HAUTE AUTORITÉ DE SANTÉ

METHODOLOGICAL GUIDE

Assessment of ethical aspects

Approved by the HAS Board: April 2013

This assessment can be downloaded from www.has-sante.fr

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Contents

1. HAS' missions concerning assessment of ethical aspects

This methodological guideline is a practical tool that may be used during the internal production of the assessments and guidelines published by the *Haute Autorité de Santé* (HAS). A description of the background to the production of this guide is included here to clarify its aims and scope.

1.1 Background

The *Haute Autorité de Santé* (HAS) was established with the French Health Insurance Law 2004-810 of 13 August 2004 to promote the quality of care for patients and to help maintain a healthcare system based on solidarity and fairness. It supports healthcare professionals in continuously improving their practice, and through its opinions HAS helps to inform public decision-making to achieve the best possible management of reimbursable medical products and services.[1]

In compliance with international guidelines (1), HAS has adopted an approach which tries to ensure that the consequences of public health decisions are documented as fully as possible. To do this, it does not always restrict itself to assessing a health technology[2] in terms of benefit-risk ratio, which is the traditional approach, but it also takes into account other dimensions, such as the economic (efficiency,[3] budgetary impact), ethical, and sociological dimensions, as well as the impact of the technology on professional practice, patients' lives and healthcare organisation. So the assessments carried out by HAS can be carried out by a multidisciplinary team of specialists; as an example, the Economic and Public Health Assessment Committee (CEESP) is made up of experts from a wide and varied range of disciplines, including economists, clinicians, epidemiologists, specialists in public health, specialists in human sciences and social sciences, representatives from patients' associations and users of the healthcare system.

At an international level, this type of broader assessment is commonly known as a 'full health technology assessment' (abbreviated to 'full HTA'). For its part, HAS decided to use the terms 'assessment of benefit to society' (SeRC)[4] after a meeting of a specialist working group formed in 2007 at the request of the HAS Board. The working group consisted of experts from many different fields (epidemiology, economics, public health and sociology), and has the task of establishing the "feasibility of incorporating societal dimensions into HAS' assessments, and the processes by which this could be done."

[1] For more details of HAS' missions and its internal organisation, see http://www.has-sante.fr.

[2] The term "health technology" refers to surgical or medical procedures involving equipment, medical devices or medicinal products used for prevention or treatment. It also covers the operational systems required to implement them and, more generally, all public health programmes.

[3] The concept of 'efficiency' refers to examining the consequences of a health technology in terms of health gain (medical efficacy) and resources used (costs).

[4] For more information see the report of the roundtable discussion of this topic during the HAS seminars held during 2007.

http://www.has-sante.fr/portail/upload/docs/application/pdf/2008-07/cr_tr17_rencontres_2007.pdf

These discussions led to the publication of a report in the series of specialist methodological guidelines focusing on the following aspects of assessment:[5]

- "Choices in Methods for Economic Evaluation" (2011) (2);
- "*L'évaluation des aspects sociaux: une contribution sociologique à l'évaluation*" [Assessment of social aspects; a sociological contribution to assessments"] (2011)[6] (3);
- "Assessment of ethical aspects", the subject of this guide.

It should be mentioned that the development process for each of these documents and their respective purposes varies according to the scientific field, regulatory constraints and institutional factors. For example, methodological guidelines concerning economic assessment have special status as HAS was made responsible for the subject as a result of the 2008 law on Social Security funding, amended by the 2012 law on Social Security funding. So economic opinions produced by the Economic and Public Health Assessment Committee (CEESP) have regulatory force in the same way as the opinions produced by the Transparency Committee (CT) and by the Committee for the Assessment of Medical Devices and Health Technologies (CNEDiMTS).

Conversely, assessing ethical aspects is not a mission conferred by law; it is one of a set of initiatives taken by HAS to improve the quality of its work. HAS' actual mission is to provide information for decision-makers and more broadly, for all stakeholders, by giving them the fullest possible information and insight about the issues. In this light, HAS is responsible for trying to identify and analyse the ethical issues raised by the health technologies HAS assesses, so that these issues may be discussed when a decision is taken on whether a technology should be introduced.[7] So it is legitimate for HAS to give an account of the principles involved, any conflicts of values and the consequences of the various choices open to decision-makers. In this way it encourages balance between the decision and the principles or values approved by society. It is also responsible for ensuring that the ethical issues inherent in the technologies it assesses should be taken into account in the recommendations it issues and in its conclusions.

Nevertheless, it is important to emphasise that HAS is not qualified to establish a hierarchy of the priorities of civil society by delivering an opinion on a general ethical question, as other institutions such as the French National Consultative Ethics Committee (CCNE) are competent to do.[8] However, HAS must take account of all the dimensions assessed and the global context of the technology being assessed. So in its conclusions HAS may weight the various conflicting arguments related to a particular technology and arbitrate between them, or it may decide to highlight the importance of referring the matter to the CCNE when a technology raises a general ethical issue that needs to be addressed independently of the technology being assessed. So HAS needs to be able to carry out ethical reflection aimed at establishing the complexity of the issues that may arise as a result of implementing technology, and take it into account when producing its conclusions. This reflection should also help HAS to make explicit any arbitration on ethical issues raised by the decision.

[5] Each of these dimensions has its own assessment method. However, the opinion delivered by HAS based on this broader assessment takes account of the conclusions arrived at for each of the dimensions. So "ethical aspects" are considered in the light of "clinical, economic, sociological and other aspects". The concept of "aspects" adopted to qualify these various components of the assessment should not be taken to mean that the various constituent parts of the assessment are independent of each other.

[6] There is no English version of this guideline.

[7] The presence of ethical issues may affect the social acceptability of a decision in terms of health policy and may compromise its anticipated effects. For some topics, the ethical dimension is very significant and issues raised by it may contribute to making a decision unacceptable or unworkable from society's point of view.

[8] *"The mission of the French National Consultative Ethics Committee for life sciences and health science is to deliver opinions on ethical problems and questions concerning society raised by advances in knowledge in the domains of biology, medicine and health."* French law of 06 August 2004.

1.2 Aims and scope

1.2.1 A practical guide

As part of its “Strategic Plan 2009-2011”, HAS undertook to establish the conditions under which it proposes to analyse ethical aspects in its assessments, and the method to be used. The aim of this work is to establish formal processes to ensure uniformity across the reports HAS produces when they include an assessment of ethical aspects, and to make it easier for its conclusions to be adopted by providing the stakeholders who are their intended audience with keys to understanding the approach used.

This guide has also been produced to facilitate collaboration between the various individuals tasked with assessing ethical aspects, i.e. HAS’ departments, external collaborators (report authors, research team, etc.), experts in the working and peer review groups, the HAS Committees and the HAS Board. Above all, it is a working tool allowing everyone involved to use a common terminology and methodological foundation.

So the guide should be used to:

- establish a method for assessing ethical aspects in order to allow the Committees and the HAS Board to ensure that the various dimensions of assessment are looked at in relation to each other;
- to make it easier to identify subjects raising ethical issues where it would seem to be useful to analyse them to inform decision-taking
- ensure that ethical aspects are assessed in the same way.

1.2.2 A guide with a limited scope

The approach used in this guide should be consistent with HAS’ particular situation as an institution; so it should make it possible to:

- analyse ethical issues and any conflicts of values underpinning them without necessarily resolving them, in accordance with HAS’ general aim of impartiality in carrying out its missions;
- propose a method for assessing ethical aspects that is appropriate for HAS’ constraints in terms of internal organisation and resources.

Specifically, these constraints govern the selection of subjects which might give rise to an analysis of ethical aspects and the analytical method proposed. In principle, all the technologies assessed by HAS could raise ethical issues. However, as described in more detail later in this document, HAS is constrained by its deadlines which prevent it from proposing routine analysis of ethical aspects. So it has to distinguish those subjects which involve the most significant ethical issues, taking account of the technology being assessed and the context in which the referral has been made.

Similarly, the method to be proposed for analysing these ethical issues should not significantly extend HAS’ deadlines and assessment costs. As an example, it could be useful to organise a focus group to identify the ethical issues raised by the health technology. However, doing this involves a relatively cumbersome organisational structure that HAS cannot use for all its assessments. Although this does not exclude the option of using a focus group for an individual assessment, other methods are preferred such as a systematic review of relevant published studies (see below, section 2.2.1).

In addition, the methodological choices made take account of HAS' experience in consultative processes. Its assessments are routinely enhanced through discussions with different stakeholders in the working groups, peer review groups or public consultations (learned societies, professional organisations, patients' and users' associations, public institutions concerned with healthcare or with other fields, etc). These consultative processes are in any case used for other dimensions of assessments, and it could be valuable to make use of them when analysing ethical aspects.

This guide does not have the authority to offer a universal approach to taking account of the ethical issues raised by assessments of health technologies other than within the context of HAS' missions.

1.2.3 A guide that forms part of a multidisciplinary and evolving approach

An ethical analysis may call on concepts relevant to a number of different disciplines. For example, the concepts of autonomy, dignity of the person and justice have for a long time been the focus of developments in political and moral philosophy. They are also key factors in legal[9] and economic[10] theories. Ethical reflections are initiated in philosophy, medical and legal studies, economic science, etc..[11] So although reference to philosophy is essential, it is important not to limit assessment of ethical aspects to a specific discipline but rather to try to take into account a plurality of approaches which can clarify these issues.

In addition, methods for assessing ethical aspects in healthcare are not as formalised as they may be in relation to other dimensions. Although approaches for taking ethical decisions have been implemented within national or hospital committees, there are no methodology guidelines issued by learned societies or research centres in France or at an international level, apart from the work carried out by EUnetHTA to produce the Core Model[12] (1). So this type of reflection needs to be started within the context of this guide. Similarly, it will be necessary to revise it in line with methodological research into analysing ethical aspects in the assessment of health technologies.

1.3 Some definitions

1.3.1 Ethics: a polysemous concept[13]

Without trying to produce an exhaustive and detailed definition of what ethics is, it is important to emphasise that the concept of 'ethics' is polysemous in the sense that different ways of considering the role of ethics coexist and they may sometimes contradict each other. Ethics may be normative or descriptive in intent, it may be seen from the point of view of the individual or of the community, in a general perspective or in specific fields.

In the introduction to the *Dictionnaire d'éthique et de philosophie morale* [Dictionary of ethics and moral philosophy], Monique Canto-Sperber introduces the concept of ethics in the following way: *"What does ethics deal with if not the diverse and contradictory forms of good and evil, the meaning of human life, the difficulty of making choices, the need to justify decisions and the aspiration to define impartial universal principles?"* (8). By proposing a definition framed as a question, Monique Canto-Sperber touches on all these different ways of conceiving ethics.

The concept of ethics, and the changes in its meaning over time, cannot be described in a simple way without immediately provoking debate, as is shown in the comments made by members of the peer review group to whom this document was submitted (a summary of the comments is included in the Appendices). So in the context of this guide, it is not possible either to define what ethics is in general, nor to specify its limits in relation to what deals with 'morality', nor again to recount the

[9] As an example, the concept of the dignity of the human person was introduced into the Civil Code by Law No. 94-653 of 29 July 1994 while the law of contracts (article 1101 and following, Civil Code), traditionally based on the autonomy of the will, in compliance with the law (article 1134), ensures that the consent of the parties involved is protected.

[10] The concept of justice is at the heart of studies carried out in the field of normative economics (see Fleurbaey 1996 (4); Gamel, 1992 (5); Sen, 2010 (6); van Parjis, 1991 (7); etc.).

[11] In addition, in France it does not have its own scientific representative within the French National University Council.

[12] The section of the Core Models dealing with ethical aspects was produced by a group of international experts, namely Mirella Marlow, Ilona Autti-Rämö, Björjn Haufmann, Samuli Saarni, Sinikka Sihvo, Aleksandra Zagorska (1). The analytical model proposed by these authors is included in the Appendices to this document.

[13] For the theoretical foundations used for this definition see the entries 'Éthique' [Ethics] by Paul Ricoeur, "Éthique appliquée" [Applied ethics] by Marie-Hélène Parizeau, "Bonheur" [Happiness] by Monique Canto-Sperber in the "*Dictionnaire d'éthique et de philosophie morale*" published in 2004 (8).

history of ethical theories. All the same, it is important to highlight the fact that different ways of conceiving ethics coexist.

In the Western philosophical tradition, ethical reflection first and foremost concerns the question of knowing how to achieve the 'Sovereign Good'. Ethics then covers all the reflections raised by the question 'What is a good life?'.[14] Subsequently, ethical reflections have been more concerned with the question of knowing 'What should I do?', bringing into play the subject's own responsibility, as well as notions of 'autonomy', 'liberty' and 'dignity of the individual'.[15] In both cases, the answers given to these questions refer to normative ethics in the sense in which they are intended to guide the behaviours of individuals, with reference to values and norms whose scope goes well beyond the strictly legal sense.

There have also been other types of debates concerning a pluralist conception of Good which raises further questions on the issue of living together in a society where values and beliefs are not necessarily shared. Adherence to pluralism had the consequence of the development of descriptive ethics, whose aim is not to determine what is good and what is bad, but rather to analyse the different ethical judgements and the argumentative structure supporting them. In this way it is possible to distinguish a first stage of ethical reflection intended to identify the principles and values held by those involved, from a second stage in which a method is proposed to allow arbitration between these principles and values when they come into conflict with each other.

Another notable development concerns the position of ethical reflection applied to particular domains and/or specific situations. This development goes hand-in-hand with the development of a pluralist conception of Good insofar as the rules making it possible to coexist and share common ethical points of reference would lead to different responses depending on the context in which the issue is raised. So for example there are medical ethics and business ethics. When ethical reflection is both situated within a pluralist perspective and involves reasoning about applied cases, it may be defined as a search for arbitration between the different values approved in a given society according to determined problems and situations.

1.3.2 What is meant by 'ethical aspects' in this guide

The aim of this guide is to propose a method to highlight the ethical questions raised by a particular health technology, in a descriptive manner. These questions may concern the health technology itself, the conditions under which it is used or its reimbursement by society through public funding. So the concept of 'ethical aspects' refers to the various arguments put forward in favour or against a health technology, brought into play in the context of these ethical questions, and which involve the values that concern the conditions of living together (social values[16]). Differences in the priorities accorded to these different values explains the conflicts of points of view; if one value is given priority rather than another during ethical reflection, opposite conclusions will be reached.

[14] The ancient philosophers saw a search for happiness and for morality as indissolubly connected. In this light, the concept of a 'good life' did not mean a life directed exclusively to the seeking of pleasure (although this hedonistic thesis was defended by Callicles in Plato's *Gorgias*, as it would be later by the classical utilitarians), but it means the idea of a life directed towards the Sovereign Good, which could involve going without certain things. The Sovereign Good can then be defined, in Aristotle's terms, as the goal in the light of which all our actions are accomplished and which is never desirable in view of anything else. (9)

[15] These concepts are questioned in Kant's works. On this point see "*Foundations of the metaphysics of morals"*.

[16] Contemporary philosophy questions the concepts of 'value' and 'norm' (see the article "Norms and values" by Ruwen Ogien (8)). In the context of this guide, we will be using the concept of 'value' (what should be) in contrast to the concept of 'fact' (what is). On the distinction between these two concepts, see Hume (10) and Poincaré (11).

In contrast, it is important to stress that the processes and modes of governance that ensure the legitimacy of HAS' assessments also involve ethical values (process values), which do certainly involve a number of stances, but which this guide does not have the authority to question, these values being independence and impartiality (in assessing each of the different dimensions, in the management of conflicts of interest and the course of discussions between the stakeholders), scientific rigour (use of rigorous, reproducible, systematic and explicit methodology without dogmatic position-taking), multidisciplinarity (taking account of all the dimensions involved in judging the benefit of a health technology)[17] (13,14). Similarly, there is no question of re-examining the ethical values underpinning the methods traditionally used for medical, economic and public health assessment (such as randomised trials, cost-utility analysis, etc.).[18] Indeed, the guide 'Choices in Methods for Economic Evaluation', published in 2011 (2), made a number of choices of methods with normative implications and which were justified by a dual concern for scientific quality and workability. However, it was felt that process values and choices of methods should be treated at a global level within HAS rather than in relation to each health technology. So the method proposed in this guide is not applicable to these issues.

Finally, it is important to remember that the aim of this guide is part of HAS' remit concerning aid to public decision-making. The opinions delivered by HAS guide stakeholders in determining the general directions of health policies. So it is not the aim of the guide to propose a method able to address all the ethical issues that may be raised by particular situations in the context of each meeting between a doctor and their patient.

Finally, for the purposes of this guide, the concept of ethical aspects is used in a very restrictive sense. The method proposed for carrying out an ethical analysis only concerns health technologies that raise a conflict of values and situations which very clearly call for ethical reflection.

1.4 Place of ethical aspects in relation to the other dimensions of assessment

How the various dimensions are related in the different types of work produced by HAS depends on the context, the technology being assessed and the question posed. It is not part of the remit of one of the methodology guides to determine the scope of one of the dimensions of an assessment in relation to the others. It is for the Committees to ensure that the different registers of the assessment have been examined in relation to each other through the opinions that they issue for the benefit of the Board.

Conversely, the guide should establish the method that the Committees and the Board will use when assessing ethical aspects to ensure that all dimensions are considered in their opinions and conclusions.

To satisfy this aim, the guide proposes tools to facilitate the identification of subjects requiring the ethical aspects to be incorporated (see section 2.1), and a method for examining the various dimensions in relation to each other (see section 2.2.3). In addition, it should be mentioned that each of the dimensions considered in an assessment sheds further light on the problem raised by a particular health technology so that the whole complexity of the issues is weighed up. So a dialogue needs to be opened up between these different dimensions, rather than considering each of them separately, in an external and autonomous manner.

[17] See report on new horizons in healthcare quality, published in 2007 (12).

[18] In fact, the tools used for carrying out an assessment of a health technology, for example an economic or public health assessment, address various normative positions. Discussions about the legitimacy of these normative positions should take place in the context of *ad hoc* work, at a global level within HAS rather than as part of an assessment of a particular health technology. For a more in-depth examination of these discussions, see Dozon and Fassin (15); Cookson and Dolan (16); Wagstaff (17); Moatti (18); Dolan (19). These references are not exhaustive. In addition, it is useful to remember that some of these questions were decided by the public decision-makers during the drafting of legislative and regulatory texts for defining the procedures for assessment used at HAS (criteria for acceptance of healthcare products for reimbursement, mission of economic assessment, mission of public health assessment, etc.).

Three examples will illustrate this type of dialogue between the different dimensions of an assessment:[19]

- the efficacy of a health technology is uncertain because of a lack of robust clinical data that makes it more difficult to arbitrate between the ethical conflicts, for example if there are doubts about the presence of side effects; assessment of growth hormones for non-deficient children raises this type of issue concerning both efficacy in terms of improvement in quality-of-life and the long-term effects of treatment (20);
- the choice of efficacy endpoints may raise ethical conflicts when it is looked at in relation to the aim of a health technology; for example, the choice of efficacy endpoint for assessment of screening strategies for trisomy 21 (number of births of children with trisomy 21 avoided compared with the number of cases screened) led to some discussion within the working group in charge of the assessment on the status to be accorded to abortion in the event of genetic abnormality (21);
- finally, there may be tensions between the results of an assessment in terms of economic efficiency and compliance with specific ethical principles; for example, the participation of individuals in a formal screening programme increases the efficiency of use of the resources allocated to its implementation, while respect for the autonomy of the individual may restrict the use of promotional campaigns to increase participation in the programme (22, 23).

Finally, the conclusions of each of the dimensions of assessment (medical, economic, ethical, sociological, legal, etc) constitute complete arguments in the ethical debate raised by a health technology. And conversely, taking account of ethical issues may affect the criteria chosen for assessing other dimensions. So all dimensions are taken into account in the production of HAS' guidelines and opinion on the subject of a particular health technology.

1.5 Guide development process

This document was produced by the *Haute Autorité de Santé's* Economic and Public Health Assessment Department by a team of authors and based on a number of sources of information.

On the one hand, the international literature was reviewed with regard to methods for incorporating ethical aspects in health technology assessments.[20] The work carried out by EUnetHTA when producing the 'Ethical aspects' section of the Core Model (1) was taken as a reference model for HAS on the subject (see Appendices).

In addition, in June 2011 HAS organised a seminar on the subject of 'Ethics in HTAs: when and how?' for experts from France and abroad, and representatives of HAS. The presentations and the discussions they gave rise to made it possible to consider what methods were relevant in the French institutional situation. The international experts made the following contributions to the seminar:[21]

- Professor Gert Van der Wilt, Radboud University Nijmegen Medical Centre: *"Current practice in the Dutch HTA experience";*

[19] The examples given are based on the medical dimension (clinical efficacy) and the economic dimension (efficiency), but like ethics, other dimensions may be taken into consideration in the assessments produced by HAS (for example, the sociological, political or legal dimension).

[20] For some years there has been an increasing number of international publications on methods for incorporating ethical aspects into health technology assessments. For example, the following works appeared in parallel with the production of the EUnetHTA Core Model on 'ethical aspects' (see above): Hofmann, 2005 (24) (25); Potter, 2008 (26); Braunack-Mayer, 2006 (27); Lehoux, 2007 (28); Hoedemaekers, 2003 (29).

[21] None of the international experts who took part in the seminar organised by HAS came from southern Europe, eastern Europe or Latin America. More widely, during the process of producing the guide, only French- and English-language publications were selected, which does limit this work, as the members of the peer review group pointed out. So the literature review only partially takes account of international discussions and North American and Northern European studies are overrepresented.

- Georg Marckmann, MD, MPH, Institute for Ethics, History, and Philosophy of Medicine, Ludwig Maximilian Universität München: *"Putting public health ethics into practice: a framework for public health professionals";*
- Sigrid Droste, IQWIG: *"Information on ethical issues in HTA assessments: how and where to find them?";*
- Mirella Marlow, Programme Director, NICE, *"Developing the ethical domain for the screening model in HTAs: the EUnetHTA approach";*
- Kai Yeung, MS, PharmD: *"Presentation of the NICE social values research group".*

Finally, feedback on HAS assessments in which ethical aspects were analysed were the starting point for this document:

- « L'hormone de croissance chez l'enfant non déficitaire, évaluation du service rendu à la collectivité », 2012 (20) [Growth hormones for non-deficient children, assessment of benefit to society];
- « Évaluation de l'extension du dépistage néonatal à une ou plusieurs erreurs innées du métabolisme par spectrométrie de masse en tandem », 2011 (30) [Assessment of the expansion of neonatal screening to one or several inborn errors of metabolism using tandem mass spectrometry];
- « Analyse des possibilités de développement de la transplantation rénale en France », 2012 (31) [Analysis of possible development of renal transplantation in France].

Special attention was paid to the problems encountered during these assessments.

The first working document was presented in March 2012 to the Human and Social Sciences technical subgroup of the Economic and Public Health Assessment Committee, and to the whole Committee, before being submitted to a peer review group.

The peer review group, made up of philosophers and representatives of other human and social sciences ─ economists, sociologists, legal experts, and others ─ (see Appendix 5), was brought together by HAS between 13 December 2012 and 15 January 2013 and tasked with judging the clarity and quality of the guide, and more specifically to assess the workability of the proposed method and its ability to satisfy HAS' objectives.

The final version of the document was submitted to the Economic and Public Health Assessment Committee on 13 March 2013 and approved by the HAS Board on 10 April 2013.

2. Method for assessing ethical aspects

The proposed method aims to make it easier to identify subjects for which it would be useful to incorporate an assessment of ethical aspects (2.1), and then to set out the details of such an assessment once it has been decided that this work is appropriate (2.2).

In view of HAS' missions in terms of assessing ethical aspects, the method should make it possible to list the competing arguments that shape the ethical debates on a given question. It is not in any way intended to produce a method that would make it possible to arbitrate between these various arguments in order to go beyond them.

2.1 Identifying assessments raising ethical aspects

It is neither possible nor relevant to routinely list and analyse all the ethical issues raised by all the health technologies assessed by HAS. So it is necessary to identify those that raise the most important questions which, more than all the others, need to be brought to the attention of decision-makers.

Based on the experience acquired by HAS, criteria are proposed for identifying subjects for which an analysis of ethical aspects is particularly appropriate. Ethical issues may be anticipated from the characteristics of the technology, or when there is conflict between the technology and fundamental rights, or when there are ethical debates between the stakeholders. These factors can be used to establish the criteria described below for identifying ethical issues. These criteria are neither discriminatory, nor independent, nor exhaustive; to some extent they constitute different approaches for identifying subjects requiring specific analysis of ethical aspects by HAS.

As far as possible, the benefit of incorporating analysis of ethical aspects in an assessment should be described at the stage when the subject is being framed.[22] However, the need for an ethical analysis may come to light later in the assessment, for example when data is being collected to be used to document the other dimensions (e.g. medical, economic or organisational).

2.1.1 Identifying criteria related to the characteristics of the technology

- Is the technology the subject of provisions in a bioethics law?
  - Example: when a health technology involves the use of embryonic stem cells.
- Does the technology involve vulnerable subjects and/or those whose consent is difficult to obtain?
  - Example: when a technology is aimed at children, individuals with mental incapacity or people in a state of physical or mental distress that may affect their capacity for judgement.
- Does the technology represent a novel process which may be seen as medicalisation, or which may be described as a revolutionary treatment?
  - Example 1: when the technology is a therapeutic response to new healthcare needs (aesthetic surgery, development and enhancement of individual performance). The significance of the ethical issues is increased when there is a high degree of uncertainty; for example, assessing the risks for aesthetic procedures, such as mesotherapy, raises questions as the benefits for the subject are difficult to quantify.
  - Example 2: when the invention itself may be described as a major technological innovation. In such a case, ethical reflection may be appropriate, especially when the medical and social

[22] During the framing stage the request is analysed and a list compiled of issues to be addressed in the assessment. The background and issues are described, the scope is decided and the questions that HAS will have to answer are listed, together with the means needed to do so. The framework document forms the routemap for a scientific assessment plan for all the stakeholders involved in carrying it out.

consequences of its use have not been clearly established. In particular this is the case for broadening of access to sequencing methods for genetic tests.

- Does assessment of the consequences of the technology raise any special problems?

  - Example 1: when the efficacy criterion is disputed from an ethical point of view, e.g. in the event of controversy on the actual purpose of the technology,[23] such as screening for trisomy 21 ('number of cases of trisomy 21 revealed' compared with 'number of births of children with trisomy 21'), routine neonatal screening for permanent bilateral deafness ('acquisition of language' compared with 'number of cases of deaf children revealed') (21, 23).
  - Example 2: when the technology is effective from the point of view of the patient or society but has negative consequences for a third party, e.g. in the event of organ donation by a living donor (31).

- Does the technology raise issues of inequality or discrimination, or does it involve a form of genetic selection?

  - Example 1: when a technology includes ethnic and/or social targeting or discrimination (e.g. screening for a genetic disease such as sickle cell anaemia which is targeted according to an individual's ethnic origin).
  - Example 2: when the technology raises problems related to the distribution of sparse resources (e.g. access to cutting-edge technology, access to certain medicinal products, allocation of organs). In this regard, issues are raised by the possible widening of the selection criteria for embryos in *in vitro* fertilisation.

- Is the technology likely to lead to conflict between individual preferences and benefit to public health?

  - Example 1: the use of prophylactic surgery (breast removal, hysterectomy) for women whose risk of developing breast cancer or cervical cancer is increased by their history and/or genetic predisposition (e.g. BRCA1 or BRCA2 mutation) is dependent on their degree of risk aversion, which is likely to vary widely between individuals.
  - Example 2: when the technology involves the implementation of preventive strategies which have a benefit to public health, but which are contested by public opinion. For example, vaccination against hepatitis B was much debated. This led the government to suspend the policy of vaccination in educational establishments in 1998.

2.1.2 Identifying criteria related to the presence of potential conflict between the technology and basic rights

- Can the technology be disputed in the name of respect for human dignity?

  - Example: in general, at the end of life, the care given, or conversely the decision to stop care, raises questions concerning respect for human dignity. In particular, the existence of a potential conflict between the desire to discontinue treatment and that of harvesting organs is at the heart of discussion about extending organ harvesting when it has been decided to stop treatment (corresponding to class III of the Maastricht classification) (31).

- Can the technology be disputed in the name of respect for the integrity of the human body?

  - Examples: the question of medical treatment for transsexualism (32) or of strategies for permanent contraception (vasectomy or tubal ligation) often raises issues concerning the integrity of the human body and the freedom to dispose of one's own body.

- Can the technology be disputed in the name of respect for freedom of choice?

[23] In this type of situation, analysis of the ethical aspects must be carried out before the assessment process in order to justify the choice of the criteria which will eventually be used by HAS. Reference may be made to it in the report in the section dealing with medical and/or economic assessment.

Example: in the medical domain, freedom of choice is often associated with respect for informed consent. However, consent by children is one of the ethical problems raised by the preservation of biological samples harvested for the purpose of future research.[24]

2.1.3 Identifying criteria related to ethical debates

- In the discourse of stakeholders participating in any debates concerning the justification for a technology, is there any reference to:
  - a claim of "the right to health"?
  - the concept of "urgency" to justify transgression of generally accepted rules or principles?
  - generally approved social values?

- Are stakeholders questioning the legitimacy of the technology, with reference to:
  - codes of ethics and good professional practice (e.g. the Hippocratic oath)?
  - the precautionary principle?
  - individual freedom, for example on the subject of containing or prohibiting the consumption of certain goods involving risks for health?[25]

To conclude on the subject of these criteria, it should be emphasised that:

1. they make it possible to identify the ethical issues that may be raised by the health technologies assessed by HAS; assessment of the ethical aspects will appear to be all the more important if the health technology satisfies a number of the identifying criteria (see illustration below);
2. these criteria will develop as new knowledge and experience are acquired by HAS, or other institutions, on the subject of assessing ethical issues raised by health technologies;
3. the criteria are neither exhaustive nor discriminatory; it is not possible to propose a ready-to-use tool which would make it possible to routinely identify beforehand all the subjects that may raise major ethical issues;
4. these criteria are analytical tools; the fact that the subject answers one of the identifying criteria proposed above does not mean that it will always be appropriate to analyse the ethical aspects raised, depending on the aim and scope of the analysis as defined by HAS, and vice versa;
5. these criteria are not intended to replace the discussions that take place in the project team and within HAS' decision-making bodies (Committees and the Board) during the subject framing stage. Examination of any ethical issues identified using these criteria should enrich the discussions and make it easier to take a decision on whether it is appropriate to assess ethical aspects raised by a particular health technology.

To sum up, the criteria mentioned above should be used when discussing whether it is appropriate to carry out an assessment of ethical aspects. The discussion should also take account of the specificity of ethical debates with regard to the issue raised, on the one hand, and any constraints such as availability of the data and resources required to assess ethical aspects, on the other. In a concern for transparency, the conclusions of this analysis of appropriateness and the arguments on which it is based should be included in the framework report.

The next section describes the three stages of the process of carrying out an assessment of ethical aspects once it has been decided that such a work is appropriate.

[24] Two problems represented by this criterion have been assessed at HAS, namely assessment of screening for inborn metabolic errors using tandem mass spectrometry (30), assessment of routine neonatal screening for permanent bilateral deafness (23) and the conditions under which deafness is managed (33), (34).

[25] This debate was notably addressed by Thaler and Sustein in 2008 (35).

2.2 Assessment of ethical aspects: three stages of work

The assessment process for ethical aspects consists of three successive stages, each having its own specific aim and method.

- The first stage consists of preparatory work, i.e. identifying all the ethical arguments that may be advanced in response to the ethical issues raised by the health technology.
- The aim of the second stage is to present the relevant arguments in a consistent manner in the assessment report.
- The third stage consists of comparing the arguments to highlight any conflicts between them and to establish which disagreements may be qualified as reasonable.

2.2.1 First stage of work: identifying the arguments

Three sources are proposed for identifying ethical arguments. They are used in a complementary manner for each subject for which consideration of ethical aspects is envisaged. In most cases, the literature review will be regarded as the main source of identification. However, in certain cases, this does not exclude one of the other two sources being the main source. In that case, the assessor should give reasons for their choice.

► First source for identifying arguments: review of the ethical literature

Aim

A number of works, particularly that of Droste *et al.* published in 2010 (36), have assessed the feasibility and relevance of searches of the ethical literature (see Box 1). In the light of these works, it would appear that a review of the French and international literature is a useful angle of approach for taking account of the ethical issues raised by a health technology. It makes it possible to produce a list of the arguments raised by the stakeholders participating in discussions through journals in the field of medicine, human science and social science.

Box 1. Proposed methods for systematic retrieval of information in the literature

Studies to assess the feasibility and relevance of methods for reviewing the ethical literature are relatively recent. In particular, Droste *et al.* (36) propose a formal literature review method which is relatively similar to those used for carrying out a literature review in other fields (medicine, economics and public health).
The method proposed by Droste *et al.* (36) has eight stages.

- First of all, the aim of stages 1-3 is to identify relevant questions and the keywords.

1. Use of a model (PICO or PIPOH) to find the relevant ethical questions and so identify the keywords to be used in the literature search strategy.
2. Modelling by linking keywords to Boolean operators.
3. Identification of synonyms for the key concepts and their translation in all relevant languages; the sources used to identify the synonyms may include dictionaries, encyclopaedias, thesauruses, glossaries, articles or systematic reviews. Sources of bibliographical data such as Pubmed may also be used to find them.

- Stages 4-6 make it possible to execute the search.

4. Numerous databases should be consulted to select relevant information sources. Ethical aspects may be identified in a wide range of studies (in the biomedical literature, in health technology assessment, social sciences, psychology and discussion specifically focusing on ethical issues). The three international biomedical sources that constitute an important information source are Medline, Embase and Science Citation Index. A number of national databases may be added to these resources (see pp. 444-6 of the article).
5. and 6. Design of a search strategy, including a preliminary analysis of results if necessary, to verify that the search strategy is appropriate for the question asked.

- Stages 7 and 8 concern the analysis of the search results.

7. The selection process for information sources should be reported clearly and explicitly. If necessary, reference management software should be used to manage all the bibliographic information.
8. A quality check may be performed to verify that the results comply with literature selection criteria.

A literature search for ethical issues is made easier by familiarity with the health technology being assessed, which makes it possible to identify more readily terms to be used to define the literature search strategy. In addition, further searches are often necessary, as is also the case for literature searches in other areas of assessment.

Source: Droste S, Dintsios CM, Gerber A. Information on ethical issues in health technology assessment: how and where to find them. Int J Technol Assess Health Care 2010;26(4):441-9[26] (36).

The ethical literature may be identified via the databases used for other aspects of assessment (medical, economics and public health) such as PubMed, Web of Science and Embase. Other social science databases may also be used, such as Google Scholar, Cairn, FRANCIS, Philosopher's, or again, more specific databases for identifying the ethical literature, such as ETHXWeb, JSTOR, Eurothics and Endebit. In addition, ethical works, or more broadly human social science works, and results from the field (anthropology, sociology, empirical philosophy), may be useful for clarifying the ethical issues specific to certain subjects.[27] In addition, ethical issues may be identified through institutional reports and the legal literature (draft laws, parliamentary reports, etc.)

Finally, ethical arguments may be identified in the context of less formal discussion forums and non-academic areas such as Internet forums, websites of various associations and the general media (systematic press reviews or reviews of the ethical press). Similarly, the grey literature is another source of information, e.g. the proceedings of colloquia and study days. These various sources make it possible to collect testimonies and to identify ethical discussions that would not have been the subject of academic publications.

Articles are selected in a literature review for ethical aspects based on methodological criteria appropriate to the characteristics of the ethical issue being assessed, which means that the many different approaches must be taken into account in order to produce a faithful report of the literature. For reviews of the economic or medical literature, it is customary to use selection criteria for articles that generally concern the method (for example, according to the number of patients

[26] This article was presented by one of its main authors at the international seminar organised by HAS. It is based on experience gained in conducting a literature search on ethical issues carried out within IQWIG (the agency responsible for health technology assessment in Germany).

[27] In this regard, the Book Citation Index in Web of Science may be a useful tool for identifying ethical issues.

included in the study, the type of economic analysis conducted, etc). In ethics, depending on the subject and what it is hoped to obtain from the ethical literature, it is not always appropriate to identify such selection criteria beforehand. So in ethics, there are two distinct types of methods for conducting a literature review, namely a systematic literature review and a narrative literature review[28] (38).

A systematic review is based on objective criteria, which are discriminatory and easily identifiable (number of subjects questioned, nature of the article, review impact factor, where the authors work, etc). However, this type of review does not always make it possible to consider all the points of view and the ethical issues. Conversely, a narrative view is based on other criteria which do not always make it possible to select articles based on the summary (relevance, originality, strength, significance, legitimacy of the arguments, etc). The main advantage of a narrative review is to increase the chances of identifying all the ethical arguments on a given question, but it does mean analysing a broader literature. Both these literature review methods share certain basic objectives, i.e. to make it possible to produce a list of relevant published articles, satisfying the requirements of transparency and reproducibility. However, they differ in the type of analysis. In a systematic review, an in-depth quantitative analysis may be used (see Box 2), while a narrative review generally involves identifying, listing and describing the arguments put forward in the literature.

The choice between these two methods should be considered in relation to the question to be answered. For example, a systematic review may be used when the technology raises an ethical issue in terms of informed consent in a specific subpopulation, in so far as the issues of informed consent have been clearly defined, and the question becomes one of identifying any special characteristics of these issues in the population under consideration. Conversely, a narrative review may be more appropriate for dealing with ethical aspects relating to a novel health technology concerning which knowledge and disagreements are still in flux.

In this way there are no methodological standards that allow prior assessment of the quality of studies based on summaries alone that can be applied to all assessments of ethical aspects. However, such criteria can be established for a given assessment and this should be done for a systematic review. Examples of properly-conducted literature reviews on specific subjects show that criteria can be identified in order to obtain a first overview of the literature based on article summaries, before a more thorough analysis is undertaken (see Box 2).

Box 2. Details of the method: example of studies carried out on human biobanks

A literature review for ethical aspects was carried out on the subject of human biobanks; this is described here as an example of a method for summarising information obtained on the available literature based on summaries.

1. The literature search focused on Pubmed and Web of Science. When duplicates were identified, Pubmed was used to retrieve the basic data for this example search.
2. The search results were presented in summary form and quantitatively according to the following criteria:

- theoretical articles were distinguished from empirical articles investigating people's opinions to obtain information about the type of publications retrieved;
- publications were classed according to their source (journals, institutions, researchers, etc.) for information about the type of environment from which ethical questions originated (institutional environment, scientific community, or other actors in civil society);

[28] For example, this method was used for ethical issues at the interface of clinical care and research practice in paediatric oncology (37).

- the topics addressed to assess the diversity of ethical aspects raised for a given intervention;
- changes in the number of publications over time were included to give an indication of the place occupied by the problem and its history;
- the number of times an article had been cited by other authors (e.g. as given in Pubmed).

All these items can be found from summaries; they provide a snapshot of the literature.

Source: Budimir D, Polašek O, Marušić A, Kolčić I, Zemunik T, Boraska V, et al. Ethical aspects of human biobanks: a systematic review. Croat Med J 2011;52(3):262-79 (39).

However, whatever method is used, the use of a transparent method entails explicitly including in the assessment report the literature search strategy used, together with the databases, works and websites consulted.

It is therefore proposed that ethical arguments should be identified initially by means of a literature analysis using a systematic or narrative method in order to comply with HAS' requirements of impartiality and transparency. In accordance with the approach of evidence-based medicine generally adopted for carrying out the missions entrusted to it, HAS tries to identify the arguments developed in ethical debates by proposing a rigorous and transparent method. A review of the human science and social science literature may satisfy these requirements. However, the proposed literature review for assessing ethical aspects is separate from other aspects of the assessment:

- it is based on ethical publications, on publications from other human and social sciences and from public discussions;
- it uses different methods to select from the literature, allowing a full range of ethical arguments to be identified.

In contrast, it satisfies the same requirements in terms of transparency.

As HAS' experience develops, the literature search strategy and literature analysis may be facilitated by the drafting of procedures.

Limitations of the literature review

Identification of ethical arguments based on the literature alone has major limitations. The two main limitations are:

- there is no guarantee that all the arguments can be identified through the literature. All the individuals concerned or those with ethical arguments to put forward do not necessarily express themselves in the context of academic publications (medical journals and human and social science journals);
- also, there may be no published references to the ethical aspects of a particular health technology because the technology is not widespread or because it is too novel.

The limitations of a literature review may be overcome by two other sources used to identify ethical arguments.

► Second source for identifying arguments: theoretical identification of ethical arguments

In addition to the literature review, ethical arguments put forward in favour or against a health technology may be identified by making a comparison with more general debates or those from a similar context. For example, it is possible to establish a comparison between the ethical issues raised by neonatal screening for inborn metabolic errors and those raised by screening for cystic fibrosis, or even the issues raised generally by neonatal genetic screening (see '*Dépistage des erreurs innées du métabolisme par la technique de la spectrométrie de masse en tandem*', HAS, 2011 (30) [Screening for inborn metabolic errors using tandem mass spectrometry]). It may be necessary to ensure that the ethical aspects identified really are transposable to those raised by the health technology being assessed; in this case, a specific report will be needed from an ethical expert[29] to identify these potential arguments beforehand.

Like literature reviews, this approach has some limitations and it cannot guarantee that all of the arguments have been identified. By transposing the arguments raised by a health technology which has some similarities to the one in question, but is not the same, it is possible to miss out specific features of the health strategy being assessed. This limitation concerns not only the transposition of arguments from one situation to another; it also concerns the theoretical analysis of the issues raised by a technology in general insofar as the index case discussed is never exactly the same as the actual case in question. The third source of identification of ethical arguments, i.e. asking experts and stakeholders under the conditions described below, may make it possible to state the specific ethical issues raised by the technology being assessed, although it is never possible to fully anticipate the individual characteristics related to actual situations.

► Third source for identifying arguments: consulting the working and peer review groups

HAS' assessments usually involve consultation with a multidisciplinary and multi-professional working group and/or peer review group, or even the organisation of a public consultation.[30] In this way it is possible with the help of these experts, and feedback from the public consultation, to identify arguments which would not come to light through a literature review or identification of the issues beforehand.

In addition, discussions within the groups may also identify problems that might be posed by weighting of the different arguments and the concrete consequences of the various ethical options that the decision-makers could adopt. Conversely, it should be emphasised that it is not part of the remit of the working or peer review groups to propose a single way of weighting the various arguments.

The constitution and conduct of the working and peer review groups are established in accordance with precise rules about composition (representativeness, diversity of skills, diversity of points of view, etc.), way of working (with supporting documents, *ad hoc* presentations, etc.), programme (number of meetings, schedule, agenda, etc.) and results of their discussions (reports, working group opinions, etc.). The groups are formed according to the subject being dealt with to take into consideration their specific features and to call on the various skills required. When major ethical issues are identified, the groups may include one or more ethicists, recruited through centres of expertise in ethics (university philosophy departments or laboratories, ethics centres in hospitals, etc.). A process for managing conflicts of interest ensures transparency concerning the activities of the experts and the project leaders.[31]

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[29] In other words, the use of one or more professionals with a qualification in human or social science.

[30] See the methodology guide "*Consultation publique dans le cadre de recommandations ou d'évaluations en santé*" [Public consultation about guidelines and assessments in healthcare].

[31] *Cahier des charges des déclarations d'intérêts et de gestion des conflits d'intérêts* [Specifications for declarations of interest and management of conflicts of interest] adopted by the Board on 03/03/2010 (13); Code of ethics adopted by the HAS Board (14).

Obtaining the opinions of stakeholders through working and peer review groups and/or a public consultation is preferred to the use of focus groups. A focus group needs a relatively complex organisational structure to be put in place specifically to deal with ethical aspects, while the other methods envisaged can be supported by proven methods for collecting the opinion of experts on all aspects of an assessment. So although the use of a focus group is not excluded for any particular subject, that choice should be justified by the anticipated contribution compared with the other sources of information collection proposed.

2.2.2 Second stage of work: presentation of the arguments in the assessment report

The aim of the second stage is to include in the assessment report a record of the ethical discussions raised by a health technology (identified in the first stage of work). The arguments featuring in these discussions should be presented and classified in a consistent manner, while complying with the aim of impartiality.

A reference framework is proposed to facilitate this presentation (2.3.1). The use of other frameworks more appropriate for the problems that certain specific health technologies may raise may also be considered (2.3.2).

► Framework based on Beauchamp and Childress' four principles

The four principles identified by Beauchamp and Childress in their work *The principles of biomedical ethics*, published in 1979 and translated into French in 2008 (40) are respect for autonomy, non-maleficence, beneficence and justice. They are used as the foundation for a frame of reference to structure the arguments retrieved via the literature review, contributed by each of the stakeholders. Beauchamp and Childress identify these four principles based on what they call "the common morality" (a more detailed description of their approach and the context of their work is given in the Appendices). An advantage of these four principles is that they are very widely known among groups of people from various disciplines, which helps promote the use of a common terminology. In addition, when the principles are defined in detail, most ethical arguments can be associated with one or several of them. For example, the concept of "vulnerability", which is often mentioned in relation to the difficulty of obtaining informed consent, involves the principle of beneficence and autonomy. Similarly, the principle of caution in relation to uncertainty about the side effects of a health technology involves beneficence and non-maleficence. So the four principles are not exclusive, and they make it possible to "*channel the discussion and make it workable"* (41).

The four principles put forward by Beauchamp and Childress (40) are used therefore as markers to classify the arguments that structure ethical discussions. In fact, the majority of discussions concern either the priority to be given to one or other of these four principles in a given situation, or the interpretation of a particular principle.

For practical purposes, a summary description of each of these four principles is given below. A few examples of theories giving rise to a different interpretation of the principles of autonomy and justice are given in Boxes 4 and 5. These examples are given as illustrations; it is of course completely possible that those involved will make reference to other theories through their arguments.

Beneficence and non-maleficence[32]

Arguments referring to the principles of beneficence and non-maleficence may be presented together in the assessment report. Beneficence is understood as the capacity of a health technology to improve the well-being of the person for whom it is intended. This principle applies

[32] Note that these principles of beneficence and non-maleficence include, but are not reduced to, the principle of the benefit/risk ratio as used in the clinical assessment of a health technology.

as much to the individuals to whom the technology is addressed directly as to all the other people involved who may be affected, such as family carers.

This principle of beneficence is often associated with the principle of non-maleficence. Together, these two principles address all the positive and negative consequences of the health technology for the individuals it affects directly or indirectly.

However, the two principles do not overlap; respecting the principle of beneficence does not routinely mean respecting that of non-maleficence, and vice versa. This is what is meant by the maxim '*Primum non nocere'* ('first do no harm'). Compliance with the principle of non-maleficence may encourage doing nothing, even though a technology might be available, if that technology could have harmful consequences. So priority can be given to the principle of non-maleficence. The context in which the technology being assessed is used is an important factor in understanding how these two principles work together. For example, the transition from medicine in a world lacking resources to medicine in a world of plenty may explain how ethical debate puts increasing importance on the requirement for non-maleficence, e.g. by the use of the concept of excessive treatment.

So although the two principles of beneficence and non-maleficence can be presented together, they describe two distinct ethical principles.

Respect for autonomy

Autonomy means the capacity of individuals to govern themselves, or in other words, to make choices without being subject to the will of a third party. The concept of autonomy was first used to describe the independence of a State,[33] and is now also used to characterise the autonomy of an individual. Autonomy means therefore that human beings are free to make decisions about the end of their own life and, when applied to health it means that the decision to accept or refuse a technology is made freely. For this reason the principle of autonomy leads on to a consideration of the conditions in which a patient's consent is obtained before a technology is used, and the level of information needed to make these choices.

Very generally, in published articles respect for individual autonomy is associated with different concepts such as freedom of choice, consent, respect for preferences, absence of external constraints, vulnerability, etc. So arguments involving norms or values referring to these concepts or those that question the patient's ability to take an informed decision are related to the principle of respect for autonomy; in particular, this applies to situations of dependency related to reduced physical capacity, or the effects of pain on individual decisions.

Box 4. Philosophical foundations of different conceptions of the principle of autonomy

- Autonomy following on from a Kantian conception

In his *Groundwork of the Metaphysics of morals* (1785) (42), Kant defines autonomy as "*the property of the will, by which it is its own law"* (in accordance with the etymology of the term *autonomia*). It results from practical pure reason, thanks to which the individual is able to identify universally valid commands and decides to submit freely to them. Autonomy is therefore defined as the capacity for taking decisions guided by reason, which are not constrained either by needs or by feelings.
So after Kant, it has become usual to consider that an individual is autonomous when they act in accordance with the dictates of their reason rather than when

[33] For further information on the subject, see the articles 'Autonomy' by Henry E. Allison and 'Individual autonomy' by Laurence Thomas (in French) (8).

they arbitrarily follow their desires.[34] This implies that unconditional respect is due to individuals, in other words the obligation to treat them as an end in itself.[35]

- Interpretations with a libertarian approach

In the face of this Kantian conception of autonomy, arguments appear regularly to remove from the debate the question of whether an individual's decision is reasonable. In this case autonomy is understood as a synonym for freedom of choice, i.e. choice made without constraint exerted by a third party. In this light, the principle of autonomy may be called on to justify the opinion that each individual owns their own body to the point that they may give or sell products derived from it (blood, organs, eggs, etc.). Each individual is free to dispose of themselves; the risks that they take cannot justify a paternalistic attitude being adopted in this regard. These interpretations of autonomy may be associated with "libertarian" philosophies which are based on the concept of self-ownership (46). This libertarian interpretation of autonomy comes down to absolute respect for an individual's wishes.

Other more recent approaches extend the libertarian ideas into a situation in which an individual would have only limited rationality. For example, Thaler and Sustein (35) consider that individual liberty is respected so long as the options remain open, but that devices may be introduced to guide individuals towards certain choices (for example, putting dietary products at the front in self-service shops).

Justice

The principle of justice consists of considering at the level of society as a whole the consequences of a health technology and the consumption of resources that it involves. In fact, a decision taken to include a health technology within the range of reimbursable care establishes the possibility that the whole population may have access to it, according to their needs. In the opposite case, access to this technology may be limited according to the social or economic conditions to which individuals are subject. In this light, the question is 'How can society respond justly to health needs when it is not possible to respond to all'?[36] Two conceptions of justice that give markedly different responses to these questions are described in the box below.

It should be stressed that HAS' methodology choices for economic assessment presuppose a specific conception of justice.[37] Nevertheless, other conceptions of justice may be identified in the ethical arguments produced by those involved. In this case, it is useful to include them in the section of the assessment report on ethical analysis, although there is no question of casting doubt on the assessment criteria used to carry out the economic assessment.

[34] *"By exerting their ability to reason, each individual is therefore more than an independent being. They are actually an autonomous being"* (article 'Individual autonomy' by Laurence Thomas (8) [in French]).

[35] Reference to the concept of respect for autonomy in the Kantian sense does not exclude the possibility of controversy. The Kantian conception of autonomy has been claimed in ethical discussions leading to different conclusions concerning the question of organ donation (43), (44), (45).

[36] *"How much priority should worse-off cases get? When do minor benefit to large numbers of people outweigh significant benefit to fewer people? When should we give people a fair chance at some lesser benefit rather than invest in the best outcomes?"* (47).

[37] See 'Choice of methods for economic evaluation', published in 2011 (2).

Box 5. Utilitarian and Rawlsian conceptions of justice

- Utilitarian conception of justice

Utilitarian ethics prefers "the greatest good for the greatest number" and imposes the obligation to consider that improving the well-being of each individual has the same value irrespective of their personal situation – each counts for one and none for more than one.[38] The legitimacy and morality of an action should be assessed according to its impact on the total sum of individual satisfactions ('utilities'). It is usual to consider that the application of utilitarian ethics to healthcare leads to distribution of public resources in such a way that the total sum of 'health gains' is maximised at the level of society on the grounds that health gains generate well-being. In this light, it is usually considered that every health gain has the same value irrespective of the personal situation of the individual benefiting from it. The moral principle guiding the distribution of healthcare resources then becomes 'everyone has the right of access to treatment, provided it has been shown that the resources used cannot be put to better use by generating more well-being.' Here, above all, is the consequentialist conception[39] of justice, which is opposed to the more procedural conception of justice defended by Rawls, for example (48).[40]

- Rawlsian conception of justice

Rawls refutes the idea that justice in public policy is measured only by the amount of total well-being that it induces. Rawls states that a society is only just when it respects the fundamental freedoms of individuals,[41] and that the way in which resources are distributed amongst citizens should be taken into account. The aim of public intervention is to ensure that each individual benefits from an environment in which they are really free to make choices. In other terms, a just society should ensure that all individuals have the resources necessary for them to have real liberty. Accordingly, Rawls identifies a set of primary goods which should be available to everyone.[42] In this objective, Rawls introduces a lexical order between a number of principles of justice in which the initial situation of each before distribution is taken into account. So the maximin principle encourages choice of the distribution that is most beneficial to the situation of those worst off without reducing the sum total of well-being.

[38] "*A just action, for utilitarianism [an action such as that of Bentham], is therefore the one that maximises utility because it treats in an equal manner all the preferences, all the interests and desires of individuals according to Bentham's formula, without being concerned with the content; the important thing is that individuals should be treated equally, which accords well with our sense of justice. Everybody counts and everybody counts equally. This is the real reason why actions that maximise utilities equally can be morally just"* (article " Utilitarianism" by Catherine Audard (8) [in French]).

[39] Unlike deontological morality which judges the morality of an action by the principle, consequentialist morality considers that the justice of an action is established by its consequences.

[40] Many other authors defend a procedural conception of justice, including all representatives of libertarian thought. However, the Rawlsian conception of justice is particularly important in explaining arbitrations made in relation to distribution and their consequence in terms of equity.

[41] Basic rights and liberties; freedom of movement and free choice of occupation against a background of diverse opportunities; powers and prerogatives of offices and positions of responsibility in the political and economic institutions of the basic structure; income and wealth; the social bases of self- respect (49).

[42] These primary goods are derived from principles of justice defined by a consensus obtained by placing individuals in an original position described as 'behind a veil of ignorance' where they are unaware of any of the motivations that result from their particular situation (their natural abilities and their position within society) (50).

Rawlsian principles of justice have been the subject of many studies to assess their relevance in the domain of health policies,[43] e.g. the works of Amartya Sen (52-54), Norman Daniels (47, 55), Daniel Hausman (56) and Marc Fleurbaey (4, 57). They are described very briefly in the Appendices. It should be stressed that this list of works is not exhaustive, and that it includes a wide range of different points of view and approaches. However, all of them could be seen as subscribing to a Rawlsian conception of justice insofar as they agree in believing that the distribution of resources allocated to health should make it possible to improve as much as possible the fate of the most disadvantaged individuals.

► Other frameworks for presenting ethical arguments

The value of the framework based on the four principles is to propose widely-known points of reference for classifying ethical arguments. However, it must be stated that the works of Beauchamp and Childress have been criticised by certain ethicists. One of the criticisms made most frequently is that their works belong to the North American ethical tradition concerning the choice of the four principles, which raises the issue of whether they are valid in the European context in general, and in the French situation in particular. The choice of an extensive interpretation of the four principles that is made in this guide should, at least partly, make it possible to avoid this pitfall. In addition, the guide also allows for the possibility of using other frames of reference centred on other principles or directly concerning the specific problems. Three examples of these *ad hoc* frameworks are given as an illustration; they do not pretend to cover exhaustively all the methodological options that could be used to construct a relevant framework for the reconstruction of ethical arguments.

- Firstly, it is possible to use a framework based on other principles. As an example, the European Biomed II project, which stressed four important concepts in terms of bioethics and biolaws in Europe, i.e. respect for autonomy, dignity, integrity and vulnerability. As Rendtorff showed in 2002, the importance attached to each of these concepts and their interpretation varies in different countries (58). So it would be possible to use these four concepts to classify the ethical arguments retrieved from the literature if it were decided that they were more suitable than the frame of reference based on the four Beauchamp and Childress principles for presenting ethical arguments on the subject of a particular health technology.

- It would also be possible to produce a framework which was not based on identified principles but was directly centred on specific topics. For example, in 2011 Budimir *et al*. (39), whose article on biobanks was cited earlier, constructed a framework for analysis structured around issues retrieved from the literature that were raised specifically by the storage of biological samples. The authors retrieved published data that enabled them to classify the ethical arguments. As it happened, the data retrieved concerned controversy about informed consent, about private life, about the conditions under which results were notified, public confidence, consent by children and consent by incapable individuals and finally, issues raised by commercial use of products derived from exploitation of these samples.

- Finally, it is possible to present different ethical arguments through classification of positions. As an example, this was the approach used in the context of assessing growth hormone for non-deficient children, for which an expert ethicist carried out a literature review (59). The different approaches were identified in published data and were classified according to whether they were restrictive or permissive with regard to prescribing growth hormones to non-deficient

[43] Applying the Rawlsian conception of justice to the distribution of healthcare resources raises a question. As Williams and Cookson state, when applied to healthcare the Rawlsian principle consists of distributing resources in order to improve as much as possible the fate of the most disadvantaged individuals, even if this leads to a reduction in the global production of 'health gains' at a community level (51).

children, and according to the degree of moderation in the expression of their opinion and tolerance of adverse points of view. By combining the two dimensions 'restrictive versus permissive' and 'pure versus moderate', it was possible to classify the arguments into four main types of possible position, i.e. 'pure restrictive', 'pure permissive', 'moderate restrictive', moderate permissive'.

It is important to emphasise that if an *ad hoc* framework is used, it should be ensured that this framework makes it possible to report the complete discussions. The approach used to produce the framework should be described transparently as it is not listed in this guide. For all these reasons, producing an *ad hoc* framework takes more time and needs much more advanced ethical expertise than using a frame of reference based on the four Beauchamp and Childress principles. However, it would be possible to expand this guide as experience is acquired to include alternative frameworks which might have been used in future assessments.

Finally, it should also be remembered that the example frameworks proposed do not represent all the possibilities. Principles such as responsibility or solidarity have an important place in ethical discussions and are not explicitly included in the previous frameworks. Although the arguments relating to these principles may be taken into account in the proposed frameworks, like the example given on the subject of the principle of precaution, they may also be the subject of an analysis when they have a significant place in the ethical debates on the subject of a specific health technology. If necessary, particular attention should be paid to aspects which are relevant to more than one dimension of the assessment; for example solidarity, responsibility and the issue of inequality are concerns that impact on different dimensions, and their definition may vary from one dimension to another. For example, the legal concept of the principle of responsibility is different from the philosophical concept of it given by Hans Jonas.[44]

2.2.3 Third stage of work: ethical arguments examined in the light of the other dimensions of the assessment, and identification of the main disagreements

Once the arguments that are present have been identified and listed during the two previous stages described above, they should be analysed and compared with each other to show up any persisting conflicts, in other words, those which result in mutually irreconcilable positions. These conflicts are classed as 'reasonable disagreements', and must be mentioned in the conclusions of the assessment as they constitute decision nodes.

► Examining the ethical arguments using a synthesis table

It is proposed to use a synthesis table to summarise all the ethical arguments to be able to analyse them in relation to the results of other parts of the assessment. This synthesis table is based on the items chosen to classify the ethical arguments identified in the literature (see second stage of work). An example table is proposed based on the frame of reference constructed using the four Beauchamp and Childress principles.[45] As the consequences of the health technology in terms of beneficence, non-maleficence, respect for autonomy and justice are partly described in relation to the other dimensions of the assessment (medical, economic and public health dimensions), a summary of the main conclusions on these dimensions should be included in the synthesis table as they represent complete and separate arguments in the ethical debate raised by the technology.

If other frames of reference have been used to classify the ethical arguments, an appropriate synthesis table should be used to put into perspective the conclusions of each dimension of the assessment.

[44] Hans Jonas, *Le principe de responsabilité [The principle of responsibility]*, 1979 (60).

[45] This analysis table also applies to the study by Marckmann and Strech in 2010 to identify the types of criteria used in the arguments. Marckmann produced a list of six items used to describe the consequences of the technology. However, these items cannot be directly transposed into HAS' situation, one of the main difficulties being that the table proposed by Marckmann is intended to lead directly to a public decision, unlike HAS which uniquely has a consultative role to assist in public decision-making. The document has not been published, but was presented at the seminar organised by HAS in June 2011.

Principle	Examples of concepts that may be put forward in the arguments	Comments
Beneficence and non-maleficence	Benefits Risks Side effects Safety Quality of life Clinical efficacy Self-esteem	For each of these principles, the arguments of the review of the ethical literature are examined in the light of the conclusions of the other dimensions of the assessment: medical public health economic sociological organisational legal.
Respect for autonomy	Consent Freedom of choice Protection of confidentiality and private life (data protection) Dependence Vulnerability	
Justice	Efficiency Equity Discrimination Geographical disparity Social inequality Accessibility Compensation	

The aim of this synthesis table is to identify the antagonistic arguments that lead to persistent conflicts. For example, from the point of view of people waiting for a renal transplant, transplantation using a kidney taken from a living donor is more effective for the recipient and less expensive for the community than the other options that may be considered. However, two ethical arguments may be identified in the debates that contradict the argument that transplantation from a living donor is justified by the principle of beneficence and/or of justice. One argument is that transplantation from a living donor may have harmful consequences to third parties (psychological and/or physical); the other is that there may be a risk of moral constraint compromising the donor's freedom of choice. In this example, the arguments relating to the principles of beneficence and of non-maleficence should be examined in the light of the results of the clinical assessment, while the results of the economic assessment could support or conversely could contradict the arguments relating to the principle of justice. Finally, the principle of respect for autonomy should be taken into account. So in this example, there may be conflicts between the different principles and with regard to the different dimensions of the analysis (principles of beneficence, non-maleficence, autonomy and justice). This example shows that examining the different dimensions of the assessment in the light of each other is crucial for identifying decision nodes.

► Analysis of conflicts between arguments

Once the arguments have been presented in a structured fashion and examined in the light of the conclusions of the other dimensions of the assessment using the analysis table, legitimate arguments need to be identified that are a source of conflict, in other words those arguments that persist after all the consequences of a technology have been examined in relation to each other. It may happen that an argument made by certain actors is based on false hypotheses or on unfounded beliefs, for example on the subject of harmful effects of treatment on the state of health. In this regard it is important to emphasise that a quantitative assessment of the ethical arguments is not relevant. The fact that one argument recurs in the discourse of those involved does not make it more legitimate than another. There is in fact a 'publication bias'; the more the argument is put

forward by powerful and committed groups, the more it is retrieved from the literature. For this reason, analysis of the arguments is basically qualitative.

In the context of this analysis, the sources of disagreement between the actors may be stated explicitly in order to separate out reasonable disagreements from all the conflicts. This explicit statement is based on analysis of all the contradictory arguments to formalise the reasons underlying the disagreements. So a disagreement may be classed as reasonable if the arguments refer to assumptions in terms of values that are by their nature irreconcilable, or again, if the arguments refer to different aspects of the situation. The examples proposed in this guide have shown that the source of disagreement may be of a different nature. Conflicts may arise out of competition between the principles of beneficence and autonomy on the subject of the conditions in which a particular health technology is used, such as preventive strategies. But they may also arise from competition between points of view; the same principle may be put forward in favour of or against a particular health technology as a function of the point of view adopted (e.g. the patient's point of view compared with the point of view of family carers). The source of disagreement may be related to the choice of theory taken as reference to define the content of the principle (see Boxes 4 and 5).

Finally, as part of this third stage the arguments have to be compared to reveal the nature of the conflict. Classifying disagreements, for example using the classifications proposed by Rawls (48) or by Beauchamp and Childress (see Box 6), may help to carry out this stage of the work. A comparison of the arguments should make it possible to confirm the validity of the ethical issues identified during the stage of deciding whether an ethical analysis would be useful.[46] In addition, it will also complete it by highlighting those of the arguments presented in the discussions which are the basis for reasonable disagreements.

Decision-makers need to be made aware of these disagreements as the position adopted in relation to them may affect the direction of the final decision about the health technology being assessed. In effect, the decision-maker will, consciously or not, be constrained to arbitrate between the different values which underlie these antagonistic positions when they take a decision about implementing the technology. Moreover, highlighting these disagreements helps to ensure that the choices are made and to identify the social values.

Box 6. Sources of reasonable disagreement according to Rawls

Rawls asked how reasonable disagreement is possible. An adequate explanation is that the sources of reasonable disagreement – what he would call burdens of reason – between reasonable persons are multiple obstacles that the proper (and conscientious) exercise of our faculties of reason and judgement encounters in the ordinary course of political life.

These obstacles are:

- *(a) Data – empirical and scientific – relating to an issue are contradictory and complex, and so the consequences are difficult to establish and assess.*
- *(b) Even when we are completely in agreement on relevant issues, it is possible that we disagree on their relative importance and we therefore arrive at different judgements.*
- *(c) To some extent, all our concepts, and not just our moral and political concepts are vague and end in insoluble cases; this indeterminate state means that we have to trust in the judgement and interpretation (in*

[46] It may be noted that the identification criteria may make it possible to identify potential sources of reasonable disagreement (disagreement on the weighting of each principle; on the interpretation of the principle or on the interpretation of data in the event of an absence of robust evidence on the balance between benefit and risk). In fact, the examples which have been used in this guide illustrate this type of disagreement.

judgements on interpretations) in a range of possibilities (which is not strictly defined) where people may be in disagreement.

- *(d) To some extent (that we cannot specify), the way we measure evidence and weight political and moral values is modelled by our entire experience, all that we have lived up until now, which will always be different for everybody. So in a modern society consisting of many functions and positions, varied divisions of labour, multiple social groups often marked by ethnic diversity, the entire experiences of citizens are sufficiently disparate for their judgement to differ, at least up to a certain point, on many relatively complex cases, if not for all.*
- *(e) there are different sorts of normative considerations and various weights on both sides of the debate, and it is difficult to produce an assessment of the whole.*
- *(f) Most of our most important judgements which involve the basic political values are made in conditions such that it is very unlikely that people could exercise their faculties of reason so as to arrive at the same conclusion, even after free and open discussion.*

Based on John Rawls, 2003, p. 61 (48).

Beauchamp and Childress also propose a classification of disagreements:[47]

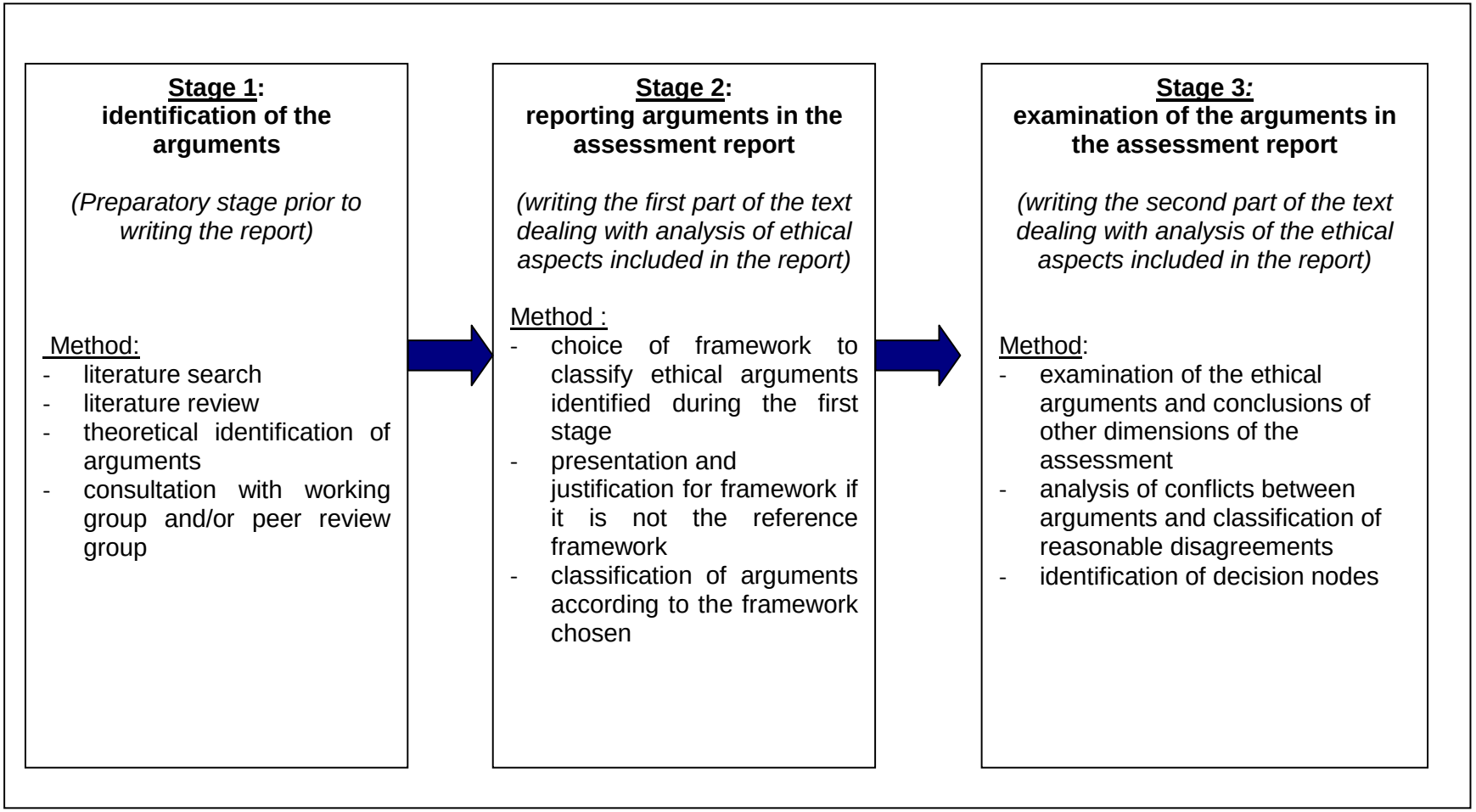
- *factual disagreements (e.g. about the level of suffering that an action will cause);*
- *scope disagreements about who should be protected by a moral norm (e.g. whether fetuses or animals are protected);*
- *disagreements about which norms are relevant in the circumstances;*
- *disagreements about appropriate specifications;*
- *disagreements about the weight of the relevant norms in the circumstances;*
- *disagreements about appropriate forms of balancing;*
- *the presence of a genuine moral dilemma;*
- *insufficient information or evidence."*

Source: Beauchamp and Childress, 2001 (original of translated version ref. 40).

[47] Note that a new edition of the Beauchamp and Childress work appeared in 2009. However, the sections quoted in this guide are based on the translation of the previous version (5th edition).

2.3 Flowchart summarising HAS' method for assessing ethical aspects

2.3.1 The three stages of work



2.3.2 Model presentation of the results of the ethical analysis in the assessment report

I. Method

I.1. Literature search strategy

I.2. Summary and quantitative presentation of the literature search results

I.3. Choice of framework for classifying the ethical arguments

II. Presentation of the ethical arguments

(when using the frame of reference based on the four Beauchamp and Childress principles)

II.1 Arguments in terms of beneficence and non-maleficence

II.2 Arguments in terms of autonomy

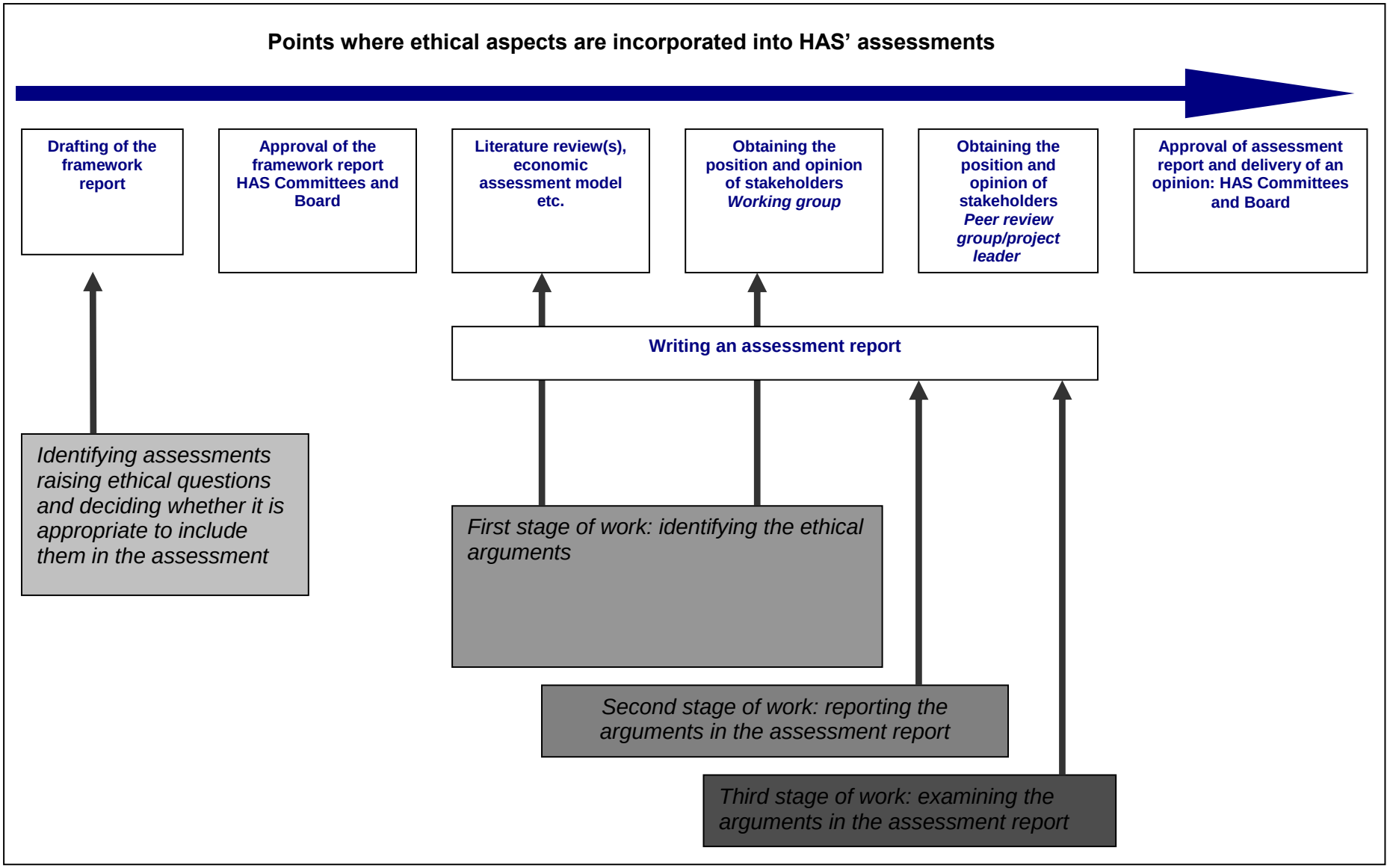
II.3. Arguments in terms of justice

III. Comparison of ethical arguments

III.1. Synthesis table to examine the ethical arguments in relation to the other dimensions of the assessment

III.2. Presentation of reasonable disagreements

2.3.3 Diagram summarising the proposed methodology for assessing ethical aspects in HAS' work



3. Conclusion

The aim of the method proposed in this guide is to encourage the incorporation of ethical aspects in HAS' assessments. It satisfies the aims of feasibility and practicality and it complies with HAS' fundamental principles and institutional constraints. It should ensure that HAS uses a standardised, rigorous and reproducible approach.

The method is based on:

- a **checklist** to identify assessments that raise ethical aspects;
- **proposals** for identifying all the ethical arguments;
- a **reference framework** to take them into account;
- a synthesis **table** to examine the ethical arguments in relation to the conclusions from other dimensions of the assessment and to identify the main conflicts;
- examples of **classifications** to help identify and describe sources of reasonable disagreement.

The method:

- respects HAS' **constraints and culture** of assessment;
- ensures that ethical debates will be **reported** in the most representative way possible;
- reports **ethical arguments** in a consistent manner;
- specifies ways of **identifying the disagreements** that must be taken into account in decision-making.

Assessment of ethical aspects is one of HAS' aids to public decision-making. It aims to inform the decision-makers of issues which are not taken into account in the rest of the report, and it should increase transparency in decision-taking. Ethical assessment complements assessment of other dimensions. It is not intended to be used routinely.

In addition, the ability of this method to satisfy the needs of HAS' project leaders, report authors and partners needs to be tested. This guide is therefore a first version which could be completed, amended and expanded as HAS acquires experience in incorporating ethical aspects in its assessments.

Appendix 1. Reference model for this guide: the EUnetHTA Core Model

The aim of the Core Model is to propose a common frame of reference at international level for the carrying out and reporting of health technology assessments (HTAs). The aim is to encourage national and international agencies to use a standard structure for the information they produce (1). The Core Model should form the backbone of the assessment report, while the substance of the information is likely to vary from one country to another because of the specific nature of the situation in which health technologies are used. For this reason, although there was a common framework, the conclusions of the assessments are specific to each agency. At the present time, three Core Models have been developed:

- Core Model for Medical and Surgical Interventions;
- Core Model for Diagnostic Technologies;
- Core Model for Screening Technologies.

These Core Models include nine domains of HTA: the health problem and current use of the technology (1), description and technical characteristics of the technology (2), safety (3), clinical effectiveness (4), costs and economic evaluation (5), ethical analysis (6), organisational aspects (7), social aspects (8) and legal aspects (9).

The key points of this framework concerning ethical aspects are:

- The term "ethical aspects" is taken to cover simultaneously the ethical issues raised by the health technology itself and those raised by its implementation.
- Pluralism of social values is recognised, although through the discourse of those involved there is a corpus of implicitly shared common values (Beauchamp and Childress). Above all it is the importance given to each of these values which is likely to vary from one country to another.
- The aim of ethical analysis is to improve the transparency of the values and norms that may implicitly underpin a decision.
- Two types of approach should be clearly distinguished although they are to some extent mutually dependent: (1) ethical analysis consisting of identifying the moral issues raised by the assessment; (2) ethical analysis consisting of drawing conclusions about the use of the technology.
- The way in which ethical aspects are analysed and the place they occupy in the assessment report vary according to the resources available to agencies and each agency's remit. Whatever the case, the more authority the agency has, the more important it is that it provides itself with the resources for clarifying the regulatory implications that accompany its recommendations.
- Ethical issues are specifically related to the nature of health technologies such as screening programs, surgical interventions, diagnostic strategies etc.[48]
- There are different sources of information for identifying ethical aspects, such as literature reviews (which should be based on a search of broader databases than those normally used for the other dimensions of the assessment), experts' opinions, patients' and healthcare system users' opinions, and the points of view of other stakeholders. This identification of ethical aspects may go through an iterative process (consultation and feedback between all the actors in the assessment throughout the process).
- The opinion of experts, patients and other stakeholders may be the subject of a qualitative analysis in order to examine their expectations and reservations. This type of analysis may bring out the fact that not all the ethical issues were identified during the literature review.
- In the conclusion of the Core Model, it is clearly stated that the main benefit of choosing a method is to make it possible to provide a frame of reference to clarify the main ethical dilemmas raised by a health technology. No position is taken with regard to the methodology to be used. All are acceptable, but methods that are transferable between cultural contexts should be preferred (i.e. for EUnetHTA, notably coherentism and principlism).

[48] See *Assessment elements* at https://fio.stakes.fi/htacore/ViewHandbook.aspx

In the end, although there is a consensus about the need to incorporate ethical analysis in health technology assessments, there is no generally-accepted structured method for carrying out this analysis. At the Core Model stage, a number of methods are proposed in parallel. (See Andersen, 2005). Nevertheless, the method should be adapted to the structure of each assessment agency (its role in the decision process, experience of assessing ethical aspects, the skills available to it, time constraints and financial constraints), the subject of the assessment, the cultural context and healthcare system structures.

Although the Core Model does not propose an analytical method for ethical aspects, it cites the following approaches from Saarni *et al.* in 2008 (61):

Method	Description
Casuistry	Solves morally challenging situations by comparing them with relevant and similar cases where an undisputed solution exists.
Coherence analysis	Tests the consistency of ethical argumentation, values or theories on different levels, with an ideal goal of a logically coherent set of arguments.
Principlism	Approaches ethical problems by addressing basic ethical principles, rooted in society's common morality.
Interactive, participatory HTA approaches	Involves different stakeholders in a real discourse, to reduce bias and improve the validity and applicability of the HTA.
Social shaping of technology	Addresses the interaction between society and technology and emphasizes how to shape technology in the best ways to benefit people.
Wide reflective equilibrium	**Aims at a coherent conclusion by a process of reflective mutual adjustment among general principles and particular judgements**.

Note that this is a simplified and non-exhaustive description; it is based only on the methods mentioned in the context of the Core Model. In addition, these approaches are neither exclusive nor incompatible; for example, a principlist analytical framework may involve coherence analysis as a method of justification. They are therefore not necessarily to be seen as being of a similar level in an ethical analysis that combines them. In addition, there are different variants of these methods and the discussions that take place suggest that none of them may be defined without clarifications being required.

Appendix 2. The principlism of Beauchamp and Childress

The origin of Beauchamp and Childress' four principles

Beauchamp and Childress (40) propose a framework for analysing bioethical discussions that is based on what they call "the common morality".[49] The common morality contains moral rules that are universal and that are distinct from the moral norms that spring from particular cultural, religious and institutional sources which are community-specific.[50] Within this common morality, Beauchamp and Childress identify four principles that they believe underpin all debates on bioethics. These four principles appear explicitly or implicitly in most classical theories:

- respect for autonomy;
- non-maleficence;
- beneficence;
- justice.

According to Beauchamp and Childress, each of these principles is a *prima facie* obligation, in other words they must be respected unless a conflict arises between these principles. In a particular situation "all things considered", one principle may still take priority over the others. Identifying the "priority" principle justifies the transgression of one or more of the other three principles mentioned above.

Arbitrating between the various principles when they come into conflict with each other is at the heart of any consideration of ethical issues. Beauchamp and Childress propose elements of a method to identify the main priority principle even if there may be disagreements between individuals. Most of the time, the disagreement does not concern the basic values that underpin their judgement, but rather a disagreement on how one or other of the principles is interpreted in a particular situation, or on the priority to be accorded to the various principles involved. In this way Beauchamp and Childress recognise that certain disagreements cannot be resolved and that neither morality nor ethical theory can provide a single solution to each ethical problem. For this reason, principlism is resolutely pluralist.

Method proposed by Beauchamp and Childress to arbitrate between the principles

When principles are in conflict, a consideration of ethical issues will require the principles to be specified and weighted.

Specification

Specification is a process of reducing the indeterminateness of abstract norms in a particular context. As a method, it incorporates into a broader model the justification for certain specifications rather than others (Beauchamp and Childress prefer the coherentist model of justification – sometimes called 'reflective equilibrium' or 'theory of coherence'[51] – as proposed by Rawls (50)). Beauchamp and Childress felt that there was something to be learned from each of the theories; where one theory explained certain aspects of moral life less well, another theory often explained them better. So they were able to focus on acceptable features from different theories, without having to choose one rather than another.

[49] *"All persons who are serious about living a moral life already grasp the core dimensions of morality. They know not to lie, not to steal property, to keep promises, to respect the rights of others, not to kill, or cause harm to innocent persons, and the like"* (chapter 1, p. 3 [of EN 5th edition]) (40).

[50] Principlism forms part of the set of recent ethical theories that conceive ethics as the fact of reflecting critically on norms and actual moral practices. Beauchamp and Childress state that they propose an approach that will contrast with the old popular conceptions of ethics theory, which, from the end of the 18th century up to the end of the 20th century, try to define and justify general norms as a system (e.g. Kantian ethics, utilitarianism, liberal individualism, etc.). Beauchamp and Childress do stress the benefit of being aware of these theories insofar as they enrich ethical reflection.

[51] Beauchamp and Childress' general position was to say that a particular specification, or any revision of a moral conviction, was justified if it resulted in better consistency in a global set of convictions accepted after reflection.

Balancing

Balancing is a stage in assessing the scope of the various principles that are competing in a given context. This involves determining which principle takes priority over the others in the event of conflict. In a particular situation, for a principle to be considered to have priority over the others, it has to satisfy the following conditions:

- acting according to the principle with priority implies that there are better reasons to act with regard to this principle rather than according to the principle transgressed;
- the moral aim that justifies the transgression represents a realistic perspective;
- the transgression is necessary in the sense that it cannot be replaced by any other morally preferable action;
- the chosen transgression should be the weakest possible and it should be in proportion to achieving the main aim of the action;
- the negative effects of the transgression should be as minor as possible;
- the choice is made impartially towards all the parties concerned, in other words the decision resulting from the transgression should not be influenced by morally inappropriate information in relation to the parties.

Beauchamp and Childress admitted that they constantly encountered inconsistencies and counterexamples in relation to their convictions, as well as new situations which challenged their moral framework. In this light, moral reflection was similar to the scientific hypotheses that are verified, changed or rejected through experience and experimental thought. The freedom to balance *prima facie* principles in the event of conflict leaves room for compromise, mediation and negotiation, and the need to specify them allows a deeper understanding and moral progress.

Appendix 3. Rawlsian principles in health technology assessments: four proposals

The works of **Amartya Sen**, which take as a starting point Rawls' criticisms of a utilitarian conception of justice, are now very well-known (52-54). Like Rawls (50), Sen proposes that economic analysis should no longer focus on the results of an intervention in terms of individual satisfactions (or utilities), but on what it represents for the individual as a means of improving the range of that individual's options. However, unlike Rawls, Sen prefers the concept of capabilities rather than that of primary goods. While primary goods are general means which are also necessary for everyone (liberties, income, education, social basis of self-respect, etc), capabilities cannot be defined *a priori* as they vary depending on the situation in which each individual develops. Among the examples that Sen proposes to illustrate what might be called capabilities are conditions related to health (e.g. not dying prematurely).[52]

Norman Daniels identifies three arguments justifying the concept that the general principles stated by Rawls can be used to guide public choices in the matter of health technology assessments (47, 55).

1) Health, conceived as "normal functioning", is a condition of having access to opportunities which it is just that each individual has access to. For this reason it is legitimate to consider that the distribution of health gains has a special moral importance.

2) Since Rawls developed his theory of justice as fairness, epidemiological studies have shown a relationship between individuals' state of health and their socioeconomic characteristics such as income or education.[53] Health inequalities are unjust when they are the result of unjust economic inequalities. Social justice should therefore encourage access to better health.

3) Rawls' contributions in terms of democratic deliberation enable decision-making processes to be established to determine how to respond fairly to health needs when they cannot all be satisfied. To be just, decisions must be reasonable, i.e. they should satisfy:

- the Publicity condition: (decisions regarding responses to health needs and their rationales must be publicly accessible);
- the Relevance condition: (the rationales for coverage decisions should include a reasonable explanation of how value for money is achieved with regard to health gains under reasonable resource constraints);
- the Appeals condition: (mechanisms must exist for challenging coverage decisions in the light of further evidence or arguments);

[52] Although Sen does not propose a list of capabilities, reference is commonly made in this regard to works of Nussbaum who does offer a list of 11 basic capabilities, among which health occupies an important place: (i) being able to live to the end of a complete human life, as far as is possible (…); (ii) being able to have good health, to be adequately nourished, to have adequate shelter; having opportunities for sexual satisfaction; being able to move about from place to place (…) (iii) being able to avoid unnecessary and non-useful pain, and to have pleasurable experiences; (iv) being able to use the five senses; being able to imagine, to think and reason (v) being able to have attachments to things and persons outside ourselves; etc. (Nussbaum, 1990) (62).

[53] On this subject Daniels (47) cites in particular the works of Michael Marmot (The Status Syndrome: How Social Standing Affects Our Health and Longevity. New York: Time Books; 2004), Margaret Whithead, Peter Townsend and Nick Davidson (Inequalities in Heath: The Black Report and the Health Divide. London: Penguin Group; 1988) and George Davey-Smith, Martin J. Schipley, Geoffrey Rose (Magnitude and Causes of Socioeconomic Differentials in Morality: Further Evidence from the Whitehall Study. J of Epidemiol Community Health 1990; 44(4): 265-70). For France, see the following works by R. Boarini, G. Demuijnck, C. Le Clainche and J. Wittwer (*Déterminants des inégalités sociales et économiques et intervention publique: une analyse des intuitions morales des individus* [Determinants of social and economic inequalities and public intervention: analysis of individuals' moral intuitions]. Report for la Mire; 2006) and M. Devaux, F. Jusot, A. Trannoy, S. Tubeuf on "*les inégalités des chances en santé: influence de la profession et de l'état de santé des parents* [Inequalities in health opportunities: influence of parents' profession and state of health], Bulletin d'information en économie de la santé, No. 18 February 2007.

- the Enforcement condition[54] (there must be public regulation of the process to ensure that conditions 1-3 are met).

Daniel Hausman proposes an alternative method to the traditional cost-efficiency assessment to measure health gains in order to take account of the impact of the technology on the activities an individual can pursue (56). Rather than asking people a question such as 'Do you prefer health state 1 to health state 2?', the question they would be asked is 'Does health state 1 limit your ability to live well and pursue valuable aims more than health state 2?' According to Hausman, this method of measuring health gains does not necessarily invalidate the tools that are currently used to describe health states. However, he does envisage an alternative tool based on only two dimensions, i.e. activity limitations and health-related feelings.

Similarly, **Marc Fleurbaey** has developed the concept of health equivalent income which uses an original index to measure individual well-being. He also proposes introducing into the traditional cost-benefit assessment a weighting of results depending on society's degree of aversion to inequalities (4, 57). Both these methods propose introducing principles developed by Rawls into economic assessment of health technologies, but they contradict each other on a number of points, particularly on the place accorded to individual preferences.

[54] For a more precise definition of these four conditions, see Daniels (2009).

Appendix 4. Summary of comments made by the peer review group

The opinions of the peer review group, whose members are listed in Appendix 5, p. 58, contributed to the writing of this guide. Comments made by members of the peer review group helped to substantially enhance this document. In particular, the requests for clarification, editorial corrections and clarifications about content helped to improve the clarity of the text. The peer review group also suggested many lines of research for HAS and all those involved in incorporating ethical aspects into health technology assessment. This summary was produced to report on the discussions which took place between these experts; these discussions could not always be included in the guide itself, which is intended mostly as a working manual.

1. Comments on the section 'HAS missions concerning assessment of ethical aspects'

Globally, the members of the peer review group had very different expectations about the description of HAS' missions and the context in which this guide was written. Some comments seem to suggest that this introductory section was too detailed, while others indicated that on the contrary, it should have been expanded further.

1) The choice not to discuss the normative assumptions underlying health technology assessment methods in general in the guide was criticised.

Several members of the peer review group regretted that the present guide excludes from its scope the ethical questions raised by health technology assessment methods in general, as mentioned in the body of the text ("Similarly, there is no question of re-examining the ethical values underpinning the methods traditionally used for medical, economic and public health assessment (such as randomised trials, cost-utility analysis, etc.) p. 9"*):*

> *"The position adopted here by the authors is clearly normative (and therefore not neutral). Without claiming that this choice of normative position is not the right one, I feel that it is questionable in principle (…) The choice (which to my mind is regrettable) is even made explicit in the report [..]. The choices of assessment methods are crucial for judging the plausibility of ethical arguments. And, more generally, it seems that there has been a growing consensus in the field of ethics applied to technical and scientific questions since the end of the 1990s that that is exactly what you have to do, you have to go back to an earlier stage in the report production and policy-making processes, rather than just looking at the later stages and limiting discussion to 'impacts' and 'social acceptability'."*
>
> *"It is certainly rather contrived not to explicitly consider the ethical issues raised by the economic assessment criteria. However, you can understand the desire for a dimension-by-dimension approach."*
>
> *"It is surprising to see right at the start an immediate reference to the benefit/risk approach, which is perhaps a natural and direct point of reference for an economic assessment, but not for ethical assessment. Why make this a point of reference right from the start (was it to point out that we have to go beyond this point)?"*

2) The concepts of "neutrality" and "impartiality" were discussed.

Several members of the peer review group stressed the limitations of aiming for neutrality and impartiality.

> *"I would like to provide a comment towards what is considered the major objective of [an] HTA body (HAS' mission is indeed to inform decision-makers, and more broadly, all stakeholders, impartially, consistently and exhaustively so as to provide the most complete statement possible of the issues involved). I clearly support this position within the HTA exercise and I clearly see the difference with the mission described by the French National Bioethics Committee. However, I would also like to question to what extent the idea or objective of neutrality is achievable, and where potential limitations are. My question is in fact to what extent it might be possible to clearly point out the elements on which there is complete agreement by the members who wrote the report? Or elements of disagreement? Are there specific choices that would for example be completely unacceptable? In*

social ethics, I know that sometimes reference is being made to the fact that tolerance is the intolerance of non-tolerance. Translating to bioethical discussions, I can also imagine that some positions might not be acceptable. Neutrality might be a rather thin concept in such cases. I would like to point to the opinions of the Belgian Consultative Bioethics Committee which has adopted an approach in which no single option is being issued, but different societal options on burning ethical debates are being provided. Consensus and dissensus opinions are being alternated within a single document. I think this approach might be useful as well for this process."

"One could observe that mentioning 'neutrality' in ethics might seem a little bizarre. There are many ethical exercises that can be carried out while remaining neutral. But as soon as you start dealing with substantial subjects that have some relationship to practice or advice, it is misleading to try to remain neutral right to the end. Are we going to ignore ethical commitments like those expressed by human rights, for example? Particularly in the field of health, we should make a commitment to consider carefully the challenges to certain principles towards which informed members of the public and public institutions are not neutral. A State which carves the words 'liberty, equality, fraternity' on the pediments of its monuments is not morally neutral! What good does it do to skirt round ethics if it's ethics we're dealing with, anyway?"

"We have to distinguish between impartiality and neutrality (Lacey 1999). Impartiality applies to assessments (here, of ethical aspects) which do not make value judgements. Neutrality consists of claiming that all the background choices that situate an assessment in a particular perspective have been blended together, or combined. In other words, neutrality is the idea that all value judgements are considered equally in these assessments. It seems to me that what the report is trying to describe is impartiality (no position is taken) rather than neutrality (all positions are considered equally). On the one hand, HAS as an institution is explicitly guided by its values and these are the first words of the report. HAS aims to maintain solidarity and fairness in the healthcare system whose beneficiaries should be the patients. This is neither neutral, nor irrelevant to an ethical assessment. On the other hand, the choice and positioning of the analysis framework is explicitly normative."

"Does one committee have more claim to legitimacy or authority in making statements about orientation than another? No one can be discharged from the need for ethical consideration by such or such authority or expert report. There are no 'ethicists' with the authority to take over the debate for themselves. In addition, deciding to carry out an ethical consideration (including "establishing formal processes" 1.2.1), is itself an ethical process. Whether the decision resulting from this is 'ethical' is still a problem but the 'aim of neutrality' (1.2.2) does not exclude an approach resulting in identifying what is the most and least ethically justifiable. One has to some extent the impression that the concern not to make the guide a normative tool has been confused with the concern not to introduce partiality into the initiative."

"Rather than invoking only the 'aim of neutrality' that HAS is pursuing with regard to ethical aspects, a position that is difficult for any organisation to approach on the subject of ethics, it would have been more relevant rather to invoke the imperative of promoting respect for the ethical principles, norms and values on which there is a general consensus in society."

"I think that there should be a little more detail on the meaning of an initiative which gives weight to descriptive aspects and a little less on talking about looking for a hypothetical 'neutrality', which in practice is hardly accorded to the subject. We should not suggest that legitimate descriptive tasks (describing errors of logic, changes in definitions, social forms related to moral concepts that act as references, opinions and moral beliefs, predominant moral judgements in a situation, logical relationships between arguments or judgements or theses, etc) would have the authority to replace a real work on ethics."

Following on logically from these issues, the experts emphasised that the guide should state that *"ethical controversies involve different (conflicting) priorities, which agitate civil society, and if HAS is to clarify these controversies, it 'expresses' these priorities in the sense that it gives an account of them. However, it cannot define a single order of the priorities of civil society, and even less impose it, and so mix duty and fact."*

In addition, the experts stressed that it would be useful to identify more clearly the stakeholders, the people who would be involved in the discussions about ethical controversies after the latter had been identified by HAS.

3) The experts wondered about the impact of incorporating ethical aspects in HAS' work, about decisions which might be taken on their basis, and their acceptability.

"I think that taking account of the ethical dimension, and particularly the realisation of the concept through the legal provisions, should be described in more detail to bring out the importance of the ethical aspects in the hierarchy of norms and in parliamentary processes. The issues are also related to the use which will be made of this guide."

"I wonder about the impact of these new sources of knowledge (ethical arguments, content and topicality of the discussions) on the decision-making process = what importance is accorded to the assessment of ethical aspects with regard to the other aspects. The assessment of ethical aspects is placed at the same footing as the other aspects - medical, economic, social, etc. – but these aspects seem to be of another order, highly political. So one wonders about HAS' 'ethical doctrine' (in the same way as HAS' 'economic doctrine' is becoming increasingly explicit... and it also incorporates an ethical position, as mentioned in the document). (…) In more concrete terms, it is the 'complementary nature' (I cite the text) of the different aspects of the assessment which raises questions. Are the ethical dilemmas raised by the subject described, but not taken into account in the assessment made by the Committees and Board? Or is the 'taking account' of ethical aspects real, and in that case, there should be a statement of how this will be done, and so how the different aspects of the assessment will be dealt with together, if not ordered into a hierarchy (cases where the existence and severity of ethical dilemmas may make it impossible to produce a recommendation?) and so once again, the ethical doctrine needs to be made explicit."

"Being concerned with the ethical dimension of the subject in question and stating it should improve its social acceptability; we have in fact had the experience that it is a part of the method which is generally very much appreciated by the stakeholders on the ground."

2. Comments on the section 'Definitions'

As was stated in the body of the text, it is clear that the definitions put forward for ethics in general and for what is understood by 'ethical aspects' in the context of this guide were the subject of much discussion within the peer review group. Overall, the peer review group's comments on the subject were ambivalent. Some members felt that the definitions lacked detail and certain conceptual distinctions should have been given more prominence. Others felt that on the contrary, this section was too abstract and was not relevant to the purposes of the guide. As an example, while certain members stressed the importance of mentioning the most important ethical questions such as '*What is a good life?'*, or even proposed going further in reporting these considerations, others felt that it would be better to avoid making reference to philosophical concepts of '*a good life'* and '*sovereign good'* which are insufficiently concrete and practical.

More specific proposals were also made:

- One reviewer stated that it was important to distinguish two levels: "(*1) a practical level (prescription of actions/assessment of actions to be committed or actions committed); (2) reflective level (examination of the foundations and origins of the statements that derived from the practical level)."* The reviewer felt that *"irrespective of the terms used, a distinction should be made between the plan of action (to be committed/omitted, or to be assessed) and the plan for examining this action (what is the relevance of the prescriptive judgements or evaluative statements issued with regard to the actions?). In other words, if 'moral' characterises all the judgements prescribing an action according to values or all the judgements assessing the actions committed, then 'ethical' would stand for reflection on the relevance, validity and legitimacy of the prescriptive judgements and moral evaluative judgements."*

  In this light, he proposed *"to reintroduce the distinction between 'moral' and 'ethical', even though it is true that the dividing line is controversial and that it is notable that every philosopher proposes their own demarcation line (Habermas and Ricoeur do not define these terms in the same way) – when they do not deny its existence (Ogien)".* He felt that without this conceptual distinction between moral and ethical it was not possible to characterise HAS' task, nor to provide an exact analysis of the levels of action concerned by this guide. He felt that morality then characterises all the judgements prescribing an action according to values or all

the judgements assessing actions committed, while ethics referred to reflection on the relevance, validity and legitimacy of prescriptive judgements and moral evaluative judgements.

In addition, he suggested introducing a distinction between:

- *"The ethical aspect 'in the situation': it concerns the search for the arguments given by the actors in the situation together with their expectations which are not always made explicit. This aspect is perceived at the level of the actors.*
- *The ethical aspect 'of the situation': the processes of analysis, description and assessment of the situation. This aspect is reserved for experts – even though the actors, individually or collegially, may step back from their situation and consider it then from the point of view of the expert opinion.*
- *The ethical aspect 'in situation': the context and the sense that it gives to the same action. This is now at the level of experts and the actors when the context may be made explicit or even understood."*

So, according to this reviewer, HAS' task should be differentiated according to *"(1) whether it means finding the moral arguments, with their implicit expectations, used by the actors present in the situation (level of morality), or (2) according to whether it means assessing these arguments (ethical level) - or even (3) according to whether it means arbitrating between these arguments to retain the one that seems to be the most consistent with the general values held by society (level of morality). An intermediate task may therefore be sketched out (4): to present, from among all the arguments and processes, those that HAS considers sufficiently relevant that they are the ones decision-makers have to pronounce on rather than on others."*

- Other authors also focused on the distinction between ethics and morality.

  "The fundamental aspect of the question is, however, the contemporary distinction made between ethics and morality. This distinction breaks with tradition and opens up a truly modern reflection which takes place under the name of 'medical ethics'. It is also the only guarantee of absence of confusion between moral pluralism (the diversity of individual moralities which is to be protected in a democratic society within a certain limit, circumscribed notably by the universal nature of human rights), the common morality (in the sense of Beauchamp and Childress, mentioned in the report, of a common transcultural fund of universal moral evidence) and ethical reflection as a specific consideration of moral life with the intention of translating requirements of common morality to the specific problems and situations under examination, and to construct agreements that respect the moral pluralism when this itself respects the right of individuals and members of the public living together in solidarity in a single society."

  "There is an 'enforceable' but well made distinction between ethics and morality in the Preface of the Dictionary of moral philosophy edited by M. Canto."

- The original definition of ethics given in the version of the document submitted to the peer review group could wrongly suggest opposition between the ethics of antiquity and modern ethics, which would have the effect of reducing the latter to pluralism.

  "Section 1.3.1 is not quite sound: it abruptly (and to my mind, falsely) opposes the ethics of antiquity and modern ethics and reduces the latter to pluralism (but there are many modern monisms, starting with utilitarianism). To my mind, the ethics of antiquity was much less normative than modern ethics, firstly in the sense that it is based not on norms, but on values, and secondly in the sense that it has an attractive rather than an imperative conception of good: for an attractive conception, good is not the object of a compulsory action, but of a praiseworthy act (blameworthy versus forbidden, respectively). Kant is highly normative, as are utilitarianism and Rawls: the fact that for the latter, there is no single conception of a good life (that just precedes good) does not result in descriptive ethics, but in the normativity of the just (at the level of which there is no pluralism, as Engelhardt commented when criticising it)."

  "What is described as an ethical approach for contemporary society cannot be generalised (and it should perhaps be mentioned that we are talking about only a few societies in the world) and relative (the ethical situation cannot be presented as a single piece); finally, and most importantly, the description for

the contemporary situation bears a strange resemblance to the work programme... of Aristotle in The Nicomachean Ethics."

- Finally, several experts pointed out that the guide was focusing on analysis of ethical conflicts and that this perspective was debatable.

  "In general, the report assumes a 'natural' link between ethics and controversy. This is an influence of principlism (and doubtless of its context of having been developed in North America, sensitive to jurisprudential logic), but it could be held that not all ethical issues take the form of conflict. Ethical consideration is embodied equally well in attention to respecting certain values and revealing the complexity of the issues in a situation (as is mentioned later in this subsection) as in the resolution of conflicts. Similarly, one may arbitrate between options that are equally legitimate (for example, in a situation that is undecidable), without having to think of the values or principles in question as the terms of a 'conflict', as an ethical concern could simply be manifested in a number of different ways. (…). However, it is clear that the situation of controversy is the one that calls most clearly for ethical reflection to be included."

  "One question I find myself asking when reading this subsection is to understand why the ethical dimension is associated with conflict and tension. Is this a state of fact, an intrinsic requirement? It would be useful to have a decision on this point."

- One expert stated that there is a risk of confusion between *'bioethics'* and *'medical ethics'*; both words do not necessarily have the same meaning.

- One expert said that assimilating ethics to good practice, to deontology or to Ethics Committees' decisions was going in the wrong direction, while another reviewer emphasised the importance of leaving a place for these elements in an evaluation of ethical aspects.

3. Comments on the section 'Identifying assessments raising ethical aspects'

In their comments, the experts repeated the point that the criteria for identifying appropriate assessments were inadequate for determining 'in advance' whether an ethical analysis was needed as some issues could have emerged completely unpredictably and unexpectedly. In general, the comments of the peer review group emphasised the problems that identifying ethical aspects could raise.

> *"But it is the question of 'how' that is the most difficult: what the document brings out very clearly is the fact that ethical issues are not intrinsic to techniques - in the sense that it would be sufficient to look at these techniques to understand the ethical implications - but they arise in the work performed to define their applications and their incorporation into socio-technical systems. In fact, the document shows clearly that ethical issues are, by definition controversial issues, and in different areas of life, i.e. sometimes in public, at other times in more confined worlds such as that of ethicists."*
>
> *"But experience proves that in this field, totally unpredictable and unexpected questions may emerge that will not be identified using the methods given here. For example, how would one identify the request for opening up a new right not anticipated by society (right-liberty that might be disputed) such as the right to have a child, or the right to active help to die."*
>
> *"Any social characteristic or fact related to the health technology may pose an 'ethical' problem once it has been 'valued' by a type of stakeholder, in other words, considered to have a moral value, as being something 'good' or 'bad'. The actors (professionals, lay actors, users, institutions) involved in an assessment may help to identify them, they should be asked."*

The experts also pointed out the lack of uniformity in the set of identifying points that were originally proposed in the version of the document submitted to the peer review group. From feedback from the peer review group, the section had been reworked to propose a set of criteria that can be classified in a more obvious way.

Finally, the comments included some reflections on the method.

> *"Between step 1 (identification) and step 2 (three stages of work) there seems to be a step missing in the sense that before we go to step 2 we need to know exactly which problem or question we aim to*

solve. What is the issue? What is the ethical problem, the ethical question or the case that demands an ethical judgement? I think this is slightly different from the step 1 in which you identify ethical problems related to a specific intervention. I think this can easily be addressed by adding some kind of conclusion at the end of your step 1, in which you enumerate the different options (like for example accepting intervention, accepting intervention under certain criteria, or refusing intervention). However, I see this is partly taken into account [later on in the guide]."

"An approach by 'decision'; I think it would be useful to understand what distribution of skills or roles produces a 'distributed decision', and also how patient 'pathways' are constructed. I do not know how easy it is to introduce such considerations into an ethical guide, but I feel they would be useful for understanding how ethical dilemmas emerge, and how they change in a given social configuration."

4. Comments on the section 'First stage of work: identifying the arguments'

The comments of the experts in the peer review group concerning identification of the arguments emphasised the fact that this stage is complex.

Concerning the literature review, one expert suggested that a literature review is not a simple tool and analysis of the data retrieved assumes significant ethical prerequisites. Another expert added that it is costly in terms of time, and that it would be better *"to invest this time in identifying current debates (outside the scientific literature)".* The importance of adapting such strategies to each subject being dealt with was also emphasised in the comments. Another reviewer said that it would be possible to develop heuristics, but this would need HAS to have acquired more experience.

Concerning the theoretical identification of arguments, the experts stated that this stage should not only be presented as a way of alleviating the limitations of published data.

Concerning consultation with stakeholders, one expert said that the results to be anticipated from this depended on its constitution, the work and the time given to it.

Peer review group members proposed other sources to be consulted:

- fiction (literature and film), popular (folk) tales and oral culture that reveal the fears of a society;
- legal codes and compendia of legal texts;
- human sciences, particularly anthropology and history;
- dictionaries of philosophy and human sciences.

Finally, additional methods for identifying ethical aspects were proposed:

- Field studies (anthropology, sociology, empirical philosophy) with qualitative methods (interviews, observations);
- analysis of bills and the impact studies associated with them, together with parliamentary works *"After Émile Durkheim, it may be considered that part of law 'crystallises social relationships'; in this light, it might be considered that analysis of law provides information on the conceptions at work in society, as well as on the choices that society has made at a given time between contradictory interests. In this light, law is a very practical instrument, or even economic (as in terms of method it is fairly easy to use, not requiring complex empirical searches) for accessing 'social morality'.*
- methods for structuring group decision during the stage when experts are consulted: *"It would always be possible to try using methods for structuring group decisions, as are currently being studied, notably at the 'Logiques de l'agir [Logics of action]' laboratory at Franche-Comté University. Some of these methods make it possible to understand the impact of differences in points of view. Some of them (for example EthXpert) are specifically directed toward ethical issues."*

5. Comments on the section 'Second stage of work: Presentation of the arguments in the assessment report'

The relevance of the frame of reference based on Beauchamp and Childress' four principles prompted a number of different opinions within the peer review group. For example, some experts stated that the principlism of Beauchamp and Childress belonged to North American ethics which only partly correspond to European moral and political philosophy. Conversely, one expert said that the four principles were sufficiently broad to incorporate so-called *'European'* norms, particularly in relation to the principles of justice and autonomy. He felt that the argument that it would not be appropriate to use principlism because it was part of a North American ethical framework was not relevant.

In general, the practical nature of this framework was recognised, although its limitations were highlighted. In addition, one expert recounted his experience: *"I have used it, in a slightly different form, within the Clinical Ethics Centre at Cochin Hospital for a number of years and I find it functional."* Concerning the use of the framework, several of the experts pointed out that, in practice, ethical analysis lies in the work of interpreting the principles in particular situations.

> *"It would perhaps be relevant to mention that for Beauchamp and Childress, it was less a case of four principles as of four 'clusters of principles', and that what counts for more than the principles are the more specific norms that flow from these very general norms."*

> *"Although the specified principlism offers the advantage of proposing a common language, it does nevertheless contain a problem, which is to postulate a (*prima facie*) common understanding of principles that are however yet to be established (…). Now, it is in this spontaneous understanding of the concepts that moral sensitivities are expressed (values), and it is with the explicit determination of the same concepts (subjects of discussion) that the theoretical work of ethics (examination of normativities) is justified."*

> *"The 'principles' (here, a term specific to the particularist approach propounded by Jonathan Dancy in 1993, for example, and edited to some extent by Beauchamp and Childress in 2008) are only convenient ways of classifying oppositions of priority. So they do not themselves have precise content, and to believe so would lead to disappointment."*

> *"Yes (the frame of reference is suitable for the purposes of this guide), insofar as they act not as principles, but rather as benchmarks to arrange together different versions of assumptions inferred from proposals or refusals of conflicting interventions."*

> *"A true analysis of the ethical issues requires the use of an inductive approach according to the fields and subjects as those of ad hoc frameworks* (mentioned in the document)*."*

> *"Using the Beauchamp and Childress approach might lead to some criticisms and scepticism. However, the way it is presented here seems to use the mentioned framework as a kind of general framework or checklist. Personally, I would not have chosen the framework as such, but I would have tried to translate the principles and the underlying issues in[to] a set of questions that have to be answered. I would like to refer here to the work done within the ACCE framework (http://www.cdc.gov/genomics/gtesting/ACCE/index.htm).*

Independence between the four principles was discussed and a number of experts cast doubt on the idea that it is possible to position an argument in relation to one of the four principles in particular:

> *"More generally, this guide assumes that it is possible to isolate ethical 'dimensions' related to principles, which in particular would be marked, for each principle, by recourse to certain concepts typical of this principle (…). This does not mean that the approach is invalid, but rather - and I will come back to the first point mentioned - that it would be better to take these 'principles' as simple signposts in an analysis of the arguments. (…). For example, it would seem at first reading not to be necessary to add to the principle of beneficence the principle of non-maleficence (since if one aims at beneficence, one would also avoid maleficence). Now it is only necessary to add this principle because one can also envisage supporting a 'weak' morality, which wants to avoid any paternalism and therefore leads only to prohibiting oneself from harming others, without aspiring to being able to*

want their good in their place. But this shows that the addition of non-maleficence is made according to one of the other principles, i.e. autonomy. The principles are therefore not dimensions, at least in the sense where this concept implies that the different dimensions are independent of each other. They are simply easily acceptable ways of grouping together certain orders of priorities revealed by the arguments, based on opposing them to each other, one argument giving priority to an assumption and another putting the assumptions in a different order - as has just been revealed by the justification for the distinction between beneficence and non-maleficence, non-maleficence placing respect for autonomy before the requirement of beneficence."

Concerning the definitions presented in the guide on the subject of each of the four principles:

- One expert criticised the joining together of the principles non-maleficence and beneficence, as he felt it risked masking important distinctions and leading to a poor understanding of both terms. Conversely, another expert approved this choice.
- The use of the concept of 'benefit-risk balance' was highlighted in assessing a health technology in terms of beneficence: *"it would be a good idea to expand a little on what one might call the principle of beneficence and above all to orient it towards the use of the benefit-risk balance for health, as a valuable tool for establishing parity between several options. Similarly, one should also refer to the question of values targeted in a benefit-risk balance: benefit-risk balance for health, benefit-risk balance for individual performance, benefit--risk balance for the full development of the individual."*
- One expert questioned the distinction used between the Kantian conception of autonomy and libertarian interpretations: *"Kant draws a distinction between 'motive' (subjective intent) and 'reason' (valid for any reasonable being) to say that morality should not be tainted by subjective inclination with the exception of the moral will, which serves as a motive in the specific sense where the latter is then confused with reason. Apart from this exception, Kant excludes motives from the foundations of morality (see the 1765 text itself cited in the Guide). The opposition of Kantian and libertarian thought is therefore characterised in a curious way."* According to the same expert, *"Libertarian thought does not so much require absolute respect for 'the patient's consent' (consent has already been established by a situation in which the patient does not have the initiative) as their will. Above all, it is not necessarily opposed to Kantianism from the point of view of the patient's representatives. To take a well-known example, Nozick, an eminent libertarian thinker, claims to be more in accord with the Kantian imperative of respecting the dignity of the person in question as an end in itself than Rawls."* Conversely, another expert pointed out that the Kantian concept of autonomy and libertarian interpretations are definitely mutually contradictory and need to be distinguished.
- One expert emphasised the risks induced by *'disastrous psychologisation'* of Kantian autonomy: *"A more precise analysis would even show that the auto-affection of the Kantian subject by the law and the pure feeling of respect in itself prohibits any simplistic assimilation of their autonomy with the idea of self-government by oneself (the 'self-determination' of the English-language literature)."*
- The description of libertarian interpretations of autonomy was criticised in itself by one expert: *"The reference to contemporary libertarian ideology (as if it were a moral philosophy) leads to confusion; in particular it lacks any relevance to the medical field, where the competition of other people and institutions is systematically involved in the making of autonomous choices."*
- Finally, one expert emphasised the fragmentary nature of the definitions concerning the principle of justice; he felt that justice should also be understood in a legal perspective and the examples given did not offer an overview of all the different forms of justice (distributive, corrective, reparative, procedural). He also stated that the two perspectives chosen (utilitarian and Rawlsian) are not generally found in French society which leans more towards a view of positive law within a framework of a social contract, with mutual commitment to protection.

Most of the experts approved the possibility of using other frameworks, or even felt that this should have been even more prominent. Conversely, one reviewer criticised the possibility of using other frameworks. For him, the risk of that option was that it might lead HAS to propose *"a half-hearted method,"* as the principlist approach should be used routinely to identify and resolve conflicts.

Finally, some experts proposed using alternative frames of reference based on *'more European'* principles, such as the seven principles/values of the Charter of Fundamental Rights of the European Union (as proposed by Biomed II) or on the principles of liberty, equality and fraternity, or they even questioned the use of a reference framework as such to classify ethical arguments. One expert described the benefits of the Budimir approach, which he felt seemed to come under casuistry.

6. Comments on the section "Third stage of work: ethical arguments examined in the light of the other dimensions of the assessment, and identification of the main disagreements"

The experts stressed the need for caution when using the analysis table to compare the arguments in relation to each other. In particular, one expert said that there was porosity between the different elements of the table because of the interdependence of the principles. This observation led him to propose an alternative method for analysis and presentation of the arguments (see above).

Most of the experts agreed on the value of using the concept of 'reasonable disagreements' under certain conditions. In particular, it was pointed out that the dividing line between reasonable and unreasonable is itself normative to the extent that the vigilance is expected on the part of assessors in qualifying such a disagreement. The terms '*reasonable disagreement'* were themselves discussed. One expert felt that it would have been better to use the expression '*relevant disagreement'* to qualify '*a disagreement based on consistent arguments conforming to traditions, and to sets of values'.* One expert said that for his part, *"this stage seems to be based on the conviction that we are always dealing with disagreement between reasonable people in the Rawlsian sense of the term. [..] [This] is part of an eirenic and rationalist vision which I do not feel corresponds to the actual situation."* He proposed to make explicit the difference understood between *'rational'* and '*reasonable'* and to start from the differentials of power of positions, public stances, etc.

Finally, several experts proposed extending this third section, in particular for describing approaches with a view to resolving the ethical conflicts. One expert mentioned that in his opinion, this third stage was not actually more discriminatory than the first two stages. He then proposed to go further and emphasise more the processes of *'permanent self-correction',* '*communication and participation'.* Another expert said that a description of the mechanism for arbitration during the discussion could be included to extend this section.

7. Alternative methods proposed by the experts of the peer review group for analysing ethical aspects

Members of the peer review group made some concrete proposals for alternative methods for analysing ethical aspects. Some of these work to a greater or lesser extent with the method which is proposed in this guide and therefore form possible extensions that could be envisaged in the context of future work.

- One expert emphasised that the role accorded 'to ethical arguments' could bias the conclusions of the analysis. He felt that the guide wrongly considered that ethical issues, social values and visions of the good are always formulated as 'arguments'. *"By emphasising that ethics exists only in an argumentative form, the report overlooks the relationship with the emotions and the collective representations studied by social psychology."* He said that on the contrary, the box illustrating reasonable disagreements invites the user to adopt a pluralist and open perspective on the topic of reasons for disagreement without assuming that they could necessarily be reduced to 'arguments'.
- Observing the interdependence of Beauchamp and Childress' four principles, one expert proposed an alternative method for analysing ethical arguments consisting of identifying conflicts in order to then go back to the principles:

  > *"it seems that this type of approach, which would start from oppositions between conclusions, and would go back to the differences between the order of priorities for assumptions, would be more modest and above all more practical than that of 'principles' (the term 'principle' does assume that one has gone back to first principles, but nothing here ensures that). In fact, one may find modes of*

textual analysis that start from opposing conclusions concerning a decision for treatment and intervention, and which may relate the proposals presented to different assumptions, according to different priorities (see the literature on reasoning and its links with non-monotonic logics, put forward by Walton or Van Eemeren, and more formally by Gabbay and Schlechta, and by Hans Rott).
This approach would have the advantage of making it possible to construct an 'analysis table for examining the ethical arguments in relation to the other dimensions of the assessment' that this guide would like, but does not provide. For the division of ethical, sociological, organisational, legal, economic, public health, medical (according to the nomenclature proposed) domains is made itself according to the points on which there could be conflict about a decision, because the inferences that lead to the decision being taken and those that lead to its being rejected are distinguished by giving priority for some (for example) to social projects, for others to legal norms, or for some to public health projects and for others to the individual, but socially costly, efficacy of a therapy; and similarly, mutatis mutandis, *for the other domains.*

This method would then involve going further into the work of analysing arguments. It would, in effect, involve analysing 'inferential processes related to the various 'arguments''.

When reasoning one may limit oneself to invoking a value (a concept of value); or to combining two principles; or applying one to one situation, i.e. directly from the general to the particular, or weighting it according to the context; one may suggest that the conclusion makes it possible to forget the premises, or even recognise the dependence of the conclusion in relation to the priorities given to one value over another; or again, to test the consistency of the different positions and that of the consequences of the values invoked.

- One expert proposed a reference framework which would be suitable for the ethical issues encountered specifically by HAS, so that it would be more appropriate and more practical than the framework based on the four principles. He felt that this framework could be established by an *ad hoc* working group brought together by HAS, to include carers, experts in human and social sciences, and representatives of the general public. The expert felt that the principlist framework would then be seen as a provisional tool until the working group had produced its conclusions.
- One expert regretted that there had not been a more complete presentation of the use of '*nudges'* in the decision-making process. This expert felt that consideration of the construction and role of these *'devices'* in the processes for taking complex decisions should have had a place in the guide, *"unless it is considered that ethical problems are not an appropriate situation for the use of nudges, except to reiterate the position of the authors who never asked themselves about how they could design nudges."*
- One expert proposed structuring the method for analysing ethical aspects in a different way, in three stages:
  - *Specification of the ethical expectations of the stakeholders in a situation by means of the arguments they produce or by means of the actions they recommend and those they do not approve of;*
  - *Formulation of these expectations by means of a classification. For example, by classifying the situations used in classical rhetoric and then in moral theology: Who? What? Why? Using what? How? When? Where? It should be possible to revise this wording and it should therefore be tested by discussions between experts*.
  - *Statement of the arguments and structuring of the arguments according to the modes of reasoning (analogical reasoning; reasoning by subsumption, etc).*

Additional references

The additional references suggested by experts in the working group can be divided into two categories:

1. Additional references on ethics in general

Nussbaum's works on the philosophy of moral emotions.

Works by Laugier and Gaille on the philosophy of ordinary life.

Callon M, Lascoumes P, Barthe Y. *Agir dans un monde incertain, essai sur la démocratie technique*. Paris: Seuil; 2001.

Thiel M J, Thévenot X. *Pratiquer l'analyse éthique. Étudier un cas, examiner un texte.* Paris: Cerf, 1999.

Van Eemeren, Walton, Gabbay and Schlechta, and Hans Rott for the literature on reasoning and its relationship with non-monotonic logics.

Rosenhead and Mingers, Rational Analysis for a Problematic World Revisited, on structuring group decisions.

Culyer on the concept of satisfying needs and the ability to benefit.

The works of Garfinkel on casuistry.

The works of Raymond Massé on participatory methods for addressing ethical issues in public health.

The works of E. Morin, P. Ricoeur, H. Jonas, G. Le Cardinal, M. Mauss and A. Broca were also cited in completing the definition of ethics.

Works in the Erès – APHP Collection, Director E. Hirsch, the journal *Éthique et santé*, the opinions of the French National Consultative Ethics Committee and reports by ANESM, the French Agency for Assessment and Quality in Health and Social Services, were also consulted for these assessments in particular, and for some parts of the discussion on methodology.

2. Additional references for identifying ethical arguments

- Websites:

http://www.cdc.gov/genomics/gtesting/ACCE/index.htm

http://www.prisma-statement.org/

http://nosophi.univ-paris1.fr/docs/RAES/notionssocialesgenerales.pdf: the DELICOM project, which establishes standard principles for describing arguments and their mutual relationships.

- Dictionaries of philosophy and social science:

Vocabulaire Technique et Critique de la Philosophie (A. Lalande, PUF)
Les dictionnaires Larousse et Ellipses pour la philosophie et les sciences humaines.
Le dictionnaire des sciences humaines des PUF.
Les encyclopédies Routledge et Stanford de la philosophie.
International Encyclopaedia of the Social and Behavioral Sciences.

- *Methods for carrying out a review of the ethical literature*: systematic literature reviews

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Appendix 5. The team

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It was coordinated and written by Cléa Sambuc and Clémence Thébaut.

The guide owes much to the involvement of Jean-Claude K. Dupont, member of the Economic and Public Health Assessment Committee.

We also thank all the members of the human and social sciences subcommittee for their involvement, and more widely, members of the Economic and Public Health Assessment Committee, chaired by Lise Rochaix, for their contribution.

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This guide was submitted for assessment to a peer review group made up of experts in human and social sciences specialising in ethical issues related to public policy and healthcare policy. In addition, ethics research centres and ethics units in hospitals were asked to take part in the peer review process. The members of the peer review group are listed below.

► The following ethics centres and ethics research laboratories were approached in relation to forming the peer review group

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Appendix 6. Report summary

Heading	TITLE
Work method	Methodology Guide
Date published online	17 May 2013
Date published	Only available in electronic format
Aim(s)	The aims of the guide are: - to establish a method for assessing ethical aspects so that HAS' Committees and Board can ensure that the different dimensions of the assessment are examined in relation to each other. - to facilitate the identification of subjects raising ethical issues for which analysis would be useful for informing decision-making; - to ensure uniformity of the assessment methodologies for ethical aspects. First and foremost this guide is a working tool, to enable everyone involved to refer to a common terminology and methodological foundation.
Professional(s) concerned	This guide is aimed at anybody working on HAS' reports and opinions, i.e. those responsible for assessing ethical aspects (HAS' departments and external collaborators, such as project authors, research teams, etc), experts in the working and peer review groups.
Request	Internal referral from *Haute Autorité de Santé*
Sponsor	*Haute Autorité de Santé*
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Heading	TITLE
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