimbursement pathway.
- In the US, the Institute for Clinical and Economic Review and the Peterson Health Technology Institute (ICER-PHTI) developed an assessment framework based on the outcome of three DHTs assessments.
- The two frameworks and related appraisals have been analysed to understand how the use of RWE can support access and reimbursement of DHTs.

METHODS

- Firstly, the two assessment frameworks were analysed in terms of evidence requirements, focusing on the use of RWE. Secondly, a hand-search of published appraisals in relation to these frameworks was conducted in September 2024, and retrieved appraisals were reviewed.
- PECAN framework comprises of four requirements, of which two (*Conformité Européene* [CE] mark and innovativeness) are assessed by *Commission Nationale d'Évaluation des Dispositifs Médicaux et des Technologies de Santé* (CNEDiMTS), whereas the remaining two (data protection and data accessibility) are assessed by *Agence du Numérique en Santé* (ANS). This analysis is focused on the CNEDiMTS assessment only.
- Besides the financial impact (not evaluated here), ICER-PHTI framework comprises of three requirements (user experience, safety and effectiveness, and health equity) for clinical impact. It also includes an overall evidence rating matrix to rate the safety and effectiveness of the DHT. We analysed the outcome of the DHT assessment report that informed the ICER-PHTI framework and matched it to the requirements. Because of their therapeutic nature, we considered the DHTs in the report as Evidence Tier 3b (therapeutic interventions for "an established clinical diagnosis") according to the framework, which in general requires randomized controlled trials (RCT).

RESULTS

France

- In France, six DHTs have been assessed since 2023 under the PECAN framework, of which only two received a favourable opinion from the CNEDiMTS.
- The two DHTs with a positive opinion (see **Table 1**) were considered innovative and likely to bring clinical benefit and progress to the organization of care, based on the available data and despite the identified limitations. No use-related risks were identified.
- Five of the assessments included RCTs as part of their evidence package, four of which also included RWE. Additionally, the sixth assessment included RWE. Among the five assessments providing RWE, no objections were raised on the use of this type of evidence.
- Availability of data on the real-world use of the DHT under assessment, where possible, is one of the criteria specified in the PECAN framework that will contribute to the CNEDiMTS opinion. In the assessments analysed, a study on the performance of the algorithm (Cureety Techcare), and a pragmatic study showing the feasibility and performance in reducing emergency department (ED) visits (Presage Care), among others, were used as supporting RWE evidence.
- Although RCTs remain the gold standard for assessing health technologies, alternative methods such as RWE studies, are regarded as an acceptable source of evidence for permanent reimbursement in France by the CNEDiMTS.

US

- In the US, no DHTs were assessed since the new framework has been in place. Two assessments of the three that informed the framework included RWE (see **Table 2**). Likewise, two assessments included RCT data. Despite that DynamiCare lacked RCT and the panel evaluated the net health benefit as negative overall, all DHTs received an evidence rating of moderate certainty, with comparable or small net health benefit.
- Main concerns of panellists regarded the lack of long-term follow-up data in patient outcomes and the lack of benefit compared to standard of care. DynamiCare´s observational study potentially received a favourable rating due to a large sample size and longer follow-up time.

CONCLUSION

- The two assessment frameworks pave the way for a more streamlined access for DHTs in France, the US, and potentially beyond these two countries.
- While RCTs remain the gold standard, the two frameworks allow for RWE use, and observational studies or retrospective analyses have received favourable appraisals (France) / evidence ratings (US). Based on our analysis of the evidence package in the appraisals identified, we can assume this was due to the robustness of the studies, with large sample size and longer observation terms. RWE provide several advantages over RCTs. For instance, a larger pool of patient data can be analysed, which is reflective of clinical practice. Nonetheless, the key value drivers assessed were innovativeness and clinical improvement demonstrated by the technologies.
- Publication of the two frameworks has wider implications. Positive reimbursement decisions in France and the US, along with the corresponding types of evidence submitted, could potentially be used as examples in other markets where the two health technology assessment agencies are referenced in decision making.

2 DHT as adjunct to medication assisted therapy for opioid use disorder assessments by ICER-PHTI, published on December 11, 2020

DHT	reSET-O	Connections	DynamiCare
Indication	Opiod use disorder		
Evidence rating for safety & effectiveness[1]	C+	C+	C+
Framework requirements for clinical impact			
1. **User experience**: Assessment of engagement of end users in the design and development process 1.1 Measured among a diverse set of prospective or active end-users (**real-world population**) 1.2. If used in health care setting, measured under a diverse set of practice setting and conditions	Not assessed in the report, no reason given	Not assessed in the report, no reason given	Not assessed in the report, no reason given
2. **Safety and effectiveness** of therapeutic interventions (panel evaluation of net health benefit): Minimum requirement for Tier 3b is RCT[2]	✗	✗	✗
3. **Health equity**[3]: Culturally and linguistically appropriate, low barrier to entry for digital literacy, instills or exacerbates implicit biases, and is meets the usability needs of health disparity populations	✓	Not mentioned in the report	Not mentioned in the report
[1]Evidence ratings on safety and effectiveness according to ICER Evidence Rating Matrix™ arises from a joint judgement of the level of confidence provided by the body of evidence and the magnitude of the net health benefit. The comparative clinical effectiveness ranges from A = "Superior" – High certainty of a substantial (moderate-large) net health benefit, to D = "Negative"- High certainty of an inferior net health benefit. C+ corresponds to "Comparable or Incremental", which means that there is moderate certainty of a comparable or small net health benefit, with high certainty of at least a comparable net health benefit. [2]RCTs for all Tier 3b DHTs should capture patient-important outcomes, compare the new DHT to a reasonable active comparator (e.g., well-managed standard of care), and demonstrate durability of treatment effect to a pre-established timepoint guided by expert opinion [3]Health Equity also includes evaluation of accessibility (usable with disabilities or impairments can use the DHT), through the CDC Clear Communication Index. However, this was not assessed in the report.			
Clinical evidence			
Clinical evidence package	- 4 RCT - 1 RWE (observational study) - 1 retrospective study using claims data	No key studies; RCT pilot study with published results for the CB4CBT part	Observational study only, informed from a white paper on the use of DHT in general substance use population
Inclusion of specific RCTs	✓	✓	✗
Inclusion of RWE	✓	✗	✓

Source: All data can be found in the final report by ICER-PHTI under https://icer.org/assessment/icer-phti-assessment-framework-fordigital-health-technologies/

Abbreviations: ANS: *Agence du Numérique en Santé*; CE: *Conformité Européene*; CNEDiMTS: *Commission Nationale d'Évaluation des Dispositifs Médicaux et des Technologies de Santé*; DHT: Digital Health Technology; HTA: Health Technology Assessment; ED: Emergency Department; ICER-PHTI: Institute for Clinical and Economic Review and the Peterson Health Technology Institute; PECAN: *Prise en charge anticipée des dispositifs médicaux numériques*; RCT: Randomized Controlled Trial; RWE: Real-World evidence; US: United States

Sources: for France, the assessments are published by Haute Autorité De Sante on https://www.has-sante.fr/. For the US the assessments can be found in Tice, Whittington et al. Digital Health Technologies as an Adjunct to Medication Assisted Therapy for Opioid Use Disorder; Final Evidence Report. Institute for Clinical and Economic Review, December 11, 2020. https://icer.org/assessment/opioids-digital-apps-2020/#timeline

1 Recent DHTs appraisals in France under the PECAN framework

DHT appraisal	CUREETY TECHCARE[1]	TUCKY CENTER[2]	PRESAGE CARE[3]	AXOMOVE THERAPY[4]	CONTINUUM+ CONNECT[5]	HELLOBETTER Insomnie[6]
Publication date	**31/07/2023**	**19/10/2023**	**30/11/2023**	**25/06/2024**	**15/07/2024**	**02/08/2024**
Indication(s)	Remote monitoring of patients with cancer undergoing systemic treatment and/or treated with radiotherapy	Remote monitoring of: 1) patients undergoing chemotherapy; 2) post-operative follow-up of patients after bariatric surgery; 3) hypertension in pregnant women	Predictive and preventive remote monitoring of unplanned hospitalisations	Remote monitoring of adult patients with osteoarticular conditions	Remote monitoring of adult patients with cancer undergoing systemic treatment	Chronic insomnia in adults
CNEDiMTS opinion	**POSITIVE** *- 2023 -*	**NEGATIVE** *- 2023 -*	**NEGATIVE** *- 2023 -*	**NEGATIVE** *- 2024 -*	**POSITIVE** *- 2024 -*	**NEGATIVE** *- 2024 -*
Framework requirements*						
1. The DHT has a CE mark for the considered indication	✓	✓	✓	✓	✓	✓
2. The DHT is presumed innovative, particularly in terms of clinical benefit or progress in the organization of care, based on the initial available data and considering any relevant comparators	✓	✗	✗	✗	✓	✗
2.1 If the DHT is likely to bring progress in the organization of care, and this progress must not compromise the quality of care.	✓	✗	✗	✗	✓	✗
2.2 The DHT is the subject of ongoing studies that are presumed to provide sufficient data for CNEDiMTS to subsequently give an opinion on the request for coverage under LPPR within 6 months or LATM within 9 months.	✓	✗	✗	✗	✓	✗
*Criteria 1 and 2 are the only PECAN requirements based on which CNEDiMTS will provide its opinion. Remaining requirements (3 and 4) are assessed by ANS						
Clinical evidence						
Evidence package**	- 3 specific studies - 4 non-specific studies, including one not selected - Recommendations from the European Society for Medical Oncology (ESMO) 2022 - 3 ongoing or planned studies	- 3 claimed indications **Indication 1:** - 5 non-specific studies - 2 planned studies **Indication 2:** - 4 non-specific studies - 2 planned studies **Indication 3:** - 3 non-specific studies - 1 planned study	- 4 specific studies - 6 non-specific studies - 5 ongoing studies	- 1 specific study - 3 non-specific studies - 2 ongoing studies	- 1 specific study - 3 non-specific studies - 2 specific ongoing studies - Recommendations of the European Society for Medical Oncology (ESMO) (non-specific) - 1 technical claim of equivalence with RESILIENCE PRO	- 7 non-specific studies - 4 meta-analyses (non-specific) - 4 good clinical practice recommendations (non-specific) - 1 technical equivalence claim with previous generations of HELLOBETTER Insomnia, which have been the subject of clinical studies - 1 ongoing study
Inclusion of RCT(s)	✓ non-specific	✓ indications 1, 2; non-specific	✗	✓ specific (ongoing)	✓ non-specific	✓ non-specific; specific (ongoing)
Inclusion of RWE	✓ specific	✓ indication 2; non-specific	✓ specific and non-specific	✓ specific	✓ specific	✗
** Specific studies concern studies specific to the DHT under assessment Sources: [1] HAS, CUREETY TECHCARE Avis sur les dispositifs médicaux numériques, 31/07/2023; [2] HAS, TUCKY CENTER Avis sur les dispositifs médicaux numériques, 19/10/2023; [3] HAS, PRESAGE CARE Avis sur les dispositifs médicaux numériques, 30/11/2023; [4] HAS, AXOMOVE THERAPY Avis sur les dispositifs médicaux numériques, 25/06/2024; [5] HAS, CONTINUUM+CONNECT Avis sur les dispositifs médicaux numériques, 15/07/2024; [6] HAS, HELLOBETTER Insomnie Avis sur les dispositifs médicaux numériques, 02/08/2024						

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