C/Can

Adopting digital health interventions in LMICs

Guidance for value assessment

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1. List of abbreviations

AI	Artificial Intelligence
ASCP	American Society of Clinical Pathology
C/Can	City Cancer Challenge
CAP	Certified Analytics Professional
COPPA	Children's Online Privacy Protection Act
CT	Computerized Tomography
DHI	Digital Health Initiative
DHT	Digital Health Technology
DRG	Diagnosis Related Group
EHR	Electronic Health Record
HER	Health Electronic Record
EU	European Union
FDA	Food and Drugs Authority
GDPR	General Data Protection Regulation
HIMS	Hospital Information Management System
HIPAA	Health Insurance Portability and Accountability Act
HIS	Health Information System
HCP	Health Care Professional
HTA	Health Technology Assessment
ICT	Information and Communication Technology
ISO	International Organization For Standardization
IT	Information Technology
LIMS	Laboratory Information Management System
LMIC	Low- and Middle-Income Country
LEPL	Legal Entity of Public Law

M&E	Monitoring and Evaluation
MD	Medical Doctor
MDD	Medical Device Directive
MDR	Medical Device Regulation
MDT	Multidisciplinary Team
MoH	Ministry of Health
MVP	Minimum Viable Product
NGO	Non-Governmental Organization
NICE	National Institute for Health and Care Excellence
ODA	Official Development Assistance
PACS	Picture Archiving and Communication System
PSA	Prostate-Specific Antigen
QC	Qaulity Control
ROI	Return on Investment
SaaS	Software as a Service
UHC	Universal Health Coverage
UICC	Union for International Cancer Control
WCAG	Web Content Accessibility Guidelines
WHO	World Health Organization

2. Introduction

Cancer is now the second most common cause of death worldwide, accounting for nearly one in six of all recorded deaths (nearly 10 million) in 2018. Lung, prostate, colorectal, stomach and liver cancer are the most common types of cancer in men, while breast, colorectal, lung, cervical and thyroid cancer are the most common among women (World Health Organisation 2022).

Approximately 70% of all cancer deaths occur in low- and middle-income countries (LMICs), where fatality rates are particularly high because health systems are ill-equipped to handle the growing cancer burden, This results in late, poor-quality diagnosis and limited access to cancer treatment (Brand, et al. 2019). Conversely, in countries with strong health systems, survival rates for various cancer types are improving thanks to accessible early detection, quality treatment and survivorship care (World Health Organisation 2022).

Digital health technologies (DHTs) are key to these improvements; in countries with stronger health systems, they are being implemented across the cancer care continuum. These technologies can facilitate access to care, overcome time and location challenges and provide greater clarity around patients' health status (Marthick, et al. 2021).

Indeed the field of oncology presents several clear opportunities for digital health innovation. These include the implementation of patient-centred technologies that improve patient experience, safety, and patient-clinician interactions; the introduction of technologies that improve clinicians' ability to diagnose pathology and predict adverse events; and the provision of quality-of-care and research infrastructure to improve clinical workflows, documentation, decision support mechanisms and clinical trial monitoring (Parikh, et al. 2022).

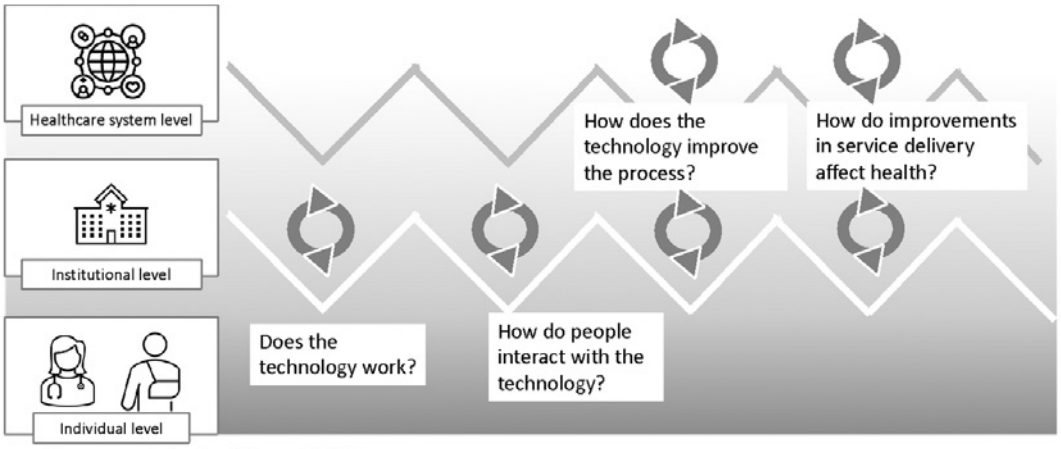
However, before adopting these DHTs, healthcare decision-makers including health care professionals (physicians, nurses and healthcare workers), politicians, payers and funders must determine the potential value of their adoption. Specifically, in fragile healthcare systems with resource and budget constraints, a value-for-money assessment is crucial to inform funding allocation decisions, drive sustainable adoption in routine cancer care and strengthen the healthcare system.

The sheer diversity of potential DHTs requires us to:

- Firstly, understand who the target user and primary and/or secondary beneficiaries of the technology will be, and
- Secondly, create clear metrics to define the value of the technology.

This second requirement is particularly challenging because the value of DHTs is perceived differently at each level of the healthcare system, ranging from an individual level (healthcare professionals, or HCPs, and patients) to an institutional level (hospitals, clinics, provider organisations) and onto an aggregated healthcare system level (politicians, payers, community and society).

Figure 1: Value of DHTs for different stakeholders in a healthcare system



Source: Adapted from WHO

3. City Cancer Challenge Foundation & Digital Health

City Cancer Challenge Foundation (C/Can) supports cities around the world as they work to improve access to equitable, quality cancer care.

At its core, C/Can's city-based partnership initiative aims to transform the way stakeholders from the public and private sectors collectively design, plan, and implement cancer solutions. This partnership model is founded on the principle that cities can drive impact at national level by crafting data-driven solutions with the support of a network of global, regional, and local partners, tailored to the unique local context.

C/Can was launched by the Union for International Cancer Control (UICC) at the 2017 World Economic Forum Annual Meeting in Davos, and was established as a standalone Swiss foundation in January 2019. It is currently working with cities in nine LMICs across Africa, Asia, Eastern Europe and Latin America.

These partnerships reflect a wider desire among LMICs to upgrade their healthcare systems with digital innovation. In cancer care, DHTs offer attractive opportunities to:

- Support the **delivery of integrated care.**
- Enable access to real-time shared data to **reduce duplication and errors.**
- Open new opportunities for **remote care** including treatment planning and diagnosis or collaboration practices like virtual multidisciplinary care and training.
- Increase the quality of **diagnosis** and **treatment** thanks to data diagnostics.
- Revolutionise the patient experience.
- Internet availability in health institutions and/or homes.

When poorly applied, however, DHTs may create an excessive financial burden and their deployment is often unsustainable due to the financial cost involved.

To proactively prevent these problems, C/Can works closely with healthcare professionals from its network of cities to support the development of successful digital transformation projects. These collaborations help to define the processes to be digitised, design the technical requirements, build the capacity of users and develop policy mandates.

Since its inception, C/Can has strived to bring best practices and innovative approaches from other healthcare fields, and the wider world, into the specific discipline of cancer care. Specifically, C/Can has led initiatives to help cities identify sustainable financing solutions, build business cases for investors, payers and funders, and develop evidence-based assessments that will ultimately enable the cities to mobilise resources independently.

Today, one of C/Can's key priorities is to facilitate the process of sustainable funding, reimbursement, and adoption of DHTs by helping stakeholders add transparency and completeness to their value assessment. The aim is to reduce complexity, enhance consistency and enable decision-makers to make informed funding and investment decisions in confidence.

This aim has led to the idea of developing a systematic guide to evaluating digital health interventions for health decision-makers including C/Can's key stakeholders.

3.1 Who is the Orientation Guide for?

Target Audience	Benefit
Healthcare professionals (clinicians and care teams)	› A framework to evaluate the potential impact of DHTs on the care process. › A consistent set of criteria to understand the functionality and appropriateness for individual patient use cases. › A checklist to support documentation of patient data.
Healthcare facilities and their authorising personnel qualified to authorise the use of the DHT in their organisation	› A consistent set of criteria to make investment decisions on DHTs. › A guide for internal processes to collect information around the acceptance and adoption of DHTs by clinicians and care teams within the facility. › A checklist to assess the attractiveness of innovation for patients, communities and healthcare professionals.
National payers/health insurers responsible for the resource allocation, funding, or reimbursement of a new technology Digital Health officers at different country levels (e.g., state, municipality etc.) responsible for the digital health strategy in their country Local community-level public and private funders, commissioners and NGOs responsible for joint purchasing decisions in healthcare	› A consistent set of criteria to evaluate DHTs for reimbursement/ funding. › A checklist to structure the information that payers and digital health officers seek from manufacturers. › A set of criteria that can be used flexibly depending on the technology. › An additional resource that can be used alongside existing frameworks and policies. › A means to compare different technologies based on the same criteria. › A means to align decisions at different levels of the healthcare system. › An aid to more transparent, comprehensive, and faster decision-making. › Data that can inform the design of patient benefit schemes.
Manufacturers of DHTs, Digital Health Innovation Hubs & Technologists	› Transparency around expectations of decision-makers – what matters to them to drive funding and adoption. › A framework to prepare business cases and value propositions. › A flexible checklist for iterative product design and testing for usability.

3.2 How was the Orientation Guide developed?

Several value frameworks have emerged in the last couple of years, primarily to guide DHT manufacturers through the product development process. These frameworks are often based on a health technology assessment by pharmaceutical firms and are primarily targeted at healthcare systems in high-income countries.

We have reviewed these frameworks and the scientific literature and consolidated the most important and coherent criteria into a framework that we have iteratively tested with different experts in LMICs.

As a first step, we obtained feedback from academia, international NGOs, policy-makers, regulatory and HTA agencies and the pharmaceutical industry (please see Chapter 8).

As a second step, we then tested the framework by:

a Developing four typical, hypothetical use cases of DHTs in cancer care:

- AI in radiology.
- Telepathology.
- Multifunctional collaboration.
- Revolutionise the patient experience.
- Internet availability in health institutions and/or homes.

b Conducting deep-dive interviews with decision-makers in Africa, Latin America, and Eastern Europe to apply the framework with the use cases (please see chapter 8 for the list of experts involved).

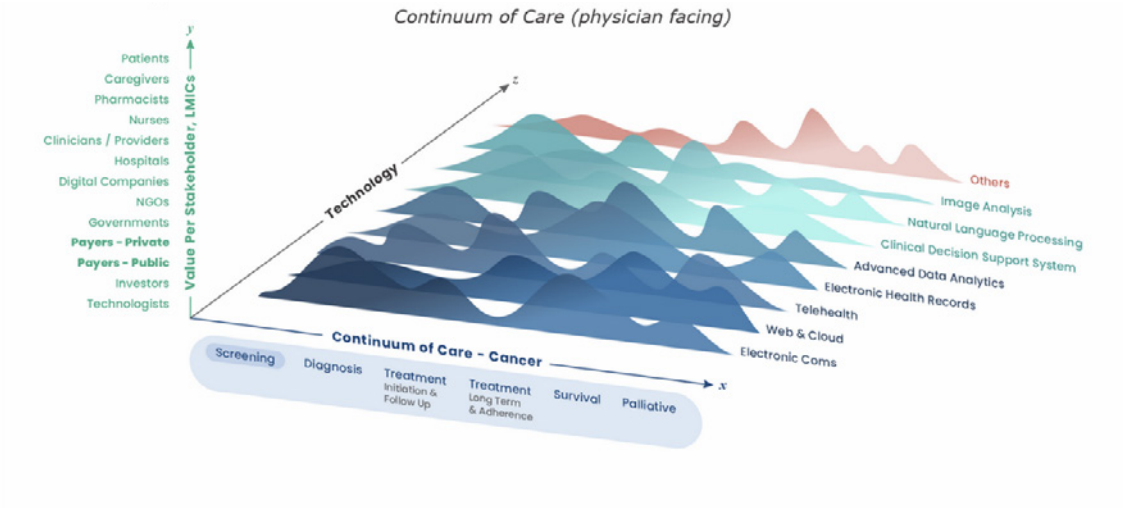
Based on the feedback from decision-makers across the different geographies, we developed a flexible orientation guide that can be adapted to local country needs and complement existing local frameworks.

4. The Scope of the Orientation Guide

There are significant differences between individual digital health product types and technologies. Each has a different purpose, functionality, and target user and they all address different touchpoints in the continuum of care, from screening to diagnosis, treatment initiation to palliative care.

Here is a graphic to illustrate the relationship between users/stakeholders, technology and the continuum of care. As you'll see, the value of different DHTs rises and falls at each stage of the continuum.

Figure 2: Digital Health Technologies Stakeholder Matrix

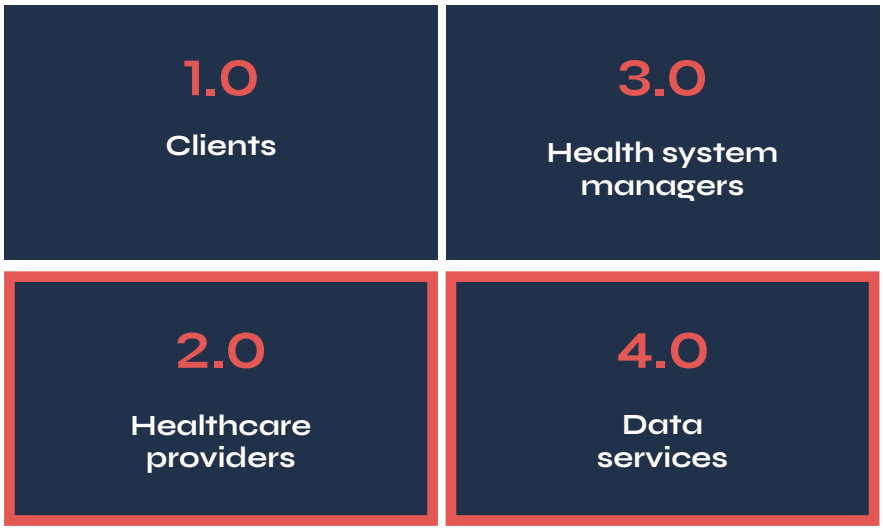


In this orientation guide, we have focused specifically on DHTs at the following touchpoints of the continuum:

- Diagnosis (e.g. AI in radiology and telepathology).
- Monitoring after treatment initiation (e.g. telepathology, evaluation of treatment-related symptoms).
- Management of care alongside the continuum (e.g. multidisciplinary collaboration, evaluation of treatment-related symptoms).
- Communication (e.g. multidisciplinary collaboration, telepathology) along the continuum.

To define each kind of technology, we have used the World Health Organization's Classification of Digital Health Interventions, published in 2018.

Figure 3: Digital Health Technology Scope



Source: WHO, 2018

Specifically, we focus on DHTs in the WHO category 2.0 (Healthcare Providers) and 4.0 (Data Services).

- 2.0 technologies are primarily used by healthcare providers. They include health records, decision support systems, telemedicine, communication tools, referral coordination, prescription and medication management tools, laboratory systems and diagnostic imaging management.
- 4.0 technologies are used for data collection, management and use, data coding and data exchange and interoperability.

This focus is informed by previous examples of digital transformation of cancer care systems, observed in both C/Can cities and other LMICs.

In accordance with the categorization of DHTs by the National Institute for Health and Care Excellence (NICE) in the UK, decision-makers should take into account the level of risk caused by the DHT to both the patient and the system. The evidence should become more robust as the risk to patients increases.

Decision-makers should also consider the following questions:

1. Is the DHT used to release cost or staff time to improve efficiency?
2. Is the DHT used to **treat or diagnose** specific conditions or guide diagnosis or treatment choice?
3. Does the DHT have a **direct measurable impact** on health outcomes?
4. Is it a **medical device or invitro diagnostic or screening tool** (requires regulatory approval for CE mark)?
5. Does it include **AI or non-AI** software?

4.1 The Scope of the Orientation Guide

It is important to understand what this guide does – and does not – try to achieve.

What it IS!

Empirical Orientation Guide for LMICs on the important aspects & criteria to assess the value of DHTs

Comprehensive overview in one document

Summary of all relevant aspects for the assessment of DHTs.

Flexible and living document adaptable to local requirements, emerging methods, and technologies.

Support tool for decision makers

Helps to inform the commissioning, funding, and adoption of DHTs in LMICs.

Accounts for LMICs needs & conditions.

Country & region-agnostic.

Acts within existing healthcare system structures, legal frameworks, and digital health governance models.

Focus on mature and marketed DHTs

What it is NOT!

NOT binding or prescriptive.
Does NOT provide:

Methodological guidance

Definitions of evidence criteria & measures.

Study designs for data collection or data sources (e.g., data bases etc.).

Statistical analysis methods

Detailed technology requirements

Specific technologies (Software, hardware etc.).

Software (AI or not).

E-health enterprise architecture.

DHTs in early development (e.g., prototype, MVP) are excluded from this guidance.

Policy recommendations

Changes in structure, governance. leadership, financial organization, and human resources.

4.2 Examples of Potential Use Cases

Here are four potential use cases of DHTs in cancer care, taken from previous examples of digital health transformation.

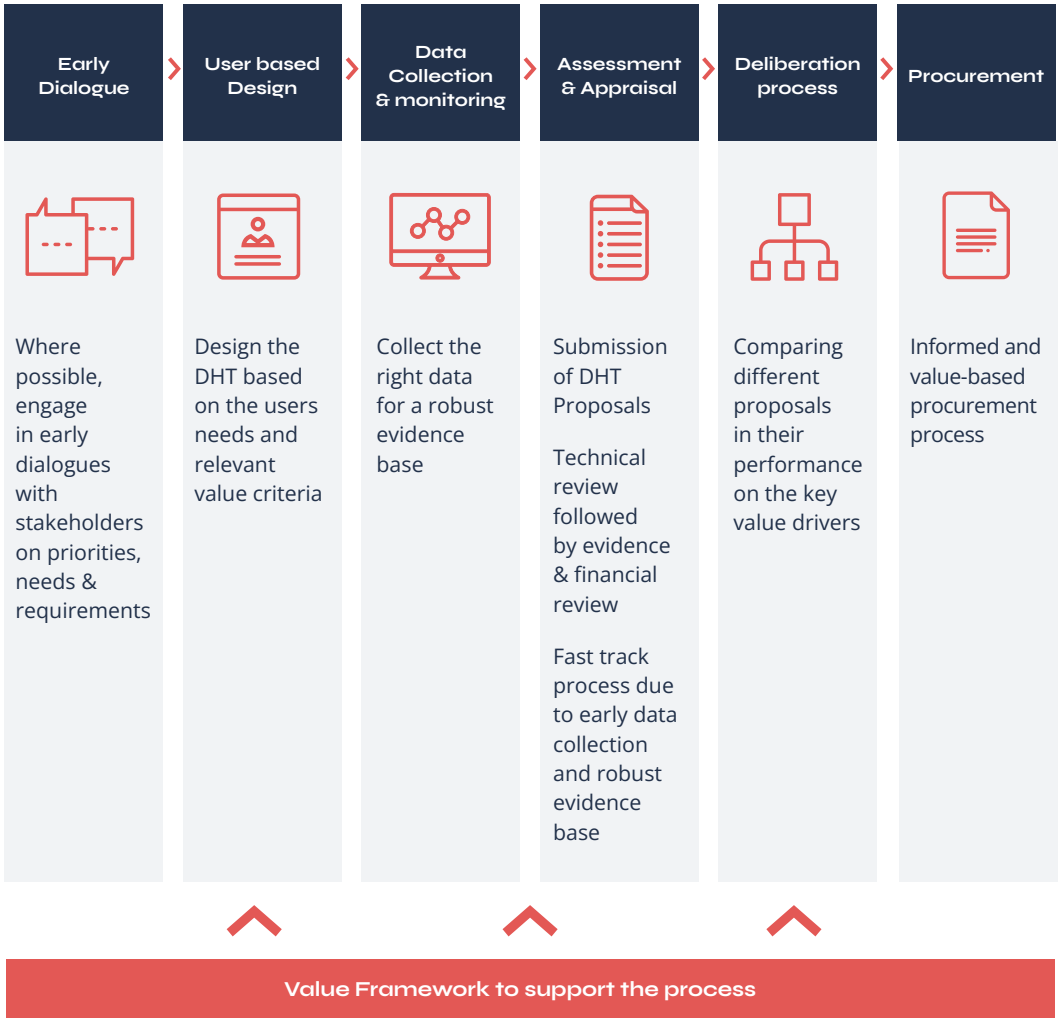
Hypothetical Use Case AI in Radiology	Hypothetical Use case Telepathology
Hypothetical Use case Evaluating Treatment-related Symptoms of Cancer Patients with and w/o AI	Hypothetical Use Case Multidisciplinary Collaboration with and w/o AI

The full list of hypothetical use cases can be found in the appendix.

5. Development, Submission & Evaluation Process

This valuation toolkit can support various stages of the overall decision and procurement process at both a national and a regional level.

Figure 4: Illustrative DHT Value Assessment Process



The diagram above illustrates how such a process may work hypothetically (please note that some countries may not have a formalised assessment process established).

Within the scope of this guide, the process should always be seen in the context of cancer care and the clinical purpose for which the technology should be used.

When applied effectively, the framework can:

1. Aid the preparation of early dialogue between different stakeholders involved in the decision and procurement process (e.g. the Ministry of Health, non-governmental Organisations or NGOs, HCPs, technology providers and public-private partnerships). This early dialogue can aid understanding and alignment in priorities, needs and requirements for the design of DHTs.
2. Inform the design of DHTs based on the key indicators and value criteria that matter most to the different stakeholders. This can facilitate adoption by users, funders, and political decision-makers.
3. Support the collection and monitoring of relevant data to demonstrate the DHT's value.
4. Help decision-makers select those value criteria that are most important when assessing and appraising submission proposals.
5. Guide technology providers to prepare their submissions.
6. Fast-track assessments through early documentation, collection and analysis of the relevant data and hence robust evidence.
7. Provides a reminder of value criteria that are less prominent but nonetheless important.
8. Guide the deliberation process comparing different proposals in their performance on key value criteria, e.g., evaluating business model and fair market value.
9. Facilitate an informed procurement process.

6. The Value Framework

The value framework below is fit for purpose for the evaluation of physician-facing digital health technologies in low- and middle-income countries.

It provides a summary of the value domains that are deemed relevant by the different stakeholders in Africa and Latin America involved in the development of this framework. We used the stakeholders' feedback on the application of the framework with the hypothetical use cases mentioned above (see Chapter 2).

It should be emphasised that the order of the seven value domains can differ between healthcare systems and contexts, according to specific country situations and priorities. Their current order is not an order of priority but merely a numbering format. Therefore, the framework should not be understood as a static framework but rather a flexible grid that can be used according to each country's and decision-maker's specific requirements.

The following chapters provide a description and guidance for each of the seven value domains. It focuses on those sub-domains that are considered the most relevant by stakeholders involved in the guide's development.

6.1 Health/Healthcare system problem & current use of technologies

When evaluating the value of a DHT, it is important for decision-makers to understand the context in which it is used. The healthcare system, and its priorities, frame the allocation of financial resources across all healthcare programmes.

An important aspect of this context is the intended clinical purpose of the DHT alongside or within the cancer care continuum.

Within the context of your national healthcare priorities and/or national eHealth strategy, if available, it is usually valuable to ensure:

1. A positive impact on the continuity of care alongside the cancer care continuum

- Decision-makers should ensure that the proposed new DHT solution can connect / link up with the continuum of care and harmonise/synchronise with existing technologies regardless of the indication or type of cancer.
- Decision-makers should also clearly define the priority given to the DHT within the clinical care continuum, considering a range of factors including accuracy of diagnosis, clinical management and decision support, meaningful engagement during palliative care, PRO self-monitoring, information and data-sharing and second opinion.
- It is important to understand how current cancer care programmes operate in practice, including the workflows and information flows across all levels of the health system, and to identify the gaps.
- Another key factor is how many patients could be served with the new DHT solution to allow for optimisation and efficiencies from a government perspective.
- The new DHT solution should enhance the coordination and harmonisation of the care process, ensure continuity of care along the patient journey, and address care gaps.
- Generally, referral management along the cancer care continuum should be seamless and should help to reach all patients in the country in order to improve the efficiency of the overall health care system.

2. A clear definition of target user groups

- Decision-makers should note that the continuum may comprise several stakeholders, including physicians, nurses, healthcare workers, IT & technical support staff, and patients. So the user groups and their specific unmet need(s) should be identified and described.
- It is also important to assess how well the new DHT solution addresses the unmet need of the different user groups.

3. The beneficiaries are made explicit

- As is the case with users, there could be multiple beneficiaries of the continuum, such as patients, healthcare providers and managers of other non-communicable disease programmes. The valuation process should explore their needs and how they could be addressed by the new DHT solution.
- Decision-makers should also explore potential synergies between beneficiaries to maximise the return of the DHT investment.
- It is also important to understand the number of beneficiaries that could be served by the new DHT solution, to ensure high coverage and sustainable efficiency.

6.2 Technical Product Information & Use

- The description of the technical product's characteristics, functionality, and regulatory status (whether it holds a CE mark, whether it carries AI, even whether it qualifies as a medical device) can vary in detail depending on the person carrying out the assessment.
- The medical device registration should be carried out in accordance with the country's regulatory requirements.
- The assessment phase may require information around:
  - **The functionality in relation to existing technology, infrastructure, and alignment with the national priorities;** specifically, the interoperability of the new technology with current information systems should be demonstrable.
  - **Transparency around how the functionality has been tested.** For example, in the case of AI-driven technologies, the type of data sources used to train the algorithm should be made clear.
  - **The accuracy of the data and reliability.** Indeed, the new DHT solutions should be aligned with scientifically validated interventions.
  - **Alignment.** It is important to consider whether the technology is aligned with the national Health Information System (HIS)/digital and IT framework architecture for interoperability reasons (this is highly advisable).

Decision-makers are encouraged to engage with technical committees, if established, on issues that may be important to them later in the assessment process. This could be, for example, the minimum number of users required for these DHTs to remain functional, or the digital literacy level of the target users.

- **For procurement**, information on the maturity and full functionality of the application and whether it has already been launched in other markets may be useful.
- Overall, **sustained functionality** can be greatly encouraged by the provision of a quality management system.
- Data **protection & compliance** should be carried out in accordance with the country's national data protection law.
- If AI is involved, it is important to ensure:
  - There is a **clear purpose statement** for the algorithm (guaranteeing fair and ethical implementation of the algorithm in the healthcare setting).
  - **The algorithm is appropriate** in the context of application.
  - There is a clear **explanation of the strengths and limitations** of the algorithm and the use of the data.
  - **Access, implementation, and resource issues** have been considered.
  - **Sensitivity and specificity** (model performance and accuracy) have been covered.
  - **The algorithm's characteristics** have been clearly characterised and described.
  - **Transparency and reproducibility of results** has been guaranteed
  - **Data characteristics** have been set out. Selected data sets should be justified, and characteristics known (training, test, and validation sets).
  - **Outputs** of the algorithm are **clearly understandable** to both the HCP and patient.

  (William V Padula 2022)

6.3 Usability & accessibility

1. Decision-makers must ensure ease of use for clinicians and other HCPs (e.g., nurses, healthcare workers, other therapists)

- The user-friendliness of the software and the application is essential for the adoption of the technology. So it is important to check whether the proposal specifies the role that each end-user group will play in the product design and testing phase.
- Decision-makers should also check whether user accessibility and functionality testing has been performed and is continuously performed. If established, liaise with the Technical Committee on these aspects.
- Information on potential improvements to the HCPs' and healthcare workers' workflow should be clearly established. Instant, intuitive use of the technology without extensive training requirements, and more efficient care delivery, will increase users' motivation to use the technology in daily clinical practice, which in turn contributes to return-on-investment. Relevant metrics include the percentage of users who report satisfaction with the use and content of the health information received via the DHT.
- Information on user-training offered with the application should also be provided.
- Data on users' learning-curve, measured in error before users can integrate the application without error, is beneficial.
- A useful framework to consider is the Clinical Information Quality for DHTs (Fadahunsi, et al. 2022):
  - **Usability concerns the ease of use of clinical information**
    - *Conformity.* The extent to which information is presented in the desired format.
    - *Consistency.* The extent to which information is presented in the same format.
    - *Maintainability*. The extent to which information can be maintained.
  - **Availability concerns the functionality of the system holding clinical information**
    - *Accessibility:* The extent to which existing information is easily obtainable.
    - *Portability:* The extent to which information is accessible in different systems.
    - *Security:* The extent to which information is protected from unauthorised access and corruption.
    - *Timeliness:* The extent to which current information is available on time.
  - **Usefulness of digital information for clinical purposes**
    - *Accuracy:* The extent to which information is correct.
    - *Completeness:* The extent to which no required information is missing.
    - *Interpretability:* The extent to which information can be understood.
    - *Plausibility:* The extent to which information makes sense based on common knowledge.
    - *Provenance:* The extent to which the source of information is trustworthy.
    - *Relevance:* The extent to which information is useful for the intended task.

2. Consider data on patient satisfaction with the service enabled by the new DHT solution

- Access to care and technology for patients are important criteria of patient satisfaction and scalability. Key metrics may include the additional percentage of patients that could be reached, diagnosed, and treated with the DHT, and the percentage of patients satisfied with the service.
- If patients are directly involved in the usage of the DHT solution, they should be part of the design process to ensure acceptance and trust in the technology.

6.4 Safety

1. Ensure Evidence on Clinical Safety is provided

- Information on clinical safety is vital as it has a direct impact on patients' health.
- The manufacturer/provider should clarify the risks related to side effects, the potential risk of misuse of DHT outputs, specificity, and the potential sensitivity of the DHT used for diagnostics and monitoring (for example an AI tool used to predict diagnosis and/or outcomes in fields such as radiology).
- The manufacturer/provider should clearly describe how the intervention aligns with evidence-based clinical guidelines or protocols.

2. Ensure Documentation of the Technical Safety

- Documentation of technical reliability and stability, providing key details such as the minimum number of users required to maintain the efficacy of a DHT or plans for lifecycle management, can help demonstrate functionality and sustainability of use.
- Data storage/hosting is an important data protection issue. Manufacturers and providers should be guided by the local legal frameworks (for example the Rwanda Data Protection Law 2021, or the Information and Communication Technologies ICT Law 2016), and may need to register their product with the local supervising authorities (such as the National Cyber Security Authority).
- A governance model should also be clearly defined, detailing the roles and responsibilities of stakeholders. This should include a national agency with the power to monitor and report any cases of noncompliance (indeed, there should be a protocol in place to respond to compliance breaches).

3. Prepare Communication around Safety

- A process for the correct identification of the DHT's users should be defined.
- The process to communicate changes to or the transfer of patient's care should also be clearly described.
- Also, the process for notification of critical risk information should be clarified. Ideally, doctors or nurses will communicate risk directly to the patient if required (for example receiving a diagnosis or a change in treatment regimen).

6.5 Effectiveness

1. Evidence on Clinical Effectiveness is paramount to demonstrate the value of DHTs and how it impacts patient needs and clinical outcomes

- Measurement of effectiveness is relevant for those DHTs that directly impact patient outcomes. These DHTs are usually classified as medical devices and require regulatory approval.
- Clinical effectiveness is primarily relevant to the overall healthcare system. The submission of data that explains the benefit to the patient and any potential changes in their morbidity, mortality, and quality of life should be framed by the requirements of the overarching system.
- Depending on the research question, data can come from randomised-controlled trials or real-world data from routine clinical practice, provided that advanced statistical methodologies are applied to address potential bias. (Note: pilots need to be conducted to demonstrate the reliability and validity of real-world data for the evaluation of DHTs as mandated by the European Commission in 2021).
- Regionality of the data is important; if country data is not available, regional data representing similar populations could represent an acceptable proxy.
- Ideally, if the impact on patient outcomes (morbidity, quality of life, progression-free survival, response to treatment and mortality) is relevant due to the potential benefits of the DHT, outcomes should already have been demonstrated in a randomised-controlled trial. These could be pragmatic trials (real-world evidence with randomisation to intervention and control groups). Quasi-experimental local studies could also be used to evaluate the impact on the local target patient population.
- Even though efficacy and effectiveness of the DHT may have been proven outside the target country, it is important to also demonstrate these benefits in the local context, using local data.
- Real-world data from well-designed evidence studies, or observational data from quasi-experimental cohort studies, should be provided to demonstrate how the DHT solution has changed the care process in routine clinical practice from a national healthcare perspective.
- Patient follow-ups are also advantageous, as they can document and demonstrate the impact of the DHT on patient health outcomes and measures, along with patient experiences in receiving health services – accountable for improving patient-reported outcomes and patient-reported experiences (PROMs and PREMs).

To give you an example of how to demonstrate improved health outcomes, let's consider the delivery of essential drugs to remote areas.

Traditionally, these essential medicines were delivered with trucks where an entire day was often spent on the road while losing valuable time to reach critical care patients. Now, these transportation times have been reduced to a few minutes with the use of drones.

Note: this is an example of transformational value-add. The added value of DHTs to individual users is often more incremental, and the gains need to be collected and documented to prove their added value.

2. Strengthening the business case with evidence of added effectiveness and productivity

We recommend that decision-makers provide information to demonstrate the extent to which the DHT solution can contribute to:

- Easing the patient journey, particularly by including patients from under-served areas.
- Involving patients as partners in the healthcare agenda (including a 'how-to' breakdown) and empowering them to take control of their own care journey (by accessing their own health records, for example).
- Improving productivity.
- Increasing user effectiveness.
- Providing a measurable impact on intervention delivery, care process, and workflow from the perspective of both individual HCPs and the wider care team. This may include:
  - Service efficiency:
    - Time savings (workflow for HCPs, travel & waiting time for patients).
    - Patient reach and throughput.
    - Waiting time reduction.
    - Resource consumption.
    - Improved billing systems.
    - Effective referral management, etc.
  - Quality of disease management:
    - Learning curve required of medical professionals.
    - Appropriateness of the application to effectively manage specific conditions.
  - Reduced burden on individual HCPs:
    - Utilisation of care services (e.g. number of contacts with care providers, number of patients per HCP).
  - Communication:
    - Improved interactions/communication within the care team.
    - Improved communication with the patient.

3. Demonstrating "added value" of the DHT on organisational effectiveness and productivity gain.

This is essential for the adoption of a DHT, not just by HCPs but also by hospitals and other care organisations. Evidence of organisational efficiencies and usability should be tangible, understandable, and reliable.

For example, a reduction in waiting and consulting times would reduce direct medical and indirect costs for a specific clinical service. Avoidance of travelling times is also a meaningful benefit for both HCPs and patients.

6.6 Cost & Economic Evaluation

- In most countries, the perspective of the healthcare system is a relevant factor when government/national decision-makers come to decide the value of a DHT for funding & reimbursement. Decision-makers want to understand the impact on the overall healthcare budget and predict the cost impact compared to other existing interventions.
- So it is advisable to lay out the total cost, including the initial investment cost and the expected follow-up cost for product/software updates, maintenance, training services and the service fees for HCPs who apply the DHT.
- From the perspective of both the individual healthcare organisation (e.g. the hospital or clinic) and the national healthcare system, a cost-consequence analysis may be the most suitable approach to measure the financial impact of cost and effect. This type of analysis assesses a wide range of costs and consequences (effects) of the DHTs and reports them separately. It includes all types of effects, including health, non-health, negative and positive effects, both to patients and other parties (for example, caregivers) and gives decision-makers a comprehensive summary of the different costs and effects, so it tends to take a broad perspective (see also https://www.gov.uk/guidance/cost-consequence-analysis-health-economic-studies).
- Moreover, budget impact analysis helps to identify the budgetary impact for both individual hospitals and the national health system, if the total number of potential patients served is accounted for.
- To avoid "hidden costs", transparency around the operating business model of the DHT is advisable to avoid. For example, it is important to clarify that a DHT is offered free of charge but fees are charged at each consultation.
- An estimated ROI from a funder's perspective should be considered in the business case, including the monetisation of additional key activities.
- When considering clinical outcome data, it is important to frame data on resource use and cost within the local context.
- Opportunities for data and evidence generation should also be explored, as should the potential benefits of collecting patient data with digital technology (for example using AI in radiology and storing the results in an Electronic Patient Record, analysing the data across different patient populations to understand the effectiveness of the technology in subpopulations etc.).

6.7 Ethical Aspects

- Considerations of data security (confidentiality, integrity, and availability) should be framed by the data protection laws of the specific country. Patient privacy, governance, and consent processes are critical to the use, trustworthiness, and safety of DHT solutions.
- It is also important to ensure clear governance structures around data ownership across the care continuum, both to avoid the stigmatisation of specific populations according to gender, ethnicity, geographies, religion, income or previous disadvantage (such as a previous HIV diagnosis) and to ensure equity and justice. This also includes sharing data with different institutions or stakeholders for public health research purposes.
- Local data storage and processing structures, and information on how information is protected against unauthorised use and access, are also relevant considerations.
- In the interests of digital health literacy, decision-makers should clarify how information and training around the DHT can help users maximise the technology.
- In some countries, National Digital Agencies may be in place to monitor data security practices.

7. Empirical Checklist

The following Empirical Checklist will help decision-makers to prioritise the value domains and criteria that are important in assessing the value of a DHT for reimbursement or an investment decision and/or adoption in your daily clinical practice.

Each part of the checklist will be around one of the seven value domains (see value framework chapter 4) which are explained in the figures below.

1

Health / Healthcare system problem and current use of technology

Intended clinical purpose	Target user group(s) and their needs	Beneficiaries of the technologies	Current relevant alternatives used	Contextual Issues
○ Medical Indication ○ Priority in the clinical care continuum. E.g — Accuracy of diagnosis — Clinical management and decision support — Meaningful engagement during palliative care — PRO self-monitoring — Information & data sharing — Second opinion etc.	○ Patients ○ Multidisciplinary stakeholders (e.g: Tumor board) ○ Individual physicians (e.g: GPs, specialists, oncologists, tumor board members etc.) ○ Nurses ○ Laboratories ○ Pharmacies ○ Caregivers ○ Research & Academy ○ Corporate entities	○ Individual Physicians (e.g. GPs, specialists, oncologists, tumor board members etc.) ○ Patients ○ Nurses ○ Payers	○ Standard diagnostics ○ Standard procedures	○ Standard of legislatives/ regulatory procedures ○ Contextual barriers to DHI adoption & uptake. E.g. — Limited network access — eHealth literacy — Smart & digital knowledge ○ Contextual enablers to DHI adoption & uptake e.g. — National eHealth strategy in place — Clinical endorsement — Integration of all stakeholders

1 Health/Healthcare system problem and current use of technology

Instructions to complete the checklist

Please tick or mark one response per question.

Is the intended clinical purpose of the DHT sufficiently described?

- Medical indication or disease area provided.
- Priority in the clinical care continuum defined.

  (e.g., accuracy of diagnosis, clinical management & decision support, engagement during palliative care, patient-reported outcomes self-monitoring, information & data sharing, second opinion).

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Are the target user groups and their needs sufficiently described?

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Are the beneficiaries of the technology and their needs sufficiently described?

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Is it clear which of the current relevant alternatives can be compared to the new DHT?

(e.g., currently used diagnostic tools, standard procedures, paper-based methods etc.).

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Are the contextual issues clearly described?

- Standard of legislative / regulatory procedures.
- Contextual barriers to DHI adoption & uptake, e.g.,
  - limited network access,
  - eHealth literacy,
  - smart & digital knowledge, etc.
- Contextual enablers to DHI adoption & uptake, e.g.,
  - national eHealth strategy in place,
  - clinical endorsement,
  - integration of all stakeholders.

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Overall, is the problem with the health or healthcare system, and the current use of technologies, sufficiently articulated?

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

2

Technical Product Information & Use

Description of Technical characteristics	Transparency	Quality Management System
Clear nomenclature of the DHI/Tools (according to WHO classification)	Data protection & Compliance	Information quality
Service functionalities	— Type of information gathered	Service quality
Interoperability, compatibility & integration feasibility with other systems	— Patients involved	— Regular product maintenance and product support
Accessible design according to WCAG 2.1 guidelines (https: www.w3.org/TR/WCAG21/)	— Permission system and auditability	— Technical support, help desk, downtime
	— Transparency of data processing	— Product replacement
	— Privacy policy	— Time to response as part of quality management
	— Consent	Organized testing environment, real time feedback and experience
	— Notice of use and disclosure	Refresher Training
	— Data access mechanism	
	— FAIR Principles	

2 Technical Product Information & Use

Instructions to complete the checklist

Please tick or mark one response per question.

Is the product type and its functionality sufficiently described?

- Does the assessment prove functionality of the new technology, for example:
  - Digital Health Intervention input (e.g., image, physiological status, symptoms etc.).
  - Digital Health Intervention algorithm (e.g., equations, analysis engine model logic, algorithm, etc.).
  - Intervention output (e.g., inform, treat, diagnose).
  - Reproducibility of results in different settings (populations, geographies and infrastructure).
- Is the risk class and regulatory framework made clear, e.g.
  - MDD, MDR, local authorities' approval etc.
  - If non-medical device, which classification rules are followed?

○ Sufficient ○ Partially sufficient ○ Not sufficient ○ Not required

Is the maturity of the application sufficiently described?

- Does the assessment demonstrate:

  Alignment with the national digital/IT framework architecture, for example:
  - HIMSS Maturity Model.
  - Electronic Medical Record Adoption Model.
- Alignment with user needs/clinical workflows.
- Recognition of the technology by key stakeholders.

○ Sufficient ○ Partially sufficient ○ Not sufficient ○ Not required

Is there sufficient information on the market availability?

- Does the assessment highlight the use of product in other sites/ countries.
- Is there a clear description of the jurisdiction/countries where the technology is used.

○ Sufficient ○ Partially sufficient ○ Not sufficient ○ Not required

Are the technical characteristics sufficiently described?

- Is the nomenclature of the DHI/Tools clearly defined (according to WHO classification).
- Are service functionalities laid out clearly.
- Is the product's interoperability, compatibility & integration feasibility with other systems clearly demonstrated.
- Does the assessment demonstrate accessible design according to WCAG 2.1 guidelines (https://www.w3.org/TR/WCAG21/).

○ Sufficient ○ Partially sufficient ○ Not sufficient ○ Not required

Is there sufficient information on Transparency on data protection & compliance? Is the product type and its functionality sufficiently described?

- Special assessment should be paid to
  - Type of information gathered.
  - Parties involved.
  - Permission system and auditability.
  - Transparency of data processing.
  - Privacy Policy.
  - Consent.
  - Notice of use and disclosure.
  - Data access mechanism.
  - FAIR Principles.

Sufficient
Partially sufficient
Not sufficient
Not required

Is there sufficient information on the Quality Management System of the new DHT?

Has sufficient attention been paid to:

- Information quality (pre-analysis, content, alerts).
- Service quality:
  - Regular product maintenance and product support.
  - Technical support, helpdesk, downtime.
  - Product replacement.
  - Time to response as part of quality management.
- Organised testing environment, real-time feedback and experience.
- Refresher Training.

Sufficient
Partially sufficient
Not sufficient
Not required

Overall, is the technical product information and usage description sufficient?

Sufficient
Partially sufficient
Not sufficient
Not required

3

Usability & Accessibility

Clinician User Experience	Patient Experience	Other User's experience
Integration into current care pathway	Accessible design (WCAG 2.1 guidelines)	Hospital, IT, healthcare worker, other caregiver and non-caregiver
User satisfaction and friendliness	— Involvement of users in the product design and testing of the Digital Health Technologies	Accessible design (WCAG 2.1 guidelines)
Accessible design (WCAG 2.1 guidelines):	eHealth literacy	
— Accessibility assessment	— Education, training, support	
— Involvement of users in the product design and testing of the Digital Health Technologies	Usefulness & overall satisfaction	
— Access to all participants	Safe, effective, patient-centered, timely, efficient and equitable care delivery	
Accuracy of the application (e.g. diagnostics)	Shared decision making	
Ability to obtain actionable information	Ability to use the application	
Availability for shared decision-making & multidisciplinary alignment	Timeliness and convenience	
Personalized patient curve	HCP-patient interaction	
	Access to care and technology	
	Infrastructure, connectivity	
	Patient feedback and patient-reported outcomes	
	PREMS	

3 Usability & Accessibility

Instructions to complete the checklist

Please tick or mark one response per question.

Is there sufficient information on the Clinician User Experience?

- Sufficient
- Partially sufficient
- Not sufficient
- Not required

- How is the DHT integrated in the current care pathway?
- Is there evidence of user satisfaction and friendliness?
- Is there evidence of accessible design? (WCAG 2.1 guidelines):
  - Accessibility assessment.
  - Involvement of users in the product design and testing of the Digital Health Technologies.
  - Access to all participants.
- Is there evidence of the accuracy of the application? (e.g., diagnostics).
- Is there data on the ability to obtain actionable information?
- Is there scope for shared decision-making & multidisciplinary alignment?
- Does the product provide a personalised patient curve.

Is there sufficient information on the Patient Experience?

- Sufficient
- Partially sufficient
- Not sufficient
- Not required

- Followed accessible design (WCAG 2.1 guidelines):
  - Involvement of users in the product design and testing of the Digital Health Technologies.
- eHealth literacy:
  - Education, training, support.
- Usefulness & overall satisfaction.
- Safe, effective, patient-centred, timely, efficient, and equitable care delivery.
- Shared decision making.
- Ability to use the application.
- Timeliness and convenience.
- HCP-patient interaction.
- Access to care and technology.
- Infrastructure, connectivity.
- Patient feedback and patient-reported outcomes.
- PREMS.

Is there sufficient information on the Other User's Experience (e.g., Hospital, IT, healthcare worker, another caregiver and non-caregiver)?

- Followed accessible design (WCAG 2.1 guidelines).

Sufficient
Partially sufficient
Not sufficient
Not required

Overall, is the information on Usability & Accessibility sufficient?

Sufficient
Partially sufficient
Not sufficient
Not required

4

Safety

Technical safety	Clinical safety	Communication for safety
● Technical reliability and stability ● Data storage ● Data protection law ● Procedural safety across different components	● Risk related to — Side effects (product-related in terms of physical, mental, social or financial ham) — Misuse — False Positive/negative diagnostic — False treatment/disease management — Delayed treatment — Any safety surrogates that influence medical outcomes ● Clarity of clinical protocols and guidelines used by the system	● Process for correct identification of users of Digital Health Intervention ● Process to communicate changes to or transfer of patient's care ● Process for alarm of critical risk information

4 Safety

Instructions to complete the checklist

Please tick or mark one response per question.

Is there sufficient information on the Technical Safety?

- Technical reliability and stability.
- Data storage.
- Data protection law.
- Procedural safety across different components.

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Is there sufficient information on the Clinical Safety?

- Risk related to:
  - Side effects (product-related in terms of physical, mental, social or financial harm).
  - Misuse.
  - False positive/negative diagnostic.
  - False treatment/disease management.
  - Delayed treatment.
  - Any safety surrogates that influence medical outcomes.
- Clarity of clinical protocols and guidelines used by the system.

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Is there sufficient information on the Communication around Safety?

- Process for correct identification of users of Digital Health Intervention.
- Process to communication changes to or transfer of patient's care.
- Process for alarm of critical risk information.

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Overall, is the information on the Safety of the DHT sufficient?

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

5

Effectiveness

Organizational /Care Effectiveness/ Productivity	Clinical Effectiveness
● User effectiveness — Impact on intervention delivery, care and workflow (e.g. disease management, waiting time for medication and treatment, social dependency, social functioning) — Utilization of care services (e.g. number of contacts with care providers divided into type of contact) ● Appropriateness ● Staff training ● Length of hospital stay	● Health outcomes — Morbidity, mortality condition-specific or overall — Quality of life gain and general well-being (cancer- specific and overall) — Patient- reported outcomes in general and cancer- specific ● Behavioral outcomes (e.g. lifestyle changes) ● Accuracy of diagnosis and appropriate disease management — Compliance with clinical guidelines

5 Effectiveness

Instructions to complete the checklist

Please tick or mark one response per question.

Is there sufficient information on the Organisational / Care Effectiveness or Productivity of the DHT?

- Evidence on user effectiveness:
  - Impact on intervention delivery, care and workflow (e.g., disease management, waiting time for medication and treatment, social dependency, social functioning).
  - Utilisation of care services (e.g., number of contacts with care providers divided into type of contact).
  - Learning curve of medical professionals.
  - Time savings.
  - Resource consumption.
- Data on appropriateness.
- Information on staff training.
- Information on length of hospital stay.

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Is there sufficient information on the Clinical Effectiveness of the DHT?

- Health Outcomes:
  - Morbidity, mortality condition-specific or overall.
  - Quality of life gain and general well-being (cancer-specific and overall).
  - Patient-reported outcomes in general and cancer-specific.
- Behavioural outcomes (e.g., Lifestyle changes etc.).
- Accuracy of diagnosis and appropriate disease management (e.g., compliance with clinical guidelines etc.).

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Overall, is the information on the Effectiveness of the DHT sufficient?

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

6

Cost & Economic Evaluation

Organizational/ Institutional cost	Healthcare System Cost	Individual's Cost
Start-up, recurring & maintenance cost for device, equipment, infrastructure/ network, software purchasing cost	Overall cost and consequences along the care continuum (direct treatment cost)	Cost occurring to the individual (user, beneficiary)
Affordability	Personnel cost	Saving due to efficiencies in the care provision
Cost for the service/ treatment (HCP-related cost)	Cost- effectiveness	
	Budget impact — Indirect benefits vs. cost estimation, ROI estimation (long term)	

6 Cost & Economic Evaluation

Instructions to complete the checklist

Please tick or mark one response per question.

Is there sufficient information on the Organisational / Care Effectiveness or Productivity of the DHT?

- Start-up, recurring & maintenance cost for device, equipment, infrastructure/network, software purchasing cost.
- Affordability.
- Cost for the service/treatment (HCP-related cost).

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Is there sufficient information on the Healthcare System Cost associated with the DHT?

- Overall cost and consequences along the care continuum (direct treatment cost).
- Personnel cost.
- Cost-effectiveness.
- Budget impact (Indirect benefits vs. cost estimation, long-term ROI estimation).

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Is there sufficient information on the Individual's Cost associated with the DHT?

- Cost occurring to the individual (user, beneficiary).
- Savings due to efficiencies in the care provision.

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Overall, is the information on the Cost and Economic Evaluation of the DHT sufficient?

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

7

Ethical Aspects

Equity & Justice	Autonomy	Data Security	Responsibility
Non-discrimination	Consent of data collection & use	Data protection laws	Trust in provider/ manufacturer, e.g. corporate legacy
Non-stigmatization	— Awareness of data collection and use (information)	— Security standards and data protection requirements (e.g., COPPA, HIPPA, GDPR, etc.)	Legal vs. custodian data ownership
Data ownership	— Ability to withdraw consent at any time	Data privacy	Process flow transparency
— Data as an object vs. public good	Right to know the results	Protection against cyber crimes (primary and secondary data-sharing)	Regular auditing
Education	Freedom of choice, e.g. platform etc.	Location of data storage and processing	Ethics of data usage and engagement
— Health data and digital literacy			
IPO ownership/ open-source technology			

7 Ethical Aspects

Instructions to complete the checklist

Please tick or mark one response per question.

Is there sufficient information on the Equity and Justice?

- Non-discrimination*
- Non-stigmatization*
- Data ownership:
  - Data as an object vs. public good.
- Education.
- Health data and digital literacy.
- IPO ownership/open-source technology.

* geographical, gender, ethnicity, previously disadvantaged, income etc.

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Is there sufficient information on Autonomy for the use of the DHT?

- Consent of data collection & use:
  - Awareness of data collection and use (information).
  - Ability to withdraw consent at any time.
- Right to know the results.
- Freedom of choice, e.g., platform etc.

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Is there sufficient information on Data Security around the use of the DHT?

- Compliance with data protection laws:
  - Security standards and data protection requirements (e.g., COPPA, HIPPA, GDPR, etc.).
- Esurance of data privacy.
- Protection against cybercrimes (primary and secondary data-sharing).
- Location of data storage and processing.

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Is there sufficient information on Responsibilities and governance of the DHT?

- Trust in provider/manufacturer, e.g., corporate legacy.
- Legal vs. custodian data ownership.
- Process flow transparency.
- Regular auditing.
- Ethics of data usage and engagement.

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

Overall, is the information on the Ethical Aspects of the DHT sufficient?

○ Sufficient
○ Partially sufficient
○ Not sufficient
○ Not required

7.1 Summary of Decision-Making Process

Application of Checklist in Decision Making Process Steps

Next step(s), based on the above summary of each Value Domain

- **Proceed to next step in national and/or regional review process**
- **Request more information &/or clarity from DHT proposal submitter at current step**
- **Stop at current step in national and/or regional review process**

Date of decision

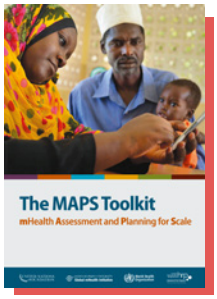
Notes

7.2 Useful Additional Tips for Manufacturers

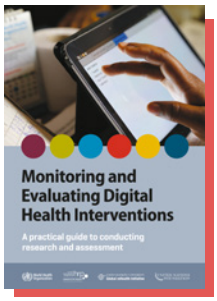
The checklist above can also be used by DHT manufacturers to guide the development of an evidence-based business case for submission to national and local decision makers for funding and/or reimbursement. In their submission, Manufacturers of DHTs should include any documentation, studies, research reports, and certificates that support the value criteria detailed in the Checklist, e.g.:

- Availability of workflow diagrams and patient journey that describe the current workflow with inefficiencies, and a future workflow with digital health technology as a solution.
- Any technical documents that provide information according to the checklist including regulatory approval certificates according to the local regulations.
- Any studies and publications that support the efficacy, effectiveness, safety, economic value of the DHT.
- Any research report that provides evidence of Usability & Accessibility according to the criteria in the checklist.
- Any documentation of the ethical aspects as detailed in the checklist.
- A list of key stakeholders involved in the decision & deliberation process and engagement plan.
- A clear budget plan and business model.
- Any appraisal documentation from decision-makers in other countries.

8. Useful resources



https://apps.who.int/iris/bitstream/handle/10665/185238/9789241509510_eng.pdf



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- 30 January 202o, Last updated 19 October 2021.
  Available at https://www.gov.uk/government/collections/evaluating-digital-health-products.

10. Stakeholders involved

Name	Position & Institution
Dr. Wisdom K Atiwoto	Director, Research, Statistics & Information Management Ministry of Health, Accra, Ghana
Dr. Juan Carlos Bartolo	Former Vice Minister of Health, Oncologist, Mg Biostatistics, Manager of Public Policies and Innovation Doctor in Medical Informatics, Expert in digital health & global health informatics and telemedicine. Consultant for Proinversión in medical images and teleradiology Facultad de Ciencias y Filosofía de la Universidad Peruana Cayetano Heredia
Jean Baptiste Byiringiro	Chief Digital Officer, Ministry of Health MoH, Kigali, Rwanda
Dr. Bernadette Cotrina	Medical Radiologist, Expert in health services administration. Directora General de Telesalud Referencia y Urgencias Ministry of Health, Peru
Dr. Lumbwe Chola	Health Economist at the Norwegian Institute of Public Health
Jari Haverinen	Senior Planning Officer at FinCCHTA, Oulu University Hospital / Doctoral Researcher at MIPT, Faculty of Medicine, University of Oulu, Finland
Dr. Izzuna Mudla Mohamed Ghazali, MBBS, MPH, MPH	Medical Development Division Ministry of Health Malaysia, Malaysian Health Technology Assessment Section (MaHTAS), Putrajaya, Malaysia
Dr. John Kabukye	Health informatics specialist & researcher at Uganda Cancer Institute
Kenneth Kwing Chin Lee, MPhil, PhD	School of Pharmacy, Taylor's University Malaysia
Dr. Brigitta Monz	Chapter Lead Access Evidence, Global Access & Policy in Roche Diagnostics, Switzerland
Ivaylo Petrov	EUnite Innovative Solutions Lead at Oncology Policy and Healthcare Systems Novartis Region Europe
Dr. Roberta Sarno	Digital Health Manager at APACMed
Dr. Stephen Stephani	Clinical Oncologist. Professor of Health Technology Assessment and Health Economics, UNIMED, Brazil
Varun Veigas	Health Policy and Patient Access l Strategic Regulatory Affairs and Policy I Chair Digital Health Committee - APACMed
Dr. Damian Walker	Health Economist at Management Science for Health
Thomas Wilkinson	Economist at the World Bank
Dr. Diego Venegas	Medical Oncologist, Expert in Health Administration and Public Health Manager of the Integrated Health Network, Lima, Peru
Keelee Moseley	Associate Director, IT Delivery and Transformation Lead- Patient & Consumer Engagement · Merck
Carl Erwin Johnson	Director, Policy Evidence Research Merck

11. Appendix with Hypothetical Use Cases

Case 1
DHI with AI in Radiology

Preface

This hypothetical case study should provide an example of a typical use case to fund/reimburse physician-facing digital health technologies.

Specifically, the case study will help us to test the preliminary payer value framework for the evaluation of Digital Health Interventions (DHIs) for cancer care in low-to-middle income countries (LMICs) with key stakeholders in different countries/healthcare systems.

The focus of this use case is on a DHI with **AI in Radiology**.

Please read this case study and the value framework and address the following questions:

1. What information for each value domain and subdomain is most important for you to make a funding / reimbursement decision of AI in Radiology?
2. What level of evidence do you require to grant funding and reimbursement of AI in Radiology?
3. What information do you think is missing in the provided use case to make a funding/ reimbursement decision?

Your feedback on the different value aspects and level of evidence needed to grant reimbursement/ funding will provide practical guidance for payer and funding decision-makers.

Healthcare System Context

eHEALTH CONSIDERATION

In this case, the healthcare system established an eHealth strategy in 2010 but this has only been partially implemented and has not been updated. Electronic Health Records (EHRs) are available in all the country's public teaching hospitals and are currently being deployed in secondary hospitals too.

EHRs between different hospitals are not connected, and Digital Health Interventions (DHIs) are not yet integrated with the EHR system.

Telemedicine facilities are currently being rolled out and available at primary care level in 10% of the main community centres, connecting to district hospitals' clinicians.

In terms of internet connectivity, 80% of the country has stable access to the internet. The remaining 20%, situated in remote communities, have poor connectivity or none at all.

In this use case, the DHI with Artificial Intelligence (AI) in radiology is considered a "diagnostic strengthening" technology. The AI technology component itself is not further specified in this use case.

EXPECTED HEALTH INFRASTRUCTURE

The infrastructure for which the technology is being considered includes:

7
teaching hospitals, of which 5 use the technology daily

25
district hospitals

424
community centres

25
radiologists
(8 are retired but still practising) in public sector

28
radiologists in private sector

There is no data available on primary care centres and physician offices, or private sector facilities.

PRIORITY AND COVERAGE OF CANCER CARE

In the last two years the country's Ministry of Health has prioritised female cancers and lung cancer.

Universal Health Coverage (UHC) is in place as an administration unit within the Ministry of Health. However, UHC covers female cancers only.

The coverage includes basic diagnostics and treatment packages, according to national cancer management guidelines published in 2020. In practice, patients need to cover up to 40% of in-hospital expenditures out of their own pocket.

Care for all other cancer types must be paid out of pocket in 100% of cases. Although there are faith-based support systems available across the country, their effective coverage cannot be estimated.

In public institutions, technologies are procured via public budget allocation. Every year, each institution needs to send a budgetary request to the central government for procurement.

Telemedicine infrastructure is financed by private funding agencies (ODAs). Up to now, all consultations given at community level have not been billed to patients but instead delivered on a voluntary basis by district hospital clinicians.

No DRG payment system exists. Every hospital places a manual request for reimbursement to the central UHC administration.

Private insurance penetration is around 30% of the population, but no private insurance coverage for cancer is available at this point. Only basic diagnostic testing is covered (blood tests for PSA, mammograms, etc.).

Population: overall, there are **24,000,000 inhabitants**. The **incidence of cancer** is estimated to be **78,000 new cases per year.**

COVERAGE OF DIGITAL HEALTH INTERVENTIONS

No specific reimbursement codes of digital health services are available. Public hospitals' claims departments bill these services directly to the UHC, which might not cover the cost.

In some cases where patients are eligible to receive treatment in the private sector (when service is not available in the public sector within 150km of place of residence), private hospitals deal with the UHC.

THE HEALTHCARE PROBLEM TO BE SOLVED WITH THE AI IN RADIOLOGY DHI

Universal Health Care (UHC) covers only basic diagnostic and treatment packages. There is a shortage of radiology centres in the country, which leads to a delay in cancer diagnosis, greater severity of cases and a high burden placed on patients and their families.

AI for radiology is not reimbursed by the National Health Service. However, the use of AI in radiology could serve a higher number of patients, detect cancer earlier without increasing the cost for additional radiologists, and help more patients to be treated earlier.

COVERAGE OF DIGITAL HEALTH INTERVENTIONS

There is no specific reimbursement code for digital health services. Public hospitals' claim departments have to directly bill the cost of digital health services, such as AI in radiology, to the UHC.

In some cases where patients are eligible to receive treatment in the private sector (when service is not available in the public sector within 150 km of place of residence), private hospitals deal with the UHC.

The Use of the technology and Value Proposition

THE TECHNOLOGY

The Technology is a SaaS platform on which images are uploaded manually. It uses locked AI algorithms which have been developed and tested in a different geography.

The DHI was developed as a **medical device per ISO 13485** and is **approved as medical device 2a in EU.**

The algorithm was trained on two different ethnic groups, one partially overlapping with the population in the country of deployment.

Testing is to a large extent mandatory for medical device certification. The tests demonstrated an accuracy of 8% better than gold standard (images assessed by radiologists) in comparable settings (test). Sensitivity is estimated at 93% and specificity at 97%. These results have not been published.

Data are reproducible to a large extent, but variations are expected depending on image quality and patient group ethnicity.

The **security standards** are compliant with the highest EU regulations (GDPR). The only constraint is data hosting, which relies on a Cloud server located outside of the country.

However, if the medical data is anonymised, the country data protection law does not affect or limit the external hosting.

The lead radiologist group of the teaching hospitals are the champions of the project and have **full understanding of the performance matrix**. They selected the software based on several criteria, including performance. They are drafting all recommendations to the Ministry of Health (which is the payer).

The **system is constantly updated** and under revision in accordance with new protocols/guidelines.

Software updates are pushed by the technology provider on a regular basis. The testing is conducted on the technology provider's side and not at the country level (there is no input from the country level).

THE COST

A recurring SaaS licence fee of 5,000 USD per year, paid upfront per centre, which delivers up to 100 images per day. There is no minimum time commitment related to the fee.

Installation and training are both covered by the licence fee, and there is no hidden fee.

THE USER

The AI radiology DHI is used in five centres on a daily basis and in seven centres overall. The main users of the technology are 14 radiologists in 7 centres (so far). These are medical doctors whose radiology specialisation is recognised by the MoH.

These doctors were provided with training on how to use the tool by the technology provider (vendor). One power user per teaching hospital provides refresher training.

The technology is used in about 20% of cases in teaching and higher acuity hospitals.

Full online resources for training and teaching are available. As part of solution onboarding, each power user in the centre needs to fill in check boxes to verify their understanding. Radiologists' understanding varies from centre to centre, with different levels of resistance. Five out 7 centres are daily users.

PURPOSE OF USE

The **main indications** for which the technology is used are **breast, chest, head and neck cancer**.

The **unmet need** addressed by the technology is the **shortage of radiologists** in the public sector, which leads to **not enough time available for multi-disciplinary treatment decision making & consultations**.

The number of cases analysed amounts to 43 cases per day on average. The purpose of using the AI based technology is:

- Image reconstruction.
- Clinical decision support.
- Identification of potential image quality issues.
- Tumour contouring and heat map.
- Consistency of performance across all image qualities and standards.

The project is realised in partnership with

- The technology provider (software company from abroad).
- Funder (ODA).
- Technical cooperation provider and implementer (international NGO).

The main purpose of the technology is to:

- Shorten the time clinicians spend on complex cases, especially when images are sent to colleagues for second opinion and validation.
- Shorten time to provide reports to patients.
- Improve accuracy by highlighting image quality issues (machine failure, degradation, poor positioning practices, etc).

VALUE PROPOSITION

- To address the shortage of radiologists by improving access to radiology through better quality and better productivity:
  - More images can be assessed in a shorter period without additional cost for radiologists.
  - More patients can be diagnosed earlier and consequently treated earlier.
  - This will lead to reduced mortality, morbidity and cost and improved quality of life.

HOSPITAL / SITE EXPERIENCE

The overall workflow of radiologists has improved:

- The time spent by radiologists on complex cases has drastically reduced. Data from a randomised-controlled trial using AI in cardiothoracic radiology demonstrated a 22.1% mean reduction in interpretation times among three cardiothoracic radiologists for whom the AI results were made available (https://www.itnonline.com/content/ai-saves-one-hour-daily-chest-ct-interpretation-time-prospective-randomized-study).
- However, there is no time tracking feature on used PACS systems.
- A survey conducted in seven centres showed that 20% less time had been spent on readings overall.
- The number of cases transferred dropped by 60%.
- No data on case transfer (transfers happening on non-trackable platforms).

In terms of improved service quality, no data has been collected. However, the local radiology Society strongly supports the project after an initial status review and comparison of senior radiologists' performance.

The overall MD's perception is that the specific quality of complex cases has improved.

The use of the platform has a positive effect on the retention of expert personnel.

However, the innovation is not directly visible to the patient.

CLINICIAN EXPERIENCE

The use of the technology is perceived to be very easy after training by the technology provider on site.

In terms of trust in the technology and decision-making, it took the user an average of two months to trust decisions using the DHI in five regular user centres. Two other centres are still struggling to trust in the technology.

The quality of results in terms of reproducibility, interpretability and transparency seem to be very consistent and this enables radiologists to detect image issues and details which could be missed, especially during high peak and demanding workload periods.

Although the AI radiology DHI is not integrated into the overall hospital information system, images produced by digital equipment can easily be imported on the platform.

The system is very reliable. Downtimes are only experienced during times of interrupted internet connection, which occurs on average for half a day, twice a month.

Accessibility of the system

The system can be accessed on a specific website by individual password. Only radiologists can access the system, and the user receives technical support via a chat function.

Impact on workflow and workforce

Much less time is required to transfer images to other radiologists or to consult within the team. More time should be dedicated to multi-disciplinary treatment meetings.

Some clinicians started using the platform as a training tool for support/technical staff, to explain the impact of poor patient positioning. More time for MDT meetings is appreciated by oncologists.

PATIENT EXPERIENCE

The main benefit is the time saved:

- For complex cases, reduction of imaging reporting could be reduced by two to three days on average.
- Overall waiting times for patient appointments could be reduced from three to two weeks.

However, patients are not aware of the technology.

EVIDENCE ON THE BENEFIT OF THE TECHNOLOGIES

Clinical benefit

- Surveys were conducted around productivity, with positive findings in terms of freeing time for value-generating activities like multi-disciplinary meetings.
- Data collection around the number of images reported per day: +8/day average.
- Data collection on radiology waiting lists for chest/head CT: Reduction from three to two weeks' waiting time.

Economic benefit

In terms of productivity, the results showed savings of 18.6% (eight out of 43 cases) in operational costs for the department allocated to those indications, which amounts to 8% of the department's overall cost.

In terms of resource use, numbers were extracted from EHR on readmissions, survival rate, and other key factors. However, when analysing other aspects of the performance of those departments involved in oncology care, it was deemed difficult to isolate the impact of the DHI. No specific collection but extrapolation on misdiagnosis reduction based on company data.

Benefit of Care Structure

The DHI made care more accessible, with a reduction in waiting lines.

Case 2

DHT used for Multidisciplinary Collaboration in Cancer Care

Preface

This hypothetical case study should provide an example of a typical use case to fund/reimburse physician-facing digital health technologies. Specifically, the case study will help us test the preliminary payer value framework for the evaluation of Digital Health Interventions (DHIs) for cancer care in low-to-middle income countries (LMICs) with key stakeholders in different countries/healthcare systems.

The focus of this use case is a DHT used for **Multidisciplinary Collaboration in Cancer Care (i.e. a multidisciplinary tumour board)**.

Please read this case study and the value framework and address the following questions:

1. Which piece of information for each value domain and subdomain is most important to you when making a funding / reimbursement decision over a digital tool for multidisciplinary collaboration for cancer care, with and without AI?
2. What level of evidence do you require to grant funding and reimbursement for this digital technology?
3. What information do you think is missing in the supplied use case to make a funding/reimbursement decision?

Your feedback on the different value aspects and level of evidence needed to grant reimbursement/ funding will inform practical guidance for payer and funding decision-makers.

Healthcare System Context

eHEALTH CONSIDERATION

This DHT considered for this case will evaluate the treatment-related symptoms of cancer patients. The healthcare system has established Electronic Health Records (EHR) and a national cancer registry, but an eHealth strategy is not yet implemented.

Since the registry was introduced three years ago, it has changed existing data collection technology methods, facilitated the implementation of a personalised data system based on individual patient data, and helped raise overall data quality. However, there are still some challenges that will form the basis for future activities.

EXPECTED HEALTH INFRASTRUCTURE

The following table provides an overview of the infrastructure for which the technology is being considered:

127 In-patient facilities	**382** Out-patient facilities	**10** Ambulance stations
10 Blood transfusion stations	**17,292** Physicians	**8,266** Nurse

PRIORITY AND COVERAGE OF CANCER CARE

In 2017, the National Strategy and Action Plan for Non-Communicable Diseases Prevention and Control was approved. This included a National Cancer Control Strategy to prioritise the allocation of funds and projects for cancer care improvement.

A Universal Healthcare (UHC) programme, implemented in the country in 2013, has had a positive impact on the accessibility of health services, reduced financial barriers and out-of-pocket costs for the population. UHC insurance covers 80% of the costs of cancer treatment, however diagnosis (pathology and imaging exams) and targeted therapy are not covered by the UHC insurance.

The LEPL Information Technology Agency, part of the Ministry of Health, is responsible for reimbursement/funding of digital health services. The Ministry of Health overall is a key decision-maker and frequently includes medical professionals as technical advisors.

Population: the total population of the city is 1,201.769 inhabitants.

46,915 patients are registered in the **National Cancer Registry**.

THE HEALTHCARE PROBLEMS TO BE SOLVED

Currently, there is no standard practice for the management of cancer patients. Furthermore, while multidisciplinary teams are sometimes assembled to solve complex cases and increase compliance with national cancer care guidelines, this approach is not universal.

Similarly, data-sharing is not common practice; this leads to delays in diagnosis and initiation of treatment, poor patient outcomes and a high economic burden to the healthcare system.

The Use of the technology and Value Proposition

THE TECHNOLOGY

The technology is a combination of hardware and software. It includes a teleconference package, and a large screen with an internet connection and video streaming capabilities.

The setup includes microphone and speakers. The system is installed in a dedicated room for meetings and equipped to enable virtual discussions. Colleagues from international reference centres can connect to the discussion and support the decision process.

The presentation platform is a unique piece of software gathering all patient information on one single access page. The system is installed in the health system's largest teaching hospital, and connected to other hospitals/facilities in the country via a direct integration with meeting platforms such as Zoom or MS Teams, which enhances the Multidisciplinary Teams (MDT)/city collaboration. The software platform is integrated with the EHR.

The different components of the system are connected via Bluetooth, internet, or local area networks. No tool for interinstitutional communication is available, and there is no information/data exchange between institutions.

The technology is not a medical device according to MDR or FDA classification. The system has already been established in other countries and used by virtual Multidisciplinary Tumour Boards.

Security measures include the signing of a confidentiality agreement when patient-related data is involved.

Local firewalls are used to increase navigation security. Cloud storage has not yet been considered, but Cloud implementation is planned to enable image upload and test results in the future.

Data confidentiality and protection is carried out in accordance with the country law on personal data protection (#5669-რს, 28/12/2011).

The system has already been tested in other countries.

THE COST

The infrastructure requires the purchase of a TV, a computer, internet connection equipment, (camera if not included) and an internet subscription with stable connection. The estimated cost per hospital is 15,000 USD, when the hospital does not already possess such infrastructure.

There is an additional software licence cost of around 3,000 USD per institution. This is a subsidised cost, largely sponsored by pharma companies' partners. It is an all-inclusive package including all update costs (push updates).

Based on data from other reference cities, approximately 300 cases of breast cancer and 200 of cervical cancer are the minimum number of patients to justify the use of the technology.

THE USER

The main users of the technology are multidisciplinary teams (MDTs), whose principal aim is to ensure that **every cancer patient receives optimal care as defined by the city treatment guidelines**.

MDTs are typically composed by both core members and non-core members.

Core members are members who are considered as essential because of their contribution to therapeutic management decisions.

Core members will include:

- Medical oncologists.
- Radiation oncologists.
- Surgical subspecialties according to diagnosis (Ex. gynaecologists, oncologists, breast surgeons).
- Histo-pathologists.
- Radiologists.
- Oncology nurses.

Non-core members are not essential to therapeutic management decisions but make a valuable contribution to other aspects of patient care.

Non-core members will include:

- Medical palliative care specialists.
- Palliative care nurses.
- Psychologists.
- Dietitians.
- Spiritual support workers.
- Social workers.
- Pharmacists.
- Laboratory technicians.
- Community health workers.

The roles and responsibilities are defined as follows:

Medical and radiation oncologist:

- Perform consultation.
- Make treatment decisions.
- Present cases.
- Lead multidisciplinary teams.

Surgical Subspecialist:

- Perform consultation and staging.
- Perform biopsies and required surgeries.
- Present cases.
- Make treatment decisions.

Histo-pathologist:

- Analyse biopsies and provide pathology reports.

Radiologist:

- Perform and provide imaging for both diagnosis process, staging and follow-up.

Oncology Nurse:

- Cooperate with the medical team during patient consultation, diagnosis, treatment and follow-up.
- Perform Chemotherapy mixing and administration.
- Perform patient education and follow-up.

Non-core member role in MDT

- Provide holistic assessments to meet palliative care needs for cancer patients and family.
- Provide quality pain management.
- Perform psychological needs assessments and offer support to cancer patients and family.
- Offer social and nutritional needs assessments and support to cancer patients and family.
- Procure both pain medicines and necessary chemotherapy MEDICINES/EQUIPMENT?
- Facilitate referral processes from community to health facility for cancer patients.
- Facilitate discharge processes and follow-up from hospital to the community for cancer patients.
- Provide counselling for newly diagnosed cancer patients and family.
- Facilitate support groups.

Team membership is decided by the core members. Non-core members may also be requested to join, depending on the characteristics and needs of the cases.

Basic training is required to build understanding of the system. This amounts to a one-hour training course provided as an in kind contribution either by pharma companies or the software provider.

Specific access is given to all potential nominated MDT team members of each hospital. Usernames and passwords are provided for the digital MDT software.

PURPOSE OF USE

All cancer types can (and should) be managed using a multidisciplinary collaboration approach. For difficult and advanced cases, the need to use this technology increases given the need for a second opinion and/or tumour board discussion.

The **unmet need** addressed by the technology is:

- The standardisation of an MDT collaboration with access to image sharing, data storage and interoperability with patient medical records.
- Access to second opinion/other specialties.
- Lack of consideration of socio-economic and psychological parameters in treatment decisions.

VALUE PROPOSITION

The technology facilitates multidisciplinary collaboration by enabling structured, virtual communication between the cancer core care team, subspecialty HCPs and other caregivers along the cancer care continuum, and encouraging the exchange of data and information. The DHI thereby increases adherence to treatment guidelines and reduces delays in diagnosis and treatment, which leads to improved patient outcomes and reduced costs.

From a workforce enhancement perspective, the technology offers continuous learning opportunities for team members and empowers relevant staff inside and outside the organisation.

Furthermore, for health centres that do not have access to specialists and subspecialists (for example Radiotherapy and specialised surgeons) the technology provides access to case discussion and more effective cancer treatments.

The tool can also facilitate collaboration between centres of excellence around the globe and thereby improve learning and capability-building.

HOSPITAL / SITE EXPERIENCE

The main improvements that can be catalysed by within the organisation are related to access to external/second opinion. The case discussions and expert support fostered by an MDT management approach have fostered better treatment decisions, innovative solutions and implementation of evidence-based treatment guidelines.

Moreover, the communication and collaboration between the care team members has significatively improved. This includes the nursing team, who have been empowered to become patient navigators. Moreover, the continuity of care and referral process among institutions is enhanced, for example patients from lower-level care institutions are referred to providers of higher and more complex care and vice versa.

The communication is restricted to the HCP level; patients or family members are not included or considered.

No specific KPIs or metrics have been collected to measure the experience of the hospital/ site nor have any quality improvement measures been established.

It can be observed, however, that more MDTs have been created and implemented, to the extent that most cancer types now have a subgroup for treatment decisions. Consequently, the quality of care has improved.

The workforce motivation and level of engagement of the team has also increased. Team members feel that they are not left alone in difficult diagnosis and treatment decisions, and decisions can be made in a more informed way through enhanced collaborative knowledge and expertise

CLINICIANS' AND OTHER HCPS' EXPERIENCE

MDT training is part of the city's project focus. The quality measures of the project include scientific Visits to reference centres with established routine MDT working patterns for best-practice sharing. The visits were followed by an on-site workshop with international experts to resolve enquiries and support MDT implementation.

- To ensure staff gain the skills to use digital MDTs, basic internet access, connectivity to the platform and EMR are required. Most MDT members are well-trained in the required skills.

Medical team users typically face an initial steep learning curve regarding MDT collaboration. Over time, however, as the benefits of MDT approaches have become clearer, the adherence and willingness to participate has increased. Trust in the MDTs for decision-making has also increased.

Several issues for care teams have also been resolved, especially the reduced number and availability of certain specialists. The inclusion of pathologists/imaging specialists as core members of the MDT has notably improved response times for diagnostic tests and pathology results.

- Improved quality of diagnosis, treatment decision, adherence to clinical guidelines have all been observed. No cross-comparison with patient outcomes has been performed.

Overall, team members value the improved support for decision-making and the increased learning opportunities catalysed by the new approach.

- Internet connection has become more stable, although its velocity can affect the communication at times, but no power outages have yet interrupted the system's functionality.
- An email invitation with a link is sent to each participant to ensure access to email and communication platforms.
- Each hospital receives IT support to help HCPs to continuously use the platform.

PATIENT EXPERIENCE

Improvements to the patient experience, such as shorter periods for diagnosis and treatment, have not yet been measured. However, the perception of improvement is evident within the team.

Adherence to cancer type guidelines has notably improved. Monitoring and prevention of side effects/treatment complications has also been included with the feedback and participation of team members such as palliative care, nutrition, nursing. In consequence, patients are treated in a holistic manner, improving both treatment adherence and quality of life.

Advancement to the second/third line of treatment is decided in MDT meetings once other treatment alternatives have been considered. Dose adjustments are performed primarily by the treating oncologist.

Patient education and health literacy improvement should be part of the MDT/tumour board discussion, but have not yet been included as a topic.

Patients and their families should be better informed about the outcomes and decisions of the MDTs, specifically regarding decisions on treatment plans to increase the patient's adherence and empower them to better cope with their disease.

EVIDENCE ON THE BENEFIT OF THE TECHNOLOGIES

No data have been collected to demonstrate the clinical benefits of digital enablement of MDTs.

However, the suggested data points and information are very important and should be considered by the different stakeholders.

Compliance with clinical guidelines and documentation of deviation from guidelines have been measured for the first time thanks to this project. A first estimate is based on 40% of the documented cases for guidelines compliance. Among this 40%, 60% show strict compliance and 40% have documented reasons for deviation.

FThe one-year and five-year survival rates are monitored but results are not available yet due to the longer time horizon.

The project is tracking the number of patients from satellite hospitals who do not need oncologist consultation in the main teaching hospital. First data estimates show that 30% of patients in satellite hospitals are no longer referred to the teaching hospital for confirmatory diagnostics and treatment decisions.

Surveys are also being conducted for patients from satellite hospitals, comparing those hospitals that are participating and the ones that aren't. It is difficult to ascertain the precise impact of the MDT platform, although a marginal satisfaction increase of 5% has been demonstrated in participating hospitals.

A survey conducted in the teaching hospital shows a 65% satisfaction rate of patients' families regarding the process and transparency of treatment decision-making. A previous survey conducted 10 years ago showed a 30% satisfaction rate.

Case 3
DHT with Telepathology

Preface

This hypothetical case study should provide an example of a typical use case to fund/reimburse physician-facing digital health technologies. Specifically, the case study will help us to test the preliminary payer value framework for the evaluation of Digital Health Interventions (DHIs) for cancer care in low-to-middle income countries (LMICs) with key stakeholders in different countries/ healthcare systems.

The focus of this use case is on a DHI with **Telepathology.**

Please read this case study and the value framework to address the following questions:

1. Which information for each value domain and subdomain is most important for you to make a funding / reimbursement decision of telepathology?
2. What level of evidence do you require to grant funding and reimbursement of Telepathology?
3. What information do you think is missing in the provided use case to make a funding/reimbursement decision?

Your feedback on the different value aspects and level of evidence needed to grant reimbursement/ funding will inform the basis of practical guidance for payers and funding decision-makers.

Healthcare System Context

eHEALTH CONSIDERATION

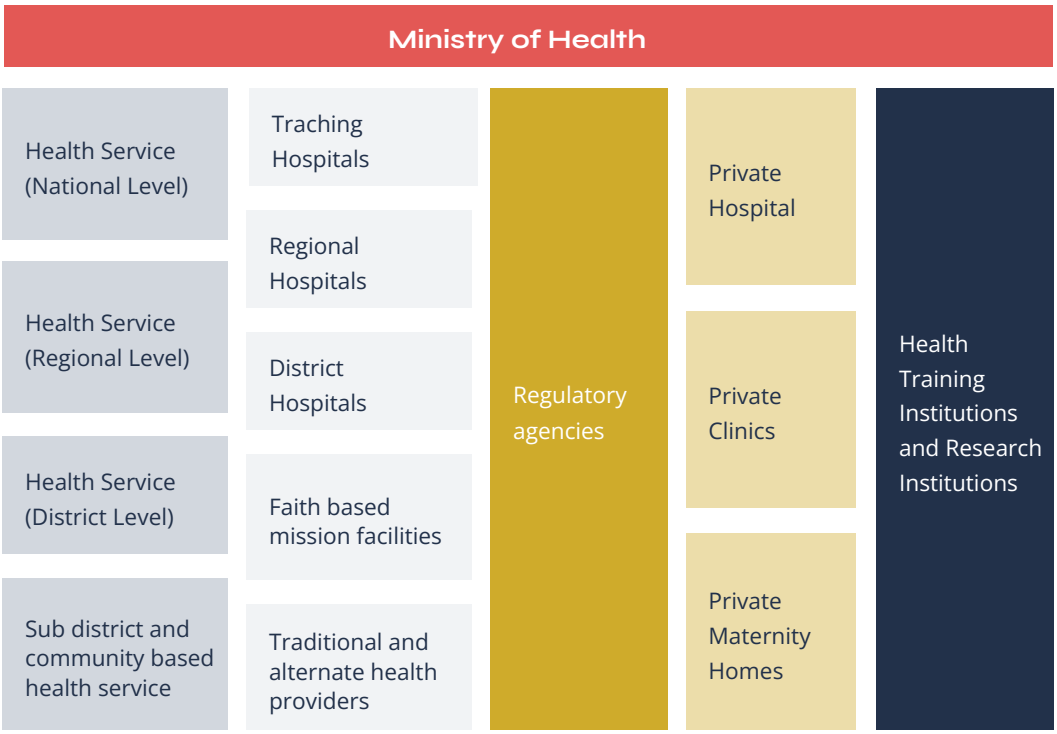
The Healthcare system in which the Telepathology technology is being considered established an eHealth strategy in 2010 to accelerate progress towards Millennium Development Goals.

Information and Communications Technology infrastructure improvements include new computer equipment for hospitals, multimedia systems, imaging devices, communication, and internet systems.

However, the development of a well-defined e-health architecture is still in progress. The existing systems are not based on any defined standards for data collection or data processing. Most applications are running "in silos" on different operating systems. The use of health management information is not widespread and mostly concentrated in the capital via the District Health Information Management System.

EXPECTED HEALTH INFRASTRUCTURE

This figure provides an overview of the structure of the healthcare administration.



Laboratory Services in the city are a mix of public and private institutions, including the Christian Health Association. These laboratories provide services to the health facilities but are stand-alone institutions.

In total, there are 28 hospitals, of which 20 are private and 8 public.

The total number of pathology labs is 10 of which one is tertiary, eight are secondary and one is at primary level.

PRIORITY AND COVERAGE OF CANCER CARE

Under the National Strategy for Cancer Control, the priority of cancer has been elevated with a specific focus on improving access and the quality of treatment and care for different types of cancer.

The country has established national health insurance for health care service payments. The National Health Insurance Benefit Scheme covers diagnostics and treatment of cervical and breast cancer. Other cancers are not covered.

Population: overall, there are **3,348,000 inhabitants**. The **incidence of cancer** is estimated to be **46,1 new cases/ 100 000 inhabitants (at city level). At the country level, there were 24,009 new cases** in 2020. The **5-year prevalence** was **47,029 cases**.

Overall, there are 4'000 tissue samples per year to be evaluated and 700 samples for immunohistochemistry analysis.

THE HEALTHCARE PROBLEM TO BE SOLVED WITH TELEPATHOLOGY

There is a delay in cancer diagnosis and consequently in treatment initiation, specifically in complex cases, due to a lack of capacity and capability in pathology services. Modern diagnostics and treatment of cancer require multidisciplinary collaboration. Often, there is a need for further testing including flow cytometry. This should be confirmed with a second opinion or consultation of other experts. Currently, however, this is rarely done.

The Use of the technology and Value Proposition

THE TECHNOLOGY

Telepathology is about digitising pathology slides via slide scanners, enabling the sharing of slide images and remote slide reading and interpretation.

Different kinds of scanners were deployed:

- Two at high capacity in two of the country's main laboratories.
- Low throughput scanners (different brands, sourced mostly second-hand).

Each scanner operates on its own embedded software, sending scanned information to the Laboratory Information Management System (LIMS). Each laboratory has its own LIMS. The telepathology solution is operating based on a health information exchange between different LIMSs. These systems are not included in the project, but have already been deployed in laboratories. However, the health information exchange infrastructure was deployed in the context of this project.

The tele-expertise is mostly delivered by designated expert pathologists who are part of the network of participating laboratories. Around 25% of pathologists are currently providing tele-expertise.

The technology has an on-demand embedded cell count solution on images being transmitted to support and accelerate the remote slide reading.

For the transmission of telepathology images, appropriate connectivity, bandwidth, and computing capabilities should be in place to support the transmitted image type. Bandwidth for real-time viewing of images will be higher than for asynchronous transmission.

Internet connectivity can therefore be an issue but real-time viewing is not really essential.

The slide scanners and the cell count system are all medical devices. However, the health information exchange software component is not.

THE COST

Slide scanners with low throughput are sourced at an average cost of 12,000 USD each. The high throughput scanners cost about 45,000 USD. However, these two have been donated as in-kind assistance. The maintenance of the scanner is absorbed by the existing maintenance teams of the healthcare facilities and adds insignificant costs. The in-kind software package includes a period of 10 years of updates.

The cost of the LIMS is not included in the overall project cost but is a pre-requirement. Mostly open-source software is used.

The cost of the health information exchange infrastructure amounts to around 30,000 USD for its development. Recurring costs are around 5,000 USD / year.

Added cost is the need for backup power supply and a storage area for the physical samples (parafina) with temperature control.

The average internet, storage and other recurring cost per year is around 6,000 USD / year per laboratory.

Capacity to get high stable internet/quality service is a challenge for facilities across Sub-Saharan Africa. Connectivity is expected to improve drastically in 2024.

THE USER

The users of the technology are pathologists with training and certification in telepathology (American Society of Clinical Pathology has a course). Basic knowledge and availability of a laboratory information system is also a requirement.

To have the infrastructure to house this equipment/slides. The slides shouldn't be transported to other facilities for scanning.

PURPOSE OF USE

The technology is mainly used for

- the diagnosis of difficult, complex cancer cases.
- the diagnosis of undifferentiated tumours.
- advanced testing, such as semi-automatic FISH quantification on digital slides and flow cytometry.
- interoperative consultation.
- rapid cytology.
- multidisciplinary interaction (Tumour Boards).

The **unmet need** addressed by the technology is the **time delay in diagnosis and treatment of complex and difficult cancer cases due to a lack of capacity and capability of single centres.**

The project is realised in partnership with international professional organisations and vendors (ASCP, CAP as professional associations, Thermofisher, Leica as support tech providers, CHAI as implementing partner)

The main purpose of the technology is to improve the quality of the diagnostic, optimise laboratory processes which can accelerate the diagnostic process and lead to more accurate diagnosis.

VALUE PROPOSITION

Telepathology allows:

1. external consultation of difficult cases, consultation of experts in real time to provide guidance. This in return will improve the diagnostic capacity of the department.
2. Faster turn-around of diagnostic cases.
3. Training and capacity building (training other pathologists in LMICs).
4. Quality assurance (the external lab will control the slide quality/production of the associated lab, providing feedback, suggestions, adjustments to technique, process...).

Ultimately, complex cancer cases can be detected earlier, and personalised treatment initiated earlier which increases the chances of better survival and/or patient's quality of life.

HOSPITAL / SITE EXPERIENCE

The combination of LIMS and telepathology is improving the workflows of the laboratories, who are struggling to get proper image interpretation done by the pathologists. 40% of pending cases who are waiting for interpretation can be reduced with telepathology systems.

However, digitising the slides is disrupting the traditional workflow because digital pathology is still seen as an "exception": Digitization may on one hand reduce the workload of the pathologists but may increase the workload of lab technicians.

A first quality audit by an external certification body was conducted in 10 participating laboratories. The audit showed that the quality of diagnosis has improved drastically on complex cases. However, there is no systematic quality measurement process to verify the impact of telepathology vs without the deployment of telepathology.

Telepathology is a component of a broader quality improvement program including ambitious capacity development.

For the hospital, Telepathology technology offers a revenue opportunity for the laboratories doing the remote reading by charging a tele-expertise fee of 30 USD /service to laboratories that request the service. This is already used in the private sector.

CLINICIAN EXPERIENCE

EASE OF USE

Users require specific training in telepathology. Once they are trained, the use of the technology is easy.

QUALITY

The quality of the outputs varies with the age of the scanner technology: older scanners deliver lower quality outputs which do not allow diagnosing complex cases. 10% of the slides do not match the quality standards.

INTEROPERABILITY WITH OTHER SYSTEMS

There is full interoperability between LIMS thanks to the health information exchange. However, no integration of LIMS with HMIS yet.

RELIABILITY OF THE SYSTEM

Given that the images are stored in a cloud, once the slides are scanned, the images are sustainably saved and accessible for a long time. The physical slide has the risk of being lost/ broken. It is of great value to have this reliability component.

The facilities are implementing backup batteries, solar power, etc. to prevent power outages that interrupt the scanning process.

ACCESSIBILITY OF THE SYSTEM

Each device has a different type of system access that requires a username and a password. Each staff member needs to be identified individually. The use is restricted to pathology laboratory staff with training and credentials.

Reference laboratory designated staff are the only ones who can do remote reading and therefore have access to that part of the system.

AVAILABILITY OF TECHNICAL SUPPORT

The vendors of the systems provide remote training which requires the availability of high-speed internet. Professional organisations like ASCP mandate local trainers depending on financial resources available with them.

IMPACT ON WORKFLOW AND WORKFORCE

Users have a quick learning curve due to most residency programs. The technical training for support staff includes the introduction and exposure to telepathology. More specific training is required for each type of technology, but overall, they are similar in their procedures.

The technology improves the turnaround time for diagnoses and the quality of diagnosis. By improving the quality of the pathology products, the overall quality of the practice improves.

Negative impact can be the staff attitude towards technology, adopting a technology changes the culture.

Moreover, the burden of additional maintenance can affect the existing maintenance staff of the healthcare institutions.

The staff's morale is affected when the equipment is down and not available for use.

PATIENT EXPERIENCE

There is no data on patient satisfaction available for telepathology.

EVIDENCE ON THE BENEFIT OF THE TECHNOLOGIES

The benefits of the technology are described in peer-reviewed publications:

- Overview of telepathology: https://doi.org/10.1016/j.path.2015.02.018
- The role of telepathology in diagnosis of pre-malignant and malignant cervical lesions: Implementation at a tertiary hospital in Northern Tanzania. DOI: 10.1371/journal.pone.0266649
- Diagnostic digital pathology implementation: Learning from the digital health experience. DOI: 10.1177/20552076211020240

CLINICAL BENEFIT

The average time for transmission of an image and review by a remote pathologist was 10 minutes per case. Consequently, the time to diagnosis was improved given the resolution of difficult cases and diagnostic questions with the fast response of a second opinion.

The system achieved a 40% reduction of cases waiting for review and interpretation by pathologists for more than 2 weeks.

It was also shown that around 20% of all slides are now digitised and sent for peer-review using the telepathology system.

Evidence shows a concordance of diagnosis with a second opinion laboratory located in the US of 97% which shows good practices for diagnostic pathology in the country. Patients were obtaining the right diagnosis prior to treatment start.

Regarding the risk of misidentification/misdiagnosis, a comment was made by the city pathologist stating that the risk is still present to have errors in uploading/labelling the scanned slides, file corruption in the cloud, malfunctioning servers. However, the risk of tissue/slide damage is completely reduced with the scanning.

Time to start treatment is reduced for difficult cases that require a second opinion. In addition, the need for a second sample or extended tissue sampling is decreased.

However, it is difficult to measure these data points due to lack of a patient tracking system.

The participation of external experts in Multidisciplinary Tumour Boards via telepathology, the revision of the quality of the slides compared to international standards, and the ability of further testing improves the overall care pathway and has a very positive impact on the quality of care.

The more precise the diagnosis prior to starting the treatment, the better the outcomes for the patient can be.

Qualitative surveys support these benefits. But quantitative data are lacking due to lack of systematic patient monitoring and tracking.

ECONOMIC BENEFIT

Extrapolations were made based on productivity increase: Results showed savings of 18.6% (8 out of 43) in operational cost of the department allocated to those indications, which is 8% of overall cost of the department.

In terms of resource use, numbers were extracted from HER on readmissions, survival rate, etc. However, it was deemed difficult to isolate the impact of DHI among other changes in the departments involved in oncology care.

No specific collection but extrapolation on misdiagnosis reduction based on company data.

Benefit of Care Structure/Organization

By promoting the implementation of telepathology the current laboratory infrastructure will be strengthened and have a well-structured QC program that includes best practices for the overall organisation.

Telepathology is also used as a training platform to upskill pathologists who are not remotely present in centres of excellence. The training is recognized as a key reason and benefit to invest in the program, to upskill the workforce outside of the capital area. 60% of pathologists do not have access to continuous upskilling due to their remote location. Around 20% of those have started a mentorship program with expert pathologists

Case 4

DHT with Evaluating Treatment-related Symptoms of Cancer Patients, with and without AI

Preface

This hypothetical case study should provide an example of a typical Use Case to fund/reimburse physician-facing digital health technologies. Concretely, the case study will help us to test the preliminary Payer Value Framework for the evaluation of Digital Health Interventions (DHIs) for cancer care in low-to-middle income countries (LMICs) with key stakeholders in different countries/ healthcare systems.

The focus of this Use Case is on a DHI with **Evaluating Treatment-related Symptoms of Cancer Patients, with and without AI.**

Please read this case study and the Value Framework and address the following questions:

4 Which information for each value domain and subdomain is most important for you to make a funding / reimbursement decision of using a digital tool for the evaluation of treatment-related symptoms of cancer patients with and without AI?

5 What level of evidence do you require to grant funding and reimbursement for this Digital Technology?

6 What information do you think is missing in the provided use case to make a funding/ reimbursement decision?

Your feedback on the different value aspects and level of evidence needed to grant reimbursement/ funding will inform practical guidance for payers and funding decision makers.

Healthcare System Context

eHEALTH CONSIDERATION

The Healthcare system in which the Digital Health Technology to evaluate treatment-related symptoms of cancer patients is being considered, has established an eHealth strategy in 2013 with a time horizon to 2019. The technology of concern in this case study is part of two strategic pillars of the eHealth strategy "Healthcare Workers'sTime Saving" and "Patient Empowerment".

EXPECTED HEALTH INFRASTRUCTURE

The infrastructure, where the technology is being considered:

5
public tertiary hospitals and 7 private tertiary hospitals

20
district hospitals

+300
primary hospitals and private clinics

Currently, the 5 tertiary hospitals and 20 community sites are using the dual modality technology – patient navigation and AI component for clinician's use. The technology is deployed in batches.

PRIORITY AND COVERAGE OF CANCER CARE

Cancer care is part of the 10-year non-communicable disease strategy with a priority for skin, lung and breast cancer.

Universal Health Coverage (UHC) is in place to cover healthcare services in public facilities without fee or co-payment. There are financial transfers from the central federal government to state owned hospitals to cover the cost of operations, not on the basis of fee per patient, but on department budget request basis.

A full coverage of health services depends on the availability or provision of the service at the site/hospital.

The out-of-pocket payment rate is 50% which is still high as patients often choose to get treatments in private facilities depending on their availability, quality of treatment and time. Private sites are easily accessible in terms of waiting time and geographical presence, while offering better attention to patient and perceived quality of care.

Population: overall, there are **11,000,000 inhabitants**. The **incidence of cancer** is estimated to be **30'000 new cases per year.**

THE HEALTHCARE PROBLEM TO BE SOLVED WITH A DIGITAL TOOL TO MANAGE TREATMENT-RELATED SYMPTOMS IN CANCER PATIENTS

There is a lack of resources in clinical staff to ensure a proper patient monitoring and follow-up. This leads to poor patient outcomes, a high rate of hospitalizations and emergency consultations which result in an unnecessary overload of tertiary hospital capacities with patients that could be managed in primary or secondary care centres.

The Use of the technology and Value Proposition

THE TECHNOLOGY

The Technology is a desktop application for patient monitoring, connected to the oncology module of the tertiary centre's EHR for patient tracking and identification of patients in triage.

The technology includes a backend to set up parameters of monitoring and triage at the institution level. An AI recommendation engine is embedded that helps inform the triage process of the patients. However, the AI is still a research component. Data is collected by the care team on a regular basis to adjust the logic of the algorithm.

The system located at the tertiary site is connected with a community/patient mobile App on the other side to collect data from patients and community nurses.

The system is used in two different ways:

Use Case 1

For patient tracking, as scheduling assistance, and reminder for follow-up visits.

Use Case 2

Triage for survivorship management and symptom management by patients by refining the criteria for the triage algorithm and improvement of the triage process.

For Use Case 2, the user needs access to a mobile device either directly or through the community healthcare professional who acts as an intermediary with patients in the community. Currently, there is good connectivity coverage in the country except for 5% of the most remote communities.

The technology is not a medical device.

The software is deployed as per national security standards (hard modification of the code needed in terms of storage security, transparency of the triage algorithm and continuous quality management).

A dashboard enables clinicians to change parameters (e.g., cancer type, treatment modalities, demographic, geographic, name of primary healthcare centre, as well as what gets reported in the app: intensity of symptoms, mental health status, etc.) as per their needs. There is no central control or policy to change system parameters; instead, every institution is drafting its own parameter change policy. However, the state government considers drafting a policy to regulate such adjustments but is lacking capability at this point of time.

Overall, **5'800 patients are monitored during 12 months** of usage, out of those, 2'200 cases account for use case 2 (triaging).

200 cases are **from private accounts** and **2'000 cases** come from the **community care intermediary**.

There is no direct patient education campaign but a big effort of change management in community centres.

THE COST

The initial purchase and local customization cost amount to 120,000 USD for both technology components.

The software ownership is now at the local level. The approximate data storage and maintenance cost are around 10,000 USD per year per tranche of 5,000 patients.

THE USER

The main users are nurse navigators, resident oncologists and patients.

For **Use Case 1, nurse navigators** are using the tools to schedule follow-up visits with patients. For them the objectives are to ensure sustained follow-up of the patient, prevent drop out of the patients on their complicated care journey and to save time.

In **Use Case 2, patients** record their symptoms during treatment and the clinical teams (**resident oncologists**) use the data to identify cases eligible for a followed-up visit at the care centre.

All users receive different types of training:

1. Care teams are intensively trained on the navigation of patients, including a module on optimal usage of the platform as part of patient navigation workflows.
2. Patients and families are trained in hospital during visits if they are considered as likely to directly use the platform.
3. The biggest part of the training program is to train community healthcare workers to act as intermediaries to the communities.

PURPOSE OF USE

The **main indications** for which the technology is used are **Breast, cervical and skin cancer**. These indications are **prioritised for navigation training purposes**, but each institution is free to use it for all cancer indications. In practice, a broad range of cancer sites is represented on the platform.

The **unmet need** addressed by the technology is the **shortage of resources of clinical teams** to ensure a proper patient monitoring and follow-up.

Many patients seek care at the tertiary centre when they would not need to and leads to an overuse of hospital capacity.

The purpose of using the Digital Evaluation of Treatment-related Symptoms in Cancer patients is to:

1. Reduce of dropout rates from the complete diagnostics journey.
2. Help patients to complete their treatment cycle.
3. Reduce the time spent per patient on follow-ups, aiming at ensuring 100% follow-up coverage which was a vastly ignored topic before the use of the technology.
4. Decrease the number of visits to hospital by triaging only the necessary visits to maintain hospital capacity and reduce consultation cost. The AI component of the technology should help achieve this objective by improving the model parameters.
5. To increase patient survival as there is a high need to reduce return to hospital.

HOSPITAL / SITE EXPERIENCE

The collaboration scheme is centrally driven by the state government. All public hospitals benefit directly from data sharing agreements. Otherwise, each institution willing to participate needs to adhere to the standard agreement with the State Government.

There is resistance from some private institutions to share data with public authorities.

Around 40% of community centres are satisfactorily responding to defined workflow after 12 months.

There is a clear benefit in terms of workflow improvement related to patient follow-up as roles and responsibilities among the users are clearly defined and the accountability is enabled by the platform. Data from the monitored patients are visualised for the department heads and their operational decision making is enabled.

Data from Monitoring & Evaluation show a reduction in oncology patient flow returning to hospitals by 11%.

However, these data cannot be qualified in terms of the patients' need for a physician's consultation or physical examination. These parameters are not trackable yet. Hence, it is difficult to interpret whether this has a positive or negative impact on the patient's disease management. A new indicator has been introduced for clinicians to assess the importance of the on-site visit and will be available in 6 months.

The triage functionality is showing highly variable results per institution. One institution has avoided up to 60% returning patients thanks to the advice to community health care workers and teleconsultations, the lowest rate being around 30%. On average the program is at 44% reduction of hospital revisits.

For private hospitals, the use of the technology could help drive patient and community satisfaction leading to a revenue opportunity for private community centres to monetize their intermediation with patients.

However, for the public centres there is no direct revenue opportunity but a benefit in terms of efficiencies in the clinical operation.

CLINICIAN EXPERIENCE

Clinicians receive intensive training on patient navigation, follow-up and triage **as they** control the follow-up and triage parametersInitial feedback shows that it takes the user's 2 weeks of regular usage to understand the details of the solution at tertiary level.

Some teams **show a** poor adoption **of the technology as they only** partially attended the training.

Results are highly dependent on the parameters set by clinicians **in terms of** follow-up adherence and **of the** response rate of communities **due to the complexity of this multi-layered initiative**.

Results are so far highly variable from one institution to the other, which has driven the State Government to consider **developing a** policy **based on** the lessons **learned from the use of the program. This policy has not yet been implemented.**

The system **is perceived to be reliable**. The only issue so far is the device down-time at community level.

The interoperability **of the system works in so far as** EHR connects in two-ways: the patient symptoms/triage reports are exported back to the EHR, as well as the communication history.

At the tertiary site level, the system can be accessed by designated clinicians on a desktop or tablet. At the community or patient-level, patients and/or community workers can access the system on a mobile phone or tablet.

Technical support is available from the State Government IT team. Some issues of delays in responding to requests have been highlighted.

Users show a massive learning curve, depending on the sense of ownership of the tertiary hospital. As they have control on parameters, they trust what they set for themselves, and the AI helps evolving their thinking.

In terms of workforce improvements, users show a better accountability for the follow-up of patients.

About 80% satisfaction among oncologists involved as they can reduce waiting lines and do more value addition consultations.

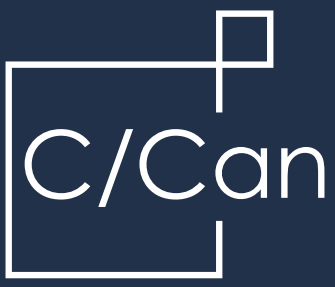
PATIENT EXPERIENCE

Patients feel to be better monitored and taken care of. The systems help to avoid unnecessary travels for follow-up visits to tertiary sites.

The patient pathway is substantially improved by the community healthcare worker as a mediator between clinician and patient through improved communication. Community health workers highlight the fact that they are now directly listened to and have a platform to raise the voice of the patients. There is a 77% satisfaction level of community health workers that have been involved for more than 3 months.

EVIDENCE ON THE BENEFIT OF THE TECHNOLOGIES

M&E and satisfaction survey data are available to demonstrate the reduction in hospital returns and improvement in clinician, healthcare community worker and patient satisfaction. Please see chapters 2.5.1, 2.5.2 and 2.5.3 above.



https://citycancerchallenge.org/

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