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The Leuven Ethical Question Framework: A Guide for Evaluating Health Technology Innovations

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Abstract: Due to current digitalization and automation processes, health technology innovations (HTIs) are entering healthcare settings at an accelerating pace. As all medical advancements, HTIs have a double nature that could either benefit or harm. Hence, how do we ensure an ethical assessment of HTIs? Many frameworks to ethically evaluate HTIs already exist, but few are developed and reported in a transparent and systematic way, and most rely either solely on theoretical or empirical data. This paper reports on the development and content of the Leuven Ethical Question (LEQ) Framework, a new tool for evaluating HTI impacts. The methodology used to develop the LEQ Framework consisted of deepening the results of a previously carried out systematic review of frameworks to ethically assess or evaluate HTI. These results were fleshed out in an iterative manner by multiple stakeholder meetings and expert consultations thus integrating the patient, healthcare professional, technology professional, and the health policy perspective within the framework. The LEQ Framework is a question matrix covering three stages in the HTI lifecycle: design, development, and use. These stages are analyzed from four contexts of ethical evaluation: global, societal, organizational, and individual-relational. Finally, the LEQ Framework contains a section of challenges which need to be considered throughout the entire HTI lifecycle. The Framework is preferably used in a deliberative setting and for stimulating ethical awareness of and reflection on the multiple impacts of HTIs. The LEQ Framework attempts to cover all dimensions of HTI and the contexts of its impacts from an ethical perspective. It aims to be comprehensive in its evaluation of ethical aspects of HTIs and to be practical for different stakeholders. Moreover, by using the LEQ Framework, HTIs are recognized as not only individual and local healthcare developments, but also developments that need to be perceived in ever enlarging societal and global contexts.

Keywords: 1 Health technology innovations; 2 Ethics; 3 Evaluation; 4 Frameworks; 5 Healthcare; 6 health technology assessment

1. Introduction

Health Technology Innovations (HTI) are being developed and used with the goal of restoring or maintaining people's health, and/or improving their quality of life (World Health Organization (WHO 2010)). As such, HTIs are entering and shaping every dimension of healthcare (WHO 2019). These dimensions are treatment (e.g. gene therapy); testing (e.g. drug testing); materials used in treatments (e.g. nanotechnologies); equipment and devices (e.g. robotics); information gathering and diagnostics (e.g. AI imaging applications for diagnosis); and various procedures and medical techniques (e.g. triage) (Warren-Jones 2013). With this in mind, HTIs can be understood as "[…] material

expressions of human knowledge in devices, techniques, procedures, and systems that are or will be used in a healthcare context" (Vandemeulebroucke, Denier, Mertens & Gastmans 2022b).

We inscribe ourselves in Stiegler's foundational premise that humans are technical beings. It is by their reliance on technological objects that humans become human (Stiegler 1998). Moreover, for Stiegler, each technological object is a pharmakon (Greek φαρμακόν or farmakón), the Greek concept for "medicine", entailing that they are characterized by a simultaneous possibility to benefit or harm people depending on how it is designed and used (Stiegler 2011). In a similar vein, the same can be said about HTI. HTIs have an inherent two-sided dynamic that magnifies or diminishes ethical values. Either the dynamic causes us to engage more intimately with and within healthcare or it alienates us from it (Ihde 1990; Kiran 2015; Vandemeulebroucke, Cavolo & Gastmans 2022a). Whether it will bring a positive impact on individuals and society will mostly depend on how the HTI is designed, developed, and used. Hence, we need an ethical framework that can assist us in guiding the design, development, and use of HTIs to ensure the possibility to positive effects rather than to harm .

This explains why the past years saw a growing interest in the development of ethical frameworks that promote the beneficial effects of HTIs and minimize the risk of their harmful effects (Vandemeulebroucke et al. 2022c). Currently, the main focus of research is on development of ethical frameworks for the implementation-and-use phase of the HTI life cycle, especially in the context of health technology assessments (HTA) (Vandemeulebroucke et al. 2022b). Specifically, current research focuses on which ethical frameworks are used in health technology assessments (HTAs) (Assasi, Schwartz, Tarride, Campbell & Goeree 2014); on the reasons ethics needs to be included in HTA (Hofmann 2008); on guidelines on how ethics can be integrated into HTA (Assasi, Schwartz, Tarride, Campbell & Goeree 2014); and on the barriers and enablers in using ethical frameworks for HTIs (Assasi, Schwartz, Tarride, O'Reilly & Goeree 2015; Bellemare et al. 2018).

This focus on implementation and use of HTIs and on the context of HTA has only recently been complemented by widening the scope to include the design and development of HTIs (Vandemeulebroucke et al. 2022c). This adjusted focus brings into view approaches like value-sensitive design (VSD) (van Wynsberghe 2013a, 2013b) and responsible research and innovation (RRI) (Aicardi, Fothergill, Rainey, Stahl & Harris 2018; Fothergill, Knight, Stahl & Ulnicane 2019; Lipworth, & Axler 2016; Pacifico Silva, Lehoux, Miller & Denis 2018; Stahl & Coeckelbergh 2016; Thorstensen 2019) to consider in ethical evaluations. Including these phases of the HTI life cycle and approaches broadens the concept of HTIs to be thought of as world objects; that is, "[…] objects that affect the world as a whole and not just a small corner of it" (Feenberg 2017, p. 5). We do not only need to scrutinize the impact of HTIs on national or regional healthcare systems, on particular healthcare organizations and directly affected stakeholders, but also HTIs' impact(s) on other aspects of the world (e.g., mining of natural resources for technical elements , pollution), and on other persons (e.g., those involved in the different supply chains and procurement processes behind HTIs).

A specific observation that can be made regarding the existing ethical frameworks for the evaluation of HTIs which are reported in the scientific literature is that, to our knowledge (Vandemeulebroucke et al. 2022c), many ethical frameworks are developed in the context of bigger (EU-)projects (e.g. EUnetHTA, INTEGRATE-HTA, M-Eco, SORMAS) by which the development methodology often is not described, not described in-depth, or not easy to find among the project's documents (Autti-Rämö & Mäkelä 2007; Bond & Weeks 2017; Denecke 2017; Gutiérrez-Ibarluzea 2012; Kosta, Pitkänen, Niemelä & Kaasinen 2010). An overview of the articles included in the systematic review and their methodological

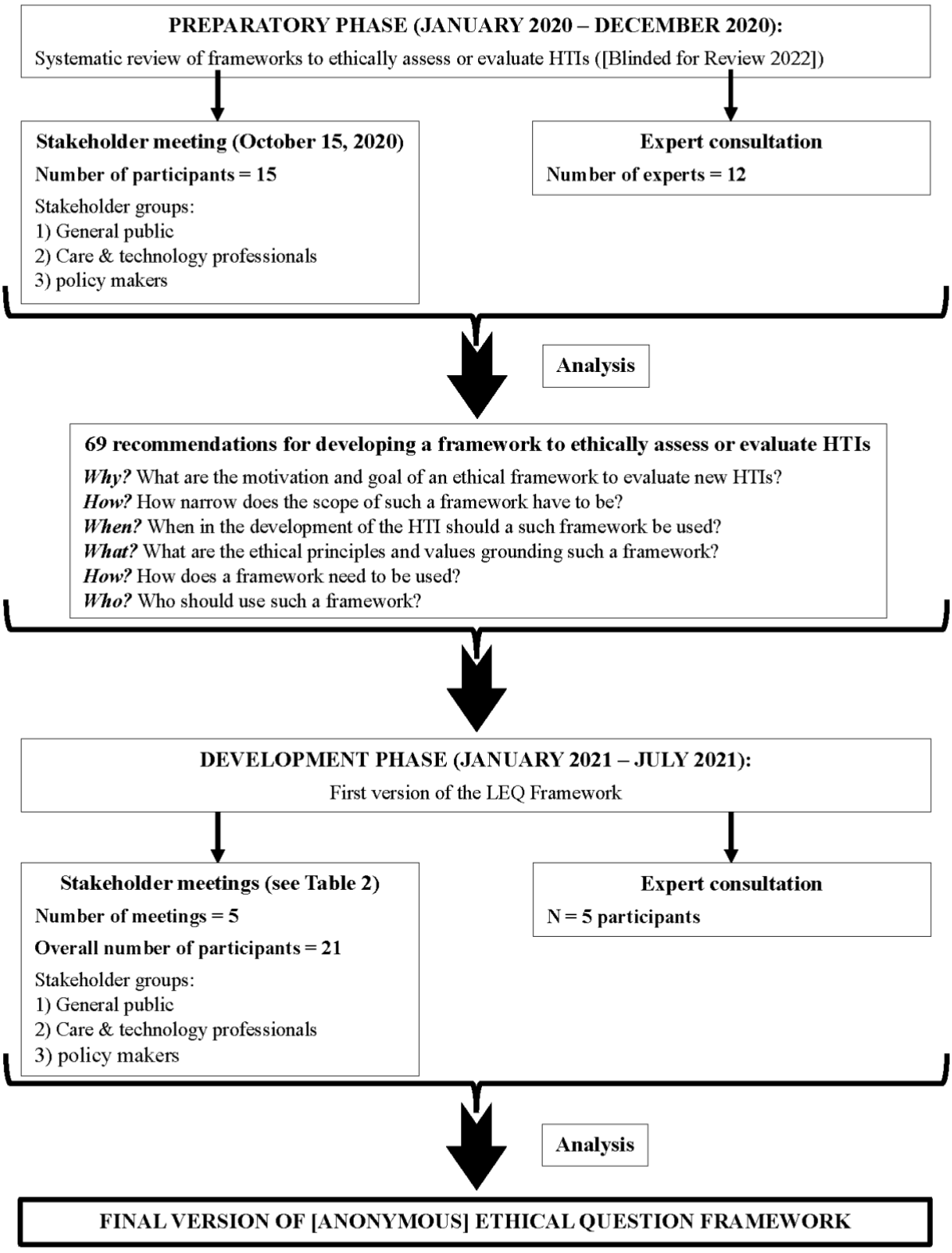
shortcomings (if present) is provided in the supplementary material S1. The lack of knowledge of how an ethical framework was developed impacts its rootedness, relevance, trustworthiness, and applicability. Further, more often than not, ethical frameworks are developed by solely relying on established ethical or philosophical traditions (e.g. bioethical 4-principles approach, wide reflective equilibrium, capabilities approach, care ethics) and/or abstract theorizing (Vandemeulebroucke et al. 2022c). The sole reliance on abstract theorizing and ethical traditions makes the practical implementation and the effectiveness of these frameworks weaker because it often lacks concrete suggestions on how to apply the theoretical principles in real-case scenarios. Stakeholders without a specific ethical and philosophical training might struggle using these framework in their daily work. Similarly, philosophers who have no training in engineering or medicine, or who do not have direct experience with certain care contexts might overlook important nuances in theorizing. Hence, engagement between the theory and all stakeholders has the potential to better bridge theory and practice.

To meet the need to analyze HTIs in larger contexts through a framework developed in a systematic and transparent way whose practical implementation and effectiveness can be ensured, we developed the Leuven Ethical Question Framework (LEQ Framework). In this paper we first zoom in on the preparatory work for the LEQ Framework. Additionally, we give an account of the methodology used to develop the LEQ Framework itself. In a second step, we then give an in-depth overview of the different characteristics of the LEQ Framework and its ethical content. In a last step, we indicate the strengths and limitations of the LEQ Framework by discussing its' usefulness and implications for the practice of health technology assessment and evaluation, for education of healthcare and technology professionals and ethicists, and for academic research related to HTI.

2. Methodology

The LEQ Framework was developed through a rigorous methodology inspired by the co-creation method (Stier & Dobers, 2017) that integrated theoretical insights from the existing literature and empirical insights from stakeholders, overcoming, in this way, some of the weaknesses identified in previously existing frameworks that solely relied on theoretical or empirical insight. Concretely, the development of the LEQ Framework followed two consecutive steps; the preparatory step and the developmental step. Figure 1 provides more information on these phases.

Figure 1. Overview of the development process of the [Anonymous] Ethical Question (LEQ) Framework


PREPARATORY PHASE (JANUARY 2020 – DECEMBER 2020):
Systematic review of frameworks to ethically assess or evaluate HTIs ([Blinded for Review 2022])
Stakeholder meeting (October 15, 2020)
Number of participants = 15
Stakeholder groups:
1) General public
2) Care & technology professionals
3) policy makers
Expert consultation
Number of experts = 12
Analysis
69 recommendations for developing a framework to ethically assess or evaluate HTIs
Why? What are the motivation and goal of an ethical framework to evaluate new HTIs?
How? How narrow does the scope of such a framework have to be?
When? When in the development of the HTI should a such framework be used?
What? What are the ethical principles and values grounding such a framework?
How? How does a framework need to be used?
Who? Who should use such a framework?
DEVELOPMENT PHASE (JANUARY 2021 – JULY 2021):
First version of the LEQ Framework
Stakeholder meetings (see Table 2)
Number of meetings = 5
Overall number of participants = 21
Stakeholder groups:
1) General public
2) Care & technology professionals
3) policy makers
Expert consultation
N = 5 participants
Analysis
FINAL VERSION OF [ANONYMOUS] ETHICAL QUESTION FRAMEWORK

First, in the preparatory step, we conducted a systematic review of HTIs ethical frameworks (Vandemeulebroucke et al. 2022c). This step was crucial to identify gaps in the literature. It identified several frequently used ethical theories, traditions, or approaches underlying existing frameworks (Supplementary materials S2). The review was complemented by a first workshop with 15 stakeholders belonging to one of the following categories of citizens: (1) general public (e.g., lay people, informal caregivers); (2) care and technology professionals (e.g., nurses, medical doctors, engineers); (3) policy makers (e.g., politicians, advisory committees) (Gauvin et al. 2010). Based on the review and on a guided discussion with stakeholders, 69 recommendations (supplementary materials S3) were provided on how to develop a stronger ethical framework to guide the design, development, and use of HTIs. For example, they suggested what ethical principles and values should ground such a framework and who should use it. We also asked for feedback via email to a selected group of experts in relevant fields (e.g., health law, bioethics, health technologies). An overview of participating stakeholders and experts is provided in Table 1.

Table 1. List of stakeholders and experts who were consulted during preparatory and development phases of the Leuven Ethical Question (LEQ) Framework and areas of expertise

Consulted during preparatory phase			
Stakeholders		**n = 15**	
Profession			
Healthcare professionals		5	
Policy makers		3	
Academics		3	
Civil society organization (e.g., patient representation organization)		2	
Health technology professional (e.g., private developer)		2	
Experts		**n = 12**	
Profession			
Academics (total n)		5	
	Health law	1	
	Philosophy	1	
	Health economics	1	
	Health technology	1	
	Healthcare	1	
Civil society organization (e.g., patient representation organization)		3	
Independent research organization		2	
Health technology professional (e.g., private developer)		1	
Healthcare professional		1	

Consulted during development phase	
Stakeholders	**n = 21**
Profession	
Policy makers	7
Healthcare professionals	5
Civil society organization (e.g., patient representation organization; company representation organisation)	5
Health technology professionals (e.g., private developer)	3
Academics	2
Experts	**n = 5**
Profession	
Academics (total n)	2
Health law	1
Philosophy	1
Healthcare professionals	2
Civil society organization (e.g., patient representation organization)	1

Second is the developmental step; a first draft of the LEQ Framework was prepared based on the insights gained in the preparatory step. The Framework was then refined based on four rounds of stakeholders' meetings and feedback from experts. An overview of the developmental process of the LEQ Framework is provided in Table 2.

Table 2. This is a table to be inserted here

Development of first version of framework	1.	Preparatory study
	FIRST VERSION OF ETHICAL FRAMEWORK	
Development of second version of ethical framework	2.	First stakeholder meeting to discuss first version of ethical framework – 26 March 2021
	3.	Analysis of first stakeholder meeting
	4.	Second stakeholder meeting to discuss first version of ethical framework – 30 April 2021
	5.	Analysis of second stakeholder meeting
	6.	Integration of stakeholders' input into first version of ethical framework
	SECOND VERSION OF ETHICAL FRAMEWORK	

Development of third version of ethical framework	7.	Third stakeholder meeting to discuss second version of the ethical framework – 26 May 2021
	8.	Fourth stakeholder meeting to discuss second version of the ethical framework – 1 June 2021
	9.	Analysis of third and fourth stakeholder meetings
	10.	Integration of stakeholders' input into second version of ethical framework
	THIRD VERSION OF ETHICAL FRAMEWORK	
Development of fourth version of ethical	11.	Opportunity to give written commentary on the third version of the ethical framework by stakeholders and experts – Invitation send on the 10 June 2021
	12.	Analysis of written input
	13.	Integration of stakeholders' and experts' input into third version of ethical framework
	FOURTH VERSION OF ETHICAL FRAMEWORK	
Development of final version of ethical framework	14.	Fifth stakeholder meeting to discuss the fourth version of the ethical framework – 28 June 2021
	15.	Analysis of fifth stakeholder meeting
	16.	Integration of stakeholders' input into fourth version of ethical framework
	FINAL VERSION OF THE LEUVEN ETHICAL QUESTION FRAMEWORK	

A semi-structured interview guide was used for every stakeholder meeting. This interview guide was a result of multiple meetings within the interdisciplinary research team. Experts were required to provide feedback using a questionnaire based on the interview guide. The output of the stakeholders meetings and the experts' feedback were analyzed using the QUAGOL (Dierckx de Casterlé, Gastmans, Bryon & Denier 2012). QUAGOL was selected because it provides a systematic and transparent framework for analyzing qualitative data while preserving a close connection between participants' narratives and the emerging conceptual interpretations. A distinctive feature of QUAGOL is its emphasis on an iterative process that moves between detailed case-level analysis and cross-case comparison, supported by the development of conceptual interview summaries before formal coding begins. This approach facilitates in-depth interpretation, reflexivity, and rigor in the analysis.

The used interview guide, questionnaire, and developed analysis reports can be found here: https://osf.io/qcbkg. An in-depth description of the methodology used to develop the LEQ Framework is provided in the supplementary material S4.

In terms of ethical considerations, all necessary measures were taken to ensure the integrity of each participant. All participants received an information leaflet about the study, their rights, and the measures taken to ensure anonymity and confidentiality.

Additionally, a quick presentation of the study and participants' rights was repeated at every stakeholders' meeting, including their right to withdraw participation. All involved stakeholders and experts gave their explicit informed consent to participate and to use their anonymized comments as the basis to develop the Framework. Further, confidentiality of personal information and anonymity were guaranteed in accordance with the General Data Protection Regulation of 25 May 2018. A detailed explanation of how we safeguarded participants' integrity and confidentiality is offered in the Supplementary material S3.

3. Results

The result of this extensive process is the LEQ Framework. In this section, we will first explain the main characteristics of this framework in terms of goals, how and when to use the Framework, etc. Then we will include the Framework itself. For the sake of conciseness, we included the LEQ Framework without the introduction and glossary. The full version of the Framework can be found here: https://osf.io/zj9fa.

3.1. Characteristics of the LEQ Framework

3.1.1 Goals of the LEQ Framework

The LEQ Framework has four goals:

First, to increase ethical awareness of HTI developers, users, and other relevant stakeholders in terms of the impact of HTIs. By using the LEQ Framework, stakeholders can identify blind spots that could cloud their perceptions of ethical aspects of the HTIs being designed, developed or used.

Second, to increase the transparency of the design, development, and use of HTIs. In order to be transparent, one must be open, communicative, and be accountable and the LEQ Framework might help developers to do just that.

Third, to facilitate the involvement of stakeholders in the design, development, and use of an HTI by employing deliberative methods. Hence, using the LEQ Framework aspires to have an emancipatory effect.

Fourth, to improve how the values of social justice and sustainability are implemented throughout the different phases of HTI development. The LEQ Framework is an embodiment of the recognition that healthcare also comes with its own impacts on society and on the natural environment, and as such, on the determinants of health (Health Care Without Harm & Arup 2019; Lefebvre 2011; Lenzen 2020).

3.1.2 User(s) of the LEQ Framework

The term "stakeholder" covers a broad range of different persons and groups, be it HTI developers and producers, care receivers and caregivers, healthcare organizations, governments, etc., or a mixture of these. In Belgium, for example, the smartphone application to track COVID-19 infections was meant for both the government and individual citizens. For the government, it was meant for certain governmental departments to gain insight into the number of infections and the dynamics of pandemic development; for individual citizens, it was meant for them to gain spatial and temporal insights into whether they might have been in close proximity with infected persons.

3.1.3 Structure of the LEQ Framework

The LEQ Framework is a question-based framework to encourage a deliberative approach among stakeholders (Burls et al. 2017; Heintz et al. 2015; Hofmann 2005; Hofmann et al. 2014; Lehoux & Blume 2000; Lipworth & Axler 2016; Pacifico et al. 2018; Saarni et al. 2008; Stahl & Coeckelbergh 2016; Thorstensen 2019). Further, the LEQ Framework is envisioned as an ethical matrix combining phases of the technology life-cycle—design, development, and use— (Aicardi et al. 2018; Fothergill et al. 2019; Lipworth & Axler 2016; Pacifico Silva et al. 2018; Stahl & Coeckelbergh 2016; Thorstensen 2019) and different contexts of ethical analysis—global, societal, organisational, individual-relational (Vandemeulebroucke et al. 2020, 2021, 2022b). At the end of this matrix, a section of general aspects of ethical reflection of HTIs, which occur on each technical level and in each context of reflection, is included: (1) the purpose of the HTI; (2) the involvement of different stakeholders in the different phases of the HTI life cycle and the ethical evaluation; (3) climate, environment, and ecology issues; (4) and the sustainability of the HTI and its ethical evaluation. An in-depth overview of collected questions distilled out of papers included in the systematic review can be found in the supplementary material S5.

3.1.4 Using the LEQ Framework

The LEQ Framework is a standardized framework, meaning that in principle, it is aimed to be used to evaluate every HTI. Depending on the HTI of interest, the Framework can be used in a more specific way, emphasizing specific reflection questions and leaving others aside.

We envision the LEQ Framework to be used in a deliberative and dialogical setting. This means that, ideally, in each technical phase of the HTI development, all relevant stakeholders need to be identified, included, and/or represented in the evaluation of the HTI of interest. The LEQ Framework is an evaluation instrument to establish discussions, leading to dynamic co-creations by which stakeholders are stimulated to formulate concrete recommendations directed to ethically responsive design, development, and use of an HTI.

Using the LEQ Framework entails only a minimal normative character. The Framework is used to direct its users in an open manner but does not direct them on how to interpret the different questions or what the final evaluation of an HTI needs to be.

3.1.5 When to use the LEQ Framework

We consider the evaluation of ethical aspects of an HTI to be a continuous process, one that unfolds throughout its three different technical phases. Preferably, the stakeholders who are involved in the evaluation during the design phase, are also involved in the evaluation during the development and use phases. Of course, other stakeholders can be involved too.

Nevertheless, the Framework can also be divided in line with the three different technical phases. Depending on the specific phase in which the evaluation takes place, the specific questionnaire can be taken out of the Framework and be used as an independent instrument without considering the other phases.

3.1.6 Ensuring deliberative soundness

The Framework relies on specific, widely accepted principles of deliberative ethics. These principles justify dialogues or deliberations according to the four basic conditions of the Accountability for Reasonableness (A4R) model (Daniels & Sabin 2002; Daniels & van der Wilt 2016).

The conditions of the A4R model comprise the following:

1) Relevance – The arguments used during the evaluation of an HTI, as well as the evaluation, need to be relevant to the distinct properties of the HTI. The stakeholders' emotions and intuitions can be relevant during the evaluation of an HTI, but are, in themselves, insufficient to guarantee its rational basis. Moreover, different steps of the evaluation process need to be relevant in the sense that unnecessary endeavors are avoided.

2) Publicity or transparency – With the evaluation of an HTI, the argumentations used during the evaluation need to be clear and easily accessible to the stakeholders and the broader public. They should be openly discussed and motivated or reports should be openly accessible.

3) Revisability – Mechanisms should be in place to ensure that the evaluation of an HTI can be revised in light of new scientific evidence or ethical argumentation.

4) Regulation – Mechanisms should be in place that guarantee conditions 1 through 4 are met.

These four conditions are complemented with a fifth:

5) Collectivity and inclusiveness – The evaluation of an HTI should not be a single act. Rather, the outcome of an evaluation is the result of a collective process of reflection and discussion in which all relevant stakeholders are included.

3.2. *The* Leuven *Ethical Question (LEQ) Framework*

In this section we will provide the full list of questions of the LEQ Framework organized by HTI life cycle phase. A table providing an overview of collected questions distilled out of papers included in the systematic review is provided in the Supplementary Material S5. A short description of content per phase is also provided. More detailed information on how these different phases are interrelated can be found here: https://osf.io/zj9fa.

3.2.1 Design phase

The HTI life cycle begins with the design phase (Table 3), in which a new device or application is conceptualized and abstractly concretized. For the ethical evaluation of this first phase, the LEQ Framework has 15 specific ethical reflection questions structured across the four contexts of ethical evaluation–global, societal, organizational, and individual-relational—and 16 general questions related to general ethical challenges of designing an HTI. The ellipses (…) at the end of each context of evaluation indicate that the questions should not be perceived as an exhaustive list but instead as questions that could be modified and adjusted throughout the different uses of the LEQ Framework.

Table 3 List of questions of the Leuven Ethical Question (LEQ) Framework organized by contextual levels – HTI design phase.

		Phases of developing a health technology innovation (HTI) – Design
Context of ethical evaluation	***Global***	• In what manner is the intended HTI an answer to **global challenges** in healthcare *(e.g., questions about healthcare as universal human rights, questions about health(care) inequalities among countries,…)*? • What are the political, economic or other **obstacles** in a global context related to the intended HTI *(e.g., poor structural conditions or lack of resources, questions about regional labor conditions, unbalanced economic relations between countries and/or companies,…)*? Can and how will these obstacles **be dealt with**? • Does the possibility exist that the intended HTI could be used for **other than the intended purposes** *(e.g., military ('dual use') or criminal ('misuse') purposes,…)*? If yes, **what** might the purposes be? Can and how will this risk be dealt with/mitigated? • …
	Societal	• In what manner is the intended HTI an answer to **societal challenges** in healthcare *(e.g., providing new possibilities to people, demographic groups or minorities who otherwise are difficult to reach, or to meet unanswered healthcare needs, or to reduce healthcare costs,…)*? • Are existing **legal frameworks** applicable to the intended HTI? If not, how will this be dealt with? • What are the **obstacles** in a societal context related to the intended HTI *(e.g., economic or political climate before the implementation of the HTI, or difference in views on the HTI between countries/demographic groups,…)*? Can and how will these obstacles **be dealt with**? • …
	Organizational	• In what manner is the intended HTI an **answer to organizational challenges** in healthcare *(e.g., about work pressure among healthcare professionals, or follow-up of patients,…)*? • What are the **obstacles** in an organizational context related to the intended HTI *(e.g., regarding necessary technical knowledge and skills of users and healthcare professionals, or the necessary technical infrastructure,…)*? Can and how will these obstacles **be dealt with**? • …
	Individual-relational	• In what manner is the intended HTI an answer to **individual/relational challenges** in healthcare *(e.g., improvement of the access to healthcare, improved quality of healthcare, increased self-sufficiency, social relations, decreased care costs,…)*? • Is and to what extent is **data collection** necessary? Which strategies will be implemented to guarantee safe **data management**? How will **transparency** about data collection and management be provided? • In what manner will the **privacy** of the user(s) and their social environment be guaranteed by the intended HTI? How will **transparency** about privacy be provided *(e.g., in compliance with GDPR[b]-legislation,…)*? • Is it necessary that the intended HTI will be **universally accessible** *(e.g., financially, technologically, user-friendly,…)*? How can this accessibility be guaranteed? What are the arguments to not make HTI accessible to everyone? • In what manner do we account for **unintended/undesired side effects** of the intended HTI *(e.g., becoming over-dependent on the HTI, addictive mechanisms, misinterpretation of data, reduced social contacts,…)*? • Does the intended HTI have a possible impact/influence on our **conception of humans** and the **world** in which we live? • Will the intended HTI produce **new ethical questions/tensions**? What could these be? In what manner will these be dealt with?

	General Ethical Challenges
Purpose(s)	• **Why** should the intended HTI be designed? Why this particular HTI and not another one? What **purpose/s** is/are aimed for with the intended HTI? • What **strategies** are implemented to reach this/these purpose/s *(e.g., regarding needs studies, market creation, correct marketing,…)*? • What are the possible **benefits or disadvantages** of the HTI for the intended users and their social environment *(e.g., improved health, better access to healthcare, lower care costs,…; or declining social contacts in vivo, presupposed technical skills,…)*? • Which **ethical values** are intended when set purpose/s is/are reached? Why these and not other values *(e.g., health improvement and prevention of disease/illness, increasing self-sufficiency, more freedom, decreasing social isolation, job creation,…)*? • …
Stakeholders	• **Who** are the relevant stakeholders *(e.g., those who are directly involved, such as intended users, healthcare professionals, policy makers,… & those who are indirectly involved, such as civilians, future generations, natural climate representatives,…)*? • Are these stakeholders **effectively involved** during the design of the intended HTI? Why are they involved? Why not? • **In what manner** can stakeholders be involved in the design of the intended HTI? What are their roles and responsibilities? Is there a balance in the composition of the stakeholders group *(e.g., gender, age, ethnicity, health or technology literacy, social-economic status,…)*? • Do the stakeholders need to be **involved throughout** all the phases of the HTI development (design, development, use)? How will this involvement be established? • What are the **interests** of the involved stakeholders? Which benefits/disadvantages could they have because of their involvement? • Who is **responsible** for **monitoring** the design of the HTI and its ethical evaluation? • …
Climate, environment, and ecology	• Is the **ecological footprint** *(e.g., impact on natural environment and particular ecosystems; impact on the natural climate,…)* of the HTI life cycle accounted for? In what manner? • What strategies are put in place to deal with **negative impacts** on the ecological footprint of the HTI life cycle *(e.g., compensation regulations, sustainable materials, choice of suppliers, recycling,…)*? • …
Sustainability	• Has this **ethical evaluation received due attention** in the design of HTI? In what ways does it show this? • Does the intended HTI presuppose an **extended or new technological infrastructure** to be effective? How will this be established *(e.g., 5G network, new healthcare structures,…)*? • How will **societal and demographic differences** of prospected users be accounted for in the design of the HTI *(e.g., gender, age, ethnicity, health or technology literacy, social-economic status,…)*? • How will the interests of **future generations** be accounted for with the intended HTI? • …
Are there relevant questions/points of consideration that are not included in the foregoing list?	

[a] Questions presented here are an English translation of original Dutch.

[b] GDPR, General Data Protection Regulation (Regulation (European Union) 2016/679).

3.2.2 Development phase

For the ethical evaluation of the development phase (Table 4), the LEQ Framework has 10 ethical reflection questions besides the 16 questions related to general ethical challenges of the HTI. As with the design phase, the questions are structured according to the different contexts of the ethical evaluation. The ellipses (…) should be understood as explained in the *design phase* above. New questions might be included.

Table 4 List of questions of the Leuven Ethical Question (LEQ) Framework organized by contextual levels – Development phase

		Phases of Developing of health technology innovation (HTI) – Development
Context of ethical evaluation	***Global***	• What are the political, economic or other **obstacles** in a global context that can obstruct the development of the intended HTI *(e.g., transport, materials, production lines,…)*? Can and how will these obstacles **be dealt with**? • What is the location of origin of the necessary natural and technical **raw materials and resources** to develop the HTI? Why do these materials and resources need to come from there? Why could or couldn't alternative locations be considered? • In what **labor conditions** were the natural and technical raw materials and resources collected and developed? In what labor conditions is the HTI being developed? • Does or could the possibility exist that the development of the HTI or the collection and the development of natural and technical raw materials and resources lead to **human rights** violations? • How can **transparency** about these and other factors be provided? • Does the possibility exist that the HTI could be used for **other than the intended purposes** *(e.g., military ('dual use') or criminal ('misuse') purposes,…)*? If yes, what might these purposes be? Can and how will this risk be dealt with? • …
	Societal	• What are the **obstacles** in a societal context related to the intended HTI *(e.g., new start-ups, impact on the local region, production certification,…)*? Can and how will these obstacles **be dealt with**? • Are existing **legal frameworks** applicable to the development of the HTI? If not, how will this be dealt with? • …
	Organizational	• What are the **obstacles** in an organizational context related to the intended HTI *(e.g., regarding necessary minimums of people and resources and supplies,…)*? Can and how will these obstacles **be dealt with**? • …
	Individual-relational	• When the developed HTI will be **tested**, will all necessary conditions be met to obtain **informed consent** from the participants? What **strategies** will be implemented to obtain this informed consent? • …
		General Ethical Challenges
	Purpose(s)	• **Why** should the intended HTI be developed? Why this HTI and not another? What **purpose/s** is/are aimed for with this particular HTI? • What **strategies** are implemented to achieve this/these purpose/s *(e.g., regarding needs studies, market creation, correct marketing,…)*? • What are the possible **benefits or disadvantages** of the HTI for the intended users and their social environment *(e.g., Improved health, better access to healthcare, lower care costs,…; or declining social contacts in vivo, presupposed technical skills,…)*? • Which **ethical values** are intended when set purpose/s is/are reached? Why these and not other values *(e.g., health improvement and prevention of disease/illness, increasing self-sufficiency, more freedom, decreasing social isolation, job creation,…)*? • …

Stakeholders	• **Who** are the relevant stakeholders *(e.g., those who are directly involved such as intended users, healthcare professionals, policy makers,… & those who indirectly involved such as civilians, future generations, natural climate representatives,…)*? • Are these stakeholders **effectively involved** during the development of the intended HTI? Why are they involved? Why not? • **In what manner** can stakeholders be involved in the development of the intended HTI? What are their roles and responsibilities? Is there a balance in the composition of the stakeholders group *(e.g., gender, age, ethnicity, health or technology literacy, social-economic status,…)*? • Do the stakeholders need to be **involved throughout** all the subsequent phases of HTI development (use)? How will this involvement be established? • What are the **interests** of the involved stakeholders? Which benefits/disadvantages could they have because of their involvement? • Who is **responsible** for **monitoring** the development of the HTI and its ethical evaluation? • …
Climate, environment, and ecology	• Is the **ecological footprint** *(e.g., impact on natural environment and particular ecosystems; impact on the natural climate)* of the HTI life cycle accounted for? In what manner? • What strategies are put in place to deal with **negative impacts** on the ecological footprint of the HTI life cycle? • …
Sustainability	• Has this **ethical evaluation received due attention** in the development of HTI? In what ways does it show this? • Does the intended HTI presuppose an **extended or new technological infrastructure** to be effective? How will this be established *(e.g., 5G network, new healthcare structures,…)*? • How will **societal and demographic differences** of prospected users be accounted for in the development of the HTI *(e.g., gender, age, ethnicity, health or technology literacy, social-economic status,…)*? • How will the interests of **future generations** be accounted for in the intended HTI? • …
Are there relevant questions/points of consideration which are not included in the foregoing list?	

[a] Questions presented here are an English translation of original Dutch.

3.2.3 Use phase

The final phase of the HTI life cycle refers to when the HTI is put into use by the target audience (Table 5). For this phase, the LEQ Framework has 34 ethical reflection questions besides the 16 general ethical challenges questions. The reason there are more questions in this phase is because existing research on the ethics of HTIs still heavily focuses on use of new HTIs and much less on their design and development (Vandemeulebroucke et al. 2022c). Also here, the ellipses (…) should be understood as explained in the design phase and indicates an openness for new questions.

Table 5 List of questions of the Leuven Ethical Question (LEQ) Framework organized by contextual levels – Use phase.

Context of ethical evaluation	Phases in developing a health technology innovation (HTI) – Use	
	Global	• Does the possibility exist that the HTI could be used for **other than the intended purposes** *(e.g., military ('dual use') or criminal ('misuse') purposes,…)*? Can and how will this risk be dealt with? • In which **countries** will the HTI be available? Will it be available for all countries? If so, how can **experiences** and **knowledge** of using the HTI be **shared**? • …
	Societal	• Does the possibility exist that use of the HTI will generate, maintain or reify a form of **discrimination** between people? Which strategies will be implemented to deal with this? • Does the possibility exist that use of the HTI will contribute to **solidarity** in society? Which strategies will be implemented to make use of this potential? • Does the possibility exist that use of the HTI will lead to **more accessible healthcare**? Which strategies will be implemented to make use of this potential? • Does the possibility exist that use of the HTI will create **more value** for **more people** while **decreasing costs**? In what way does the use of the HTI lead to this? • Does the possibility exist that use of the HTI will cause **tensions** between social, cultural, religious, or philosophical values, convictions, or institutions? Which strategies will be implemented to deal with these tensions? • Are existing **legal frameworks** applicable to the use of the HTI? If not, how will this be dealt with? • What are the political, economic, social or other **obstacles** in a societal context that can hinder use of the HTI *(e.g., new start-ups, impact on local region, production certification, …)*? Can and how will these obstacles **be dealt with**? • Does the possibility exist that use of the HTI will impact/influence our **conceptions** of **humans** and **society** *(e.g., our conceptions of responsibility, justice, solidarity,…)*? How will this possibility be dealt with? • Does the possibility exist that use of the HTI will change **human existence** *(e.g., our conceptions of humanity, embodiment, behaviors, lifestyles,…)*? How will this possibility be dealt with? • In what way does use of the HTI **impact the image** of healthcare professions and/or of patients, those who are cared for? *(positive or rather negative; e.g., 'the caregiver as programmer' or 'the nurse as care engineer',…)*? • What **scenarios** exist to remove the HTI from society if scientific evidence and good argumentation lead to this necessity *(e.g., changing societal perceptions, proved negative effects in the intermediate or long term (think for example of the discussion about CFK's in the air, micro-plastics,…, financial reasons,…)*? • …
	Organizational	• Which are the other **obstacles** in an organizational context that can obstruct the use of the HTI *(e.g., energy provision, architecture, infrastructure, environment,…)*? Can and how will these obstacles **be dealt with**? • Will the use of the HTI cause **tensions** with social, cultural, religious, or philosophical values, convictions, or institutions from an organizational perspective *(e.g., mission statements, ethical policies in organizations,…)*? Which strategies will be implemented to deal with these tensions? • Does the use of the HTI rely on **distraction/nudging/deception** *(e.g., electronic teddy bears, virtual architecture and interior design, virtual/augmented reality, overestimation of the possibilities of the HTI,…)*? In which way is this

		distraction/nudging/deception established? Which are the argumentations to justify this distraction/nudging/deception? • Does the possibility exist that the availability of the HTI will lead to a perceived moral or other **obligations** for an organization to use the HTI *(e.g., social pressure, pressure from the healthcare sector,…)*? • Which **scenarios** exist to take the HTI out of the organization if scientific evidence and good argumentation leads to this necessity (*e.g., changing societal conceptions, proved negative effects in the intermediate or long term, financial reasons, …)* ? • …
	Individual-relational	• How will users and their social environment be informed about the possible implications of the use of the HTI? Are the users capable to give **informed consent** for the use of the HTI? Will the benefits and disadvantages of the use of HTI be explained in an approachable way? How will informed consent of vulnerable people or their representatives be obtained *(e.g., children, disabled people, people with dementia,…)*? • Why and to which extent is **data collection** necessary? Which strategy will be implemented to guarantee safe **data management**? How will **transparency** about data collection and management be provided? • In what way will the **privacy** of the user(s) and their social environment be accounted for by the intended HTI? How will **transparency** about privacy be provided *(e.g., in compliance with GDPR-legislation,…)*? • In what way will use of the HTI impact/influence the **autonomy** of the user(s)? • In what way will use of the HTI impact/influence the **dignity** of the user(s)? • How will the physical, psychological, and moral **integrity** of HTI users and their social environment be protected *(e.g., sex robots for older adults with dementia or people with a disability, video monitoring of people,…)*? • Will **tensions** occur between the use of HTI and social, cultural, religious, or philosophical values, convictions, or institutions in an individual-relational context *(e.g., personal convictions and moral values, or the convictions or moral values of the social environment,…)*? What are these tensions? Which strategies will be implemented to deal with these tensions? • In what way will use of the HTI **impact/influence healthcare professions** and conceptions of informal caregiving *(e.g., health literacy, HTI as support or replacement, facilitating or obstructing medical or care practices,…)*? • In what way will the use of the HTI impact/influence the **social environment** of the user(s) *(e.g., loved-ones and close social environment, colleagues, carers,…)*? • Does the use of the HTI rely on **distraction/nudging/deception** *(e.g., electronic teddy bears, virtual architecture and interior design, virtual/augmented reality, overestimation of the possibilities of the HTI,…)*? In which way is this distraction/nudging/deception established? Which are the argumentations to justify this distraction/nudging/deception? • Does the possibility exist that the availability of the HTI will lead to a perceived moral or other **obligations** for an individual to use the HTI *(e.g., social pressure, pressure from the healthcare sector,…)*? • Will use of the HTI impact/influence our thought about being a **person**, our feeling of self-worth and dignity and our relation to our **environment**? • Will use of the HTI induce **new ethical questions/tensions**? Which could these be? In what way will these be dealt with? • Is it necessary that the HTI will be **universally accessible** *(e.g., financial, technical, user-friendly,…)*? How can this accessibility be guaranteed? What are the arguments not to make HTI accessible for everyone?

		• In what way do we account for **unintended/undesired side effects** of the use of the HTI *(e.g. becoming too dependent on the HTI, addictive mechanisms, misinterpretation of data, reduced social contacts,…)*? • What **scenarios** exist to remove the HTI from the sphere of individual use if good argumentation leads to this necessity *(e.g., misuse of the HTI, over-dependency, declining social contacts,…)*? • …
	General ethical challenges	
Purpose(s)		• **Why** should the intended HTI be used? Why this HTI and not another? What **purpose/s** is/are aimed for with the use of the HTI? • Which **strategies** are implemented to reach this/these purpose/s *(e.g., regarding needs studies, market creation, correct marketing,…)*? • Which are the **possible benefits or disadvantages** of using the HTI for the intended users and their social environment (loved ones, caregivers, …) *(e.g., improved health, better access to healthcare, lower care costs,…; or declining social contacts in vivo, presupposed technical skills,…)*? • Which **ethical values** are intended when set purpose/s is/are reached? Why these and not other values *(e.g., health improvement and prevention of disease/illness, increasing self-sufficiency, more freedom, decreasing social isolation, job creation,…)*? • …
Stakeholders		• **Who** are the relevant stakeholders *(e.g., those who are directly involved such as intended users, healthcare professionals, policy makers,… & those who indirectly involved such as civilians, future generations, natural climate representatives,…)*? • Are these stakeholders **effectively involved** during the design of the intended HTI? Why are they involved? Why not? • **How or in what way** can stakeholders be involved in the use of the HTI? What are their roles and responsibilities? Is there a balance in the composition of the stakeholders group *(e.g., regarding gender, age, ethnicity, health or technology literacy, social-economic status,…)*? • What are the **interests** of the involved stakeholders? Which benefits/disadvantages could they have because of their involvement? • Who is **responsible for monitoring** use of the HTI and its ethical evaluation? • …
Climate, environment, and ecology		• Is the **ecological footprint** *(e.g., impact on natural environment and particular ecosystems; impact on the natural climate,…)* of the HTI life cycle accounted for? In what way? • Which strategies are put in place to deal with **negative impacts** on the ecological footprint of the HTI life cycle *(e.g., compensation regulations, sustainable materials, choice of suppliers, recycling,…)*? • …
Sustainability		• Has this **ethical evaluation received due attention** in the use of the HTI? In what way does it show this? • Does use of the HTI presuppose an **extended or new technological infrastructure** in order to be effective? How will this be established *(e.g., 5G network, new healthcare structures,…)*? • How will **societal and demographic differences** of prospective users be accounted for in use of the HTI *(e.g., gender, age, ethnicity, health or technology literacy, social-economic status,…)*?

	• How will the interests of **future generations** be accounted for in the use of the HTI? • …
Are there relevant questions/points of consideration which are not included in the foregoing list?	

[a] Questions presented here are an English translation of original Dutch.

[b] GDPR, General Data Protection Regulation (Regulation (European Union) 2016/679).

4. Discussion

In this present study, we presented the systematic and transparent development process and the content of the LEQ Framework. In terms of methods, the LEQ fills the gap that we previously identified in other frameworks. Namely, it relies in a transparent development process, which increases the relevance, trustworthiness, and applicability of the LEQ Framework. Further, the LEQ relies on a robust methodology that puts empirical data from stakeholders and experts in dialogue with theoretical insights. This is a step forward compared to other frameworks that solely rely on empirical or theoretical insights, ensuring once again, the LEQ theoretical robustness and its applicability. Moreover, the fact that different stakeholders and experts participated in multiple meetings during the development of the LEQ Framework should assure potential users that the Framework has a minimum threshold of effectiveness and user-friendliness in different practical settings. From a content perspective, the main strengths of the LEQ Framework are the fact that it can be adapted to any HTI, including but not limited to (generative) AI, and that it addresses the whole life cycle of HTIs. Although the framework was developed prior to the AI Act, it still integrates a similar risk-based approach grounding the AI Act. However, our framework has a broader breath as compared to the AI Act, not only because it is applicable to any HTI, but also because it does not only focus on risk prevention but also on benefit promotion. Finally, the LEQ Framework has been approved by the Flemish Minister for Welfare, Public Health, and Family on December 21, 2021, and being made publicly available in Dutch on the governmental website (https://cdn.nimbu.io/s/5s8z9pq/channelentries/e9e9sdv/files/2021_14_Rapport_62_SWVG_EF47_2__Ethiek.pdf?be18f3m). This approval increases the chances that the LEQ Framework will find its way to practical settings and will show its practical effectiveness.

The LEQ Framework is practice-oriented, in the sense that its first and foremost goal is to be applicable in real-case scenarios to evaluate HTIs and guide their design, development, and use. Nevertheless, further considerations for practice are needed in order to ensure its actual implementation. Moreover, even though the LEQ Framework is intentionally practice-oriented, its implications extend beyond practice to encompass education and research.

4.1. Implications for practice

The LEQ Framework is grounded on a deliberative approach, which is consistent with our own perspectives about ethics and HTIs. Our goal was to develop a framework that could easily be used for HTI as technology per se as well as for a specific HTI. As such, we needed an approach that would grant enough flexibility to be adapted to different HTIs. Further, it is equally important to acknowledge that ethical evaluation surrounding

HTIs might vary depending on the context in which the HTI is used, on the culture, on legal system, on the healthcare system, etc.

Having a question-based framework to guide the ethical reflection provides several advantages. First, it will ensure rigour because it provides a structured way to approach an HTI evaluation. As such, the LEQ Framework will also ensure that even groups with no or minimal experience with ethical evaluations are able to navigate the ethical discussion, although we do consider ethicists as stakeholders. Second, it ensures that all relevant ethical questions have been explored. Of course, we cannot guarantee that the LEQ users will actually consider all the questions, but the fact that the Framework lists the questions to be asked increases the probability that the users will answer them or that they will reflect on why a certain question is not applicable for them. Finally, the fact that this is a question-based guide to achieve an answer rather than the answer itself, allows the users to find their own answer, the one that is most appropriate for the HTI at hand, and their context and culture. This is, again, consistent with our belief that a one-size-fits-all kind of framework in the context of HTI would be more harmful than beneficial as it would not allow to adapt to the nuances of each context.

We do acknowledge that following this question-based interdisciplinary approach is inevitably time-consuming. However, we do not believe that being time-consuming is per se an issue. Good ethical reflection takes time, especially if we truly want to identify and address all the potential ethical issues of a given HTI and involve all stakeholders. The only situation in which this could be a hindrance is an emergency situation in which an HTI has to be developed or implemented fast. Although this is not a typical case as HTIs normally take years from conception to implementation, we acknowledge that in case of an emergency a different framework might be more appropriate. Moreover, it is not always necessary to use the full LEQ Framework. We foresee situations in which there is a need to evaluate only one lifecycle phase or the impact in one specific context. In that case, it is possible to only extract the sections of the matrix relevant to the evaluation at hand, meaning that it is possible to use the LEQ in a less time-consuming way if only one or a handful of aspects need evaluation. Finally, we believe that, although using the LEQ Framework in its entirety is time-consuming in the short-term, in long-term it might actually save time. Integrating ethical reflection from HTIs conception allows to identify and address potential issues while the technology is still in development. In the long run, this can be less time- and resource-consuming than having to address ethical issues in the post-production and implementation phase.

Finally, we acknowledge that the mere existence of the LEQ Framework will not automatically lead to its implementation or to a more ethical HTI assessment. The implementation of the LEQ Framework on scale needs to be supported by proper infrastructure. The latter could take different forms depending on the context and goal. For example, important forms of support for the LEQ Framework implementation are specific trainings for stakeholders, such as healthcare professionals and developers (for more information on this point, see the next section on implications for education). Further, institutions, such as private companies and healthcare institutions, should allocate sufficient time and resources to the learning and use of the LEQ Framework.

4.2. Implications for education

The LEQ Framework has been utilized by the authors and their colleagues as an educational tool. Practically, we started by introducing and explaining the LEQ Framework to graduate students from advanced master programmes in Bioethics and in management in healthcare policy. Then, we chose an HTI (i.e., electronic tracking devices

for people with dementia), divided the class in three groups, each representing a specific HTI lifecycle stage, and asked them to use the LEQ Framework to develop ethical guidelines for the design, development, or use of that specific HTI.

This had several educational goals. It taught students the existence of the three stages of HTIs life-cycle (design, development, and use), the importance of embedding ethics in each and every stage, and the unique ethical implications of each stage. Another important aspect of the training was role assignment. Within the groups, everyone was assigned the role of a relevant stakeholder, such as engineers, persons with dementia, healthcare providers, nursing home directors, head nurses, family members, financial advisors, etc. The aim here was threefold. First, it allowed the students to reflect on the different perspectives and interests that different stakeholders might uphold. Second, it taught students how to effectively and sensitively work on ethics deliberations in interdisciplinary groups. Third, it guided them in writing and composing specific outcome-oriented ethical guidelines for the design, development, and implementation of that specific HTI.

This modus operandi could easily be integrated in university courses as well as in specific trainings for specific HTIs or groups, for example healthcare professionals, developers, or policy-makers (Pantazidou & Nair 1999; Andersson, Svensson, Frank, et al. 2022).

Importantly, by organically integrating the LEQ Framework as an educational tool within existing educational programmes, we aim to foster a culture change. By training future engineers, healthcare providers, and citizens in integrating ethics in every stage of their own work and life, we can support the creation of an environment in which ethics is easily and spontaneously embedded in daily work and life rather than being an afterthought or a compulsory checklist.

4.3. Implications for research

The LEQ Framework also proved invaluable for research purposes. Researchers in our group already used the LEQ Framework to analyse the existing literature related to a specific HTI, such as artificial womb technologies and wearable trackers for people living with dementia, to identify possible gaps in the literature (Howes et al. 2026) . In other terms, the LEQ Framework could help identify blind spots in the HTI debate. This will obviously allow to focus research on overlooked but potentially important issues. To the opposite, it will also allow to identify well developed and saturated lines of research, which could help researchers to avoid duplicating already existing work and focusing on underdeveloped areas instead. Used this way, the LEQ Framework could also be used by an individual researcher, although team work is generally always recommended.

5. Conclusions

In this article, we present the LEQ Framework, an ethical question matrix designed to assess HTIs. The Framework is the result of a systematic and transparent development process, incorporating both theoretical and practical insights. It aims to balance comprehensiveness with practicality. Additionally, the Framework connects different phases of the HTI life cycle with various contexts where ethical tensions may arise, bridging local and global perspectives on HTIs.

However, like any framework, the LEQ should not be seen as a definitive solution to all possible ethical challenges. It remains open to further refinement and adaptation over time, e.g. to reflect the ever-changing AI landscape. The Framework underscores the need

to recognize that HTIs are not solely individual, local, or health-centric issues. Instead, they must be understood within broader societal, global, and historical contexts.

Supplementary materials: **Table S1**: Overview of included articles in systematic review (N=57)**Table S2:** Overview of frequently used ethical theories, traditions, or approaches underlying existing frameworks to ethically evaluate or assess HTI (partially taken over from and modelled on Vandemeulebroucke and colleagues (Vandemeulebroucke et al. 2022c)); **S3**: English translation of participants' recommendations regarding the development of an ethical framework for the evaluation of health technology innovations; **S4:** In-depth description of the methodology used to develop the LEQ Framework. **Table S5:** Overview of collected questions distilled out of papers included in the systematic review.

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Data Availability Statement: The English translation of participants' recommendations regarding the development of an ethical framework for the evaluation of health technology innovations is provided as supplementary material (S3).

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Informed Consent Statement: A signed informed consent form is not required for this type of studies under the Belgian Law (The Law of 7 May 2004 concerning experiments on the human and The Law of 7 May 2017 regulating clinical trials on medicinal products for human use; The Law of 19 December 2008 regulating the procurement and the use of human bodily material). However, oral informed consent was sought before every stakeholder meeting.

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