

# AN ETHICAL ANALYSIS OF THE NEED FRAME- WORK: EXPLORING THE MORAL RELEVANCE AND RELATIVE ETHICAL URGENCY OF ITS CRI- TERIA



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## LIST OF ABBREVIATIONS

| ABBREVIATION | DEFINITION                                      |
|--------------|-------------------------------------------------|
| CD           | Crohn's Disease                                 |
| NEED         | Needs Examination, Evaluation and Dissemination |
| PGC          | Principle of Generic Consistency                |
| R&D          | Research and Development                        |
| YLL          | Years of Life Lost                              |

## GLOSSARY

| Term                                  | Definition                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>John Rawls</i>                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Veil of ignorance / Original position | A hypothetical condition proposed by Rawls ensuring fairness in the selection of principles of justice from behind a veil of ignorance. Because they do not know their future social status or personal characteristics, decisions are made without bias or self-interest, allowing the selected principles to be regarded as fair and acceptable to all.                                                                                                  |
| Primary goods                         | Goods that individuals are presumed to want, since they contribute to carry out their objectives in life, whatever they may be. They are divided into two categories of primary goods, i.e., natural and social primary goods.                                                                                                                                                                                                                             |
| Natural primary goods                 | Qualities or assets that individuals are born with or develop naturally such as intelligence, imagination, health or speed.                                                                                                                                                                                                                                                                                                                                |
| Social primary goods                  | Goods that are directly influenced by the design of social institutions and are essential for individuals to function and thrive in society, such as rights (e.g., civil and political rights), liberties, income and wealth, social bases of self-respect.                                                                                                                                                                                                |
| Fairness                              | According to Rawls, the principles of justice are chosen in the original position, where individuals deliberate behind the veil of ignorance. In this hypothetical situation, individuals are unaware of their personal characteristics or social status, ensuring that choices are made without bias or self-interest. The veil of ignorance is thus intended to ensure the impartiality and general acceptability of the selected principles of justice. |



|                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Equity                                       | According to Rawls, equity is addressed within the second principle, known as the difference principle (see definition below). While inequalities may exist, they are only justifiable if they improve the situation of the least advantaged, ensuring a fair distribution of resources and opportunities.                                                                                                                                                                                                                                                                                                                                                                                    |
| First principle = principle of equal liberty | The principle highlights the importance of individual autonomy and equal access to freedom in a just society. Each person has a right to equal basic liberties, which should be compatible with a similar scheme of liberty for all. These liberties must be secured by all citizens.                                                                                                                                                                                                                                                                                                                                                                                                         |
| Second principle = difference principle      | This principle aims to balance fairness with practical socio-economic arrangements. It comes into practice after the first principle, preferring fair equality of opportunity. Social and economic inequalities are acceptable only if they improve the situation of the least advantaged members of society to the greatest extent.                                                                                                                                                                                                                                                                                                                                                          |
| <i>Martha Nussbaum</i>                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Capabilities                                 | Nussbaum distinguishes between capabilities, which refer to the real opportunities individuals have to achieve valuable ways of being and doing, and functioning, which refer to the actual states of being and doing they realise. Capabilities may be available or secured to varying degrees. Capabilities are considered to support constructing a normative conception of social justice. This is only possible by specifying a definite set of the most important capabilities, which need to be protected to allow individuals to achieve a fulfilled life. Once they are defined and embedded in a normative structure, they can be claimed as necessary to achieve a fulfilled life. |
| <i>Alan Gewirth</i>                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Agency                                       | The capacity of a person to act voluntarily and purposively, that is, to pursue purposes or goals that the person regards as good. In Gewirth's theory, agency is the starting point of moral reasoning because all agents necessarily require certain conditions for successful realisation of their agency. .                                                                                                                                                                                                                                                                                                                                                                               |
| Agent                                        | A person who is capable of voluntary and purposive action. In the context of the NEED framework, patients, informal caregivers, healthcare professionals, and other affected persons may be considered agents insofar as their freedom and well-being are relevant to their ability to act.                                                                                                                                                                                                                                                                                                                                                                                                   |
| Institutional duty-bearers                   | Institutions are not agents in the same sense as persons, but they may bear duties to secure, protect, or promote the conditions of agency. In the NEED context, healthcare systems and public institutions are ethically relevant because their decisions can affect persons' freedom and well-being.                                                                                                                                                                                                                                                                                                                                                                                        |
| Prospective agent                            | A person whose present or future agency is morally relevant, even if their current ability to act is limited, developing, or dependent on others. This may include persons with severe illness, disability, cognitive impairment, or children in a paediatric context.                                                                                                                                                                                                                                                                                                                                                                                                                        |



|                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Dialectically necessary method         | <p>Method for the justification of a moral principle from the first person perspective of agents.</p> <p>Step 1: Identify the essential and universal characteristics of agency, such as purposive action and voluntariness.</p> <p>Step 2: Based on these characteristics, agents are logically required to recognize certain rights and corresponding duties as conditions of action. These recognitions give rise to a normative structure governing agency.</p> <p>Step 3: This reasoning culminates in the Principle of Generic Consistency, according to which agents must acknowledge that the same generic rights they claim for themselves must also be accorded to all other agents, thereby universalizing those rights.</p> |
| Principle of Generic Consistency (PGC) | <p>The Principle of Generic Consistency is a fundamental moral rule that explains why rights and duties apply to everyone. Gewirth argues that anyone who wants to act freely and purposefully must accept certain basic rights. If we accept these rights for ourselves, we must also accept that others have the same rights. The PGC ensures that our actions are morally fair and respectful of others, because it requires us to treat everyone consistently.</p>                                                                                                                                                                                                                                                                  |
| Generic rights/goods                   | <p>In Gewirth's theory, generic goods are the necessary conditions of agency. They consist primarily of freedom and well-being. Freedom refers to the agent's ability to control and direct their own actions without undue constraint. Well-being refers to the basic conditions and capacities required to act purposively, including physical and mental health, bodily integrity, and other conditions necessary for pursuing one's purposes. Because all agents require these goods, Gewirth argues that they must be recognised as generic rights.</p>                                                                                                                                                                            |
| Basic goods                            | <p>Basic goods are the minimal conditions necessary for agency itself. They include not only survival-related goods such as life, bodily integrity, food, shelter, and basic healthcare, but also elementary physical and mental functioning without which purposive action is seriously undermined. In the NEED context, unmet needs qualify as basic goods when they threaten the fundamental conditions required for persons to act at all.</p>                                                                                                                                                                                                                                                                                      |
| Non-subtractive goods                  | <p>Non-subtractive goods are conditions that protect persons from losing already secured levels of freedom and well-being. They preserve agency by preventing deterioration, exclusion, dependency, or avoidable loss of functioning. In the NEED context, they include needs whose fulfilment helps patients or other affected persons maintain their ability to act and participate.</p>                                                                                                                                                                                                                                                                                                                                              |
| Additive goods                         | <p>Additive goods are conditions that enhance or expand persons' freedom and well-being beyond the preservation of existing agency. They support the further development of capacities, opportunities, autonomy, participation, and quality of life. In the NEED context, they include needs whose fulfilment strengthens persons' ability to pursue purposes and improve their well-being.</p>                                                                                                                                                                                                                                                                                                                                         |



## ■ SCIENTIFIC REPORT

### 1 BACKGROUND

#### KEY POINTS

- The NEED initiative aims to guide health policy, research and innovation towards unmet health-related needs identified from patient and societal perspectives.
- The NEED assessment framework covers health, healthcare and social needs across patient, society, future and transversal equity dimensions.
- Its selection and organisation of domains, dimensions, criteria and indicators raise normative questions about what counts as a relevant need and how different needs should be assessed and prioritised.
- Examining these normative foundations and ethical implications can strengthen the transparency and ethical justification of future decisions informed by NEED.

#### 1.1 Context

The Needs Examination, Evaluation and Dissemination (NEED) project<sup>a</sup> was launched at the end of 2022 and aims to develop and apply a structured methodology for assessing health-related unmet needs from the perspectives of both patients affected by specific conditions and society. The initiative was established in response to the observation that health innovation is often predominantly supply-driven, with research and development efforts tending to focus on areas with the greatest commercial potential rather than on those addressing the most pressing unmet needs of patients and society. Its objective is to identify areas requiring improvement and to highlight those most crucial for guiding health policy and research and development (R&D).<sup>1</sup> By doing so, the project seeks to draw attention to unmet needs that might otherwise be overlooked, whether due to a lack of (financial) interest, insufficient data or knowledge, the absence of viable solutions, or because they affect “invisible” populations. The NEED project represents a critical effort to direct investments toward areas of greatest need and to make the health system more patient-oriented.

The NEED assessment framework constitutes the methodological core of the NEED project. It provides a structured approach for assessing unmet health-related needs across different health conditions and support decision-making in health policy, research prioritisation and innovation (see section 1.2). Since its initial development, the framework has been refined through Belgian and European expert consensus and complemented by a standardised research protocol<sup>2</sup> and a practical toolbox<sup>3</sup> to facilitate its implementation across different health conditions. Although the framework was developed through a systematic literature review and informed by expert input (notably using the Delphi method), its purpose is not purely descriptive. By identifying unmet health-related needs and informing decisions about which needs warrant attention in health policy, research and innovation, the framework necessarily involves normative questions about what counts as a relevant need and how different needs should be assessed and prioritised. Its specific design choices concerning domains, dimensions, criteria and indicators therefore also have ethical implications.<sup>1, 4</sup>

Before the NEED framework is further developed for use in practical decision-making, its normative foundations and implications should therefore be examined explicitly. Such an ethical analysis can

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<sup>a</sup> Needs Examination, Evaluation and Dissemination: <https://health-needs.eu/index.php/en/> (last access: 25<sup>th</sup> June 2026).

clarify the values and normative considerations reflected in the framework's overall architecture, including the selection and organisation of domains and dimensions, as well as its criteria and indicators. This is important both for transparency and for the ethical justification of future decisions informed by the NEED framework.

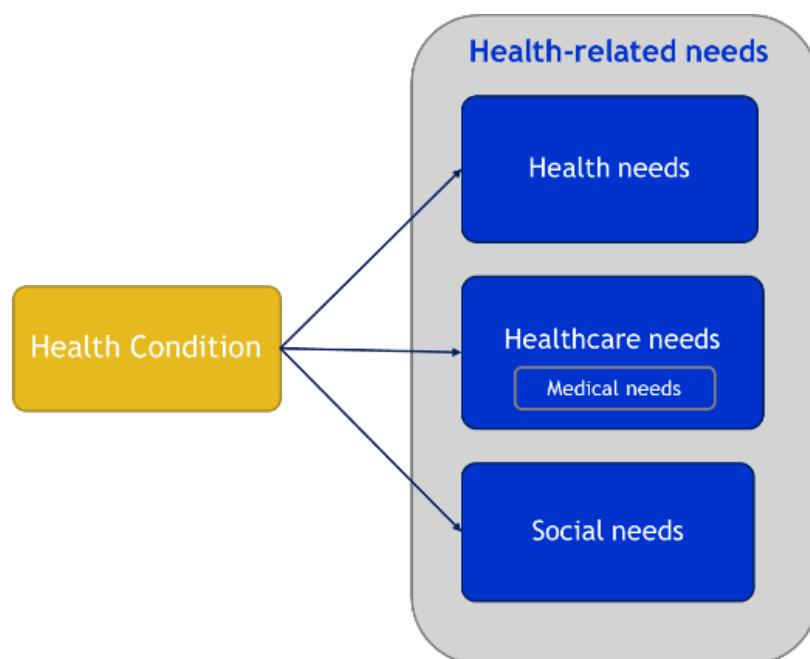
The present report therefore examines the normative foundations and ethical implications of the NEED framework. It seeks to clarify why unmet health-related needs matter morally, how differences in their relative ethical urgency can be understood, and what this implies for the interpretation and future use of the framework. For this purpose, a normative ethical approach is selected and applied to the NEED framework and to empirical NEED case studies. The rationale for this theoretical choice and the insights it provides are set out in the following chapters.

## 1.2 Unmet health-related needs and the NEED assessment framework

Because there is no consensus understanding of “unmet needs,” and because existing definitions did not capture the full scope of the NEED project, the research team developed an operational concept grounded in a comprehensive perspective on health. The terminology adopted was **unmet health-related needs**. In this context, the term encompasses both the needs of individuals affected by the health condition and broader societal needs arising from the condition's impacts on groups not directly affected (i.e., externalities).<sup>1</sup> To identify and measure these unmet health-related needs, the project therefore adopted a systematic approach through the development of a dedicated framework. Figure 1 illustrates different types of health-related needs, which constitute part of the conceptual foundation of the NEED framework.

The NEED assessment framework is organised into several interconnected components. It is designed to assess unmet health-related needs associated with a given health condition. For each health condition, unmet needs are examined across **three domains** (health, healthcare, and social needs) and **from four complementary dimensions** (patient, society, future, and equity). Within each domain and dimension, the framework defines a set of criteria and corresponding indicators that provide a structured basis for assessing unmet health-related needs. The following sections briefly introduce these different components.

**Figure 1 – The Health-Related Needs Concept**





All of the defined needs of Figure 1 are addressed with the framework. Within this project, these needs represent **a certain domain**, which can be affected when having a certain health condition. The scope of each is as follows:

- **Health needs:** are needs for better health (e.g. in case of illness, disability, or injury).
- **Healthcare needs:** are needs for healthcare services in a large sense, including medical treatments but also preventive measures, diagnostic procedures, case management services, nursing services, etc.<sup>1</sup>
  - Medical needs (included in healthcare needs): most often refer to therapeutic needs or needs for medical treatment. Medical need is often used for the need for a medicinal treatment and therapeutic need was introduced to refer to the need of a treatment in general (can be pharmaceutical or other type of treatment -surgery, physiotherapy etc).<sup>1</sup>
- **Social needs:** are needs that are neither health needs nor healthcare needs. In the NEED framework, this category covers both individual-level needs, such as social support or workplace accommodations, and broader societal-level needs, such as addressing the environmental impact of healthcare.<sup>1</sup>

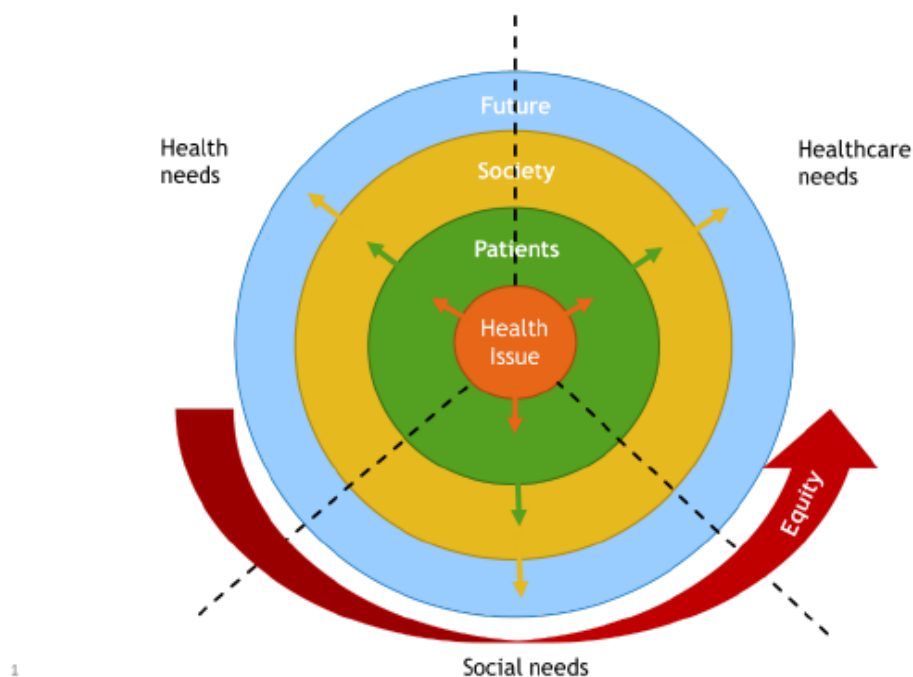
The different domains of need as described above can be viewed from different perspectives, called **'dimensions'** in the NEED framework as they represent different dimensions to health needs, healthcare needs and social needs: the patient, society, future and (transversal) equity dimension.<sup>1</sup>

For instance, the dimensions focus on:

- **Patient:** identifying unmet health-related needs of individuals affected by the health condition, such as improving health-related quality of life, autonomy, access to effective treatments and social life.<sup>1</sup>
- **Society:** identifying the externalities of health condition that affect society as a whole, beyond individual patient needs. For instance collective or common needs, such as the transmissibility of diseases, economic burden and environmental impact of healthcare practices.<sup>1</sup>
- **Future:** identifying the anticipated impact of a health condition on patients and society in the future. It highlights the relevance of tackling health conditions by considering future burden of disease and economic costs.<sup>1</sup>
- **Equity:** highlighting the absence of unfair and avoidable differences in health, healthcare and social needs among population groups which are classified by socioeconomic, demographic or geographic aspects. Therefore, the dimension of equity is transversal and applies across patient, societal and future needs.<sup>1</sup>

Figure 2 provides an overview of the overall architecture of the NEED assessment framework and illustrates how health condition (health issue), domains and dimensions are related to one another. Together, the dimensions, domains, criteria, and indicators constitute the structure of the NEED framework, enabling comprehensive data collection and the systematic generation of health-related evidence.

Figure 2 – The structure of the NEED assessment framework



From Maertens de Noordhout et al.(2024)<sup>1</sup>

As noted above, the framework has not yet integrated an explicit ethical perspective. Ethical reflection can strengthen the NEED project by making the normative assumptions underlying its domains, dimensions, criteria, and operational definitions more explicit and transparent. This is important because the framework does not merely describe unmet health-related needs; it also supports judgments about which needs should receive greater attention in health policy and research and development.

## 2 OBJECTIVES

This report aims to examine the normative foundations of the NEED framework and its ethical implications. It makes explicit the normative assumptions underlying the framework and analyses how unmet health-related needs can be interpreted in terms of their moral relevance. To this end, the report considers a limited selection of ethical theories in order to make the theoretical choice transparent and to identify a normative approach that is particularly well suited to articulating the ethical implications of the NEED framework. The aim is not to establish a general hierarchy between ethical theories, but to show how the selected approach contributes to understanding why particular unmet needs matter morally and how differences in their relative ethical urgency can be interpreted.

The research questions are:

1. How can a transparent, limited consideration of selected ethical theories inform the choice of a normative approach for analysing the ethical implications of the NEED framework?
2. How does the selected approach help to interpret the moral relevance and relative ethical urgency of the needs, criteria, and indicators included in the NEED framework?
3. How can these ethically interpreted NEED criteria be applied to the empirical findings of selected NEED case studies in order to explore their relevance for future decision-making?



### 3 METHODS

#### KEY POINTS

- A theory-based approach in normative and applied ethics was used, drawing on a review of philosophical literature and iterative interdisciplinary discussion with the co-authors.
- A limited, purposive selection of ethical theories – Rawls' theory of justice, Nussbaum's capabilities approach and Gewirth's Principle of Generic Consistency – was considered to make the theoretical choice explicit and transparent.
- Gewirth's approach was selected for its agency-based justification of freedom and well-being and its differentiation of generic goods according to their necessity for agency.
- Guiding questions were developed to interpret the moral relevance and relative ethical urgency of NEED criteria and applied to empirical findings from the Crohn's disease and malignant melanoma case studies.

A theory-based approach was chosen to analyse the ethical implications of the NEED framework and the concept of “unmet health-related needs” on which it is based. The aim is to clarify the normative assumptions underlying the framework and to identify an ethical theory that can support a coherent interpretation of why particular unmet needs matter morally. The analysis is intended to provide an explicit normative basis for the interpretation and future use of the NEED framework in decision-making.

This report is situated in normative and applied ethics.<sup>5, 6</sup> It does not judge the NEED framework externally as morally right or wrong, but examines how its underlying assumptions, categories, and criteria can be ethically interpreted and justified. The NEED initiative, a research program aimed at developing and applying the NEED framework for identifying and assessing unmet health-related needs, has a normative structure because it aims to identify unmet health-related needs in order to guide health policy, research and development, and possible future decision-making. Applying a normative ethical framework is therefore appropriate because the initiative implicitly raises questions about moral relevance, justification, and priority.

Given this context, the focus lies on normative theories that explicitly address the justification of moral claims. Justification in normative ethics involves providing morally grounded reasons for why certain actions, norms or priorities should be accepted.<sup>7</sup> Normative ethical analysis requires moral claims and priorities to be supported by reasons that can be made explicit and critically assessed rather than merely asserted. In this general sense, the requirement of justification serves here as a methodological standard of rational ethical argumentation.<sup>8</sup>

A limited selection of ethical theories was considered in order to make the theoretical choice underlying the present analysis explicit and transparent. The selection was purposive rather than exhaustive. Rawls' theory of justice, Nussbaum's capabilities approach, and Gewirth's Principle of Generic Consistency were included because each provides a substantive normative account of conditions or goods relevant to persons' lives and offers a distinct way of justifying corresponding moral claims. At the same time, their different justificatory structures provide useful reference points for examining what kind of normative framework is particularly helpful for interpreting unmet health-related needs.

Gewirth's approach was considered a particularly promising option from the outset because of its agency-based justification of freedom and well-being and its differentiation of generic goods according to their necessity for agency. Rawls and Nussbaum were therefore not included as competing theories in a comprehensive philosophical comparison, but as two prominent normative reference approaches against which the rationale and implications of this theoretical choice could be clarified.

Other approaches in health ethics and political philosophy, including Daniels' work on justice and health, Tronto's ethics of care, and Dworkin's work on equality, could illuminate additional aspects of unmet health-related needs. A comprehensive review of these debates lies beyond the scope of this policy-oriented ethical analysis. Their exclusion should therefore not be understood as a judgement about their theoretical relevance.<sup>9-12</sup>

The selected theories are three influential normative approaches that provide complementary perspectives on justice, rights, and human well-being and have been widely applied or discussed in health-related contexts. These were selected because they share a normative perspective, address human rights, and are widely applied in political and health-related contexts.<sup>13</sup> At the same time, they differ in their reasoning, allowing for meaningful reflections. Methodologically, the three approaches also differ in how they justify their normative claims. Rawls seeks coherence between considered moral judgements, principles of justice, and relevant background assumptions, using the original position and the veil of ignorance to represent fair conditions for choosing principles of justice. Nussbaum's capabilities approach draws on substantive ideas about the conditions of a life compatible with human dignity, while also developing these within a framework of political liberalism. Gewirth, by contrast, seeks to derive normative commitments from the standpoint of agency itself, arguing that a consistent understanding of oneself as an agent entails claims to the generic conditions of freedom and well-being.

Each theory also includes a concept of goods: Rawls' primary goods, Nussbaum's capabilities, and Gewirth's generic goods (freedom and well-being). These concepts provide a useful link to the NEED initiative, particularly in addressing unmet health-related needs.

In sum, the theories were chosen for their normative focus, practical relevance, and comparability on a conceptual level. The limited consideration of these three approaches thus serves to clarify and make transparent the theoretical choice made for the present analysis. It is not intended as a comprehensive philosophical comparison or as a general ranking of the theories. Rather, it examines what each approach highlights in relation to unmet health-related needs and why Gewirth's framework was selected for the subsequent analysis of their moral relevance and relative ethical urgency.

On this basis, the analysis proceeded in two further steps. The ethical analysis was conducted by the first author (CF) through a review of philosophical literature. The interpretation and application of the selected theories to the NEED framework were subsequently discussed and refined iteratively with the co-authors. This interdisciplinary process brought together expertise in the assessment of unmet health-related needs and evidence-based policy (CMdN and IC) and expertise in (applied) social ethics in healthcare (CM), thereby strengthening the conceptual consistency of the analysis.

Following the selection of Gewirth's approach, its central distinctions were operationalised for the analysis of the NEED framework. A set of guiding questions was developed to examine how individual NEED criteria relate to basic, non-subtractive, and additive goods and, thereby, to differences in their moral relevance and relative ethical urgency. Each theoretical question was subsequently reformulated into a practical analytical question incorporating relevant elements of the NEED framework. These guiding questions provide a structured heuristic for the ethical interpretation of the NEED criteria; they are not intended as a decision algorithm or prioritisation rule.<sup>14</sup>

In a further step, the guiding questions and the resulting ethical interpretation of the NEED criteria were applied to empirical findings from two previously conducted NEED case studies on Crohn's disease and malignant melanoma. This served to explore how the normative analysis can inform the interpretation of empirical NEED findings and thereby contribute to future decision-making.<sup>15, 16</sup> The Crohn's disease study surveyed Belgian adults diagnosed at least two months prior, allowing proxy responses when necessary. In total, 150 participants completed the survey and 20 were interviewed, supported by a literature review.<sup>15</sup> The malignant melanoma study applied the same criteria and methodology, including 37 participants; 9 of whom were interviewed, alongside a literature review.<sup>16</sup>



The development of a formal decision-support tool or prioritisation algorithm lies beyond the scope of the present report. The case-study applications should therefore be understood as an exploratory assessment of the practical relevance and applicability of the ethical analysis.

The present analysis applies to the current adult NEED framework. Specific questions arising in paediatric contexts or in populations with substantially limited or absent current agential capacities require additional normative consideration and are addressed as limitations and areas for further development in the Discussion.

## 4 DESCRIPTION OF THE THEORIES

### KEY POINTS

- Rawls' theory of justice emphasises equal basic liberties, fair equality of opportunity and the fair distribution of social primary goods, allowing social and economic inequalities only if they benefit the least advantaged.
- Nussbaum's capabilities approach focuses on what persons are effectively able to do and be. Political institutions should secure central capabilities for all persons at least up to a threshold level compatible with human dignity.
- Gewirth's Principle of Generic Consistency grounds moral rights in agency. Freedom and well-being are necessary conditions of voluntary and purposive action; agents must recognise the corresponding generic rights of all other actual or prospective agents.
- Gewirth distinguishes basic goods, the minimal conditions necessary for agency; non-subtractive goods, which protect already secured levels of freedom and well-being; and additive goods, which enhance or expand capacities, opportunities and well-being.

### 4.1 John Rawls' Theory of Justice

John Rawls, in *A Theory of Justice* (1971), develops the concept of "justice as fairness", arguing that a just society is based on principles that rely on a justification that test whether those principles could be chosen under a veil of ignorance. In this hypothetical situation, individuals do not know their social status, abilities, or beliefs, which ensures impartial and fair decision-making.

A key component of his theory is the concept of **primary goods**, which are necessary for individuals to pursue their life plans. These include natural primary goods (e.g., health, intelligence) and social primary goods (e.g., rights, liberties, income, and self-respect), with self-respect considered especially important.

Rawls defines justice through two principles. The first guarantees equal basic liberties for all individuals. The second, known as the difference principle, allows social and economic inequalities only if they benefit the least advantaged members of society and if opportunities are equally accessible to all. Together, these principles aim to ensure a fair and just distribution of rights and resources.<sup>17-19</sup>

### 4.2 Martha Nussbaum's Capabilities Approach

Martha Nussbaum's capabilities approach, building on the work of Amartya Sen, focuses on **what individuals are effectively able to do and be**, rather than on the distribution of resources alone. It provides a normative framework for assessing justice, particularly in practical and policy-related contexts.<sup>20</sup>

Central to her theory is a list of **ten core capabilities**: life; bodily health; bodily integrity; senses, imagination, and thought; emotions; practical reason; affiliation; other species; play; and control over one's environment, including both political and material aspects. These capabilities are considered

essential for a life worthy of human dignity. Nussbaum argues that political institutions should secure them for all persons at least up to a threshold level.

A key aspect of the approach is the idea of combined capabilities, which link internal abilities (e.g., health and skills) with external conditions (e.g., institutions and social support). This highlights that real freedom depends on both personal capacities and enabling environments.

Overall, the capabilities approach offers a practical and normative framework for evaluating justice, particularly relevant for addressing unmet health-related needs, as it emphasises individuals' real opportunities for well-being.<sup>20</sup>

### 4.3 Alan Gewirth's Principle of Generic Consistency

Alan Gewirth's theory, developed in *Reason and Morality*, seeks to justify moral rights and obligations from the standpoint of agency. For Gewirth, persons are agents insofar as they act voluntarily and purposively in pursuit of purposes, they regard as good. Such agency necessarily depends on two generic conditions: **freedom** and **well-being**. Freedom refers to the agent's ability to control and direct their own action, while well-being refers to the basic conditions and capacities required to act at all and to pursue purposes over time. From this starting point, Gewirth argues that agents must claim **rights to freedom and well-being** for themselves and, by consistency, must recognise the same generic rights of all other actual or prospective agents.

This reasoning leads to his core principle, the **Principle of Generic Consistency (PGC)**, which states that individuals must act in accordance with the generic rights of all agents. Gewirth derives this through a dialectically necessary method: first, agents recognise from the standpoint of their own purposive agency that freedom and well-being are necessary conditions of acting in pursuit of their purposes; second, they must regard these conditions as goods to which they have claims; and third, consistency requires them to acknowledge the corresponding generic rights of all other actual or prospective agents. The PGC thus links the conditions of individual agency to universal rights and corresponding duties. Because these rights concern the protection of the generic conditions of agency, they also have implications for social and institutional arrangements: institutions are ethically relevant insofar as their structures and capacities secure, protect, or undermine persons' freedom and well-being.

A central element of this account is the concept of generic goods, which specify the conditions protected by generic rights. Gewirth distinguishes between basic, non-subtractive, and additive goods. **Basic goods** are the minimal conditions without which purposive action is not possible or is seriously undermined. **Non-subtractive goods** protect agents from losing already secured levels of freedom and well-being. **Additive goods** enhance or expand agents' capacities, opportunities, and well-being. Rather than constituting an exhaustive or rigid classification of needs, these categories function as a heuristic for distinguishing different degrees of necessity for agency and provide a basis for evaluating the ethical significance of unmet needs. Their application is context-sensitive: the significance of a particular need for agency may vary, for example, according to the severity of a health condition or its social and economic consequences. This distinction is particularly useful for the NEED framework because it allows unmet health-related needs to be assessed according to how directly they affect the conditions of agency.

For the purposes of the NEED framework, this account provides a way of interpreting unmet health-related needs according to the degree to which they affect the conditions of agency. It thereby connects the empirical identification of unmet needs with questions of their moral relevance, relative ethical urgency, and the corresponding responsibilities of institutions.<sup>14</sup>



## 5 SELECTED ETHICAL PERSPECTIVES ON THE NEED FRAMEWORK

### KEY POINTS

- Rawls clarifies institutional responsibilities for fairness and protection of the least advantaged; Nussbaum highlights people's real opportunities for health, autonomy and participation.
- These perspectives illuminate key dimensions of NEED but require further specification to assess the relative ethical urgency of particular unmet needs.
- Gewirth links unmet needs to rights and corresponding goods, distinguishing their ethical urgency according to how strongly they affect the conditions of agency.
- His approach connects patient needs with societal responsibilities and supports equitable responses to differences in the severity of unmet needs.
- Gewirth was selected for this specific analytical contribution; the choice implies neither theoretical superiority nor an automatic ranking of needs.

This section considers how the selected ethical approaches illuminate key aspects of the NEED framework and the moral relevance of unmet health-related needs. The purpose is not to compare or rank the theories as philosophical accounts, but to make transparent the different normative perspectives they offer and to clarify the rationale for using Gewirth's approach in the subsequent analysis of moral relevance and relative ethical urgency.

The assessment is based on the core aspects of the framework identified in section 1.2. The health condition (health issue) serves as the entry point of the NEED framework, while the dimensions of patient, society, future, and equity represent its key analytical components. The patient dimension focuses on identifying unmet needs at the individual level, whereas the society dimension addresses collective implications of a disease and the role of institutions. The future dimension highlights inter-generational responsibility, and the equity dimension, defined as reducing unjust and avoidable disparities, cuts across all others. Finally, the analysis also considers questions of relative ethical urgency and prioritisation. Although the current NEED framework is not designed to produce a hierarchy of needs, such questions become relevant in view of its potential future use in decision-making under conditions of limited resources.

### 5.1 John Rawls

#### 5.1.1 Health condition

Rawls' theory of justice is concerned primarily with the basic structure of society and the principles that should govern fair social institutions. Health is not excluded from this perspective, but Rawls does not develop differences in health status or health-related needs as a specific object of distributive justice in the same way as social primary goods. His approach is deliberately cautious in this respect, since individual health needs are highly variable and difficult to incorporate into a general theory of justice. For the NEED framework, Rawls therefore offers an important perspective on fairness and institutional justice, but a less direct basis for differentiating the moral relevance and relative urgency of specific unmet health-related needs.

### 5.1.2 Patient dimension

Rawls' theory approaches the patient dimension primarily through questions of justice in the basic structure of society and the fair distribution of social primary goods. This perspective is relevant for considering whether institutions provide persons with fair opportunities, rights, and access to resources. However, it does not focus on the detailed assessment of how particular health conditions affect individual experiences, autonomy, quality of life, or specific healthcare needs. For the purposes of the NEED framework, Rawls therefore provides an important institutional and distributive perspective, while the ethical differentiation of concrete patient-level unmet needs requires additional conceptual specification.

### 5.1.3 Society dimension

Rawls' theory is particularly relevant to the society dimension insofar as it focuses on the basic structure of society and on the role of institutions in securing fair terms of social cooperation. This makes it useful for reflecting on the institutional responsibilities of healthcare systems and on the fair distribution of resources, opportunities, and burdens. However, the NEED society dimension also includes more specific health-related externalities, such as disease burden, economic consequences, environmental impact, and effects on groups beyond the individual patient. Rawls' framework can illuminate the institutional justice dimension of these issues, while the more specific classification of such unmet health-related needs and the assessment of their relative urgency require additional normative specification.

### 5.1.4 Future dimension

Rawls does address future-oriented justice through his account of just savings, which concerns what each generation owes to future generations in order to maintain just institutions over time. This makes his theory relevant to the future dimension of the NEED framework, especially regarding sustainability and long-term responsibility. However, this perspective remains at a relatively general level and does not by itself provide a specific criterion for assessing the relative moral weight of present and future unmet health-related needs in concrete healthcare contexts. For the purposes of the NEED framework, additional normative specification is therefore required to assess how such needs affect conditions that are ethically relevant across time and generations.<sup>21</sup>

### 5.1.5 Equity dimension

The equity dimension is partially reflected in Rawls' difference principle, which gives special concern to the least advantaged. Rawls therefore provides an important background justification for using evidence on unmet needs to identify populations who are worse off. However, the difference principle remains at a relatively general level and does not by itself specify how particular health-related unmet needs should be morally interpreted, classified, or weighted. Rawls therefore provides an important normative perspective on equity, while the assessment of the moral relevance and relative urgency of specific unmet needs requires further specification.<sup>18</sup>

### 5.1.6 Aspect of prioritisation

Rawls' framework contains important resources for prioritisation, especially through the priority of basic liberties, fair equality of opportunity, and the difference principle. These principles are highly relevant for assessing the fairness of institutional arrangements. However, they do not translate directly into a fine-grained classification of health-related needs within the NEED framework. In particular, Rawls does not provide a specific hierarchy for distinguishing needs according to their immediate relevance for survival, health, autonomy, well-being, or agency. Rawls thus provides important principles for assessing fairness in institutional arrangements, while the fine-grained classification and prioritisation of specific unmet health-related needs requires an additional normative framework.



Overall, Rawls' theory offers an important perspective on institutional justice, fairness, and the distribution of social primary goods. For the purposes of the NEED framework, however, the interpretation and relative weighting of specific unmet health-related needs requires further normative specification.

## 5.2 Martha Nussbaum

### 5.2.1 *Health condition*

Nussbaum's capabilities approach offers an inclusive and highly relevant perspective for health-related questions, as several of her central capabilities – especially life, bodily health, bodily integrity, practical reason, affiliation, and control over one's environment – are directly affected by illness and disability. The approach is therefore well suited to showing why health matters not merely as a resource, but as a condition for what persons are effectively able to do and be. However, Nussbaum does not develop a healthcare-specific account of how different health-related needs should be classified according to their urgency. For the purposes of the NEED framework, the capabilities approach thus helps identify morally important dimensions of health and well-being, while distinguishing between different types and levels of unmet health-related needs according to their relative urgency requires additional normative specification..

### 5.2.2 *Patient dimension*

Nussbaum's approach is particularly strong with regard to the patient dimension. By asking what persons are actually able to do and be, it captures dimensions of illness that go beyond the distribution of healthcare goods alone, including autonomy, bodily integrity, social participation, emotional well-being, and the ability to pursue one's life plans. This makes the capabilities approach highly relevant for a patient-centred understanding of unmet health-related needs. However, its strength lies mainly in identifying broad dimensions of human flourishing rather than in classifying unmet needs according to their relative urgency. For the NEED framework, which aims to support transparent assessment and possible prioritisation, the translation of these dimensions into an assessment of the relative ethical urgency of particular unmet needs requires further specification.

### 5.2.3 *Society dimension*

Nussbaum's approach also recognises the importance of institutions and social conditions, since capabilities can only be secured through appropriate political, legal, economic, and social arrangements. In this sense, the capabilities approach is relevant to the society dimension of the NEED framework. Nevertheless, its primary evaluative focus remains the capabilities of individual persons. Broader societal effects, such as collective disease burden, economic consequences, environmental impact, or externalities affecting groups beyond the individual patient, are therefore not as directly addressed as in frameworks designed specifically for institutional or public-health prioritisation. The approach can illuminate why social arrangements matter for persons' opportunities, but it provides less guidance for classifying societal unmet needs within the NEED framework.<sup>22</sup>

### 5.2.4 *Future dimension*

The capabilities approach can be extended to future-oriented concerns, insofar as institutions should secure the conditions under which persons can develop and sustain central capabilities over time. This makes the approach relevant to prevention, long-term well-being, and the future consequences of health conditions. However, Nussbaum's framework does not provide a specific method for weighing present and future unmet health-related needs against one another in healthcare policy. Its contribution to the future dimension is therefore important, but less operational than what is required for the present classification exercise.<sup>22</sup>

### 5.2.5 *Equity dimension*

Equity is a central concern of Nussbaum's approach, since all persons should be secured at least a threshold level of central capabilities. This makes the approach highly relevant for analysing avoidable disadvantage, exclusion, and unequal opportunities for health and well-being. It also resonates with the NEED framework's concern for unfair and avoidable differences between population groups. However, the capabilities approach does not by itself provide a detailed procedure for determining how different health-related inequalities should be weighted when resources are limited or when several capabilities are affected simultaneously. Its relevance to equity is therefore substantial, but its operational guidance for prioritisation within the NEED framework remains limited.

### 5.2.6 *Aspect of prioritisation*

A key consideration for the present purpose is that Nussbaum's approach deliberately does not establish a fixed hierarchy among the central capabilities or prescribe a precise decision rule for resolving trade-offs between them. This is consistent with the internal logic of the approach, since the capabilities describe several irreducible dimensions of a life worthy of human dignity. However, this becomes challenging in healthcare contexts, where policy decisions often require transparent prioritisation among different types of unmet needs, different patient groups, and different forms of burden. The capabilities approach can show that many dimensions matter morally, but it provides less guidance on how they might be prioritised within a concrete assessment framework.<sup>22</sup>

Overall, Nussbaum's capabilities approach offers a rich normative perspective on unmet health-related needs by highlighting what persons are effectively able to do and be and by capturing important dimensions of health, well-being, autonomy, participation, and human flourishing. For the specific purposes of the NEED framework, the differentiation of particular unmet needs according to their relative ethical urgency requires additional normative specification.

## 5.3 *Alan Gewirth*

Gewirth's approach interprets health-related needs in relation to the conditions required for agency, especially freedom and well-being. In applying this framework to NEED, the persons affected by a health condition are discussed in their role as patients, while the underlying moral claims are grounded more generally in their status as actual or prospective agents. This allows health-related impairments to be assessed according to how they affect the conditions necessary for purposive action.<sup>14</sup>

### 5.3.1 *Health condition*

Gewirth's theory is highly compatible with the health-condition aspect of the NEED framework because it does not make moral standing dependent on a person's current level of health or functional ability. Rather, it asks which conditions are necessary for actual or prospective agency. Illness, disability, pain, psychological distress, dependency, or lack of access to care can all be ethically relevant insofar as they restrict freedom or well-being as conditions of purposive action. This allows unmet health-related needs to be interpreted in terms of how they restrict or undermine the conditions of agency, thereby providing a normative perspective directly relevant to the NEED assessment.

### 5.3.2 *Patient dimension*

Gewirth's theory offers a clear normative perspective on the patient dimension by grounding the moral significance of patients' unmet needs in the conditions of agency. Patients are not only recipients of care, but persons whose freedom, well-being, and ability to pursue purposes may be affected by illness and by the organisation of healthcare. A Gewirthian perspective therefore supports the patient-centred orientation of the NEED framework: unmet needs matter ethically when they impair the conditions under which patients can act, decide, participate, and maintain or develop their lives.



### 5.3.3 *Society dimension*

Gewirth's theory starts from individual agency, but the generic rights to freedom and well-being entail corresponding duties that extend to social and institutional arrangements. Because the generic rights to freedom and well-being generate corresponding duties, institutions and social arrangements become ethically relevant as structures that can secure, protect, or undermine the conditions of agency. Accordingly, a central implication of the theory is that institutions should be organised so that they have the capacity to protect and support the generic conditions of agency. Their normative assessment must therefore also take account of the resources, organisational arrangements, and policies required to fulfil these responsibilities effectively. This makes the theory applicable to the society dimension of the NEED framework, provided that societal effects are interpreted in relation to their impact on persons' agency – including patients, informal caregivers, affected groups, and the wider population. In this way, Gewirth supports a connection between individual entitlements and institutional responsibilities.

### 5.3.4 *Future dimension*

Gewirth does not develop a separate theory of intergenerational justice. Nevertheless, his framework can support future-oriented ethical reasoning insofar as present decisions affect the future conditions of agency for actual, prospective, or future persons. This is relevant to the NEED framework because health policy, prevention, innovation, and resource allocation can shape whether persons will have access to the conditions required for freedom and well-being over time. This provides a normative basis for considering future-oriented effects insofar as present decisions shape the conditions of agency for future persons.

### 5.3.5 *Equity dimension*

Equity is strongly supported by the Principle of Generic Consistency, which requires that the generic rights of all agents be recognised equally. At the same time, equal moral status does not imply identical treatment in all cases. Since persons may be differently affected in their freedom and well-being, Gewirth's theory allows differentiated responses according to the seriousness of the threat to agency. For the NEED framework's transversal equity dimension, this provides a way of combining equal moral concern with differentiated attention to the seriousness of threats to agency.

### 5.3.6 *Aspect of prioritisation*

For the present analysis, Gewirth's distinction between basic, non-subtractive, and additive goods provides a structured normative orientation for assessing relative ethical urgency. By distinguishing between basic, non-subtractive, and additive goods, it makes it possible to assess needs according to how directly they affect the conditions of agency. Basic goods concern the minimal conditions without which purposive action is not possible; non-subtractive goods protect persons from losing already secured conditions of agency; and additive goods enhance persons' opportunities to pursue and develop their purposes. This does not produce an automatic ranking in every case, but it provides a transparent ethical rationale for assessing the relative urgency of unmet health-related needs. Importantly, this prioritisation follows from Gewirth's rights-based account of agency and should not be understood as an automatic ranking. The relative importance of particular goods must also be considered in relation to the capacity of institutions and society to secure the conditions of agency over time.

## 5.4 Rationale for selecting Gewirth's approach

The preceding analysis shows that Rawls, Nussbaum, and Gewirth each illuminate important normative aspects of the NEED framework. Rawls offers a strong perspective on institutional justice and fair social cooperation, while Nussbaum's capabilities approach highlights what persons are effectively able to do and be and draws attention to the conditions of a life compatible with human dignity. These perspectives remain highly relevant to the ethical interpretation of unmet health-related needs.

For the specific analytical purpose of the present report, however, Gewirth's approach provides a particularly useful normative structure. Its relevance lies not simply in the distinction between basic, non-subtractive, and additive goods, but in the way these distinctions are embedded in an agency-based justification of moral rights. Freedom and well-being are understood as generic conditions of purposive action; differences in their necessity for agency can therefore be used heuristically to interpret the moral significance and relative urgency of unmet needs. Because these generic rights entail corresponding duties, the approach also provides a link between individual unmet needs and institutional responsibilities for securing the conditions of agency.

The choice of Gewirth should therefore be understood as a transparent theoretical option for the specific purposes of this policy-oriented analysis, rather than as the outcome of a general ranking of ethical theories. Rawlsian, capability-based, and other approaches may illuminate additional dimensions of unmet health-related needs, but the subsequent analysis uses Gewirth because its conceptual structure allows the NEED criteria to be related systematically to agency, moral claims, relative ethical urgency, and corresponding institutional responsibilities.

# 6 APPLICATION OF GEWIRTH'S THEORY TO THE NEED FRAMEWORK 2025

## KEY POINTS

- Health criteria primarily concern basic goods, as severe impairments in physical and mental health can undermine the minimal conditions required for purposive agency.
- Healthcare criteria may concern basic, non-subtractive or additive goods, depending on whether they secure, protect or expand the conditions of agency.
- Social criteria predominantly concern non-subtractive and additive goods, but may concern basic goods where social or material deprivation threatens health, access to care or the minimal conditions of agency.
- In the patient dimension, the link to agency is usually direct. In the society dimension, criteria also capture indirect or aggregated effects on persons' freedom and well-being and the institutional conditions required to protect them.
- Classification is heuristic and context-sensitive, as illustrated by the Crohn's disease and malignant melanoma case studies. Categories may overlap and do not provide an automatic ranking or decision rule.

## 6.1 Translating Gewirth's framework into guiding questions

Gewirth's framework is translated into the NEED analysis by asking how particular unmet health-related needs affect the conditions of agency, especially freedom and well-being. The distinction between basic, non-subtractive, and additive goods is used as a heuristic for this purpose. It does not assign needs mechanically to fixed categories but helps to distinguish different ways and degrees in which unmet needs may threaten, preserve, or enhance the conditions of purposive action.



This classification is therefore context sensitive. The ethical significance of a NEED criterion depends not only on its general description, but also on the empirical circumstances in which it occurs, including the severity of a condition, its consequences for functioning and participation, and its social or economic effects. The findings from the Crohn's disease and melanoma case studies are used below to illustrate how empirical evidence can inform such normative interpretation. The empirical findings do not themselves determine the ethical classification; rather, they provide the context needed to assess how strongly a particular unmet need affects freedom and well-being as conditions of agency. Empirical disease-specific evidence may affect the interpretation of how strongly a given criterion bears on agency, without changing the normative meaning of the categories themselves.

The distinction between the three types of goods should also not be understood as implying that only basic goods are ethically important. Basic goods concern conditions without which agency is impossible or seriously undermined and may therefore carry particular urgency. Non-subtractive goods are ethically significant because they protect already secured levels of agency, while additive goods matter because they expand persons' opportunities, participation, and well-being. The relative ethical urgency of a need therefore depends on its concrete impact on agency and cannot be inferred from the category alone. The distinction should not be read as a simple resource-allocation sequence in which basic goods are always to be satisfied first and other goods become ethically relevant only thereafter.

On this basis, the theoretical distinctions are reformulated into guiding questions for the analysis of the NEED criteria. These questions are intended to support a transparent and structured ethical interpretation rather than to provide an automatic ranking or decision rule. They also need to be considered in relation to the responsibilities and capacities of institutions to protect and support the conditions of agency.<sup>14</sup>

### 6.1.1 Patient dimension

#### 6.1.1.1 Basic goods

From Gewirth's perspective, the primary concern is whether persons possess the minimal conditions required for purposive agency. Basic goods are therefore not limited to biological survival, although survival is their most fundamental instance. They also include conditions such as bodily integrity, elementary physical and mental functioning, and the basic forms of well-being without which persons cannot pursue any purposes at all. When such goods are seriously threatened, persons have the strongest moral claim to their protection. This leads to the first question, which, according to Gewirth's theory, can read as follows: "*Which needs are to be met so that persons can act as purposive agents at all?*" The important aspects which are included focus on the agency itself.

This theoretical question forms the basis for a more practical one that aligns with the NEED framework and reflects key elements of Gewirth's theory. Given that the NEED framework identifies unmet needs, the question should target significant impairments (or deficiencies), such as basic goods like health. Basic health needs include the conditions required for survival, bodily integrity, and the ability to act as a purposive agent. These needs encompass essential physical health (such as adequate nutrition, shelter, and freedom from life-threatening illness), mental health (including cognitive and emotional functioning), and broader aspects of well-being necessary for pursuing one's goals, such as minimal social conditions and autonomy.<sup>14</sup>

Accordingly, the question can be formulated as the following: **To what extent does the NEED criterion concern fundamental conditions of agency, such as survival, bodily integrity, physical and mental functioning, or basic autonomy?** This formulation is consistent with Gewirth's view that moral agency depends on the ability to act voluntarily toward self-chosen purposes, and that the impairment of fundamental needs undermines this capacity.

### 6.1.1.2 Non-subtractive goods

Non-subtractive goods are those that protect persons from losing already secured conditions of agency. They do not necessarily create new capacities, but they prevent deterioration in freedom, health, autonomy, or well-being. The guiding question is therefore: *Which needs must be met to prevent persons from losing their existing ability to act freely and pursue their purposes?*

When translating this into a practical question for the NEED framework, it is important to clarify the aspect of “ability to act,” as this concept can vary across contexts. In Gewirth’s theory, the ability to act meaningfully depends on both freedom and well-being (as discussed in section 3.1.3). By contrast, the NEED framework often operationalises “autonomy” in more concrete terms, such as physical or mobility-related capabilities. For instance, instruments like the EQ-5D-5L assess dimensions of daily activities including mobility, selfcare, usual activities, pain/discomfort and anxiety/depression).<sup>23</sup>

Therefore, the practical question should explicitly reflect the aspects of the “ability to act” that are relevant for moral agency, while also accounting for the preservation of basic goods and the support of well-being over time.

Accordingly, the practical question becomes: **Does the fulfilment of the NEED criterion protect patients from losing their ability to act freely, including their autonomy and physical, mental and social health, and thereby support the maintenance of their well-being?**

### 6.1.1.3 Additive goods

Additive goods are those that enhance or expand persons’ opportunities for agency beyond the preservation of already secured capacities. This does not necessarily imply an improvement in health status. Rather, additive goods may increase autonomy, participation, available options, or other conditions that enable persons to pursue purposes they value. The guiding question is therefore: Which needs must be met to expand persons’ opportunities for purposive action and participation?

In practice, this means asking whether fulfilling a NEED criterion creates additional possibilities for patients to act, decide, participate, or pursue valued purposes, even where the underlying health condition itself cannot be improved.

The practical question can therefore be formulated as follows: Does fulfilment of the NEED criterion expand patients’ opportunities for purposive action, autonomy, participation, or the pursuit of valued purposes?

This distinguishes additive from non-subtractive goods: non-subtractive goods primarily protect already secured conditions of agency, whereas additive goods open up or strengthen additional possibilities for agency.

## 6.1.2 Society dimension

The society dimension requires a different approach from the patient dimension when applying Gewirth’s theory. In the NEED framework, the society dimension refers to externalities and broader effects of health conditions beyond the individual patient, such as transmissibility, economic burden, environmental impact, and effects on other persons or groups. Such effects may operate indirectly, for example when a high disease burden leads to productivity losses, increased costs, or pressure on healthcare capacity, thereby reducing the resources and institutional conditions available to protect persons’ freedom and well-being. From a Gewirthian perspective, these factors should not be understood as needs of society in the same sense in which persons have needs. Rather, they are ethically relevant insofar as they indicate how health conditions and institutional responses may affect the freedom and well-being of persons as agents. The guiding questions below therefore use societal indicators to assess whether agency-related goods are threatened, preserved, or enhanced at population level.<sup>14</sup>



### 6.1.2.1 Basic goods

At the societal level, Gewirth emphasises the importance of institutional arrangements that secure access to the conditions necessary for agency. The theoretical question can be formulated as follows: *Which societal or institutional conditions are necessary to ensure all individuals have secure access to the basic conditions of agency, such as survival, bodily integrity and primary healthcare?*

The corresponding practical question is: **To what extent do societal indicators show that these basic conditions of agency are threatened at population level, or that institutions need to respond in order to protect them?** This aligns with the NEED framework by focusing on severe impairments at the population level.

These questions reflect key elements of Gewirth's theory by addressing the conditions under which a population may lose its ability to act due to severe impacts of a health condition.

### 6.1.2.2 Non-subtractive goods

From the perspective of Gewirth's theory, the theoretical question can be formulated as follows: *How can institutions and social structures protect individuals from losing their already secured conditions of agency, for example by preventing avoidable illness, vulnerability, exclusion, catastrophic health loss, or loss of access to care?*

The practical question then becomes: **Does the way institutions meet these needs protect people's ability to act freely and autonomously, for example, by safeguarding physical, mental, and social health, so that individuals do not regress below the threshold of secure agency?**

### 6.1.2.3 Additive goods

The theoretical question for additive goods is: *In what ways can institutions and social arrangements expand persons' opportunities for purposive action, for example through prevention, innovation, education, or equitable access to supportive conditions?*

At the societal level, additive goods concern institutional arrangements that create or expand opportunities for agency beyond the preservation of already secured conditions. This may include improving access to prevention or innovation, strengthening participation, or creating more equitable conditions for persons to pursue valued purposes.

Accordingly, the practical question can be formulated as follows: **Does addressing the identified societal-level concern expand persons' opportunities for agency, participation, or access to supportive conditions, while contributing to sustainable and equitable healthcare arrangements?**

In conclusion, both the patient and society dimensions can be analysed through Gewirth's distinction between basic, non-subtractive, and additive goods, but the interpretive route differs. In the patient dimension, the link to agency is usually direct. In the society dimension, societal indicators and institutional responsibilities show how health conditions and system-level effects may influence persons' freedom and well-being at population level. The practical questions related to the three types of goods are therefore aligned in that they all focus on agency and well-being, while recognising that societal criteria often indicate indirect or aggregated effects.<sup>15, 16</sup>

## 6.2 Ethical interpretation of the NEED criteria using Gewirth's framework

The following section applies the guiding questions developed above to the individual criteria of the NEED framework. The aim is to interpret their normative significance by examining how each criterion relates to the conditions of agency and to basic, non-subtractive, or additive goods. The classification is heuristic and context-sensitive: the same criterion may acquire different ethical significance depending on the nature and severity of the unmet need and on the empirical context in which it occurs. Where relevant, findings from the Crohn's disease and melanoma case studies are used to illustrate and inform this interpretation.

### 6.2.1 Patient dimension

#### 6.2.1.1 Health domain

Within the patient dimension, the health domain focuses on the burden of disease, including pain, suffering, and reductions in well-being and quality of life.<sup>1</sup> In Gewirth's framework, health is essential for agency and therefore constitutes a basic good. The key question is whether all criteria within this domain can be classified as such.

#### IMPACT ON LIFE EXPECTANCY

This criterion measures years of life lost (YLL) due to a condition.<sup>1</sup> It directly relates to survival and the capacity for purposive action, as reduced life expectancy limits the conditions necessary for autonomy. Although YLL is calculated retrospectively, it reflects a real loss of opportunities for action. Therefore, this criterion qualifies as a basic good.

In Crohn's disease (CD), mortality is generally low and mainly linked to complications or comorbidities, with no specific Belgian mortality data available.<sup>15</sup> While CD significantly affects quality of life, it rarely threatens survival. As a result, this criterion is not applicable to CD and not a relative urgency of need.

In contrast, malignant melanoma poses a substantial mortality burden. In Belgium, YLL was estimated at 73 per 100 000 inhabitants in 2019, indicating a direct impact on survival.<sup>16</sup> Here, the criterion is highly relevant and demands priority, as it directly concerns the preservation of life.

The NEED criterion "Impact on life expectancy" must be classified as a **basic good**, since it directly concerns primary health needs such as survival and safety.

#### IMPACT ON GENERAL HEALTH-RELATED QUALITY OF LIFE

This criterion captures the overall need to improve health-related quality of life and is measured through Years Lived with Disability and the EQ-5D-5L score.<sup>1</sup> The EQ-5D-5L assesses five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, thereby reflecting both physical and mental health.

Because these dimensions directly affect patients' ability to act as purposive agents, the criterion aligns with Gewirth's concept of basic goods. Impairments in quality of life limit autonomy and functioning, making this criterion ethically significant.

Empirical data support the above reasoning. In Crohn's disease, patients report a substantial impact on daily functioning and overall well-being. 55% of patients experienced difficulties with daily activities, 46% reported pain or discomfort, 35% mobility problems, 30% anxiety or depression, and 11% difficulties with self-care. These figures highlight that Crohn's disease affects not only physical health but also mental and social dimensions, significantly restricting patients' capacity to act as purposive agents in everyday life.

In malignant melanoma, the impact on quality of life is also considerable, though the distribution of reported problems differs slightly: 46% of patients suffered from anxiety or depression, 32% from pain



or discomfort, 27% from difficulties with daily activities, 19% from mobility problems and 14% from difficulties with self-care indicating a strong psychological burden.

Thus, in both conditions, reduced quality of life directly affects physical and mental well-being, justifying its classification as a **basic good**.

### IMPACT ON PHYSICAL AND PSYCHOLOGICAL HEALTH

This criterion focuses more specifically on changes in physical symptoms (such as pain, discomfort, and functional limitations) and psychological conditions (including anxiety, depression, and stress), drawing on EQ-5D-5L data.<sup>1</sup> While analytically distinct, these dimensions remain closely interconnected and together shape patients' overall health status.

Physical impairments can directly threaten safety, bodily integrity, and the ability to carry out basic activities, thereby affecting survival-related needs. Psychological symptoms, in turn, can influence mental stability, decision-making, and coping capacity, and may also have indirect effects on social participation and relationships. Their ethical significance depends on the severity and duration of these impairments and on how strongly they restrict basic functioning. Both dimensions are therefore essential for maintaining agency.

Evidence from the case studies reinforces this. In Crohn's disease, patients report a high burden of physical symptoms (87% of respondents experienced more than four physical symptoms, including diarrhea, fatigue, cramps, and stool urgency) alongside frequent psychological distress (72% reported at least one symptom such as stress, anxiety or depression), both of which significantly affect daily functioning. Similarly, melanoma patients experience a combination of physical symptoms and notable levels of anxiety and depression (fatigue/exhaustion (30%) and swollen or painful lymph nodes (22%)), while nearly half (49%) reported psychological symptoms such as anxiety (30%), depression (24%) and stress (22%), indicating that both aspects contribute to the overall disease burden.

In sum, both theoretical reasoning and empirical evidence show that impairments in physical and psychological health can directly undermine patients' ability to act as purposive agents. These criteria should therefore be classified as **basic goods**, as they are fundamental to maintaining safety, functioning, and overall well-being.

### IMPACT ON AUTONOMY

This criterion is assessed through changes in mobility, self-care, and usual activities, based on EQ-5D-5L data collected via surveys or interviews.<sup>1</sup> Within the NEED framework, it captures autonomy in a practical sense, while in Gewirth's theory autonomy refers more broadly to the freedom and well-being required for purposive action. This broader understanding underscores its moral relevance, as limitations in autonomy directly affect agency.

The classification of this criterion depends on the severity of impairment. Significant restrictions in mobility, self-care, or daily activities can threaten basic health needs, including survival and physical and mental integrity, and thus qualify as a basic good. Less severe limitations, while still restricting freedom and well-being, may instead correspond to non-subtractive goods. The distinction between basic and non-subtractive goods therefore depends not only on whether limitations in mobility, self-care, and usual activities are present, but also on their severity and their impact on patients' independence. Empirical findings can help illustrate how different levels of impairment may translate into different degrees of autonomy loss and thus inform the classification of this criterion within the NEED framework.

Empirical findings illustrate this distinction. In Crohn's disease, substantial declines in "no problems" responses across all three dimensions indicate pronounced limitations in independence and daily functioning.<sup>15</sup> In malignant melanoma, smaller but still notable proportions of patients report difficulties in usual activities, mobility, and self-care: mobility was affected in 18.9% of respondents, and self-care in 13.5%. Although these proportions are lower than for Crohn's disease, they indicate that autonomy-

related difficulties are still present for a subset of patients. From a Gewirthian perspective, such difficulties are ethically relevant insofar as they restrict patients' ability to act independently and carry out everyday activities.<sup>16</sup>

Overall, the evidence shows that restrictions in these domains can significantly limit patients' ability to act purposively. Whether the criterion constitutes a basic or non-subtractive good depends on the extent to which autonomy, and ultimately safety and survival, is compromised. This highlights the importance of combining theoretical reasoning with empirical data in the classification process.

### IMPACT ON SEXUAL AND REPRODUCTIVE HEALTH

This criterion assesses how a health condition affects sexual and reproductive functioning, based on patient-reported data.<sup>4</sup> From a Gewirthian perspective, it relates primarily to physical and mental health. While it may not directly threaten survival, impairments in this domain can substantially affect well-being and, consequently, the capacity for purposive action. This supports its classification as a basic good.

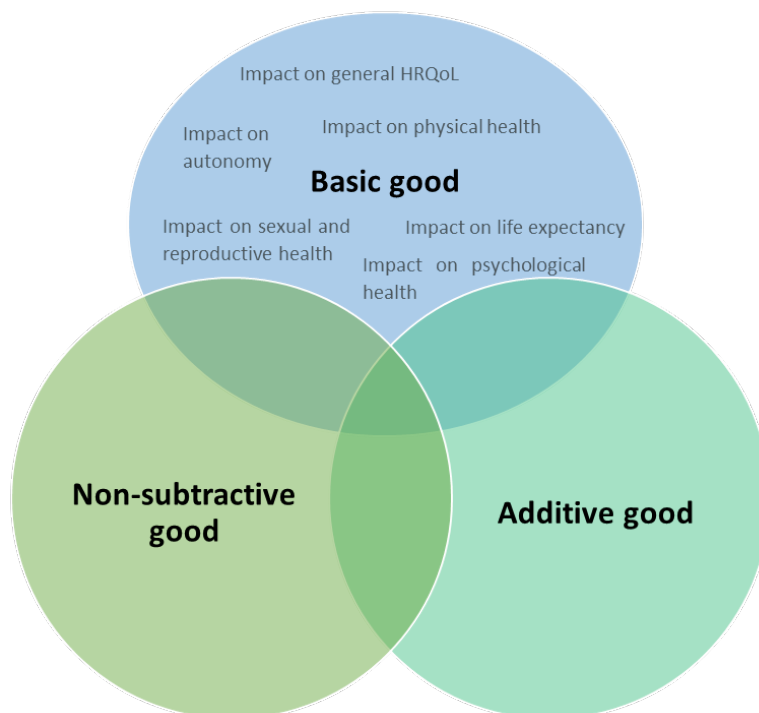
This criterion was not yet included, when the two studies, Crohn's disease and Malignant Melanoma study, were conducted. Thus, as there is no evidence, there is no data available for this indicator.

### CONCLUSION ON THE HEALTH DOMAIN

In conclusion, the health domain cannot be classified as a basic good without further conceptual clarification (see Figure 3). The analysis of the NEED criteria associated with this domain demonstrates that a critical discussion is required before such classification can be made. In this case, however, all health-related criteria have ultimately been identified as **basic goods**. This is because – depending on the severity – impairments in these areas can directly undermine physical and mental health, and thereby the capacity for agency, which is central in Gewirth's ethical framework. Accordingly, these criteria require particular attention in contexts of unmet health needs, as addressing them is essential for preserving both patient well-being and moral agency.



**Figure 3 – Patient dimension: Health criteria classification according to Gewirth’s ethical framework**



#### 6.2.1.2 Healthcare domain

In the NEED framework, five criteria represent the healthcare domain (see section 1.2). As with the health domain, each criterion will be examined in terms of its classification, with particular attention to the role played by the indicators.

#### TREATMENT EFFECTIVENESS

The criterion “treatment effectiveness” assesses how well the current standard of care performs, based on expert evaluation ranging from “not effective” to “very effective”.<sup>4</sup>

Its classification depends on the extent to which ineffective treatment threatens patients’ health and agency. When no effective alternative exists and the impact of the disease on basic health needs is high, ineffective treatment can directly endanger physical and mental health and potentially survival thereby qualifying as a basic good. In such cases, unmet treatment needs undermine the conditions required for purposive action, providing strong moral justification for prioritising this criterion.

However, treatment effectiveness may also align with non-subtractive goods. While treatment itself may be essential for recovery, its degree of effectiveness can function more as a safeguard, helping patients maintain their existing level of health and agency rather than restoring it. The classification therefore depends on how strongly treatment outcomes influence the patient’s ability to act.

Empirical findings illustrate this variability. In Crohn’s disease, limited treatment effectiveness contributes to persistent symptoms that impair quality of life, psychological well-being, and social participation.<sup>15</sup> In addition, treatments may involve significant risks, such as infections or hepatotoxicity, further restricting patients’ capacity for action. Here, ineffective or burdensome treatment can directly undermine basic health needs, suggesting classification as a basic good or, in less severe cases, a non-subtractive good.

In malignant melanoma, classification varies by disease stage. Treatment is considered very effective in early stages but only moderately effective in advanced cases.<sup>16</sup> For early-stage melanoma, treatment effectiveness may function as a non-subtractive good, maintaining health and autonomy. In advanced melanoma, however, it directly affects survival and thus qualifies as a basic good.

Overall, this criterion highlights the contextual nature of classification: its **ethical status shifts depending on disease severity and treatment impact**.

## BURDEN OF TREATMENT

The criterion “burden of treatment” captures the physical, psychological, and practical demands associated with treatment, including side effects. It is measured through patient-reported levels of burden, ranging from moderate to extreme.<sup>4</sup>

From a Gewirthian perspective, its classification depends on the degree to which treatment burden affects health and agency. When the burden severely compromises physical or mental health, it can threaten basic needs and thus qualify as a basic good. In such cases, treatment itself becomes a barrier to maintaining health and agency.

More commonly, however, this criterion aligns with **non-subtractive goods**. Reducing treatment burden helps preserve patients’ existing capacity to act by preventing further deterioration in well-being, rather than creating new capabilities. For this reason, it is less convincing to classify it as an additive good, as its primary function is protective rather than enhancing.

Evidence from the case studies supports this interpretation. In Crohn’s disease, treatments are associated with significant risks, including infections and long-term side effects (e.g. hepatotoxicity).<sup>15</sup> These burdens can impair health and highlight unmet needs, with classification depending on their severity.

Similarly, in malignant melanoma, patients report substantial side effects such as fatigue (reported by 56% of participants undergoing treatment) and joint pain, which can significantly affect daily functioning.<sup>16</sup> Even less frequent side effects may have a strong impact on well-being and autonomy.

In sum, the burden of treatment should be understood primarily as a non-subtractive good, though in cases of severe impact it may rise to the level of a basic good. Its classification ultimately depends on the extent to which it undermines health and the patient’s ability to act.

## QUALITY OF CARE

The NEED criterion “Quality of care” captures the need to improve care delivery through five indicators: coordination and continuity of care, information received, patient involvement in treatment decisions, diagnostic timing, and implementation of secondary prevention strategies.<sup>1</sup> Because these indicators affect patients in different ways, the classification cannot be made at the level of the overall criterion but must be assessed individually.

### A. Coordination and continuity of care

This indicator assesses how well care is organised and coordinated, based on patient-reported experiences.<sup>4</sup> While this does not directly determine survival or primary health outcomes, it plays an important supporting role. Well-coordinated care enables effective treatment and helps maintain patients’ physical, mental, and social well-being.

From a Gewirthian perspective, this suggests classification as a **non-subtractive good**. It does not itself constitute a primary health need, but it protects patients from losing their ability to act freely by supporting autonomy and stability in care. At the same time, coordination can also enhance patients’ ability to act, for example, by reducing uncertainty and improving access to appropriate services, giving it an additional, though secondary, additive dimension.

Findings from both case studies support this interpretation. In Crohn’s disease, patients report dissatisfaction with fragmented care and a lack of holistic, multidisciplinary approaches.<sup>15</sup>



Similarly, melanoma patients emphasise the importance of integrated care and accessible follow-up.<sup>16</sup> These shortcomings do not directly threaten survival, but they weaken the structures that sustain autonomy and well-being.

## B. Received information

This indicator measures whether patients receive clear, sufficient, and understandable information from healthcare professionals.<sup>4</sup> Although it is ethically important, it does not directly affect primary health needs such as survival or physical and mental health. Treatment is generally provided regardless of the level of information received.

For this reason, it cannot be classified as a basic good. It also only indirectly protects agency, making its classification as a non-subtractive good less convincing. Instead, it aligns more clearly with **additive goods**. Access to high-quality information strengthens patients' autonomy, enables informed decision-making, and reduces uncertainty. In doing so, it enhances their capacity for purposive action and contributes to the further development of well-being.

Empirical findings support this classification. In both Crohn's disease and melanoma, most patients report receiving clear and sufficient information, indicating that this factor primarily improves rather than safeguards agency.<sup>16</sup>

## C. Involvement in treatment decisions

This indicator reflects the extent to which patients feel involved in decisions about their treatment.<sup>4</sup> Although it does not directly influence survival or the delivery of treatment, it is ethically significant because it relates to patients' right to participate in decisions affecting their own health.

Limited involvement restricts autonomy and, consequently, the ability to act purposively. Therefore, this indicator is best classified as a **non-subtractive good**: it protects patients from losing their capacity for free and autonomous action and supports the maintenance of well-being. While involvement may also have some additive aspects, its primary function is protective rather than enhancing.

Evidence from both studies reinforces this view. In the Crohn's disease study, a considerable proportion of patients expressed a desire for greater involvement in decision-making.<sup>15</sup>

Similar concerns are reported in melanoma.<sup>16</sup> These findings show that insufficient involvement constrains agency, even if it does not directly affect physical health.

## D. Diagnostic timing

This indicator measures the time between the first medical consultation and diagnosis.<sup>1</sup> Its ethical relevance depends strongly on context. Diagnostic timing is not itself a basic or non-subtractive good; rather, it indicates whether agency-related goods may be threatened or protected through timely diagnosis. When delayed diagnosis leads to significant deterioration in health, loss of treatment opportunities, or reduced survival chances, the affected goods may qualify as basic goods. In less severe cases, timely diagnosis functions as a way of protecting non-subtractive goods by preventing avoidable harm and preserving patients' ability to act. The ethical assessment should also consider whether shorter diagnostic delays are reasonably achievable given the available medical knowledge, evidence, guidelines, and organisational resources.

This indicator was not included in the Crohn's disease and malignant melanoma studies at the time of investigation. Therefore, no case-specific classification can be made for these two examples, although diagnostic timing remains conceptually relevant as an indicator of potential threats to **basic or non-subtractive goods**.

## E. Implementation of effective secondary prevention strategies

This indicator assesses the extent to which effective secondary prevention strategies are implemented, such as interventions aimed at preventing complications, alleviating symptoms, and maintaining health.<sup>1</sup> These strategies are designed to protect patients from further deterioration rather than to create new capacities.

Accordingly, they align most closely with **non-subtractive goods**. They help preserve physical, mental, and social health, thereby maintaining patients' ability to act. Since they do not directly determine survival, they cannot be classified as basic goods.

As with diagnostic timing, this indicator was not included in the case studies.

## F. Conclusion

Overall, the criterion "quality of care" cannot be assigned to a single category of goods. Its indicators fulfil different ethical functions: some primarily protect existing health and agency (non-subtractive goods), others enhance autonomy (additive goods), and in certain contexts may even relate to basic goods.

This highlights the complexity of the classification process. Rather than applying a uniform label, each indicator must be evaluated in relation to the specific health condition and its impact on patient agency (see Figure 4).

## ACCESSIBILITY

The criterion "accessibility" is assessed through two indicators: treatment availability and foregone care. Both address whether patients can actually obtain the care they need, though from different perspectives.

### A. Treatment availability

This indicator evaluates whether treatments are financially and logistically accessible. Availability issues may arise when treatments are not authorised, not commercialised, too expensive, not reimbursed, or subject to shortages. Data are based on expert assessments of the extent to which treatment is available to the patient population.<sup>4</sup>

From a Gewirthian perspective, treatment itself can be considered a **basic good**, as it is essential for maintaining physical and mental health and, in many cases, survival. Consequently, when treatment is unavailable, primary health needs are directly threatened. For this reason, the indicator "treatment availability" should generally be classified as a basic good. This also provides a strong moral justification for its inclusion in the NEED framework.

In the Crohn's disease study, no data were available for this indicator, and therefore no empirical classification can be drawn.<sup>15</sup> In contrast, the malignant melanoma study reports supply shortages and high treatment costs, which limit access for some patients.<sup>16</sup> These barriers directly endanger health and support the classification of this indicator as a basic good.

### B. Forgone care

The second indicator refers to situations in which patients do not receive care despite a perceived need. This may result from financial barriers, long waiting times, or practical obstacles such as transport difficulties.<sup>4</sup>

The ethical relevance of this indicator depends less on the type of barrier and more on the consequences of missed care. Foregone care is not itself a basic or non-subtractive good; rather, it indicates whether agency-related goods may be threatened because access to needed care is not secured. If foregone care involves essential treatment, fundamental conditions of agency – such as bodily integrity, basic physical or mental functioning, or access to necessary care – may be put at risk, and the affected goods may qualify as **basic goods**. If the unmet care concerns less urgent or supportive



interventions, the affected goods are more appropriately interpreted as **non-subtractive**, as they primarily concern the preservation of already secured agency and well-being.

In Crohn's disease study, 13.3% of patients reported not receiving needed care, with the most common reasons being long waiting times, lack of competent staff, and insufficient information.<sup>15</sup> These barriers highlight unmet needs that may, depending on severity, threaten access to essential treatment.

In the melanoma study, most patients reported receiving the care they needed, suggesting that foregone care is less central in this context. This points toward a classification as a non-subtractive good, since access issues mainly concern the preservation of already secured agency and well-being. However, the reported shortage of dermatologists and resulting waiting times indicate that, in certain cases, access to essential treatment may still be compromised. In such situations, the affected goods may concern basic goods.

### C. Conclusion

The criterion "accessibility" **cannot be assigned to a single category of goods**. Its classification depends on the extent to which restricted access affects primary health needs and patient agency. When access to essential treatment is compromised, it constitutes a basic good; when it primarily affects comfort or continuity of care, it aligns with non-subtractive goods.

In all cases, accessibility remains a fundamental condition for agency. Without access to care, patients cannot maintain their health or act purposively, which justifies its central role within the NEED framework (see Figure 4).

### SCIENTIFIC RESEARCH

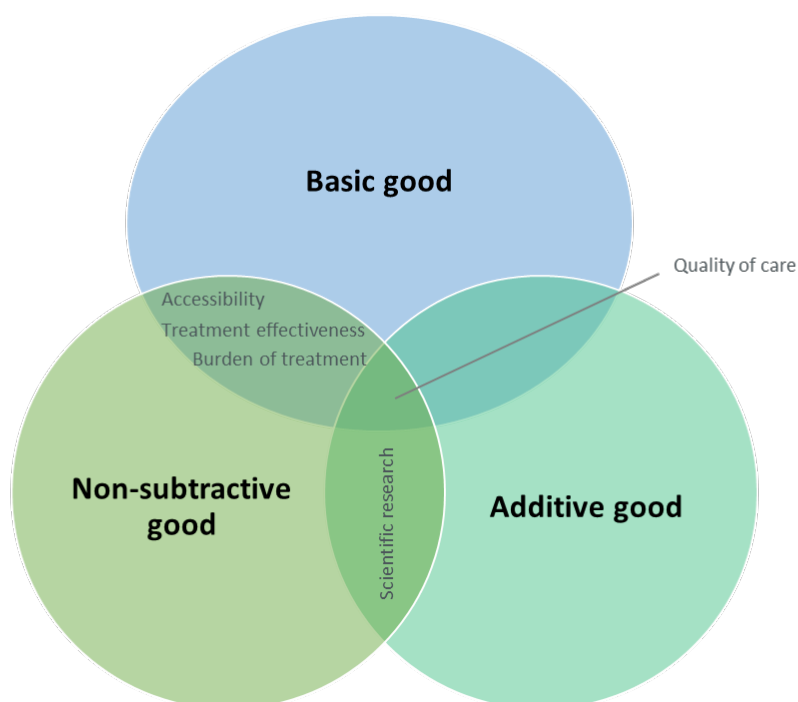
The final criterion within the healthcare domain is "scientific research," which is assessed through identified research gaps across areas such as pathophysiology, diagnosis, biomarkers, treatment, and prevention.<sup>4</sup>

From a Gewirthian perspective, this criterion can be classified either as a **non-subtractive or an additive good**, depending on the context. When little or no research exists for a disease, particularly in the absence of effective treatment, scientific research becomes essential for developing interventions that maintain or restore patients' capacity to act. In such cases, it aligns with non-subtractive goods, as it could potentially protect against the loss of health and agency.

In contrast, when effective treatments are already available, further research primarily serves to improve or expand existing options. Here, it enhances patients' opportunities and well-being beyond the current level, which corresponds to an additive good.

This criterion was not included in Crohn's disease and malignant melanoma studies, and therefore no empirical evidence is available to support its classification in these contexts.

**Figure 4 – Patient dimension: Healthcare criteria classification according to Gewirth’s ethical framework**



### 6.2.1.3 Social domain

The “Social” domain constitutes the third dimension of the NEED framework, alongside health and healthcare (see section 1.2). It captures health-related needs arising from the impact of a condition on patients’ social lives, including social participation, education, employment, and financial consequences.<sup>4</sup> In this report, the social domain should be distinguished from the society dimension. The social domain refers to needs affecting patients’ social lives, education, work, and financial situation, whereas the society dimension concerns broader effects of a health condition beyond the individual patient, including externalities and impacts on other persons or groups.

From a Gewirthian perspective, these needs are ethically relevant because social and material conditions can affect persons’ freedom and well-being as conditions of agency. Social needs should therefore not be understood as merely secondary or external to health-related needs. Rather, they may protect, restrict, or enhance the conditions under which persons can act purposively and pursue their lives.

In many cases, the social domain will primarily correspond to non-subtractive goods, because social support, employment, education, and financial stability help persons maintain already secured levels of agency and prevent deterioration in autonomy, participation, and well-being. In other cases, social needs may also have additive characteristics, insofar as they expand opportunities, strengthen participation, and enhance quality of life. In severe cases, however, social needs may also acquire the status of basic goods, for example when financial hardship, social isolation, lack of support, or loss of housing threatens access to care, physical or mental health, or the minimal conditions of agency. For these reasons, the social domain is morally relevant within the NEED framework, as it contributes to both the protection and development of agency, particularly in terms of freedom and well-being.

However, this preliminary classification requires further specification. A more precise assessment depends on the analysis of the four underlying criteria, which provide a detailed basis for evaluating its impact. The following analysis therefore classifies the social-domain criteria not by assuming that social needs are always less urgent than health or healthcare needs, but by asking how each criterion



affects agency: whether it threatens the minimal conditions of agency, prevents deterioration, or enhances persons' opportunities for purposive action.

## IMPACT ON SOCIAL LIFE

The first criterion within the social domain, "impact on social life," captures needs related to social support and social connection. These are assessed through two indicators that provide the basis for classification.

### A. Social support needs

The first indicator, "social support needs," measures the proportion of patients who report unmet needs for support in at least one area.<sup>4</sup> Social support does not usually affect survival directly. However, it can be crucial for maintaining well-being, autonomy, access to care, and the ability to manage everyday life with illness. A lack of support can limit social participation and reduce patients' capacity for purposive action. In severe cases, especially where patients depend on others for care, orientation, administration, mobility, or daily activities, unmet social support needs may even threaten basic conditions of agency. In most cases, however, this indicator is best understood as a **non-subtractive good**, because it protects patients from losing already secured levels of autonomy, participation, and well-being.

At the same time, social support may also have **additive aspects**. Depending on the context, it can strengthen autonomy and enhance overall well-being beyond its maintenance, thereby expanding patients' opportunities for action.

Findings from the Crohn's disease study illustrate this. Over half of respondents (54%) reported unmet needs for social support, particularly regarding peer exchange, administrative assistance, and help with daily activities.<sup>15</sup> These forms of support do not directly affect survival, but they contribute to maintaining, and in some cases enhancing, patients' ability to function and engage in daily life.

In the malignant melanoma study, most participants (64.9%) reported no additional support needs, although a notable proportion still indicated a lack of opportunities to connect with other patients.<sup>16</sup> This suggests that, in this context, social support functions more as an additive good, enhancing well-being rather than safeguarding it.

### B. Social connections needs

The second indicator, "social connection needs," assesses the extent to which a health condition affects relationships with partners, family, and friends.<sup>4</sup> Social connection needs should also be understood primarily as **non-subtractive goods**. Relationships with partners, family, friends, and peers can help sustain mental health, identity, resilience, and participation. When these relationships are seriously disrupted, patients may experience isolation or loss of support that restricts their freedom and well-being. In many cases, social connections also have **additive aspects**, because they enrich patients' lives and expand opportunities for participation. Their classification therefore depends on the severity and consequences of the disruption.

## IMPACT ON EDUCATION

The criterion "impact on education" assesses the extent to which a health condition disrupts a patient's educational trajectory, for example through time lost in schooling or reduced study participation.<sup>1</sup>

The classification of this criterion depends on the role education plays in the person's life course. Education often has **additive** characteristics, because it contributes to the development of skills, autonomy, future opportunities, and broader participation. However, it may also function as a **non-subtractive good** when illness disrupts an already ongoing educational trajectory and thereby risks long-term loss of opportunity, independence, or social participation. It should therefore not be understood only as an enhancement of well-being, but also as a condition that may protect future agency.

No empirical data from Crohn's disease or malignant melanoma studies are available for this criterion. Nevertheless, its impact should not be underestimated, as disruptions in education may have long-term consequences. Future research should therefore examine this criterion more closely across different health conditions.

## IMPACT ON WORK

The criterion "impact on work" addresses how a health condition affects employment, measured through changes in working capacity or employment status after diagnosis.<sup>4</sup>

Work is not only a source of income, but also a central context for autonomy, social participation, recognition, and future planning. Loss of employment or reduced working capacity can therefore significantly restrict a patient's freedom and ability to act. In Gewirthian terms, this criterion is best understood primarily as a **non-subtractive good**, because it concerns the preservation of already secured conditions of agency. At the same time, work may also have **additive** aspects when employment enhances participation, self-realisation, and quality of life. In severe cases, where loss of work leads to poverty, loss of housing, or inability to access necessary care, the consequences may also affect **basic goods**.

Empirical findings support this classification. In the Crohn's disease study, a large proportion of previously employed patients reported work incapacity, and many did not return to work.<sup>15</sup> Similarly, in malignant melanoma, reduced working ability was observed, particularly in more advanced stages, with disease symptoms and treatment side effects cited as key factors.<sup>16</sup>

These results show that the impact on work can substantially limit patients' autonomy and capacity for action. Identifying and addressing this unmet need is therefore essential for maintaining well-being and supporting agency.

## FINANCIAL CONSEQUENCES

The criterion "Financial consequences" captures the financial impact of a health condition on patients and is assessed through three indicators. From a Gewirthian perspective, financial consequences are ethically relevant not simply because they impose costs, but because they may restrict the material conditions under which persons can maintain health, access care, exercise autonomy, and pursue purposes over time. High treatment-related costs can place patients under significant financial strain, potentially restricting their ability to act and, in extreme cases, preventing access to necessary care. This may ultimately lead to a loss of agency if essential treatment is unaffordable.<sup>1</sup>

Importantly, the severity of this impact depends not only on the health condition but also on the patient's financial situation. The NEED framework addresses this through its equity dimension, recognising that similar costs can have very different consequences depending on individual resources. Consequently, classification depends on severity: when financial consequences threaten access to essential needs such as treatment, housing, or nutrition, they qualify as a **basic good**; when they primarily restrict autonomy and well-being without endangering survival, they are better understood as **non-subtractive goods**.

### A. Average out-of-pocket healthcare costs per patient

The first indicator, "Average out-of-pocket healthcare costs per patient," measures yearly healthcare expenses not covered by insurance.<sup>4</sup> When such costs prevent access to necessary treatment, they directly threaten physical and mental health and must be classified as a basic good. However, when costs remain manageable but burdensome, they primarily affect well-being and autonomy, supporting classification as a non-subtractive good. For example, in Crohn's disease, while essential treatments are largely reimbursed, additional expenses (e.g., supplements or complementary care) accumulate over time and can strain financial stability.<sup>15</sup> Similarly, melanoma patients reported financial burdens linked to non-reimbursed paramedical consultations such as with an osteopath indicating constraints on agency without necessarily threatening survival.<sup>16</sup>



## B. Perceived financial difficulties related to the health condition

This indicator reflects patients' subjective experience of financial strain.<sup>4</sup> Severe hardship, such as inability to afford basic living expenses, directly threatens survival and should therefore be classified as a basic good. In less extreme cases, it limits autonomy and well-being and thus corresponds to a non-subtractive good. Although no empirical data from the Crohn's or melanoma studies are available for this indicator, its classification clearly depends on the degree of financial impact.

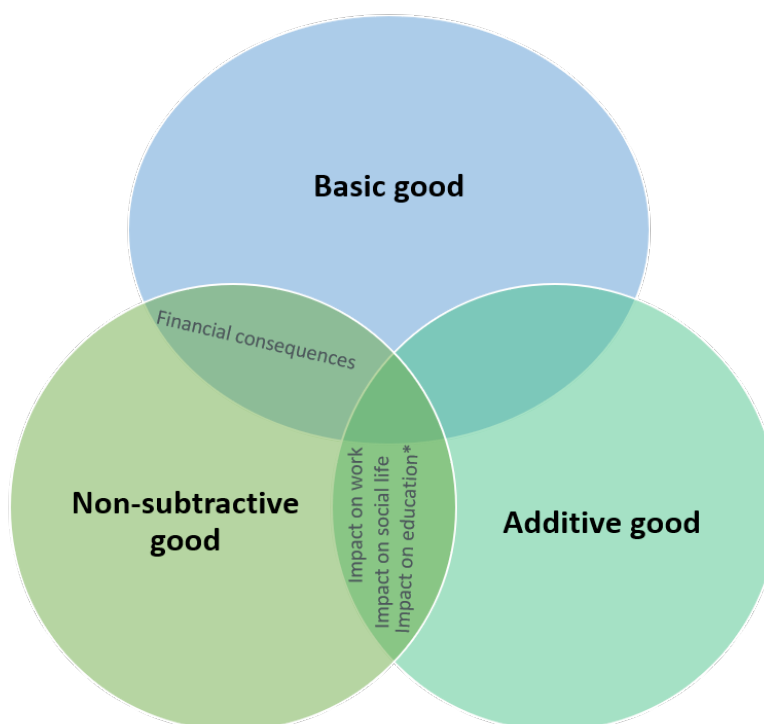
## C. Non-healthcare costs

This indicator includes indirect expenses such as transport, accommodation, or household adjustments.<sup>4</sup> While not medical in nature, these costs can accumulate significantly. If they compromise patients' ability to meet essential needs, they must be considered a basic good; otherwise, they function as non-subtractive goods by limiting autonomy without threatening survival. Evidence from Crohn's disease highlights recurring expenses (e.g., household support or hygiene-related costs), while melanoma patients reported burdens such as parking fees and non-reimbursed supportive services.<sup>15, 16</sup>

## D. Conclusion

Overall, "Financial consequences" **cannot be assigned to a single category. Its classification depends on the extent to which financial strain affects patients' ability to secure essential needs and maintain agency.** Severe financial hardship justifies classification as a basic good, whereas less critical burdens align with non-subtractive goods. This variability underscores the importance of incorporating equity into the NEED framework, ensuring that both medical and socio-economic differences are reflected in the assessment of unmet needs (see Figure 5).

**Figure 5 – Patient dimension : Social criteria classification according to Gewirth's ethical framework**



*\*Mainly additive, potentially non-subtractive depending on context*

## CONCLUSION

The initial classification of the patient dimension within the NEED framework highlights its inherent complexity. While some criteria could be classified relatively straightforwardly (e.g., impact on life expectancy), most required careful ethical reflection and comparison across multiple indicators. Overlaps between needs, as well as influencing factors such as patients' socioeconomic situations, further complicated the process, an important consideration for future analyses (see Figure 5).

Overall, the social domain should not be treated as ethically peripheral within the NEED framework. Although many social-domain criteria do not directly concern survival, they are closely connected to the freedom and well-being required for agency. Social support, social relationships, education, work, and financial stability can prevent deterioration in agency, expand opportunities for participation, and, in severe cases, protect the minimal conditions of agency itself. For this reason, the social domain is best understood as predominantly non-subtractive and additive, while allowing for classification as basic where social or material deprivation seriously threatens health, care access, or the fundamental conditions of purposive action. The analysis also confirms that overlaps between categories are unavoidable, reflecting the multifaceted nature of unmet health-related needs. In this context, the case studies on Crohn's disease and malignant melanoma were particularly useful, as they grounded the theoretical discussion in empirical evidence and illustrated how classifications operate in practice.

This preliminary classification offers an initial ethical structuring of the patient dimension. The next step is to extend the analysis to the societal dimension and compare both perspectives. Such a comparison is expected to generate further insights into prioritisation and highlight differences between individual and collective levels. Ultimately, this will contribute to a more comprehensive understanding of the NEED framework and support ethically grounded decision-making in the context of unmet health-related needs.

### 6.2.2 Society dimension

As previously mentioned, the society dimension must be approached differently from the patient dimension. The society NEED criteria within the NEED framework operate at a collective level rather than an individual level and are not intended to be interpreted as needs of individual patients. This makes the direct application of the guiding questions, originally developed for individual agency, more challenging. Nevertheless, this explorative study applies these questions, grounded in the theory of Alan Gewirth, to assess the ethical relevance of societal NEED criteria.

Within the society dimension, informal caregivers should not be understood merely as part of the external or economic burden of a health condition. They are also affected persons whose own freedom, well-being, and agency may be shaped by caregiving responsibilities. From a Gewirthian perspective, this is ethically relevant because caregiving can restrict the conditions under which caregivers themselves are able to act purposively, maintain health, participate socially, pursue education or work, and plan their lives. This is particularly important for young caregivers, whose caregiving responsibilities may interfere with education, personal development, social participation, and later professional opportunities, thereby affecting both present and future agency.

#### 6.2.2.1 Health domain

## FREQUENCY & TRANSMISSIBILITY

Within the NEED framework, "frequency" and "transmissibility" are assessed jointly, as they cannot be meaningfully interpreted in isolation.<sup>4</sup> Frequency refers to the prevalence or incidence of a condition, while transmissibility captures the extent to which a disease spreads between individuals. Together, these criteria indicate the societal burden of disease: conditions that are both widespread and highly transmissible may severely affect public health and societal functioning.



From a Gewirthian perspective, frequency and transmissibility do not themselves constitute goods in the sense of basic, non-subtractive, or additive goods. They are epidemiological indicators that describe the scale and spread of a health condition at population level. Their ethical relevance is therefore indirect: they help to assess how many persons may be affected, how seriously agency-related goods may be endangered, and whether institutional or public-health responses are required to protect freedom and well-being.

Their ethical relevance therefore depends on the extent to which frequency and transmissibility increase risks to the conditions of agency across the population. Where such risks affect large numbers of persons or place substantial pressure on healthcare systems, institutional and public-health responses may be required to protect freedom, well-being, and access to care.

Accordingly, frequency and transmissibility should not be classified as basic goods in themselves. Rather, they indicate the potential scale and urgency of threats to agency-related goods. When a condition is highly frequent or highly transmissible, it may place many persons' basic goods – such as life, bodily integrity, physical and mental health, or access to care – at risk. In addition, such conditions may put pressure on healthcare resources, which can indirectly affect other patients' access to necessary care. Their ethical significance therefore lies in their role as **indicators** of the extent to which **basic or non-subtractive goods** may be endangered at **population level**. Empirical findings illustrate this reasoning. In the case of Crohn's disease, prevalence varies geographically and is particularly high in industrialised regions such as Northern Europe. In Belgium, the Global Burden of Disease study (2019) estimated a prevalence between 153.4 and 199.8 cases per 100 000 inhabitants.<sup>15</sup> While Crohn's disease is not transmissible, its relatively high frequency reflects a substantial societal burden. In Gewirthian terms, the relevance of this frequency does not lie in frequency itself being a good, but in the fact that a comparatively large number of persons may experience restrictions in freedom, well-being, and agency as a result of the condition. Frequency therefore helps assess the scale of unmet health-related needs.

For malignant melanoma, the age-standardised incidence in Belgium was 31 cases per 100 000 inhabitants in 2020, with a prevalence of over 26 000 individuals.<sup>16</sup> For malignant melanoma, the ethical relevance of frequency must be interpreted together with severity, mortality risk, and the availability of effective prevention and treatment. Its impact on agency arises primarily from the physical and psychological burden on affected individuals and, in severe cases, from threats to life and bodily integrity. Frequency therefore helps indicate the population-level scale of these agency-related risks, while transmissibility is not applicable because melanoma is non-communicable.

In sum, frequency and transmissibility do not directly concern individual agency and should not be classified as goods in themselves. Their importance lies in showing the population-level scale and spread of health conditions that may threaten persons' freedom, well-being, and agency. They are therefore ethically relevant indicators for assessing the urgency of public-health and institutional responses, especially when widespread or transmissible conditions place basic or non-subtractive goods at risk. This becomes particularly clear in the case of highly transmissible diseases or pandemics, where the epidemiological characteristics of a condition may signal large-scale threats to life, health, access to care, and the functioning of healthcare institutions.

## BURDEN OF INFORMAL CAREGIVERS' HEALTH

The NEED criterion "burden of informal caregivers' health" captures the impact of caregiving on the physical and psychological well-being of informal caregivers.<sup>1, 4</sup>

Although this criterion is situated within the society dimension because it concerns an impact of a disease on the broader community, informal caregivers should also be considered as affected agents in their own right. Their physical and psychological well-being is ethically relevant not only because caregiving enables patient care, but because caregivers themselves require freedom and well-being as conditions of agency. From a Gewirthian perspective, sustained caregiving burdens may therefore

constitute unmet health-related needs when they undermine caregivers' capacity to act purposively, maintain health, participate socially, and pursue their own life plans.

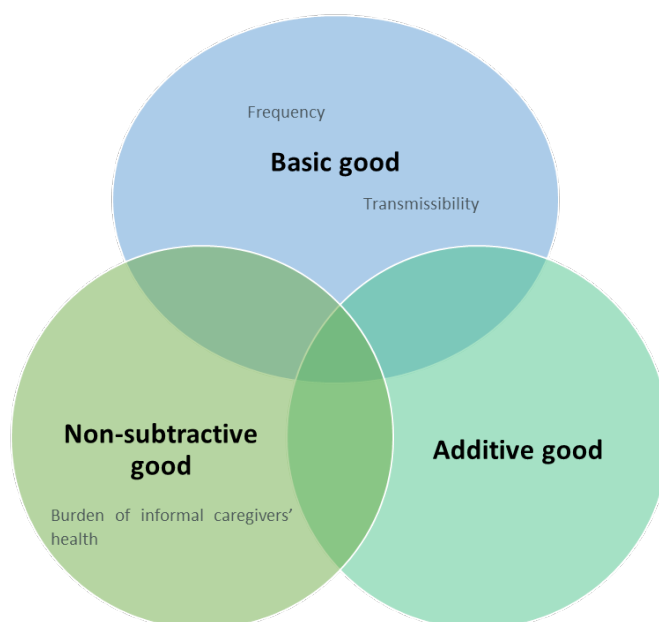
Furthermore, informal caregiving often compensates for limitations in formal healthcare systems. When institutional support is insufficient, caregivers may experience increased physical and psychological strain. In Gewirth's terms, institutions have a duty to secure the conditions necessary for agency. If this duty is not fulfilled, caregivers' autonomy, health, and overall well-being may be compromised, potentially pushing them below the threshold required for purposive action. For this reason, the criterion should at least be classified as a **non-subtractive good**, as it concerns the protection and maintenance of caregivers' existing agency. In severe cases, where caregiving threatens physical or mental health to such an extent that the basic conditions of agency are undermined, aspects of this criterion may also acquire the status of a **basic good**.

Empirical findings support this classification. In Crohn's disease, caregivers report substantial psychological burden: 41% experience stress, 73% fear for the patient's future, and 55% perceive the patient as dependent on them.<sup>15</sup> These findings indicate that caregiving responsibilities can significantly affect caregivers' well-being and, consequently, their capacity for action.

Similar patterns emerge in malignant melanoma, where informal caregivers are the primary providers of support and often experience negative effects on their psychological and general well-being<sup>16</sup>. Although further research is needed to quantify these impacts, existing evidence suggests that caregiving can impose a substantial burden.

In sum, the "burden of informal caregivers' health" is most appropriately classified as a **non-subtractive good**. When unmet, it undermines caregivers' autonomy and well-being, highlighting the need for institutional recognition and support to preserve their capacity for purposeful action (see Figure 6).

**Figure 6 – Society dimension: Health criteria classification according to Gewirth's ethical framework**





### 6.2.2.2 Healthcare domain

The healthcare domain within the societal dimension comprises two NEED criteria that address distinct unmet needs with potentially significant societal implications.

#### VALUE FOR MONEY OF STANDARD OF CARE

The NEED criterion “*Value for money of standard of care*” aims to identify inefficiencies within healthcare systems that generate unmet needs from a societal perspective.<sup>1</sup> By highlighting such inefficiencies, this criterion contributes to identifying innovative solutions to address existing efficiency gaps. Its indicator, “*Healthcare costs per unit of health gain*”, is operationalised through a dual data collection process: healthcare costs are assessed using database analyses combined with targeted literature reviews, while health gains are measured via the indicator “*Treatment effectiveness of standard of care*” (see section 1.2).<sup>4</sup>

From a Gewirthian perspective, “value for money of standard of care” should not be classified as a good in itself. Gewirth’s theory does not include a separate category of opportunity costs. Rather, it is a system-level indicator of whether healthcare resources are used in a way that supports the protection and promotion of agency-related goods. His theory compromises relevant aspects which make it possible to apply to a financial dimension. Inefficient resource use may create opportunity costs when resources allocated to interventions with low added value are no longer available for other patients whose freedom, well-being, or access to necessary care could be affected. In this sense, the criterion is ethically relevant indirectly, through the institutional responsibility to secure the conditions of agency. It will usually point to **non-subtractive goods**, insofar as improving value for money helps preserve access to care and prevent deterioration, but it may also have **additive** significance where efficiency gains expand opportunities or improve population well-being. Empirical findings support this classification by showing that the criterion primarily affects the macroscopic level rather than individual patients directly. For instance, the estimated costs related to melanoma in Belgium were already substantial (€40.1 million in 2014) and are expected to rise with the introduction of new, costly therapies.<sup>16</sup> This underlines the economic relevance of the criterion while illustrating the challenge of relating system-level efficiency considerations to Gewirth’s rights-based framework, in which institutional responsibilities are ultimately justified by their role in protecting the conditions of agency for all agents (see Figure 7).

#### PREVENTABILITY

The NEED criterion “preventability” is relevant to the society dimension because it concerns the extent to which disease occurrence or disease burden can be avoided or mitigated through preventive measures. From a Gewirthian perspective, its ethical relevance lies in the possibility of protecting persons’ physical, mental, and social health, and thereby safeguarding the conditions of agency.

Within the NEED framework, preventability refers to the possibility of averting specific health conditions through primary prevention whenever possible.<sup>1</sup> It is applied at a macroscopic level because preventive strategies often concern populations rather than individual patients alone. However, preventability should not be classified as a basic, non-subtractive, or additive good in itself. It is an epidemiological and public-health feature indicating whether disease occurrence or burden can be avoided or mitigated through available preventive measures. From a Gewirthian perspective, it is ethically relevant insofar as preventive action can protect or promote persons’ freedom and well-being by reducing avoidable threats to agency-related goods.

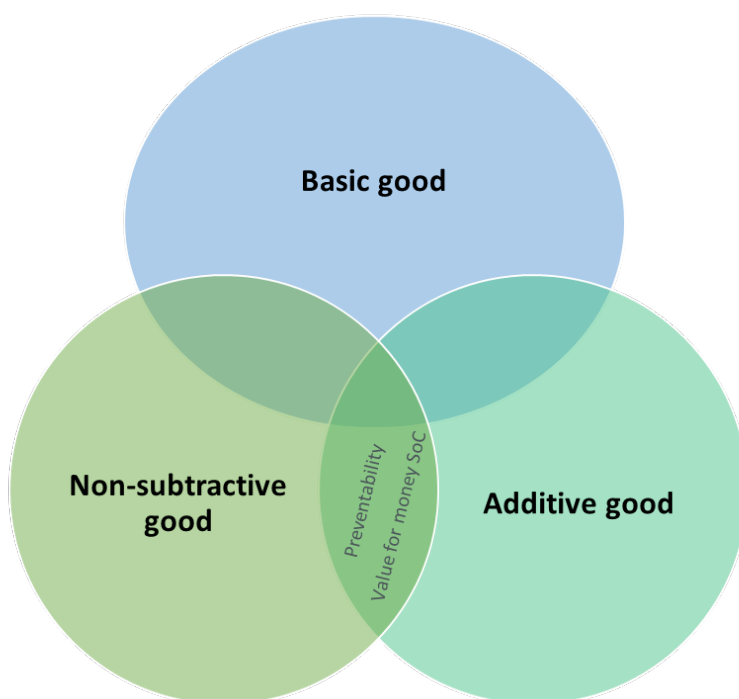
Preventive strategies may concern non-subtractive goods when they help persons maintain already secured conditions of agency by preventing avoidable deterioration in health, autonomy, or participation. They may also have additive significance when they expand opportunities for healthier lives, strengthen capacities for action, or improve population health and well-being. In severe cases, preventive measures may also protect basic goods, for example when they avert serious threats to life,

bodily integrity, or elementary physical and mental functioning. The classification therefore applies to the goods protected or promoted by prevention, not to preventability as such.

Empirical evidence supports the relevance of this criterion. Within the Crohn's disease study, several preventable dietary and lifestyle factors associated with disease risk were identified, although further research remains necessary.<sup>15</sup> These findings indicate that primary prevention may help maintain or improve health and thereby support the conditions of purposive agency.

Similarly, primary prevention through UV protection has been shown to be a cost-effective and viable strategy in melanoma prevention.<sup>16</sup> Such strategies can enable individuals and populations to preserve or improve health and thereby protect or enhance agency-related goods. This supports the ethical relevance of preventability as a NEED criterion, while making clear that the moral classification concerns the goods affected by preventive action rather than preventability itself (see Figure 7).

**Figure 7 – Society dimension: Healthcare criteria classification according to Gewirth's ethical framework**



### 6.2.2.3 Social domain

In the context of the society dimension, four criteria aim at evaluation the unmet social needs, some of them are also evaluated within future dimensions.

#### PRODUCTIVITY LOSSES

The criterion “*productivity losses*” is measured through indicators capturing the costs of work absenteeism, presenteeism, and early exit from the labour market among patients and informal caregivers. These losses are expressed as average annual productivity costs per patient and aim to identify the economic impact of health conditions at societal level.<sup>1</sup> Data are collected through database analyses, literature reviews, and patient surveys.<sup>4</sup>

Productivity losses are inherently relevant at the societal level, as their consequences extend beyond affected individuals. Reduced work capacity and absenteeism lower economic output and increase



costs for employers and public authorities. While absence allowances function as transfer payments – shifting resources within society rather than reducing total wealth – remaining productivity losses constitute a genuine economic burden.

From Gewirth's perspective, productivity losses are ethically relevant not only because they create economic costs for society, but also because they may indicate restrictions on the agency of patients and informal caregivers. Work is linked to income, social participation, independence, recognition, and future planning. When illness or caregiving responsibilities lead to absenteeism, presenteeism, reduced working capacity, or early exit from the labour market, the persons affected may lose important conditions for maintaining freedom and well-being. The societal perspective is therefore justified, but it should remain connected to the agency of the individuals whose working lives are disrupted.

In many cases, productivity losses point to **non-subtractive goods**, because reducing them helps preserve already secured conditions of agency. However, where loss of work or income leads to poverty, loss of housing, inability to access care, or long-term exclusion from education or employment, the consequences may also affect **basic goods**. Empirical evidence illustrates this relevance. In the context of CD, productivity losses are substantial, as patients are often diagnosed during their most productive years, leading to unemployment and reduced work capacity. Informal caregivers are similarly affected due to care responsibilities.<sup>15</sup> In Europe, average indirect costs related to productivity losses are estimated at €1,900 per patient per year, although figures vary by country.<sup>15</sup> These findings demonstrate how disease can impair individuals' agency, both directly and indirectly.

Similarly, productivity losses due to premature mortality from malignant melanoma in Belgium are estimated between €29.3 and €59.4 million.<sup>16</sup> While these figures describe economic losses at societal level, their ethical relevance derives from the underlying loss of persons' life, health, agency, and working capacity. Consequently, *productivity losses* represent a NEED criterion that warrants particular attention within Gewirth's ethical framework provided that they are interpreted as indicators of possible restrictions on agency-related goods rather than as goods themselves.

## ENVIRONMENTAL IMPACT OF STANDARD OF CARE

As previously noted, some NEED criteria operate across multiple dimensions. The “environmental impact of standard of care” could also be examined within the future dimension; however, since this dimension is outside the scope of this report, the analysis remains focused on the societal level while acknowledging this limitation.

The NEED framework defines this criterion as identifying the need for a more environmentally sustainable standard of care, including greenhouse gas emissions, hazardous waste, and the use of natural resources and raw materials.<sup>1</sup> Data are collected through in-depth literature reviews. Addressing this criterion may contribute to biodiversity protection, ecological balance, and the reduction of long-term health risks associated with environmental degradation and climate change.

The ethical interpretation of this criterion is complex because environmental impacts arise through global production chains, regulatory structures, and effects extending across populations and generations. Gewirth's agency-based framework can capture such impacts insofar as they affect the conditions of freedom and well-being of present and future persons, but a comprehensive analysis of these transnational and intergenerational dimensions would require further normative elaboration beyond the scope of this report.

Within the scope of the present analysis, the criterion can primarily be interpreted as having non-subtractive significance. Environmentally sustainable healthcare practices can reduce health risks and long-term vulnerabilities associated with environmental degradation and thereby help protect already secured conditions of agency. Responsibility for reducing the environmental impact of necessary healthcare lies primarily at the level of healthcare systems, providers, manufacturers, regulators, and other actors able to shape standards of care. Patients should not be expected to forgo medically appropriate treatment in order to compensate for environmental burdens arising from the design and organisation of healthcare.

The criterion may also have **additive aspects** where innovation in sustainable healthcare creates additional possibilities for providing effective care while reducing environmental harm and preserving resources for future healthcare needs.

Overall, the environmental impact of standard care combines non-subtractive and potentially additive dimensions. Gewirth's framework therefore provides a basis for interpreting its ethical relevance through its effects on the conditions of agency, while its transnational and intergenerational implications require further analysis beyond the scope of the present report.

The complexity of this criterion is reflected in the CD study, where no systematic evidence on environmental impact was identified.<sup>15</sup> Nevertheless, patients reported that frequent hospital visits and ongoing monitoring may generate environmental impacts through travel-related emissions, which vary according to transportation modes and distances. These findings do not indicate a direct impairment of patients' agency and therefore do not currently warrant heightened ethical concern from Gewirth's perspective. However, they underscore the need for further research.

A similar situation applies to malignant melanoma. Although some evidence exists, it remains limited. Available research highlights the need for further investigation into the environmental impact of melanoma care, such as the release of chemotherapy residues into wastewater and natural environments.<sup>16</sup> As with CD, the current evidence base is insufficient to support a comprehensive ethical assessment using Gewirth's framework.

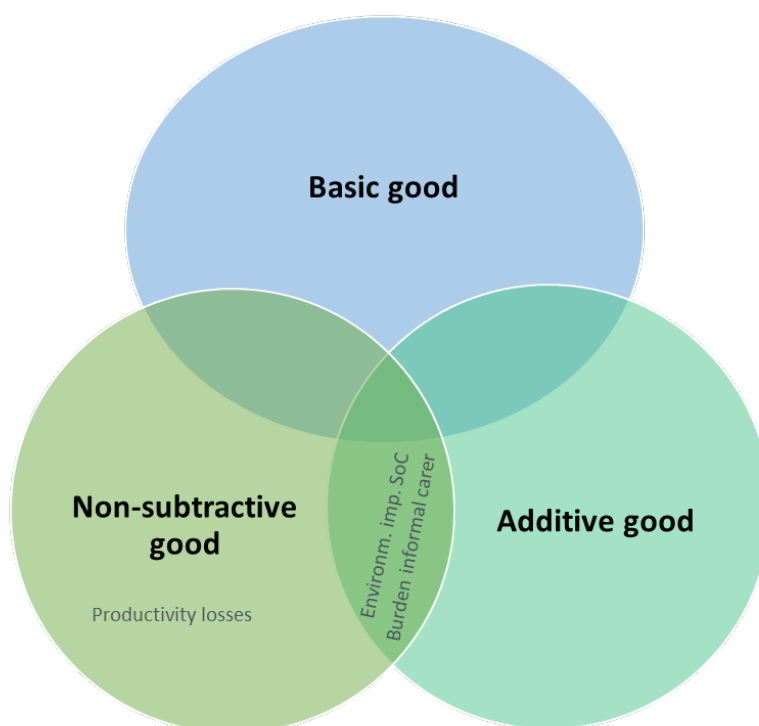
## BURDEN ON INFORMAL CAREGIVERS' SOCIAL LIFE

The "Burden of informal caregiver's social life" identifies the impact on informal caregiver's social life.<sup>4</sup> Compared with the criterion "Burden on informal caregivers' health", this criterion focuses on the impact of caregiving on social life. At first sight, such effects may seem less directly connected to basic goods than physical or psychological health burdens. However, from a Gewirthian perspective, social life is not ethically peripheral. Social relationships, participation, and opportunities for personal development can be important conditions for maintaining freedom and well-being. Severe restrictions in caregivers' social lives may therefore undermine agency, especially when they lead to isolation, psychological strain, loss of support, or long-term limitations in education, work, and personal development. This point is particularly relevant for young caregivers, for whom caregiving responsibilities may interfere with schooling, peer relationships, identity formation, and later professional opportunities. In such cases, the burden is not merely a temporary limitation of social life but may affect the development of future agency. The criterion may therefore be classified primarily as a non-subtractive good, because institutional support can help prevent caregivers from losing already secured levels of agency, social participation, and well-being. At the same time, it may also have additive aspects, since a supportive social life can strengthen resilience, autonomy, and flourishing. In severe cases, particularly where social isolation or developmental disruption threatens mental health or future agency, aspects of the criterion may approach the level of basic goods (see Figure 8).

This criterion was not yet included in the NEED framework at the time of conducting the two studies of Crohn's disease and Malignant Melanoma. Hence, no information is available regarding this criterion.



**Figure 8 – Society dimension: Healthcare criteria classification according to Gewirth's ethical framework**



## CONCLUSION

To conclude, the classification of the societal dimension has provided important insights into the NEED criteria from a socio-ethical perspective. The analysis has highlighted the complexity of this dimension in relation to Gewirth's theory, showing that certain criteria require the consideration of additional aspects before a final classification can be made.

It has become evident that many criteria can be interpreted simultaneously as both non-subtractive and additive goods, depending on the perspective adopted and the line of reasoning followed. This exercise has also demonstrated both the value and the challenges of applying Gewirth's theory to the societal dimension, as the guiding questions are not always straightforward to operationalise.

Nevertheless, the discussions generated through this process have proven highly instructive. They have not only revealed where the classification of societal needs is most complex, but also clarified which elements of Gewirth's framework are most relevant in this context. In this way, the analysis of the societal dimension has deepened the overall understanding of the NEED framework and laid the groundwork for broader conclusions in the final part of this study.

A particularly important insight concerns informal caregivers, who should be regarded not only as part of the societal consequences of illness but also as affected agents whose own freedom, well-being, and future opportunities may be impaired by caregiving responsibilities.

This is especially relevant where caregiving burdens fall on children, adolescents, or other persons whose education, social development, employment prospects, or long-term agency may be compromised.

## 7 DISCUSSION

This project sought to clarify the normative assumptions and ethical implications of the NEED framework by examining how the concept of unmet health-related needs can be interpreted through a coherent normative approach. The analysis makes explicit why unmet needs are not merely descriptive gaps in health or healthcare but can have different moral significance depending on how they affect the freedom and well-being required for agency. Gewirth's framework proved particularly useful for this purpose because it links conditions of agency to rights and corresponding responsibilities and provides a structured way of distinguishing differences in the relative ethical urgency of unmet needs.

The distinction between basic, non-subtractive, and additive goods provides a normative orientation for assessing relative ethical urgency, but it should not be understood as a mechanical hierarchy or resource-allocation sequence. Needs affecting basic goods generally warrant particular moral attention because they concern conditions necessary for agency. However, non-subtractive and additive goods remain ethically significant, and their weight depends on the severity, context, and consequences of the unmet need. In particular, the distinction does not presuppose a trajectory of continuous health improvement. For persons living with chronic conditions, preserving existing capacities and preventing deterioration may itself constitute a highly significant non-subtractive good, while additive goods may concern expanded opportunities for autonomy, participation, or valued activities even where the underlying health condition cannot be improved.

The analysis does not replace the empirical and methodological functions of the NEED framework. Rather, the two levels are complementary. Empirical evidence identifies the nature, scale, severity, and consequences of unmet needs, while normative analysis clarifies why and to what extent these findings matter ethically. The application to Crohn's disease and malignant melanoma illustrates how empirical findings can inform a context-sensitive ethical interpretation without themselves determining the normative classification. Further applications of the NEED framework will provide opportunities to refine and test this interaction between empirical assessment and ethical interpretation.<sup>14</sup>

The agency-based character of Gewirth's framework also raises questions about its application to persons whose current agential capacities are absent, diminished, or not yet fully developed. This challenge is not specific to Gewirth but arises across a range of bioethical approaches that seek to ground moral claims in autonomy, agency, interests, or capabilities. Gewirth's account contains resources for addressing actual and prospective agency, but applications to populations such as young children, persons with severe cognitive impairments, or individuals who are unconscious require further normative specification.

This issue is particularly relevant as the NEED framework is extended to paediatric populations. Rather than transferring the present classifications directly, a paediatric application should therefore undertake a context-sensitive ethical reassessment that considers developing agency, dependency, vulnerability, and the role of parents and other caregivers.

A further issue concerns environmental and intergenerational effects. The analysis showed that Gewirth's agency-based framework can capture environmental impacts insofar as they affect the conditions of freedom and well-being of present and future persons. However, the transnational, cumulative, and intergenerational character of environmental harms requires additional normative elaboration. Future work on the NEED framework could therefore explore more systematically how environmental sustainability, future health needs, and institutional responsibilities should be incorporated into the ethical assessment.<sup>14</sup>

### STRENGTHS, LIMITATIONS AND DIRECTIONS FOR FURTHER DEVELOPMENT

A principal strength of the analysis is that it provides an explicit normative interpretation of the NEED criteria rather than treating prioritisation as a purely technical or empirical exercise. Gewirth's distinction between different degrees of necessity for agency offers a structured heuristic for identifying why



some unmet needs may carry greater ethical urgency than others, while retaining the need for context-sensitive judgement.

A second strength is the connection between individual rights and institutional responsibilities. Although Gewirth's argument begins from individual agency, the generic rights to freedom and well-being entail corresponding duties and therefore direct attention to the capacity of institutions to secure the conditions of agency. This is particularly relevant to the society dimension of NEED, where economic, epidemiological, organisational, and environmental indicators acquire ethical significance through their effects on persons and on the institutional conditions required to protect their agency<sup>20</sup>.

This perspective also helps to avoid framing individual needs and system-level considerations as necessarily competing ethical claims. Institutional capacity, resource sustainability, and system-level effects matter ethically precisely because they affect the conditions under which the rights and agency of persons can be protected over time.<sup>14, 24, 25</sup>

The present analysis also has several limitations. First, the theoretical approach was selected purposively rather than through an exhaustive review of ethical theories. Rawlsian and capability-based approaches were considered as normative reference points, while Gewirth's framework was chosen because its conceptual structure was particularly useful for the specific analytical task of interpreting the moral relevance and relative ethical urgency of unmet health-related needs. The analysis should therefore be understood as a task-specific theoretical option rather than as a general judgement about the superiority of one ethical theory over others.<sup>26, 27</sup>

Second, the translation of Gewirth's concepts into guiding questions and the classification of individual NEED criteria necessarily involve interpretative judgement. The distinction between basic, non-subtractive, and additive goods functions as a heuristic rather than as a fixed taxonomy or decision rule. As the analysis has shown, the ethical significance of a criterion may vary with severity, context, and the way in which freedom and well-being as conditions of agency are affected. This context-sensitivity limits the possibility of fully standardised classification but is also inherent to the ethical assessment of unmet health-related needs.

Third, the empirical application of the analysis was limited to two case studies, Crohn's disease and malignant melanoma. These examples were sufficient to illustrate how empirical findings can inform the ethical interpretation of NEED criteria, but they do not establish the robustness or generalisability of the classification across disease areas. Further applications to a broader range of conditions and populations are therefore needed to assess how consistently the guiding questions can be used and where additional normative specification may be required.

The present analysis primarily addresses the substantive question of why unmet needs matter morally and how differences in their ethical urgency can be interpreted. It does not provide a complete account of fair decision-making procedures. Procedural approaches such as Accountability for Reasonableness may therefore offer a complementary perspective by addressing transparency, relevance of reasons, opportunities for revision, and enforcement in priority-setting processes. Future work could examine more systematically how such procedural requirements interact with the substantive normative orientation developed here.



## 8 CONCLUSION

This report examined the normative foundations and ethical implications of the NEED framework by making explicit the moral significance of unmet health-related needs and interpreting them through Gewirth's rights-based theory of agency. The central ethical insight is that unmet health-related needs matter not merely as descriptive gaps in health or healthcare, but because they may threaten, restrict, preserve, or expand the freedom and well-being required for agency. Ethical analysis thereby complements the empirical and methodological dimensions of the NEED initiative by clarifying why particular needs matter morally and why differences in their relative ethical urgency may be relevant.

Gewirth's framework was used as the primary normative approach because its agency-based structure and distinction between basic, non-subtractive, and additive goods provide a structured heuristic for interpreting differences in the moral relevance and relative ethical urgency of unmet needs. This theoretical choice should be understood as task-specific rather than as implying the general superiority of Gewirth's approach over alternative ethical theories.

The ethical interpretation of NEED criteria developed in this study provides a structured normative orientation that may inform future priority-setting, healthcare innovation, and policy development without replacing empirical evidence or fair decision-making procedures. Further work should examine the applicability of the approach across a broader range of conditions and populations, including paediatric contexts, and explore how procedural, environmental, and intergenerational considerations can be integrated into future developments of the NEED framework.



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## ■ APPENDIX

### APPENDIX 1

Table 1 – Classification of the NEED criterion of the NEED assessment framework 2025

| Criterion                                               | Indicator                                                                    | Good       | Comment                                                                                                                                                                                                                                                                                                                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------------------|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Patient Dimension</b>                                |                                                                              |            |                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Health</b>                                           |                                                                              |            |                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Impact on life expectancy</b>                        | Years of life lost (per death)                                               | Basic good | The Years of life lost (per death) can be classified as basic goods, since it has a direct impact on the safety and survival of patients.                                                                                                                                                                                                                                |
| <b>Impact on general health-related quality of life</b> | EQ-5D-5L average score                                                       | Basic good | <ul style="list-style-type: none"> <li>• Direct impact on safety and survival.</li> <li>• Direct impact on physical, mental and social health.</li> </ul>                                                                                                                                                                                                                |
|                                                         | Years of life lived with disability (per case)                               | Basic good |                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Impact on physical health</b>                        | Experienced burden of physical symptoms related to the health condition      | Basic good | <ul style="list-style-type: none"> <li>• This criterion is to be considered as a basic good. The impairment of capacity can reach a totality in which patients are incapable of action.</li> <li>• Direct impact on safety and survival and physical health</li> </ul>                                                                                                   |
|                                                         | Pain/discomfort before disease vs today                                      | Basic good |                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Impact on psychological health</b>                   | Experienced burden of psychological symptoms related to the health condition | Basic good | <ul style="list-style-type: none"> <li>• This criterion is to be considered a basic good. The impairment of capacity can reach a totality in which patients are incapable of action.</li> </ul> <p>For example, patients suffering from depression are not only physically impaired (leaving the bed) but can also be verbally impaired (too tired to speak or act).</p> |
|                                                         | Anxiety/depression before disease vs today                                   | Basic good |                                                                                                                                                                                                                                                                                                                                                                          |

| Criterion                                | Indicator                                                     | Good                       | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------------------------|---------------------------------------------------------------|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Impact on sexual and reproductive health | Impact on sexual health                                       | Basic good                 | <ul style="list-style-type: none"><li>• Direct impact on survival and safety</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                                          | Impact on reproductive health                                 | Basic good                 | <ul style="list-style-type: none"><li>• Direct impact on physical and mental health</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Impact on autonomy                       | Mobility before disease vs today                              | Basic good                 | <ul style="list-style-type: none"><li>• According to Gewirth, it is of highest priority to be able to act at all. This means that the criterion of autonomy is a basic good, since it is essential for people to be able to act. This can include physical autonomy but also verbal autonomy and of thoughts.</li><li>• Direct impact on autonomy</li></ul>                                                                                                                                                                                                                |
|                                          | Self-care before disease vs today                             | Basic good                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|                                          | Usual activities before disease vs today                      | Basic good                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Healthcare                               |                                                               |                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Treatment effectiveness                  | Effectiveness of current overall treatment (standard of care) | Non-subtractive good       | <p>Depending on the effectiveness of treatment, the patients extent of action can vary. It is categorized as non-subtractive, the effectiveness of the treatment is essential to maintain the capacity of action still existing.</p> <ul style="list-style-type: none"><li>• Not simple to classify</li><li>• Depends on the health condition and patient</li><li>• Is there already existing treatment or not?</li><li>• If the treatment is not effective, does it then become a basic good? Because then it could be seen as a “non-existing treatment” again</li></ul> |
| Burden of treatment                      | Experienced burden of treatment                               | Additive good              | Treatment is a basic good, which is essential for the goal of being able to act. Hence, the burden is an effect of the treatment, which means that of course it is more difficult to go through the treatment, but it will still be conducted.                                                                                                                                                                                                                                                                                                                             |
|                                          | Experienced burden of treatment side-effects                  | Basic/Non-subtractive good | <p>Basic good:</p> <ul style="list-style-type: none"><li>• If burden is very high, then direct impact on safety or survival can occur</li></ul> <p>Non-subtractive good:</p>                                                                                                                                                                                                                                                                                                                                                                                               |



| Criterion                                                      | Indicator                                                   | Good                           | Comment                                                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------------------------------------------|-------------------------------------------------------------|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                |                                                             |                                | <ul style="list-style-type: none"> <li>• Treatment is a mitigating intervention, that aims to support the basic good of health</li> <li>• Protects patients from losing their ability to act freely</li> <li>• -Maintains and supports their well-being to pursue their purposes</li> </ul>                                                                                                 |
| <b>Quality of care</b><br><b>Non-subtractive/Additive good</b> | Coordination and continuity of care                         | Non-subtractive good           | <ul style="list-style-type: none"> <li>• Impact on maintenance and support of well-being</li> <li>• Impact on protection of acting freely</li> <li>• Coordination and continuity of care is necessary for successful treatment</li> </ul>                                                                                                                                                   |
|                                                                | Received information                                        | Additive good                  | <p>Treatment will be done in any case. No difference whether information was received or not.</p> <ul style="list-style-type: none"> <li>• No direct impact on health</li> <li>• No impact on maintaining the status of well-being</li> <li>• Has an impact on enhancement and development of well-being and free ability of action</li> </ul>                                              |
|                                                                | Involvement in treatment decisions                          | Non-subtractive/ Additive good | <ul style="list-style-type: none"> <li>• Transparency and involvement of the patient is ethically considered as a number one priority (autonomy of the patient)</li> <li>• This indicator measures an essential part of the treatment – regarding the patient</li> </ul>                                                                                                                    |
|                                                                | Diagnostic timing                                           | Basic/Non-subtractive good     | <ul style="list-style-type: none"> <li>• Basic good: depending on the disease diagnostic timing can have a direct impact on safety or survival.</li> <li>• Non-subtractive good: For some diseases diagnostic timing has no direct impact on health</li> <li>• It can protect patients from losing their ability to act freely</li> <li>• It can maintain and support well-being</li> </ul> |
|                                                                | Implementation of effective secondary prevention strategies | Non-subtractive good           | <ul style="list-style-type: none"> <li>• It does support and maintain well-being</li> <li>• It protects patients from losing their ability to act freely and thus their autonomy, physical and mental health</li> </ul>                                                                                                                                                                     |
| <b>Accessibility</b>                                           | Treatment availability                                      | Non-subtractive good           | <p>Accessibility to healthcare remains essential, for receiving treatments or healthcare in general, that ensures the capability to act.</p>                                                                                                                                                                                                                                                |

| Criterion                     | Indicator                                          | Good                           | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------------------------|----------------------------------------------------|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                               |                                                    |                                | The accessibility is needed to maintain the existing capacity to act and ensure it doesn't get worse                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                               | Foregone care                                      | Additive good                  | No direct impact on health (to be considered: whether it concerns foregone treatment, in this case it could be considered non-subtractive)                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Scientific Research</b>    | Research gaps                                      | Non-subtractive/ Additive good | The criterion of scientific research can be seen as a non-subtractive good but also as an additive one. For instance, if there is a lack of research on a specific disease for which there is no treatment existing, then it would be considered a non-subtractive good, because the patients need to have a treatment to maintain or increase their capacity to act. On the other hand, if there are already existing treatments for disease the research would be to expand the existing treatment and thus expand the possibility of action of patients. |
| <b>Social</b>                 |                                                    |                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Impact on social life</b>  | Social support needs                               | Non-subtractive good           | <ul style="list-style-type: none"> <li>Since social life is plays a crucial role for the well-being of patients it can have an impact on the status of health. Therefore, it is classified as a second order good.</li> <li>The social support and connection needs can be impaired by a person's illness. This leads to a limitation of agency, which can negatively impact a patient's freedom and well-being.</li> </ul>                                                                                                                                 |
|                               | Social connection needs                            | Non-subtractive/Additive good  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Impact on education</b>    | Impact on education                                | Non-subtractive/Additive good  | Gewirth would categorise education as an additive good, since it is not essential for the capacity of action, but it can expand the existing capacity of action. Depending on the context, it may also be a non-subtractive good.                                                                                                                                                                                                                                                                                                                           |
| <b>Impact on work</b>         | Changes in working time                            | Non-subtractive good           | Since work is a financial resource, it is classified as a non-subtractive good. The impact of a disease on work can lead to unemployment and thus negatively influence the action of a patient                                                                                                                                                                                                                                                                                                                                                              |
| <b>Financial consequences</b> | Average out-of-pocket healthcare costs per patient | Non-subtractive/Additive       | Financial consequences can occur when having medical treatments which are very costly. These prices can lead to financial difficulties, which can lead to incapacity of action. Moreover, it can be argued that patients may not be able to pay a treatment, which                                                                                                                                                                                                                                                                                          |



| Criterion                             | Indicator                                                        | Good                                                           | Comment                                                                                                                                                                                                                                                                                                                                                                                                          |
|---------------------------------------|------------------------------------------------------------------|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                       | Perceived financial difficulties related to the health condition | Basic/Non-subtractive good                                     | means, they cannot be treated and thus they would lose their capacity to act.                                                                                                                                                                                                                                                                                                                                    |
|                                       | Non-healthcare costs per patient                                 | Basic/Non-subtractive good                                     |                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Society dimension                     |                                                                  |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Health                                |                                                                  |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Frequency                             | Prevalence or incidence                                          | Indicator of potential threats to basic/non-subtractive goods. | Aggregation of patients affected by a specific health condition can lead to significant societal effects.                                                                                                                                                                                                                                                                                                        |
| Transmissibility                      | Contagiousness                                                   | Indicator of potential threats to basic/non-subtractive goods. | <ul style="list-style-type: none"><li>• Moral justification to consider this indicator</li><li>• -Whenever institutional action is required to safeguard the health of large parts of the population</li><li>• -Both indicators must be addressed to secure conditions necessary for autonomy and societal well-being</li></ul>                                                                                  |
| Burden on informal caregivers' health | Impact on informal caregivers' health                            | Basic/Non-subtractive good                                     | <ul style="list-style-type: none"><li>• Informal caregivers are affected agents whose physical and psychological health may be impaired when care responsibilities compensate for insufficient formal support.</li><li>• This can undermine their freedom, well-being, and capacity for purposive action.</li><li>• In severe cases, caregiver health burdens may threaten basic conditions of agency.</li></ul> |
| Healthcare                            |                                                                  |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Value for money of standard of care   | Healthcare costs per unit of health gain                         | Non-subtractive/Additive good                                  | Classification into two goods: <ul style="list-style-type: none"><li>• Risk of undermining secured agency, through reduced access to care and unsustainable health systems</li><li>• Can expand opportunities and improve overall well-being when aggregated among individuals</li></ul>                                                                                                                         |
| Preventability                        | Implementation of effective primary prevention strategies        | Non-subtractive/Additive good                                  | Classification into two goods: <ul style="list-style-type: none"><li>• Can prevent individuals from getting sick, thereby preventing direct impairments of agency (physical, mental and social health)</li></ul>                                                                                                                                                                                                 |

| Criterion                                         | Indicator                                                                                             | Good                                                   | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|---------------------------------------------------|-------------------------------------------------------------------------------------------------------|--------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                   |                                                                                                       |                                                        | <ul style="list-style-type: none"> <li>Can strengthen and expand individuals health and agency</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Class</b>                                      |                                                                                                       |                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Productivity losses</b>                        | Costs related to work absenteeism, presenteeism, or/and early labor force exits of patients           | Non-subtractive good                                   | <p>In aggregation productivity losses can indirectly affect individuals, by for example paying higher taxes.</p> <p>This can have an impact on the individuals well-being and their freedom, such as their agency.</p>                                                                                                                                                                                                                                                                                |
|                                                   | Costs related to work absenteeism, presenteeism or/and early labor force exits of informal caregivers |                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Environmental impact of standard of care</b>   | Greenhouse gas emissions related to the standard of care                                              | Non-subtractive/Additive good                          | <p>Challenging classification because of external global influences and regulatory frameworks concerning greenhouse gas emissions and natural resource use.</p> <ul style="list-style-type: none"> <li>Institutions are required to address environmental sustainability to safeguard physical, mental and social health, to ensure agency</li> <li>Promoting sustainable healthcare practices enhances individuals capacity for action and fostering cooperation towards a shared purpose</li> </ul> |
|                                                   | Hazardous waste related to standard of care                                                           |                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|                                                   | Use of natural resources and raw materials related to standard of care                                |                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Burden on informal caregivers' social life</b> | Impact on informal caregivers' social life                                                            | Non-subtractive/Additive good<br>Basic in severe cases | Caregiving responsibilities can restrict caregivers' social participation, relationships, education, work, and personal development. This is particularly important for young caregivers, whose present and future agency may be affected. Institutional support may help prevent deterioration in caregivers' agency and well-being.                                                                                                                                                                 |