HAUTE AUTORITÉ DE SANTÉ

ASSESS
HEALTH TECHNOLOGIES

METHODOLOGICAL GUIDE

Organisational impact map for health technology assessment

Validated by the HAS Board on 10 December 2020

Description of the publication

Title	Organisational impact map for health technology assessment
Work method	Methodology guide prepared based on an overview of European and international health technology assessment practices, a review of the literature, and the opinion of experts assembled within a methodology guidance group
Purpose(s)	The purpose is to clarify the aspects associated with the organisational impacts of a health technology (medicinal products, medical devices and procedures) by drawing up a map aimed at both defining these impacts and at proposing criteria to assist with their documentation.
Targets concerned	Manufacturers, professional organisations, institutions, service providers, patient and user representatives
Requester	Self-referral
Sponsor(s)	*Haute Autorité de santé* (French National Authority for Health) (HAS)
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Preliminary information

Health technology assessment: a necessary update

In its [1] 2019-2024 strategic project, the HAS sought to place technological and organisational innovation at the heart of the institution's strategic orientations. Assessing the organisational impact of innovations was identified in this strategic area.

The organisational impact of a new technology becomes a major source of leverage for our healthcare systems, for updating the care and life pathway for users' and professionals' benefit. Some technologies give rise to a reorganisation of the healthcare system, particularly in the case of digital technologies.

In order to better understand the scope of this assessment of health technologies (medicinal products, medical devices and diagnostic and therapeutic procedures), it is first of all necessary to set out the relevant outlines.

The organisational impacts of a health technology can have a structural role in multiple aspects of the organisation and from the perspective of various stakeholders, in particular for patients and users.

In this methodology guide, the HAS has sought to clarify the aspects associated with the organisational impacts of health technologies by drawing up a map aimed at both defining these impacts and proposing criteria to help justify them.

This map does not indicate how the organisational impacts of a health technology will be taken into account in each HAS committee (CNEDiMTS, CEESP, CT) and by the HAS Board.

Organisational impact-related aspects are frequently claimed in medicinal product, medical device and diagnostic and therapeutic procedure assessments; they also represent one of the eligibility criteria for economic assessment.

However, this aspect of the assessment is still rarely documented and is generally confined to descriptively reported data.

The lack of a structured framework for defining the effects of the technology on the healthcare system is probably one of the main reasons for this.

Organisational impact map

The map helps specify the context of the health technology under assessment and structure how organisational impacts may be identified according to the stakeholders2 concerned: for this purpose, it proposes a classification composed of macrocriteria and criteria accompanied by examples of indicators.

Within each macrocriterion, a choice of criteria is identified corresponding to the most relevant organisational impacts, along with the indicators for depicting each criterion selected.

[1] Haute Autorité de santé. 2019-2024 Strategic Project. Saint-Denis La Plaine: HAS; 2018. https://www.has-sante.fr/upload/docs/application/pdf/2018-11/projet_strategique_2019-2024.pdf

[2] A stakeholder is deemed to be any individual or legal entity having an interest in the care or life pathway (see section 2.2 Terminology).

It is aimed at manufacturers and service providers for medicinal products and medical devices and at professional organisations and institutions3 within the scope of the assessment of a diagnostic and therapeutic procedure in order to provide information, where required, on the different aspects of the organisational impact of the health technology under assessment and the parameters used to measure them.

Selective map use

This aspect of the assessment is not intended to be used systematically. However, when an organisational impact is mentioned or claimed for a health technology under assessment, it is necessary to identify its components and demonstrate how it modifies the existing system.

This map is intended to be informative and must be used as such: to help identify the most relevant organisational impacts (positive or negative) according to the stakeholders concerned and the parameters for measuring their effects or for their justification.

As a result, it is not expected that all of the criteria proposed in this map be completed.

The map has been drawn up based on the literature and the opinion of experts assembled as part of a methodology guidance group (MGG) to allow adaptation to all medicinal products and medical devices, and to the assessment framework of a diagnostic and therapeutic procedure. Its potentially broad scope and the density of the proposed criteria are explained both by the intensity and the variety of the relationships between the technology and the system, and the need to reach a shared definition.

A health technology can have multiple organisational impact, concerning multiple stakeholders. They can be assessed when the health technology is introduced (organisational changes needed during the set-up phase) or during its rollout (organisational changes created by its use over time); they can also be positive or negative in terms of the health technology under assessment, immediate or delayed, temporary or permanent.

The map must be used to identify and document the relevant organisational impacts.

Map overview

The map **is made up of 3 parts** which are described in detail in the following sections:

- Part I: "Assessment context" (section 3)
- Part II: "Macrocriteria and criteria" (section 4)
    - Macrocriterion 1: impact on the process
    - Macrocriterion 2: impact on capabilities and skills
    - Macrocriterion 3: impact on society and the community
- Part III: "Stakeholders concerned" (section 5)
  For each criterion, it is necessary to specify the stakeholder(s) concerned: this may be the patient, a carer, a healthcare professional, but also a healthcare facility or institution, a manufacturer or any other stakeholder involved in the delivery of care and services.

The diagram below shows a summary of the map structure.

[3] An assessment of diagnostic and therapeutic procedures may be requested by professional organisations, the Association of Health Insurance Funds (UNCAM), the National Health Insurance Fund (CNAM), the French Ministry of Health, patient associations.

PART I

Assessment context

Is a conventional care solution available ?	A	**YES** The HT changes the existing conventional care (need met, existence of clinically relevant alternative)
	OR	
	B	**NO** The HT creates conventional care (unmet need, lack of clinically relevant alternative)

PART II

Macrocriteria and criteria

Macrocriterion 1	Criteria	
Impacts of the HT on the care **PROCESS** *This macrocriterion accounts for the sequence of activities carried out in the patient's life and care pathway*	1.1	Modifies times prior to initiation of the process
	1.2	Modifies process pace or duration
	1.3	Modifies process timing or content
	1.4	Modifies number or type of staff involved in the process: quantitative view of human resources
	1.5	Modifies the type or frequency of use of products, de-vices, materials, equipment, infrastructures and infor-mation systems used in the process: view in terms of material or digital resources
	1.6	Modifies the quality and safety of the environment or context in which the process takes place
Macrocriterion 2	**Criteria**	
Impacts of the health technology on the **CAPABILITIES** and **SKILLS** required of stakeholders to implement the care process *This macrocriterion includes organisational capabilities, skills and sharing of skills, working conditions, funding, etc.*	2.1	Modifies the stakeholder's required skills (knowledge, know-how and social skills), and expertise associated with the delivery or provision of care
	2.2	Modifies the ability to share and transfer skills, knowledge, know-how with other stakeholders
	2.3	Modifies scheduling and planning capacities for health care services or the patient or carer
	2.4	Modifies scheduling and planning capabilities between care structures or combinations of stakeholders
	2.5	Modifies stakeholders' working conditions or living conditions
	2.6	Modifies the terms, nature or source of stakeholders' funding
Macrocriterion 3	**Criteria**	
Impacts of the HT on **SOCIETY** or the **COMMUNITY** *This macrocriterion is a more general level of analysis compared to the previous two macro criteria and focuses on*	3.1	Impact on community in terms of health and safety
	3.2	Impact on social inequalities or accessibility to care
	3.3	Impact on social or work relationships or in terms of society as a whole
	3.4	Impact on environmental footprint

PART III

Stakeholders concerned

Stakeholders A	Stakeholders B	Stakeholders C	Stakeholders D	etc.

1. Context and steps of process

1.1. Context, purpose and method

1.1.1. Context

The HAS has drawn up this map in order to be able to take better account of the organisational impact in the assessment of health technologies (HT)[4] (medicinal products, medical devices and diagnostic and therapeutic procedures) where it is claimed or relevant.

This self-referral also follows the recommendations of the French Healthcare Industry Strategic Council (CSIS)[5].

Assessing health technologies in order to inform the decision-maker with a view to their authorisation for reimbursement by National Health Insurance, and within the scope of the negotiation of their price, is one of the regulatory duties of the HAS.

> Health technologies[6] refer to all interventions used by healthcare professionals for the purposes of acute or chronic disease prevention, diagnosis, treatment and rehabilitation. This broad term specifically targets, within the scope of this work, healthcare products, medicinal products and medical devices (MDs), and diagnostic and therapeutic procedures.

Clinical health technology assessments are conducted by the Transparency Committee (CT)[7] for medicinal products, by the Medical Device and Health Technology Evaluation Committee (CNEDiMTS) for medical devices and other healthcare products[8] and by the HAS Board for diagnostic and therapeutic procedures.

These health technologies can have impacts beyond the strict clinical, diagnostic or disability compensation benefit assessed for the patient, affecting the overall healthcare system from the perspective of the different stakeholders involved.

The organisational impact of medicinal products, MDs and other healthcare products is taken into account via the public health impact (PHI) which is an assessment criterion of the public health benefit; as for diagnostic and therapeutic procedures, clinical and organisational aspects are incorporated in health technology assessment reports prepared by the HAS.

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[4] Haute Autorité de santé. 2019-2024 Strategic Project. Saint-Denis La Plaine: HAS; 2018. https://www.has-sante.fr/upload/docs/application/pdf/2018-11/projet_strategique_2019-2024.pdf. Action sheet No. 9: organising the analysis of the impact of organisational innovations and systematising the analysis of the organisational impact of technological innovations

[5] French Prime Minister. Healthcare Industry Strategic Council. Paris: Hôtel de Matignon; 2016. http://www.gouvernement.fr/sites/default/files/document/document/2016/04/11.04.2016_rapport_conseil_strategique_des_industries_de_sante.pdf

[6] Haute Autorité de santé. General description of the diagnostic and therapeutic procedure assessment procedure. Saint-Denis La Plaine: HAS; 2018. https://www.has-sante.fr/portail/upload/docs/application/pdf/2018-03/has_methode_generale_actes_08_03_2018.pdf

[7] Haute Autorité de santé. Principles of medicinal product assessments conducted by the Transparency Committee to determine reimbursement eligibility. Saint-Denis La Plaine: HAS; 2018. https://www.has-sante.fr/upload/docs/application/pdf/2018-10/doctrine_10102018.pdf

[8] Haute Autorité de santé. Assessment principles established by the Medical Device and Health Technology Evaluation Committee (CNEDiMTS) to determine the reimbursement eligibility of medical devices for individual use. May 2019 update. Saint-Denis La Plaine: HAS; 2017. https://www.has-sante.fr/upload/docs/application/pdf/2017-11/principes_devaluation_de_la_cnedimts-v4-161117.pdf

However, this aspect of the assessment is still not extensively documented or justified and is generally confined to descriptively reported data.

The French Social Security Funding Act for 2012 supplemented the healthcare product (medicinal products and MDs) assessment process by incorporating a cost-effectiveness criterion in the price setting process[9], where the manufacturer claims a certain level of clinical improvement and the impact on National Health Insurance expenditure is significant[10].

When submitting an application to request an economic opinion from the Commission for Economic and Public Health Evaluation (CEESP), the manufacturer has the option of formulating claims in respect of impacts of the healthcare product on the healthcare system, work practices or patient care conditions[11]. Such claims result in a decision by the HAS Board to approve the eligibility of the healthcare product for an economic assessment by the CEESP once the product is liable to represent a clinical improvement (CAV or ACV I, II or III). While, for many products, impacts are claimed for at least one of the three aspects, they are only very rarely documented or are unclear in the economic assessment or budget impact analysis.

1.1.2. Objective

The objective is to structure the manner in which organisational impact can be identified/defined according to various stakeholders and to help depict them. The map proposed for this purpose is based on a classification of organisational impact made up of macro-criteria and criteria accompanied by examples of indicators.

A health technology can potentially have multiple organisational impact or concern multiple stakeholders.

The purpose of the map is to identify the most relevant organisational impact and the parameters for measuring their effects. Each impact considered or claimed as valid, the impact of which may be positive or negative, should be documented.

This is an informative tool which must not be equated with an assessment grid resulting in a score. In this way, it is not expected that all of the criteria proposed in this map be completed.

[9] French Social Security Funding Act for 2012 (article 47) and decree No. 2012-1116 of 2 October 2012 relating to the French National Authority for Health's medico-economic duties. The text currently in force is article R161-71-3 of the French Social Security Code created by Decree No. 2018-444 of 4 June 2018 – art. 1 relating to certain specialist committees of the French National Authority for Health.

[10] Decision No. 2018.0233/DC/SEESP of 5 December 2018 of the HAS Board amending Decision No. 2013.0111/DC/SEESP of 18 September 2013 relating to the significant impact on National Health Insurance expenditure triggering the medico-economic assessment of products claiming a CAV or ACV rating of I, II or III provides more details on the concept of "significant impact on National Health Insurance expenditure".

[11] Article R161-71-3 of the French Social Security Code created by Decree No, 2018-444 of 4 June 2018 – art. 1

1.1.3. Work method

In order to identify the aspects related to the assessment of the organisational impact of a health technology, it was first of all necessary to clarify the concept with a view to defining its scope and subsequently drawing up a map.

The work method, detailed in appendix 3, was essentially based on:

- preparing an overview on European and international health technology assessment agency practices in respect of assessing organisational impact-related aspects based on published information;
- the use of a targeted literature review, without confining the documentary search to the field of health, however;
- an MGG made up of multidisciplinary experts, from the field of health, but also other fields, and patient and user representatives[12];
- consultation of stakeholders: representatives of the medicinal product and medical technology industry, service providers, representatives of healthcare professionals and other institutions, representatives of patient and user associations.

This project was managed as part of a cross-disciplinary approach involving the departments of the Medical, Economic and Public Health Evaluation Division (DEMESP): Economic and Public Health Evaluation Department (SEESP), Diagnostic and Therapeutic Procedure Evaluation Department (SEAP), Medicinal Product Evaluation Department (SEM) and Medical Device Evaluation Department (SED).

A joint research strategy was set up with the Institute for Education and Research in Healthcare and Social Service Organizations (IFROSS, GRAPHOS, F-69007, Lyon, France) and the School of Management and Engineering Vaud, HES-SO // University of Applied Sciences and Arts Western, Switzerland.

1.2. Steps of process

The roadmap adopted by the HAS Board was made available online in February 2019[13].

The methodology guidance group met on three occasions, on 25 June, 28 November 2019, and 9 July 2020.

The methodology on which this map was based is described in Appendix 3.

[12] The public declarations of interests of the professionals and patients envisaged to make up the work group was analysed and reviewed by the HAS ethics committee, who assessed the connections of interest with regard to the regulations in force.

[13] Haute Autorité de santé. Methodology guide on the consideration of organisational impacts in health technology assessment. Roadmap. Saint-Denis La Plaine: HAS; 2018. https://www.has-sante.fr/jcms/c_2902770/fr/guide-methodologique-relatif-a-la-prise-en-compte-des-impacts-organisationnels-dans-l-evaluation-des-technologies-de-sante-feuille-de-route

2. Organisational impact map

2.1. Key elements

A number of elements are presented in this document to facilitate the comprehension of the map.

Elements covered under subsections of this section

- **Terminology**: key concepts enabling correct use of the map.
- **Practical use**: the practical use of the organisational impact (OI) map is explained in a subsection, to aid the user.
- **Subdivisions:** the map includes three specific parts to be taken note of before going into detail on the criteria (see section 2.4).
- **Criteria**: three macrocriteria have been defined and each of these refers to multiple criteria. The criteria are explained using a definition, examples of indicators and examples of health technologies to illustrate the criterion and the resulting organisational impacts. The indicators and the examples are non-exhaustive and should provide an understanding of the scope and nature of the elements in question to guide the user.

2.2. Terminology

This section merely lists the key concepts enabling proper use of the map; the acronyms and abbreviations used elsewhere can be found at the end of this document.

Health technologies (HTs)

The potentially broad term health technology specifically targets, within the scope of this work, healthcare products, medicinal products and medical devices (MDs), and diagnostic and therapeutic procedures.

Impact

The term impact[14] refers to an effect, consequence, result, repercussion, etc. created in this case by a health technology.

Organisational impact (OI)

The term organisational impact refers to an effect, consequence, result, repercussion, created by the HT on the characteristics and functioning of an organisation or a set of organisations (understood to be an individual or collective stakeholder) involved in the care or life pathway of users.

It is worth noting the following points:

- the organisational impact (and indicators) can be grasped through the resources required to implement the HT (e.g. requires training or clinical education for the patient) or the changes involved during its rollout (e.g. results in a change of a healthcare professional's skills);
- the organisational impact can be immediate or delayed, depending on whether the HT is in the learning phase or in the "routine" phase; therefore, it is necessary to specify the positioning considered in the health technology rollout cycle;
- the impact can be temporary or permanent; this should be specified;

[14] Based on the proxemy featured in the Centre national de ressources textuelles et lexicales (CNRTL) dictionary, https://www.cnrtl.fr/proxemie/impact, consulted on 04/03/2020.

- the impact can be positive or negative and can be conveyed by evidence of added value or reduced value associated with the establishment or rollout of the HT.

Criterion

Can be considered as a characteristic, principle, element to which reference is made to appraise, assess, define OIs.

Stakeholder

A stakeholder is deemed to be any individual or legal entity having an interest in the care or life pathway. This may be a healthcare professional, the patient, a carer or accompanying person, a healthcare institution, a healthcare manufacturer or any other stakeholder involved in the delivery of care or services (transport, services and distributors of equipment in particular).

Process

The term "process" should be understood as a "set of successive operations, organised with a view to a defined result"[15]. In the context of this document, it includes the sequencing of activities carried out in the patient's care or life pathway, with a view to maintaining or improving the patient's health or for prevention purposes.

For the practical use of the process concept within the OI map, the reader should refer to section 2.6.1. Process changes can be represented in the form of an activity/stakeholder table showing "before" *versus* "after" (see Appendix 2).

Conventional care

The conventional care denotes the arsenal available for the medical condition in question. The conventional care is that having the same diagnostic, clinical or disability compensation purpose, that can be proposed at the same stage of the strategy and intended to be used in the same cohort, on the date of the assessment.

It should be that which is expected to yield the best outcomes in patients having the medical condition.

2.3. Map

The map helps **specify the context** of the health technology under assessment and **structure how OIs can be identified** according to the **stakeholders concerned** by drawing up a classification based on three macrocriteria:

- within each macrocriterion, choice of criteria corresponding to the most relevant OIs and stakeholders concerned;
- proposal of indicators to describe each criterion selected and identify the data to be provided;
- examples of health technologies to illustrate the criterion.

The indicators and examples provided are not exhaustive and are given for illustrative and informative purposes to help the user understand the scope of the impact studied and its characteristics.

[15] According to the Centre national de ressources textuelles et lexicales (CNRTL) definition, https://www.cnrtl.fr/proxemie/processus; consulted on 24/02/2020.

Note 1: other indicators may be proposed once they make it possible to depict the reality of an impact.

Note 2: given that an HT can have multiple OIs, and that OIs can concern multiple criteria or multiple stakeholders, it is recommended to focus on the most relevant impacts and not to multiply explanations, at the risk of losing sight of the major effects/claims; selection choices must be justified.

Note 3*:* the OIs claimed for an HT are generally positive; some relevant OIs can however be negative or constraining from the perspective of the HT under assessment. It is worth pointing out that it is the responsibility of the stakeholder presenting an organisational impact analysis (manufacturers or healthcare professionals in particular) to identify any relevant impacts, even when they are negative. Choices must be justified.

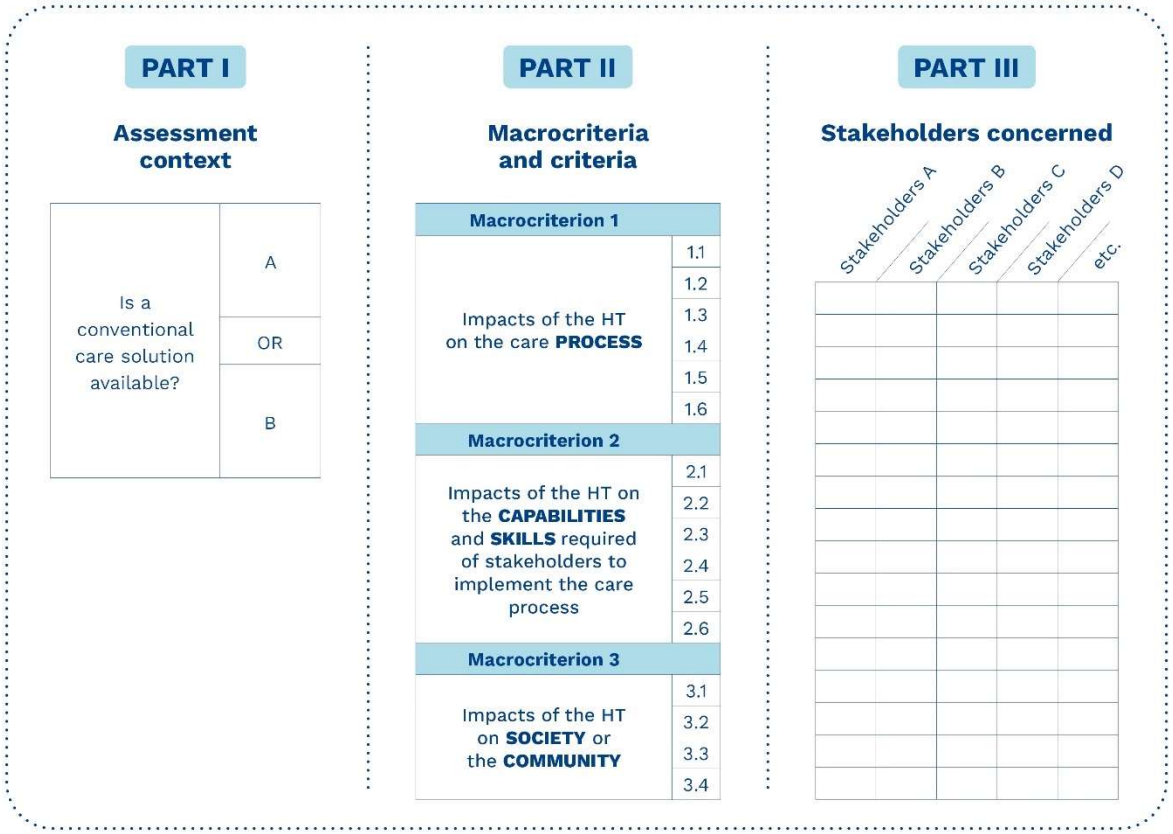
Note 4: the choice of timing of the organisational impact assessment in the health technology rollout cycle should be mentioned by specifying the start and end of the process assessment.

Note 5*:* this map is subject to change as required, in particular as regards its incorporation in the assessment framework of each committee (CEESP, CNEDiMTS, CT) and by the HAS Board.

2.4. Map subdivisions

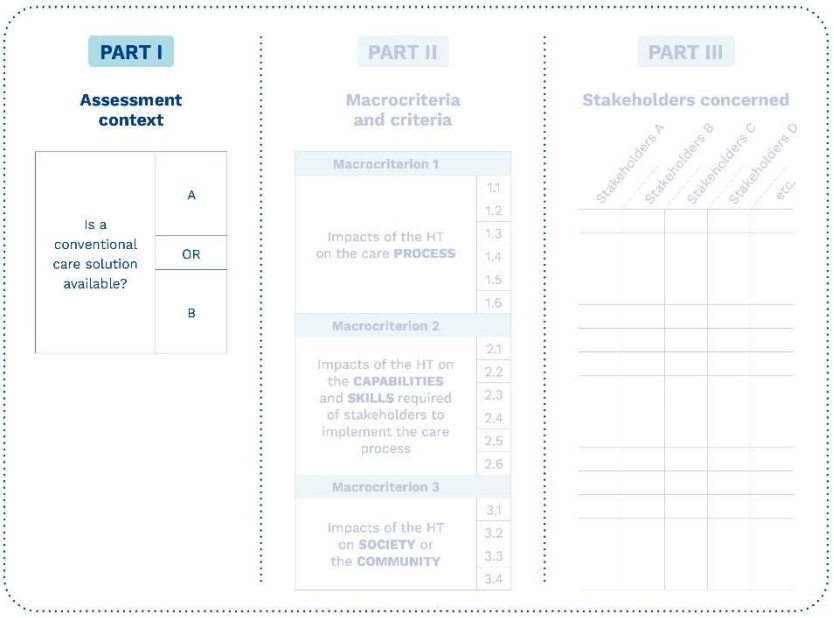
The map is made up of 3 main parts which are described in detail in the following subsections:

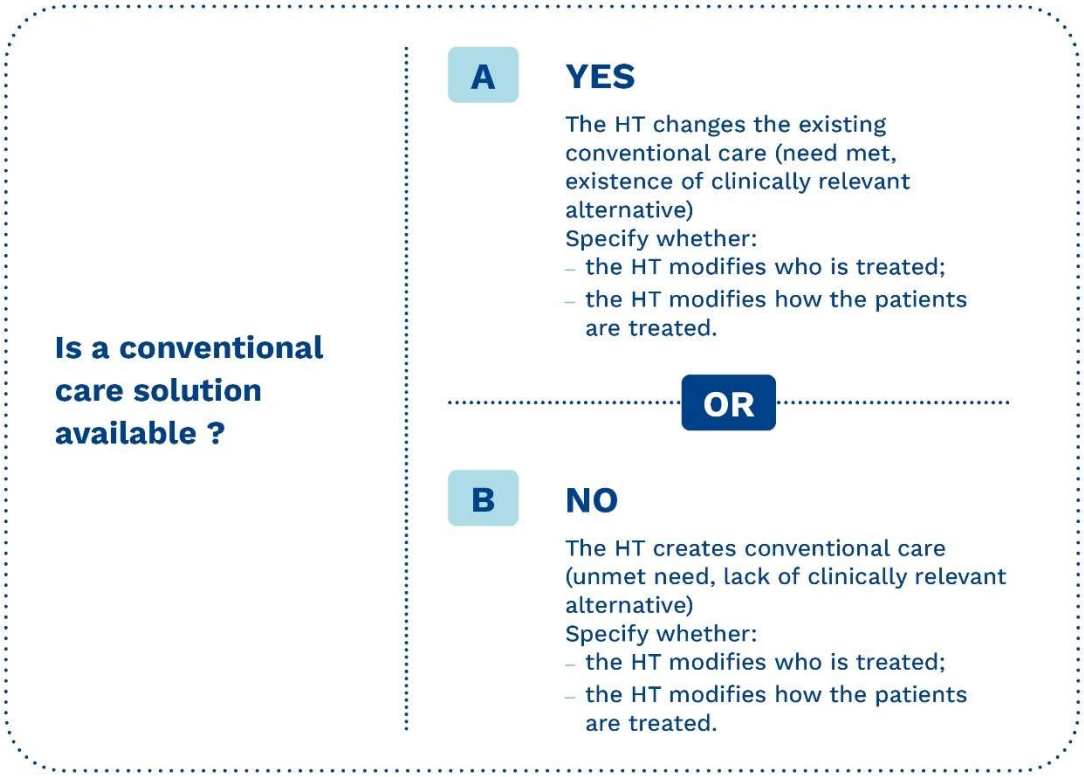
– Part I: "Assessment context"
– Part II: "Macrocriteria and criteria"
– Part III: "Stakeholders concerned"



3. Part I: assessment context

The purpose of Part I is to specify the context of the HT under assessment in relation to the existence of a conventional care solution.





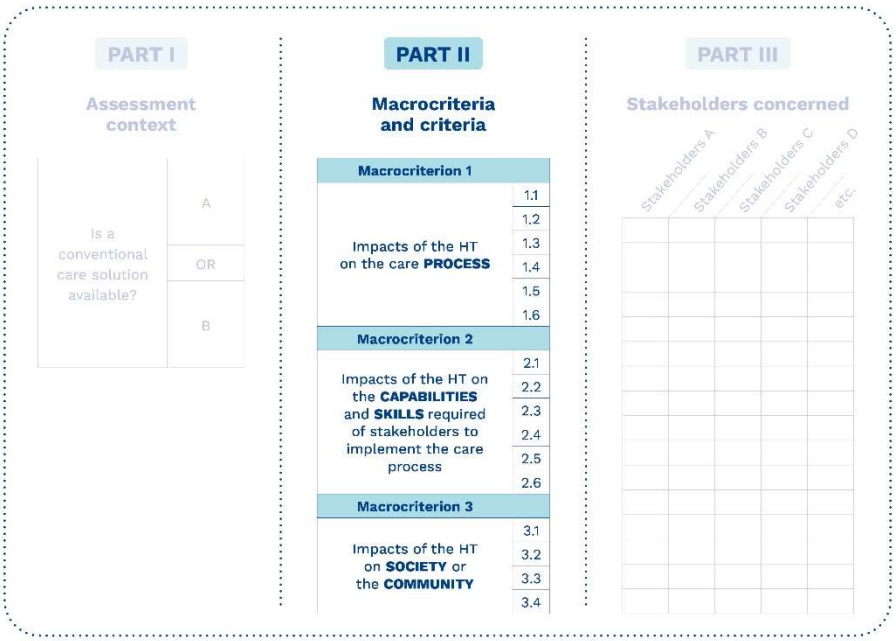
Ex. (A): connected medical device used for remote monitoring of a medical condition not modifying the target population concerned.

Ex. (B): new targeted cancer therapy, intended for a category of patients at a therapeutic dead-end.

4. Part II: macrocriteria and criteria

The purpose of Part II is to specify the macrocriteria and criteria used to document OIs.

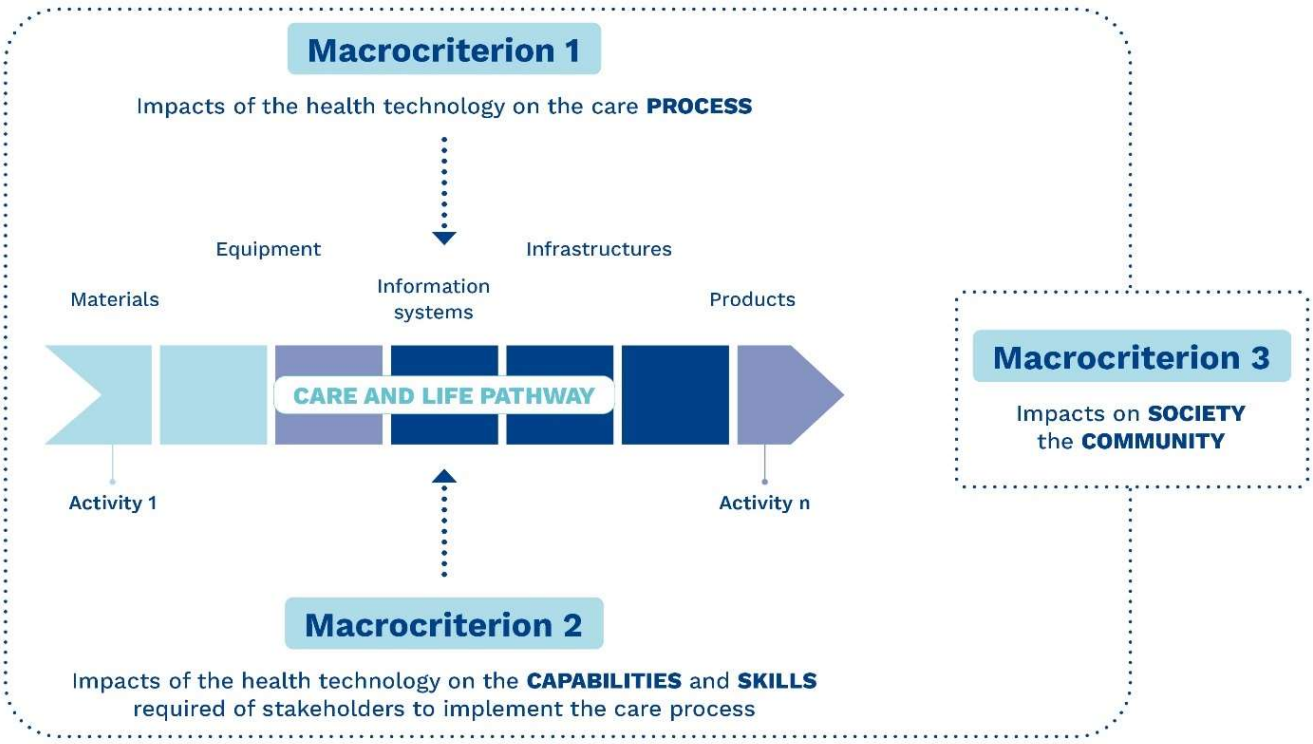
Therefore, this is the core part of the overall map design



4.1. The three macrocriteria

The core part of the map is structured into 3 macrocriteria in which criteria have been defined.

Macrocriteria 1 and 2 look at the impacts with a direct effect on the components of the process and the skills and capabilities required to implement it, whereas macrocriterion 3 is a more general level of analysis and considers effects on society or the community.



Macrocriterion 1. Impacts of the health technology on the care PROCESS

Macrocriterion 1 looks at the impacts with a direct effect on the components of the care process. It includes the sequencing of activities carried out in the patient's care or life pathway with a view to prevention or maintaining or improving their health.

Macrocriterion 2. Impacts of the health technology on the CAPABILITIES and SKILLS required of stakeholders to implement the care process

Macrocriterion 2 looks at impacts with an effect on the skills and capabilities required of the stakeholders involved to implement the care process (organisational capabilities, skills and sharing of skills, working conditions, funding, etc.).

It concerns the skills and aptitudes required by the stakeholders to perform their tasks when setting up the new HT effectively and efficiently and by the rollout, combination and coordination of their resources and skills at various stages of life or the health care pathway process. It reflects the complex interactions formed between these stakeholders 'resources and their skills when used in the process.

Macrocriterion 3. Impacts of the health technology on SOCIETY or the COMMUNITY

Macrocriterion 3 is a more general level of analysis compared to the previous two macro criteria and focuses on the impacts of the HT on the general population. It includes impacts not directly concerning the patient's care process, their care and life pathway, and the stakeholders concerned. These can be considered as indirect effects at a macroeconomic level.

4.2. Criteria and their content

Each criterion is presented with:

- a definition of the organisational impact;
- examples of indicators which could be used to document the impact;
- examples of health technologies to illustrate the criterion.

For some of the criteria of macrocriterion 1, **an activity/stakeholder table**, specifying the activities forming the process in the rows and the stakeholders in the columns, may be used as a qualitative indicator to demonstrate the changes to some steps of the process. A sample activity/stakeholder table is proposed in Appendix 2.

MACROCRITERION 1. Impacts of the HT on the care process

This macrocriterion accounts for the sequence of activities carried out in the patient's life and care pathway

Criterion 1.1	**Modifies times prior to initiation of the process**
Definition of OI	By its nature, the HT makes it possible to modify the time prior to initiation of a diagnostic or treatment process.
Ex. indicators	Time from decision to initiation of patient diagnosis or treatment by a professional.
Ex. HT	HT allowing a quicker diagnosis of a medical condition compared to the conventional method. For example: – screening on a broad population for rapid diagnostic confirmation of an eye condition; – rapid diagnostic test (RDT), rapid diagnostic orientation test (RDOT) or self-test for confirming cases of infectious disease, or diagnostic self-tests. HT which would enable remote monitoring of a parameter or marker of a medical condition: heart rate monitoring for diagnosing unexplained syncope. HT enabling early treatment, for example HIV "test-and-treat" strategies.

Criterion 1.2	**Modifies process pace or duration**
Definition of OI	The HT has impacts on the number of referrals for care or on the length of the care pathway or of certain episodes in the care process.
Ex. indicators	– Number of hospital admissions (or hospitalisation time), consultations, visits to emergency departments or intensive care units, etc. – Number of treatment administration sequences or duration of treatment. – Waiting time between provisions of care, total duration of care.
Ex. HT	New medicinal product or new pharmaceutical formulation (e.g., sustained-release form) making it possible to reduce administration frequency or shorten the total duration of the treatment or of its follow-up or hospitalisation time by enabling an early return home. Less invasive diagnostic or surgical procedure, interventional radiology *versus* surgery which has an impact on hospitalisation times. HT based on remote monitoring of a medical condition allowing longer intervals between follow-up consultations. HT enabling prevention or early detection of relapses or recurrences of a medical condition or of complications (considering that the treatment process of the medical condition has already been initiated).

Criterion 1.3	Modifies process timing or content
Definition of OI	The HT impacts the pathway content (changes in the care process without a difference in the type or quantity of care providers), the sequencing of activities or the care location.
Ex. indicators	Use an activity/stakeholder table to identify the different times or stages of the care process and show changes.
Ex. HT	HT modifying the operating procedure enabling a single surgical procedure instead of two separate operations, or vice versa: example of thrombectomy followed by thrombolysis instead of thrombolysis alone. New treatment allowing care in a non-hospital setting *versus* hospital care. Changes in care process content and care location, associated with the use of telemedicine (remote consultation, remote assistance, remote medical monitoring with continuous follow-up and alert handling). Treatment requiring increased monitoring (in terms of follow-up or adverse effects). New treatment requiring the use of a companion test or pathological analysis to adapt the treatment. HT modifying the sequences of visits to various departments during hospitalisation, or scheduling of referrals to various specialists within the framework of outpatient care.

Criterion 1.4	Modifies number or type of staff involved in the process: quantitative view of human resources
Definition of OI	The HT modifies the number and the profile of the stakeholders involved independently of any impacts on pathway content (sequences of activities or components of the care process). NB: the impacts of an HT on stakeholders' capabilities and skills are covered in macro-criterion 2.
Ex. indicators	Use an activity/stakeholder table to identify the different times or stages of the care process and show stakeholder changes: number and type of healthcare professionals or patients or carers or others.
Ex. HT	HT involving a new stakeholder in the care process: transport service provider, service provider and distributor of equipment or of computer packages. Treatment requiring the involvement of specific structures for its use, involvement of in-house pharmacies or central pharmacy for storage, preparation, etc. HT allowing the patient to self-administer their treatment, avoiding the need for home nursing (self-treatment devices).

Criterion 1.5 Modifies the type or frequency of use of products, devices, materials, equipment, infrastructures and information systems used in the process: view in terms of material or digital resources	
Definition of OI	The HT requires the use of products, devices, materials, equipment, infrastructures, including expert information systems or modifies their use.
Ex. indicators	– Number of items of equipment, materials, specific software programs or other. – Description of impacts in terms of adaptation of premises, architectural design, information systems, etc.
Ex. HT	HT requiring specific equipment which may apply to: materials (e.g. surgical instruments), a location (e.g. specific operating theatre), storage, sterilisation, etc.

Criterion 1.6 Modifies the quality and safety of the environment or context in which the process takes place	
Definition of OI	The HT impacts on the process environment in terms of quality and safety.
Ex. indicators	– Number of avoided visits to environments with a high infection risk. – Number of avoided errors. – Approval or technical certification criteria associated with the environment required for certain centres or activities providing specific patient care. Please note that this does not include the use of indicators in relation to measures for assessing the quality and safety of care taken into account in the clinical HT assessment.
Ex. HT	HT helping improve process reliability through full or partial automation or the simplification of certain stages for example: – sampling kits that can be used directly by professionals or any other stakeholder outside healthcare facilities; – cytotoxic medicinal product packaged in a ready-to-use form with no need for reconstitution; – new treatment helping reduce the risk of contamination of healthcare professionals and family members through more rapid negative conversion of viral load (case of HIV); – remote consultations helping reduce surgery visits during an epidemic. New HT helping mitigate identified supply shortages.

MACROCRITERION 2. Impacts of the HT on the capabilities and skills required of stakeholders to implement the care process

This macrocriterion includes organisational capabilities, skills and sharing of skills, working conditions, funding, etc.

Criterion 2.1 Modifies the stakeholder's required skills (knowledge, know-how and social skills), and expertise associated with the delivery or provision of care.	
Definition of OI	The HT modifies the training or initial qualification of professionals or the time required for their acquisition (including in relation to expert data collection and analysis systems), therapeutic education, patient or carer support.
Ex. indicators	– Quantity, duration frequency of training or qualification. – Frequency of tests of knowledge. – Time for acquisition of the skills or expertise associated with incorporating the HT into practice. – Volume or complexity of the data that need to be analysed to rollout the technology.
Ex. HT	HT requiring specific training of the healthcare professionals who will be required to use it, for example: – a new surgical procedure requiring learning, skills adaptation by the healthcare professional; – rollout of remote monitoring particularly involving technical training of the stakeholders involved. Introduction of an HT involving the need to train patients (and/or carers) on its use, therapeutic education or therapeutic support (use of a self-measuring device involving treatment follow-up by the patient alongside healthcare professionals). NB: the learning curve concept must be taken into account in the event of a major impact of the rollout of the HT on the consumption of time and resources and can be compared to a time to incorporate the HT into practice.

Criterion 2.2 Modifies the ability to share and transfer skills, knowledge and know-how with other stakeholders	
Definition of OI	The HT modifies a stakeholder's ability to delegate or disseminate their knowledge and skills, share key information, coordinate various stakeholders.
Ex. indicators	– Creation or modification of cooperation and task delegation protocols (existing or required). – Need for multidisciplinary review meetings. – Organisational changes associated with the need to combine multiple skills, with feedback, with best practices, with key information exchanged between the patient and professionals, etc.

Ex. HT	HT enabling task delegation: – by a medical specialist to a nurse (e.g., in the context of an organisation via remote medical monitoring of patients with a chronic condition based on a cooperation protocol). – by a general practitioner to a pharmacist (e.g., rapid diagnostic orientation test such as the strep test and set-up of an antibiotic treatment by the pharmacy). Medicinal product which, in the context of a simplified pathway, allows prescription by a general practitioner instead of a medical specialist. HT requiring upstream multidisciplinary review meetings to define patients eligible for treatment.

Criterion 2.3	**Modifies scheduling and planning capacities for health care services or the patient or carer**
Definition of OI	The HT has impacts on the specific scheduling and planning capabilities for a structure, a professional, a service provider or a patient/carer
Ex. indicators	– Impacts on the ability to receive or treat patients: variation in occupancy rate (beds, places), variation in size of patient list (active patient queue or patient list of treating doctor), flow of patients between departments, variation in activity productivity. – Variation in unscheduled requests, unsuitable referrals to other departments within the structure, etc. – Modification of organisation chart, department allocations, areas of responsibility of professionals (in the context of existing regulations or in the context of regulations to be introduced), etc. – Modification of the degree of maturity of the information system, the number of data items exchanged or produced or the quantity of redundant information. – Specific impacts for a patient/carer: time devoted to treatment follow-up, quantity of information delivered to the patient and rate of technology use, variation in number of trips, etc.
Ex. HT	HT modifying activity level, capacity or occupancy rate potentially resulting for example in a reduction in hospital admissions making it possible to increase the total number of patients treated over a given period in a department or in a modification of the occupancy rate of a department or operating theatre. HT enabling a patient to organise their care better by reducing the frequency of consultations and travel in the context of a remote medical monitoring set-up. HT making it possible to increase the active patient queue followed up by a centre (in the context of rehabilitation requiring fewer adjustments or a reduced rehabilitation time).

Criterion 2.4 Modifies scheduling and planning capabilities between care structures or combinations of stakeholders	
Definition of OI	The HT impacts on the scheduling and planning capabilities between stakeholders, it modifies the ability of multiple stakeholders to collaborate suitably for the purposes of care (apart from task delegation): care structures/care structures, care structures/patients.
Ex. indicators	– Variation in flow of patients between structures or professionals. – Variations in unsuitable referrals to other stakeholders involved in the process. – Modification of the number of information items exchanged or produced or the quantity of redundant information between different stakeholders. – Frequency and volume of information exchanges and activities between stakeholders caused by the modification of the areas of responsibility between professionals (in the context of existing regulations or in the context of regulations to be introduced) or structures. – Specific impacts for a patient/carer: frequency and volume of information exchanges and activities with other stakeholders, time spent on coordination between the stakeholders involved in the care process.
Ex. HT	Connected devices enabling remote monitoring of the patient through coordinated interaction of multiple stakeholders (between professionals and between professionals and the patient or family members). HT generating better regulation of flows of patients between stakeholders through better coordination of professionals and information exchanges: e.g. transfer of patient flows from hospital medical specialist to general practitioner. HT making it possible to modify a medical team's planning capability through having a procedure carried out by the nursing team instead of the medical team. HT enabling improvement of the transfer of information associated with a patient between the hospital and the treating doctor.

Criterion 2.5 Modifies stakeholders' working or living conditions	
Definition of OI	The HT modifies the social climate or well-being of professionals in the workplace. It has repercussions on the patient's or carer's home environment and day-to-day life linked with the living environment, work, family life, leisure (psychological impact) or social ties (sociological impact).
Ex. indicators	– Score in respect of patient autonomy, carer availability, changes in work time, frequency of need for care (including for the carer). – Ability to travel and get about, continue activities or retain social ties. – Rate of sick leave, therapeutic part-time work, turnover. – Number of occupational accidents, musculoskeletal disorders (MSD). Please note that this does not include the use of indicators in relation to measures for assessing quality of life taken into account in the clinical HT assessment.
Ex. HT	Treatments improving the patient's living and working conditions particularly by helping reduce stigmatisation: new HIV tritherapy allowing significant spacing out of treatment doses. HT facilitating living conditions of professionals or carers: patient lifting or transport device, use of manual wheelchair assist device, in particular. HT promoting a cooperative climate between healthcare professionals or all stakeholders (cases of remote consultation, remote expert assessment, remote monitoring).

Criterion 2.6	Modifies the terms, nature or source of stakeholders' funding
Definition of OI	The HT modifies the funding source, the nature of the funding, the funding amount; it involves potential transfers of expenses between stakeholders, particularly expenses borne by users.
Ex. indicators	Depicting changes in expenses generated by the HT for each funder. This involves specifying: – the type of stakeholders providing funding (examples: National Health Insurance, insurance companies or mutual insurance companies, patient, other funders); – the type of stakeholders funded (examples: hospital, medical specialist, pharmacists, patient, service provider and distributor of equipment (PSDM), etc.); – the funding procedure, if known consultation, DRG, patient co-payment, etc.; – the funding amount if known and any changes; – any transfers of expenses between funders. An analysis of the potential impact of adopting an HT for each funder and an analysis of potential transfers between the different funders are expected; this analysis cannot be performed within the scope of a budget impact analysis, generally conducted from a compulsory National Health Insurance perspective.
Ex. HT	Modification of patient co-payment associated with the HT. Transfer of funding from one professional to another (example of payment made to pharmacist instead of general practitioner with RDOT use).

MACROCRITERION 3. Impacts of the HT on society or the community

This macrocriterion is a more general level of analysis and focuses on the impacts of the HT on the general population

Criterion 3.1	Impact on community in terms of health and safety
Definition of OI	The HT has positive or negative effects on the population or health and safety.
Ex. indicators	– Population coverage rate, modification of infection transmission risks. – At-risk waste processing volume (at-risk waste from care activities involving a risk of infection or similar). – Reduction in the quantities of toxic waste or radioactive substances used.
Ex. HT	Change in the population covered by a prevention campaign linked with the HT, change in the risk of transmission following a vaccination campaign linked with the HT, projected long-term change of overall antibiotic resistance linked with an HT, etc. Substitution of radioactive substances in the composition of an HT by non-radioactive substances. HT helping limit the risks of transmission of a contagious disease (for example, in the case of an epidemic or pandemic).

Criterion 3.2	Impact on social inequalities or accessibility to care
Definition of OI	The HT has effects on individuals' equality or accessibility of care when accounting for sociocultural, ethical, socioeconomic, geographic, digital divide issues, etc.
Ex. indicators	– Rate of care provision by gender, age, socioeconomic or geographic category, rate of refusal of care, supply shortages or distribution circuit-related problems, renunciation of care, etc.
Ex. HT	Telemedicine solutions helping bridge geographic gaps in access to care or, on the other hand, HT distributed within the confines of specialist centres requiring an extended stay under medical supervision on or in the vicinity of a hospital campus. HT helping mitigate shortages associated with certain product categories. HT potentially giving rise to an increase in social discriminations or prolonged separation from home, or when it requires access to the Internet or to electronic tools not owned or not usable by certain cohorts or in certain geographic areas with poor or no coverage.

Criterion 3.3	Impact on social or work relationships or in terms of society as a whole
Definition of OI	The HT has positive or negative societal externalities for stakeholders outside the scope of the patient's pathway (businesses, associations, citizens, etc.).
Ex. indicators	Modification of need for personal service providers (whether these activities are carried out by profit-making or non-profit-making entities: effects on need for childcare due to incapacity, for temping staff by employers due to absence or sick leave, effects on healthcare-related transportation companies, etc.) or modifications of work organisation resulting from absenteeism or reduced productivity.
Ex. HT	HT guaranteeing work continuity or home help through the national rollout of personal services.

Criterion 3.4	Impact on environmental footprint
Definition of OI	The HT has a positive or negative impact on the environment.
Ex. indicators	Cost of harm caused to the environment and to ecosystems and, indirectly, to those using them.
Ex. HT	Impacts of the HT in terms of carbon cost of travel (carbon footprint), materials, modification of greenhouse gas emissions, need for processing or changes in the volume of waste to be processed or linked with material and equipment obsolescence), consumption of rare materials, etc. On the other hand, availability of a widely used and biodegradable HT.

To facilitate the reading and understanding of this core part of the map:

- ➔ **a summary of the macrocriteria and criteria is provided in the next section**
- ➔ **a summary table including the criteria, OI definition, and examples of indicators is provided in Appendix 1**

4.3. Summary of the macrocriteria and criteria

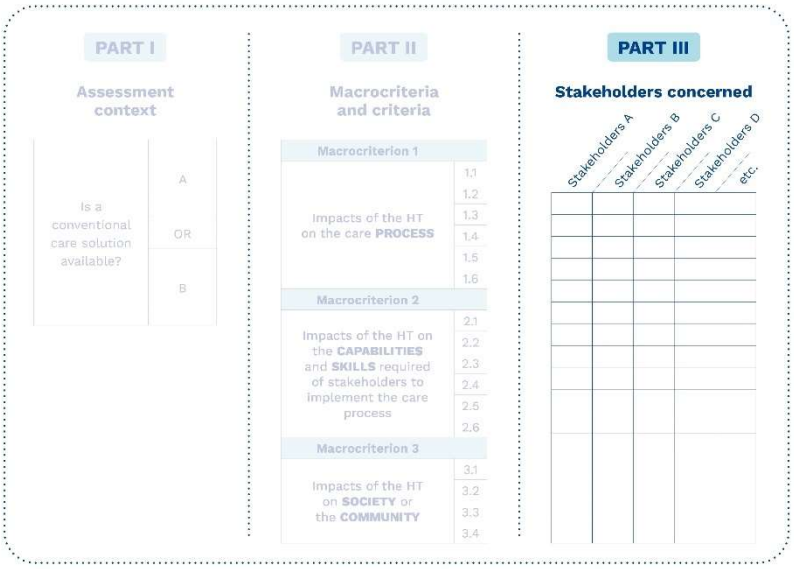
Macrocriterion 1	Criteria	
Impacts of the HT on the care **PROCESS** *This macrocriterion accounts for the sequence of activities carried out in the patient's life and care pathway*	1.1	Modifies times prior to initiation of the process
	1.2	Modifies process pace or duration
	1.3	Modifies process timing or content
	1.4	Modifies number or type of staff involved in the process: quantitative view of human resources
	1.5	Modifies the type or frequency of use of products, devices, materials, equipment, infrastructures and information systems used in the process: view in terms of material or digital resources
	1.6	Modifies the quality and safety of the environment or context in which the process takes place
Macrocriterion 2	**Criteria**	
Impacts of the health technology on the **CAPABILITIES** and **SKILLS** required of stakeholders to implement the care process *This macrocriterion includes organisational capabilities, skills and sharing of skills, working conditions, funding, etc.*	2.1	Modifies the stakeholder's required skills (knowledge, know-how and social skills), and expertise associated with the delivery or provision of care
	2.2	Modifies the ability to share and transfer skills, knowledge, know-how with other stakeholders
	2.3	Modifies scheduling and planning capacities for health care services or the patient or carer
	2.4	Modifies scheduling and planning capabilities between care structures or combinations of stakeholders
	2.5	Modifies stakeholders' working conditions or living conditions
	2.6	Modifies the terms, nature or source of stakeholders' funding
Macrocriterion 3	**Criteria**	
Impacts of the HT on **SOCIETY** or the **COMMUNITY** *This macrocriterion is a more general level of analysis compared to the previous two macro criteria and focuses on*	3.1	Impact on community in terms of health and safety
	3.2	Impact on social inequalities or accessibility to care
	3.3	Impact on social or work relationships or in terms of society as a whole
	3.4	Impact on environmental footprint

5. Part III: stakeholders concerned

The purpose of Part III is to specify the stakeholders concerned by the OI map.

Therefore, this is the final part of the overall design used to prepare the map.

The term stakeholder is defined in section 2.2



> *Note 1*: for each criterion, the impacted stakeholder(s) is/are to be specified.
>
> *Note 2*: for the same criteria, multiple stakeholders may be impacted.
>
> *Note 3*: depending on the criteria, the impacted stakeholders may not be the same.

Accordingly, for each criterion, it is necessary to specify the stakeholder(s) concerned by the OI.

Whenever necessary, this involves specifying the stakeholder(s), including in an institution: for example, in a hospital, this may be the surgical, medical pathology, day case department, etc., or, as another example, in a multidisciplinary health centre (MSP), it may be a general practitioner or a self-employed nurse, etc.

The impacts may be found within a single institution, but also among institutions or professionals or patients or carers. In other words, multiple and varied stakeholders may be affected.

For example:

- a telemedicine solution could impact not only a full hospitalisation department (e.g. the geriatrics department), but also a state-registered nurse (IDE) in an MSP, or even the patient, carer or accompanying person, service providers of transportation, I.T. solutions or service providers and distributors of equipment;
- a new treatment helping simplify the care originally provided in a healthcare facility by providing it in a non-hospital setting (simplified care pathway) will have effects on patient flow management at the hospital, for medical specialists, for patients, for dispensing pharmacies, for healthcare-related transportation companies;
- a rapid screening test conducted in a dispensing pharmacy could impact medical pathology laboratories, general practitioners and patients, or even carers.

Table of appendices

Appendix 1.Summary table: criteria, definition of OI, examples of indicators

Macrocriterion 1. Impacts of the HT on the care PROCESS **This macrocriterion accounts for the sequence of activities carried out in the patient's life and care pathway**		
Criteria	Definition of OI	Ex. indicators
1.1 Modifies times prior to initiation of the process	By its nature, the HT makes it possible to modify the time prior to initiation of a diagnostic or treatment process.	– Time from decision to initiation of patient diagnosis or treatment by a professional.
1.2 Modifies process pace or duration	The HT has impacts on the number of referrals for care or on the length of the care pathway or of certain episodes in the care process	– Number of hospital admissions (or hospitalisation time), consultations, visits to emergency departments or intensive care units, etc. – Number of treatment administration sequences or duration of treatment. – Waiting time between provisions of care, total duration of care.
1.3 Modifies process timing or content	The HT impacts the pathway content (changes in the care process without a difference in the type or quantity of care providers), the sequencing of activities or the care location.	– Use an activity/stakeholder table to identify the different times or stages of the care process and show changes.
1.4 Modifies number or type of staff involved in the process: quantitative view of human resources	The HT modifies the number and the profile of the stakeholders involved independently of pathway content (sequence of activities or components of the care process). NB: the impacts of an HT on stakeholders' capabilities and skills are covered in macrocriterion 2.	– Use an activity/stakeholder table to identify the different times or stages of the care process and show stakeholder changes: type of healthcare professionals or patients or carers or others.

Macrocriterion 1. Impacts of the HT on the care PROCESS **This macrocriterion accounts for the sequence of activities carried out in the patient's life and care pathway**		
Criteria	Definition of OI	Ex. indicators
1.5 Modifies the type or frequency of use of products, devices, materials, equipment, infrastructures and information systems used in the process: view in terms of material or digital resources	The HT requires the use of products, devices, materials, equipment, infrastructures, including expert information systems or modifies their use.	– Number of items of equipment, materials, specific software programs or other. – Description of impacts in terms of adaptation of premises, architectural design, information systems, etc.
1.6 Modifies the quality and safety of the environment or context in which the process takes place	The HT impacts on the process environment in terms of quality and safety.	– Number of avoided visits to environments with a high infection risk. – Number of avoided errors. – Approval or technical certification criteria associated with the environment required for certain centres or activities providing specific patient care. Please note that this does not include the use of indicators in relation to measures for assessing the quality and safety of care taken into account in the clinical HT assessment.

Macrocriterion 2. Impacts of the HT on the capabilities and skills required of stakeholders to implement the care process		
Criteria	Definition of OI	Ex. indicators
2.1 Modifies the stakeholder's required skills (knowledge, know-how and social skills), and expertise associated with the delivery or provision of care.	The HT modifies the training or initial qualification of professionals or the time required for their acquisition (including in relation to expert data collection and analysis systems), therapeutic education, patient or carer support.	– Quantity, duration frequency of training or qualification. – Frequency of tests of knowledge. – Time for acquisition of the skills or expertise associated with incorporating the HT into practice. – Volume or complexity of the data that need to be analysed to rollout the technology.
2.2 Modifies the ability to share and transfer skills, knowledge, and know-how with other stakeholders	The HT modifies a stakeholder's ability to delegate or disseminate their knowledge and skills, share key information, coordinate various stakeholders.	– Creation or modification of cooperation and task delegation protocols (existing or required). – Need for multidisciplinary review meetings. – Organisational changes associated with the need to combine multiple skills, with feedback, with best practices, with key information exchanged between the patient and professionals, etc.

Macrocriterion 2. Impacts of the HT on the capabilities and skills required of stakeholders to implement the care process		
Criteria	Definition of OI	Ex. indicators
2.3 Modifies scheduling and planning capacities for health care services or the patient or carer	The HT has impacts on the specific scheduling and planning capabilities for a structure, a professional, a service provider or a patient/carer	– Impacts on the ability to receive or treat patients: variation in occupancy rate (beds, places), variation flow of patients between departments, variation in activity productivity. – Variation in unscheduled requests, unsuitable referrals to other departments within the structure, etc. – Modification of organisation chart, department allocations, areas of responsibility of professionals (in the context of existing regulations or in the context of regulations to be introduced), etc. – Modification of the degree of maturity of the information system, the number of data items exchanged or produced or the quantity of redundant information. – Specific impacts for a patient/carer: time devoted to treatment follow-up, quantity of information delivered to the patient and rate of technology use, variation in number of trips, etc.

Macrocriterion 2. Impacts of the HT on the capabilities and skills required of stakeholders to implement the care process		
Criteria	Definition of OI	Ex. indicators
2.4 Modifies scheduling and planning capabilities between care structures or combinations of stakeholders	The HT impacts the scheduling and planning capabilities between stakeholders, it modifies the ability of multiple stakeholders to collaborate suitably for the purposes of care (apart from task delegation): care structures/care structures, care structures/patient.	– Variation in flow of patients between structures or professionals. – Variations in unsuitable referrals to other stakeholders involved in the process. – Modification of the number of information items exchanged or produced or the quantity of redundant information between different stakeholders. – Frequency and volume of information exchanges and activities between stakeholders caused by the modification of the areas of responsibility between professionals (in the context of existing regulations or in the context of regulations to be introduced) or structures. – Specific impacts for a patient/carer: frequency and volume of information exchanges and activities with other stakeholders, time spent on coordination between the stakeholders involved in the care process.
2.5 Modifies stakeholders' working conditions or living conditions	The HT modifies the social climate or well-being of professionals in the workplace. It has repercussions on the patient's or carer's home environment and day-to-day life linked with the living environment, work, family life, leisure (psychological impact) or social ties (sociological impact).	– Score in respect of patient autonomy, carer availability, changes in work time, frequency of need for care (including for the carer). – Ability to travel and get about, continue activities or retain social ties. – Rate of sick leave, therapeutic part-time work, turnover. – Number of occupational accidents, musculoskeletal disorders. Please note that this does not include the use of indicators in relation to measures for assessing quality of life taken into account in the clinical HT assessment.

Macrocriterion 2. Impacts of the HT on the capabilities and skills required of stakeholders to implement the care process		
Criteria	Definition of OI	Ex. indicators
2.6 Modifies the terms, nature or source of stakeholders' funding.	The HT modifies the funding source, the nature of the funding, the funding amount; it involves potential transfers of expenses between stakeholders, particularly expenses borne by users.	– Depicting changes in expenses generated by the HT for each funder. – To be specified: the type of stakeholders providing funding (examples: National Health Insurance, insurance companies or mutual insurance companies, patient, other funders); the type of stakeholders funded (example: hospital, medical specialist, pharmacists, patient, PSDM, etc.); the funding procedure, if known: consultation, DRG, patient co-payment, etc.; any transfers of expenses between funders. – An analysis of the potential impact of adopting an HT for each funder and an analysis of potential transfers between the different funders are expected; this analysis cannot be performed within the scope of a budget impact analysis, generally conducted from a compulsory National Health Insurance perspective.

Macrocriterion 3. Impacts of the HT on society or the community		
Criteria	Definition of OI	Ex. indicators
3.1 Impact on community in terms of health and safety	The HT has positive or negative effects on the population or health and safety.	– Population coverage rate, modification of infection transmission risks. – At-risk waste processing volume (at-risk waste from care activities involving a risk of infection or similar). – Reduction in the quantities of toxic waste or radioactive substances used.
3.2 Impact on social inequalities or accessibility to care	The HT has effects on individuals' equality or accessibility of care when accounting for sociocultural, ethical, socioeconomic, geographic, digital divide issues, etc.	– Rate of care provision by gender, age, socioeconomic or geographic category, rate of refusal of care, supply shortages or distribution circuit-related problems, renunciation of care, etc.
3.3 Impact on social or work relationships or in terms of society as a whole	The HT has positive or negative societal externalities for stakeholders outside the scope of the patient's pathway (businesses, associations, citizens, etc.).	– Modification of need for personal service providers (whether these activities are carried out by profit-making or non-profit-making entities: effects on need for childcare due to incapacity, for temping staff by employers due to absence or sick leave, effects on healthcare-related transportation companies, etc.) or modifications of work organisation resulting from absenteeism or reduced productivity.
3.4 Impact on environmental footprint	The HT has a positive or negative impact on the environment.	– Cost of harm caused to the environment and to ecosystems and, indirectly, to those using them.

Appendix 2.Process change description

Process map (*to be specified*) **BEFORE**

Grey out the boxes corresponding to the stakeholders involved in each activity or stage of the process of use of the technology

Stakeholders / Activities or stages											
0.											
1.											
2.											
3.											
4.											
5.											
6.											
7.											
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9.											
10.											
11.											
12.											
13.											
14.											
15.											
16.											
17.											

Process map (*to be specified*) **AFTER**

Grey out the boxes corresponding to the stakeholders involved in each activity or stage of the process of use of the technology

Stakeholders / Activities or stages											
0.											
1.											
2.											
3.											
4.											
5.											
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17.											

Appendix 3.Map drafting methodology

Review of practices of other HTA agencies

An overview was prepared of European and international agency or institution practices[16] in relation to the consideration of OI-related aspects in the health product and technology assessment context. It showed that either the topic was not addressed, or it was subject to many limitations, in particular:

1. Lack of OI definition: multiple, non-specific, definitions, often associated with the term "organisational aspects".
2. Varying degrees of OI inclusion ranging from a mere mention to a more specific description (European Network for Health Technology Assessment and HTA core model, Danish Centre for Health Technology Assessment et National Institute for Health and Care Excellence) without specifying assessment criteria and methods.
3. Vagueness in relation to OI categories, and the perspective and level adopted for their assessment.
4. Significant variations in relation to the aspects included in OI processing according to the institutions and vagueness as to the limits of their assessment with respect to items included in the medico-economic assessment: some HTA bodies actually seem to include the OI, not as a specific aspect, but by incorporating it into certain aspects of the assessment, in particular in terms of economic impacts.

OIs found recurrently in more elaborate models related to:

- processes (e.g., workflow and care process);
- structure (e.g., number of beds available and accessibility to care);
- culture (e.g., perception of the new technology).

This overview was supplemented by a query by the HAS to the InaHTA network from July to September 2019 which confirmed the above observations: OIs were either not identified or were identified in a vague and piecemeal fashion. Thus, none of the agencies that responded[17] specified an OI definition. Where some elements that can be considered as OIs are incorporated, this is done essentially within the scope of the medico-economic assessment, and they are difficult to identify.

In addition, a list of OIs was drawn up empirically based on examples of health technologies previously assessed by the HAS and having an assessment opinion or assessment report in the case of a procedure. In a first phase, a list of all potential OIs identified in medicinal product, MD and procedure assessment was drawn up. In a second phase, the different types of OI were characterised in matrix format cross-referencing the consistent impact categories identified in the HTA agency overview with the most elaborate models – process – structure – culture, and based on two levels, intraorganisational and interorganisational. This list enabled a better understanding of the different OI categories and the scope to be considered.

[16] Germany, United Kingdom, Austria, Italy, Denmark, Sweden, Australia, Brazil, Canada, New Zealand, EUnetHTA.

[17] The following bodies responded: SFOPH (Switzerland), SBU (Sweden), GOeG (Austria), NIPH (Norway), HIS (Scotland), UVT-Gemelly (Italy), INESSS (Canada, Quebec), AHTA (Australia), CDE (China, Taiwan), CMeRC (South Africa).

Health-related OI literature review

In the field of health, as in other sectors of activity, technology and organisation are closely linked. Indeed, as demonstrated by the research on the socio-technical trend in the 1950s[18], and, following on from that, research on the network stakeholder theory[19] or the theory of structures[20], the effects of introducing a new technology are determined by the social system and the organisational system in which it is introduced, which are in turn modified by the technology.

A systematic approach to assessing these effects is nonetheless lacking. In addition, documentary search work was conducted upstream from the OI classification mapping process.

The first searches were focused within the scope of health. They were intended to identify the existence of an OI definition, a classification or analytical grid. This search was first conducted in respect of International Health Technology Assessment (HTA) agencies and subsequently in the literature.

Several documentary search strategies were tested using the PubMed/Medline database over a ten-year period. The different documentary search strategies are featured in Appendix 4. The keywords used were associated with the term OI, HTA and innovation along with those used for the documentary search strategy within the scope of the drafting report of the guide on connected medical devices[21].

French publications stemming from "Ateliers de Giens", conducted on the occasion of the French National pharmacology and clinical research conferences for clinical innovation and health technology assessment held in 2014 and 2015 in Giens[22,,23], were identified.

A supplementary documentary search consisted of trying to identify the existence of publications specifying the components of a healthcare system, considering that, in this case, it would be possible to define OIs as impacts on these components. A non-systematic literature review was conducted with this in mind. No organisational "grid" (or "framework") specific to a healthcare system liable to serve as a base for this work was identified.

Review of literature on organisations and OIs outside the field of health

Following the searches described above to identify and characterise OIs in the health sector, alternative searches were conducted in grey literature, broadening the scope beyond the health sector.

The first was aimed, based on the same logic as that applied to the field of health, at identifying the main models describing the characteristics of a system. The results of this search were particularly fruitful. In this way, a large number of prisms for reading the characteristics of systems were identified.

Due to the plethora of literature on the characteristics of a system and above all the extremely broad spectrum of approaches and concepts enlisted, any selection of a definitive model, or attempt to summarise, would have been unreliable.

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> The experts of the MGG confirmed this sticking point, with no model being in principle more relevant than another.

In view of this analysis, the search was adapted more pragmatically, focussing on the impacts of technological innovations on all types of sectors of activity.

In this context, a joint OECD and Eurostat publication was selected, the *Oslo Manual*[24] (4th edition) and specifically a section on the objectives and outcomes of innovations, by area of influence[25]. The *Oslo Manual* particularly discusses the objectives and outcomes of innovation, whether developed within industrial and commercial businesses or public institutions.

This manual was used as a basis for the proposed OI classification, after transposing to health sector systems and adapting to the specific context of health technologies assessed by the HAS.

For this purpose, several steps were carried out:

- step 1: transposition of the *Oslo Manual* grid to the specific features of healthcare systems;
- step 2: adaptation to HT OI identification;
- step 3: comparison of OI classification to examples of HTs (MPs, MDs and procedures) processed by the HAS;
- step 4: after confirmation of the interest of this OI classification by the MGG, incorporation of the proposals and amendments of the MGG;
- step 5: addition of further information and details relating to definitions and examples of OIs and indicators.

> In line with the MGG, the approach adopted was essentially based on partial contributions from the literature and expert opinions, in order to draw up a map of the OIs which was put to the test and enhanced by tests on the health technologies assessed within the scope of the duties of the HAS.

The MGG experts' recommendations were also taken into account when drafting the OI map.

> The OI must be assessed in a given setting linked with the specific rollout conditions of the technology and in view of the framework of the duties of the HAS and the considerations of the committees tasked with assessing medicinal products, medical devices and procedures.
>
> The scope of the OI considered must be clearly defined according to the implementation considerations which may be expressed as components of a positive or negative impact.
>
> The map should help identify all OI-related aspects and help depict them by proposing criteria accompanied by examples of indicators.
>
> Adaptable to all circumstances, it should make it possible to account for current health priorities (for example, care, health, life pathway), short-term and long-term effects from a dynamic perspective, the specific aspects of the French, but ideally also European, context.

[24] Organisation for Economic Co-operation and Development. *Oslo Manual*: Guidelines for Collecting, Reporting and Using Data on Innovation, 4th edition [online]. Geneva: OECD; 2018. https://www.oecd-ilibrary.org/sites/8cb76644-fr/index.html?itemId=/content/component/8cb76644-fr,

[25] The *Oslo Manual* is part of the series of measurement manuals produced by the OECD entitled "*The Measurement of Scientific, Technological and Innovation Activities"*. Its aim is to help demonstrate and communicate the multidimensional nature of innovation.

Appendix 4.Documentary search strategy

1/ Exploratory search

Bibliographic database used: Medline (via PubMed)	Terms used:
Languages: EN, FR	((change*[ti] OR impact[ti] OR modification*[ti]) AND (organization*[ti] OR organisation*[ti]) OR "Organizational Innovation"[Mesh])
Time-frame: 2008-2019	AND
No. of references: 140	("Technology Assessment, Biomedical"[Mesh] OR "technology assessment"[ti] OR HTA[ti])
Languages: EN, FR	((((("diffusion of innovation"[mesh]) OR (((((((((«Equipment and Supplies»[Majr] OR device[ti]) and («Telecommunications»[Majr] OR connected[ti] OR mhealth[ti] OR mobile[ti])))) OR («Artificial Intelligence»[MAJR] OR «deep learning»[Ti] OR «Mobile Applications»[MAJR] OR «Wearable Electronic Devices»[MAJR] OR wearable[ti] OR «Telecommunications»[MAJR] OR app[ti] OR apps[ti] OR «digital health»[ti] OR mhealth[ti] OR «mobile health»[ti] OR «mobile-health»[Ti] OR «Medical Informatics Applications»[Majr]))))) OR ("Equipment and Supplies/organization and administration"[Majr]))))
Time-frame:	AND
No. of references: 213	(("Organizational Innovation"[MAJR]) OR (("organizational change*"[ti] OR "organizational issue*"[ti] OR "organizational impact*"[ti] OR "non clinical impact"[ti] OR "organizational evolution*"[ti] OR "organizational adaptation"[ti])))

2/ Search update associated with publications stemming from "Ateliers de Giens"

Bibliographic database used: Medline (via PubMed)	Terms used:
Languages: EN, FR	("Professional Practice"[Mesh] AND "Equipment and Supplies, Hospital"[Mesh])
Time-frame: 01/01/2015 – 16/10/2019	AND
No. of references: 9	((("2015/01/01"[Date - MeSH]: "3000"[Date - MeSH]) OR ("2015/01/01"[Date - Entry]: "3000"[Date - Entry]) OR ("2015/01/01"[Date - Publication]: "3000"[Date - Publication])) AND (English[lang] OR French[lang]))
Languages: EN, FR	(("Patient Care"[Mesh] AND "Equipment and Supplies, Hospital"[Mesh]) AND "Organization and Administration"[Mesh] AND ("Organization and Administration/analysis"[Mesh] OR "Organization and Administration/economics"[Mesh] OR "Organization and Administration/legislation and jurisprudence"[Mesh] OR "Organization and Administration/methods"[Mesh] OR "Organization and Administration/organization and administration"[Mesh] OR "Organization and Administration/statistics and numerical data"[Mesh] OR "Organization and Administration/trends"[Mesh]))
Time-frame: 01/01/2015 – 16/10/2019	AND

No. of references: 15	((("2015/01/01"[Date - MeSH]: "3000"[Date - MeSH]) OR ("2015/01/01"[Date - Entry]: "3000"[Date - Entry]) OR ("2015/01/01"[Date - Publication]: "3000"[Date - Publication])) AND (English[lang] OR French[lang]))
Languages: EN, FR	("Organizational Innovation"[Mesh] AND "Equipment and Supplies"[Mesh])
Time-frame: 01/01/2015 – 16/10/2019	AND
No. of references: 31	((("2015/01/01"[Date - MeSH]: "3000"[Date - MeSH]) OR ("2015/01/01"[Date - Entry]: "3000"[Date - Entry]) OR ("2015/01/01"[Date - Publication]: "3000"[Date - Publication])) AND (English[lang] OR French[lang]))
Languages: EN, FR	((("Delivery of Health Care"[Mesh] OR ("delivery"[All Fields] AND "health"[All Fields] AND "care"[All Fields]) OR "delivery of health care"[All Fields] OR "healthcare"[All Fields]) AND "improvement"[All Fields] AND ("innovation (North Syd)"[journal] OR "innovation"[All Fields] OR "innovation (Abingdon)"[journal])) AND "Equipment and Supplies"[Mesh])
Time-frame: 01/01/2015 – 16/10/2019	AND
No. of references: 38	((("2015/01/01"[Date - MeSH]: "3000"[Date - MeSH]) OR ("2015/01/01"[Date - Entry]: "3000"[Date - Entry]) OR ("2015/01/01"[Date - Publication]: "3000"[Date - Publication])) AND (English[lang] OR French[lang]))
Languages: EN, FR	((("Hospital Administration"[Mesh]) AND ("Technology, Industry, and Agriculture/economics"[Mesh] OR "Technology, Industry, and Agriculture/organization and administration"[Mesh])) AND "Equipment and Supplies"[Mesh])
Time-frame: 01/01/2015 – 16/10/2019	AND
No. of references: 64	((("2015/01/01"[Date - MeSH]: "3000"[Date - MeSH]) OR ("2015/01/01"[Date - Entry]: "3000"[Date - Entry]) OR ("2015/01/01"[Date - Publication]: "3000"[Date - Publication])) AND (English[lang] OR French[lang]))
Languages: EN, FR	("Outcome and Process Assessment (Health Care)"[Mesh] AND "Equipment and Supplies, Hospital"[Mesh])
Time-frame: 01/01/2015 – 16/10/2019	AND
No. of references: 137	((("2015/01/01"[Date - MeSH]: "3000"[Date - MeSH]) OR ("2015/01/01"[Date - Entry]: "3000"[Date - Entry]) OR ("2015/01/01"[Date - Publication]: "3000"[Date - Publication])) AND (English[lang] OR French[lang]))

3/ Health sector additions

Bibliographic database used: Medline (via PubMed)	Terms used:
	Common keyword stem

Languages: EN, FR	(Health technology[tiab] OR health equipment*[tiab] OR medical technologies[tiab] OR medical device*[tiab] OR Equipment and Supplies[Majr] OR device*[tiab] OR new medical device*[tiab] OR innovative medical device*[tiab] OR innovative medical technology[tiab] OR innovative medical technologies[tiab] OR new Health technology[tiab] OR new Health equipment*[tiab])
Time-frame: 2009-2019	AND
	("Models, Organizational"[Mesh] OR "Decision Making, Organizational"[Mesh] OR "Organizational Objectives"[Mesh] OR "Health Facility Administration"[Mesh] OR Organizational Culture[Mesh] OR "Organization and Administration"[Mesh:NoExp] OR organization*[tiab] OR organisation*[tiab] OR Health care organization[tiab] OR health organization[tiab] OR health care system[tiab] OR healthcare delivery[tiab] OR healthcare services[tiab] OR "Health Facilities"[Mesh] OR Organizational Impact[tiab] OR organisational impact[tiab])
	AND
	("Diffusion of Innovation"[Majr:NoExp] OR Implementation[tiab] OR introduction[ti] OR Diffusion[ti] OR adoption[ti] OR new medical device*[tiab] OR innovative medical device*[tiab] OR innovation[tiab] OR inovate[tiab] OR innovation[tiab])
	Supplemented by
	(Analysis[ti] OR framework[ti] OR evaluation[ti] OR assessment[ti] OR measure[ti] OR "Technology Assessment, Biomedical"[Mesh] OR measurement[ti])
	AND
	(change*[tiab] OR impact[tiab] OR modification*[tiab] OR effect*[tiab] OR outcome*[tiab] OR consequence*[tiab] OR side-effect*[tiab] OR repercussion[tiab] OR influence[tiab] OR Organizational Impact[tiab] OR Organisational Impact[tiab] OR Organizational effects*[tiab] OR Organisational effects[tiab] OR Organizational change*[tiab] OR Organisational change*[tiab])
	Or by
	(Analysis[tiab] OR framework[tiab] OR evaluation[tiab] OR assessment[tiab] OR measure[tiab] OR "Technology Assessment, Biomedical"[Mesh] OR measurement[tiab])
	AND
	(change*[ti] OR impact[ti] OR modification*[ti] OR effect*[ti] OR outcome*[ti] OR consequence*[ti] OR side-effect*[ti] OR repercussion[ti] OR influence[ti] OR Organizational Impact[tiab] OR Organisational Impact[tiab] OR Organizational effects*[tiab] OR Organisational effects[tiab] OR Organizational change*[tiab] OR Organisational change*[tiab])
No. of references: 254	

4/ Additions from other sectors

Documentary search in other bibligraphic data-bases	Results
HAS/HEIG-VD/IFROSS	Approximately 100 references consulted including the *Oslo Manual* No result on structured OI classification
HAS – Web search, grey literature	37 results including the 4th edition of the *Oslo Manual* published by the OECD in 2018 Guidelines for collecting, reporting and using data on innovation "The Measurement of Scientific, Technological and Innovation Activities".

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Abbreviations and acronyms

AB	Actual benefit
ACB	Actual clinical benefit
ACV	Added Clinical Value
ARS	Agence régionale de santé (Regional Health Board)
BIA	Budget impact analysis
CAV	Clinical Added Value
CEESP	Commission d'évaluation économique et de santé publique (Commission for Economic and Public Health Evaluation)
CEPS	Comité économique des produits de santé (French Healthcare Products Pricing Committee)
CNAMTS	Caisse nationale de l'assurance maladie des travailleurs salariés (National health insurance fund for salaried workers)
CNEDiMTS	Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé (Medical Device and Health Technology Evaluation Committee)
CSIS	Conseil stratégique des industries de santé (French Healthcare Industry Strategic Council)
CT	Commission de la transparence (Transparency Committee)
DEMESP	Direction de l'évaluation médicale, économique et de santé publique (Medical, Economic and Public Health Evaluation Division)
DRG	Diagnosis-related groups
ECB	Expected clinical benefit
HAS	Haute Autorité de santé (French National Authority for Health)
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HT	Health technology
HTA	Health Technology Assessment
IDE	Infirmier(ère) diplômé(e) d'État (State-registered nurse)
IECB	Improvement of Expected Clinical Benefit
IMT Atlantique	Institut Mines-Telecom Atlantique
LEEM	Les Entreprises du médicament
MD	Medical Device
MGG	Methodology guidance group
MSD	Musculoskeletal disorders
MSP	Maison de santé pluridisciplinaire (Multidisciplinary health centre)
OI	Organisational impact
PHI	Public health impact
PSAD	Prestataire de santé à domicile (Home healthcare provider)

PSDM	Prestataire de services et distributeur de matériels (Service provider and distributor of equipment)
PUI	Pharmacie à usage intérieur (In-house pharmacy)
RDOT	Rapid diagnostic orientation test
SEAP	Service évaluation des actes professionnels (Diagnostic and Therapeutic Procedure Evaluation Department)
SED	Service évaluation des dispositifs (Medical Device Evaluation Department)
SEESP	Service évaluation économique et de santé publique (Economic and Public Health Evaluation Department)
SEM	Service évaluation des médicaments (Medicinal Product Evaluation Department)
SNITEM	Syndicat national de l'industrie des technologies médicales (French National Union of the Medical Technology Industry)
UNCAM	Union nationale des caisses d'assurance maladie (French Association of Health Insurance Funds)

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