Healthtech
Finland

Reimbursement of digital health solutions – the case of Finland

COCIR Public Online Event on Market Access for Digital Health Solutions

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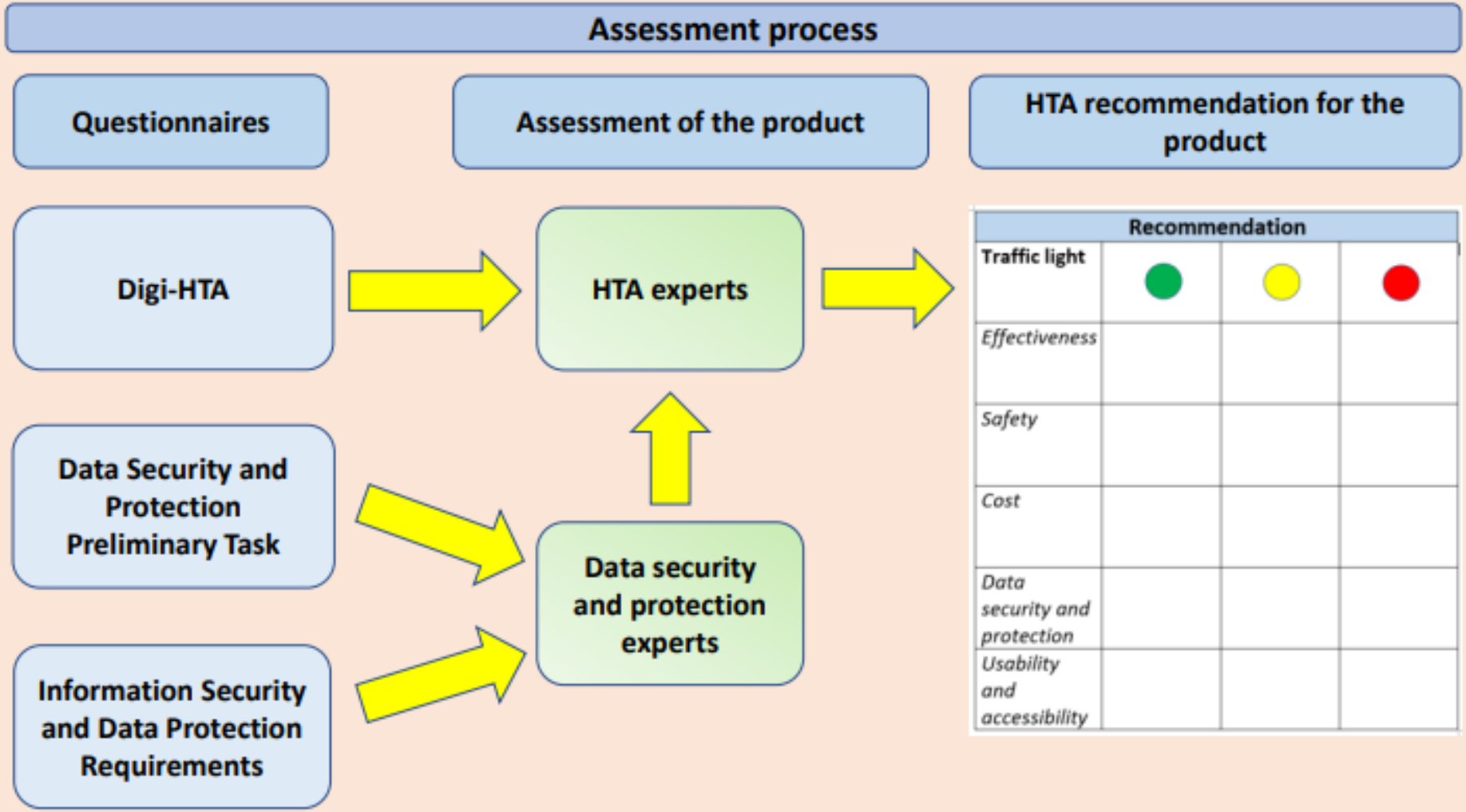
Development of the Finnish DigiHTA

- There has been a lack of health technology assessment (HTA) methods for novel digital health technologies (DHTs) such as mHealth, artificial intelligence, and robotics in Finland -> the Finnish DigiHTA application area is wide and covers all DHTs
- DigiHTA is a recommendation commissioned by the Ministry of Social Affairs and Health, and is developed in collaboration of University of Oulu and the national HTA co-ordination unit FinCCHTA.
- The evaluation criteria has been published in a scientific article: Haverinen J, Keränen N, Falkenbach P, Maijala A, Kolehmainen T, Reponen J (2019) Digi-HTA: Health technology assessment framework for digital healthcare services. Finnish Journal of eHealth and eWelfare, 11(4), 326–341. https://doi.org/10.23996/fjhw.82538


Assessment process
Questionnaires
Assessment of the product
HTA recommendation for the product
Digi-HTA
HTA experts
Data Security and Protection Preliminary Task
Data security and protection experts
Information Security and Data Protection Requirements
Recommendation
Traffic light
Effectiveness
Safety
Cost
Data security and protection
Usability and accessibility

HTA-Domain and Criteria
Company information
Contact information of company.
What is the company's business model?
Are quality management systems in use? Which ones?
Product information
The name of the product.
Short description of the product.
What is the product's readiness level (TRL levels 1–9)?
Which platforms and platform versions of the product are available?
Does the product have CE and/or FDA approval?
Is the product a medical device, and what classification does it have?
Is the product classified according to MDD or MDR requirements?
Does the product meet the electrical safety requirements for medical devices (if applicable)?
Does the use of the product require registration or login?
Does the use of the product require strong identification?
Does the company have any plans for post-market surveillance of the product?
What kind of product support does the company offer?
What is the intended use of the product?
What are the intended user groups?
What problem in the healthcare system is the product trying to solve?
Is the aim of the product to replace any existing healthcare services?
Does the introduction of the product cause any changes to the premises, information systems, or care processes?
Is the product already in use elsewhere in Finland or worldwide? Where, and for how long?
What kind of support does the end user need to use the product?
If users need training, who organizes it? When? What is the language of training?
Does the company have instructions (e.g., a project plan) for healthcare service providers to ensure fluent introduction of the product?
Technical stability
What is the company's testing process?
What is the company's process for handling error messages?
Does the company have the capacity to roll back to previous versions of the product?
Does the company have a process to proactively monitor the running of systems and system components to automatically identify faults and technical issues?
Does the company have a plan for decommissioning the product?
Has there been any downtime or impairment time in the use of the product during the last six

HTA-Domain and Criteria
Cost
What are the costs of using the product for a healthcare customer?
If the use of the product is free, what is the source of the company's income?
What kind of initial costs (estimated minimum and maximum values in detail) does the introduction of the product impose on the organization, including changes to buildings or facilities, a need for new devices and software, as well as needed training?
What are the maintenance costs (estimated minimum and maximum values) to the organization for the use of the product?
How often must devices or software versions related to the product be renewed?
Which uncertainties apply to these cost estimates?
Effectiveness
Does the product provide clinical benefits? What are they?
Does the product provide benefits to the end users by improving their behavior related to their own health? How so?
Does the product provide benefits to the organization (like improving care processes)? How so?
What kind of evidence is available for effectiveness (case studies, randomized controlled trials, Cochrane reviews, etc.)?
Are there any ongoing studies to investigate the product's effectiveness?
Does any institution like the Duodecim Current Care Guidelines recommend the use of the product?
Clinical safety
Are there any risks, possible side effects, or other undesirable effects associated with using the product?
Is there any research evidence available related to clinical safety?
Have any product-related adverse events been reported or identified?
What is the company's process to handle adverse events?
Has the product undergone a risk analysis?
Are there any undesirable effects associated with misuse of the product?
Are the error conditions of guidelines removed, or is their realization unlikely?
Is the company aware of the product register and Manufacturer Incident Report supervised by the National Supervisory Authority of Welfare and Health?
Who is the responsible person in the company for handling Manufacturer Incident Reports?
Data security and protection
Detailed criteria are defined in the following documents: *Data Security and Protection Preliminary Task* *Information Security and Data Protection Requirements*

HTA-Domain and Criteria
Usability and accessibility
Have all user groups been taken into account in product design, like people with visual or hearing impairments?
Has the product been tested with real user groups?
What kind of accessibility testing has been performed on the product?
Has the functionality of the product been tested with screen readers or other assistive technologies?
How have the product's users been taken into account in the product's text (clear, concrete language; the avoidance of professional language)?
How have the product's users been taken into account in the design of its textual content (headings, lists, and images)?
How does the company continue to collect feedback from users and make changes to the product based on this feedback?
What changes have been made to the product based on user feedback?
How is the company going to continue to evaluate and develop accessibility?
Is the product compatible with the following usability guidelines (if applicable)?
WCAG 2.0/ WCAG 2.1
Papunet Design Guide for Websites
EN 301 549 section 11-Software
Design guidelines for native application
Design guidelines for progressive web application
Does the application support OS accessibility features?
Interoperabilty
Does the product have interfaces into the website or other software?
Does the product have interfaces into the following healthcare services?
Electronic patient records (which ones?)
Finnish Kanta PHR
Other (what?)
Are proprietary formats used to store and transfer data?
Are the definitions of the original proprietary formats openly available?
Does the product have interfaces for other companies' services?
Can the data contained in the product be exported in a commonly used or standard format?
Does the product use data from other systems via interfaces?
If yes, can the data produced by others be separated in the system?
Does the product connect with health or wellness devices?
If yes, is it compatible with ISO/IEEE 11073 Personal Health Data (PHD) Standards?

HTA-Domain and Criteria
Artificial intelligence
Exactly what defined problem is going to be solved by the AI?
What is the classification of AI? Visualization only, AI–assisted (e.g., diagnosis/classification/decision), or solely AI–controlled?
Could the problem be solved without the AI solution?
Is the solution based on machine learning or a neural network?
Do the staff have sufficient capacity to understand the operational logic of AI (e.g., do they need additional training)?
Are the conclusions and decisions of the AI solution transparent, i.e., can medical staff understand what the decisions are based on?
Is the AI solution validated in the environment in which it will be used?
What are the data sources for the AI solution?
Are the data sources used in the training of AI solutions relevant to a final use case (e.g. are the age and gender composition of training groups comparable to that of real user groups)?
Are the access rights required for the use of the data in order, and have data protection (e.g., GDPR) and security issues been taken into account?
When it comes to classifier teaching, are there enough data relative to the size of the smallest class?
Can the AI solution use incomplete data?
Can the AI solution use noisy data?
Is retraining possible for the AI solution?
What are the data sources for retraining?
How is it ensured that the system is not taught with irrelevant data?
How many tests or results are needed for the AI model?
Is the algorithm purchased software as a service (SaaS) or its own design?
What performance criteria are used?
Does the AI solution change care processes? How?
When does the AI solution propose an action? How, and who will actually implement it?
Is staff's approval needed for action proposed by the AI?
Robotics
Is there any possibility that using the robot could create safety risks for healthcare personnel or customers (e.g., forces that could be destructive or collision with people)?
How have those risks been avoided in the robot's design?
What kind of arrangements are needed to teach or program the robot to operate?
If the robot is battery-operated, what are the operating, idle, and charging times?

Key Assessment Domains

Points	Effectiveness	Safety	Cost	Data security and protection	Usability and accessibility
2	Sufficient	Sufficient	Reasonable	Sufficient	Sufficient
1	Promising but more evidence is needed	Probably at a sufficient level but not known well enough	High	Minor shortcomings	Minor shortcomings
-4	Weak or unknown	Weak or unknown	Unreasonably high	Shortcomings	Shortcomings

Recommendation Scale

Total score	Definition
10	USE OF THE PRODUCT IS RECOMMENDED The use of this product is recommended because of strong evidence for its effectiveness. Safety, data security and protection, and usability and accessibility of the product are at an adequate level. The cost of using the product is reasonable.
9	THERE IS ONE THING TO CONSIDER WHEN USING THE PRODUCT An organization considering the deployment of the product should note that **in one key area there are things to consider**. Information about the effectiveness of the product could be promising, but the information is scarce. Product safety could be at a sufficient level but not known well enough. Product costs may be high. There could be minor shortcomings in the product's data security and protection or in usability and accessibility.
7-8	THERE ARE A FEW THINGS TO CONSIDER WHEN USING THE PRODUCT An organization considering the deployment of the product should note that **in two or three key areas there are things to consider**. Information about the effectiveness of the product could be promising, but the information is scarce. Product safety could be at a sufficient level but not known well enough. Product costs may be high. There could be minor shortcomings in the product's data security and protection or in usability and accessibility.
5-6	THERE ARE MANY THINGS TO CONSIDER WHEN USING THE PRODUCT An organization considering the deployment of the product should note that **in four or five key areas there are things to consider**. Information about the effectiveness of the product could be promising, but the information is scarce. Product safety could be at a sufficient level but not known well enough. Product costs may be high. There could be minor shortcomings in the product's data security and protection or in usability and accessibility.
≤4	THERE ARE CRITICAL THINGS TO CONSIDER WHEN USING THE PRODUCT An organization considering the deployment of the product should note that **there are shortcomings in one or more key areas.** Information about the effectiveness of the product is untrustworthy or of low quality. There may be shortcomings in the product's safety, or information related to it may be unreliable or of low quality. Product costs may be prohibitively high. There could be shortcomings in the product's data security and protection or in usability and accessibility.

DHTs are not currently reimbursed in Finland

- DigiHTA is in place, but reimbursement issues are still pending
- Finland does not have a formal reimbursement model for DHTs, the DigiHTA is only a recommendation
- There have been roundtable discussions, but concrete actions are lacking
- In order for DHTs to be reimbursed there should be consensus of its coverage and extent (which medical device risk classes should it cover?)
- A starting premise: CE-marked medical device status
  - Would rule out reimbursement of wellbeing devices
- Barriers: speed and low number of available Digi-HTA-recommendations, readiness of healthcare, difficulties in demonstrating utility
- Action points: inputs into the Government program, new legislative actions needed in Finland, deeper Nordic/European collaboration

Thank you!

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