

Ethical aspects of health care interventions

A guideline to identifying relevant ethical aspects

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These guiding questions¹ are designed to support the identification of ethical questions that the project team may need to describe in more detail as part of the systematic evaluation of interventions² in health care. For more information, please check SBU's handbook on the assessment of methods in healthcare and social services [2].

Before reviewing the questions, the project team should discuss the main ethical aspects that can be spontaneously identified regarding the intervention and the patient population³ in relation to the context from the start of the project work. Thereafter, the guideline questions can be used to see whether further relevant aspects can be identified. Which, of the questions will be in focus will depend on the subject of the assessment.

¹ This guideline is a revised version of the one originally developed at SBU in 2013 [1].

² Intervention is here used as a collective term for all types of measures and interventions in healthcare; and medical care; everything from diagnostic methods, medical and nursing methods to organisational changes and aids.

³ The term patients' here means the person/group with access to the intervention – even though all of these may not be patients in the proper sense, or in all situations.

Starting points for the identification of ethical aspects

1. **SEVERITY LEVEL:** What is the severity and duration of the condition?
2. **HEALTH:** How does the intervention affect the health of patients in terms of quality of life and longevity (including side effects and other adverse secondary effects)?
3. **EVIDENCE GAPS:** If there are significant evidence gaps about the intervention – what ethical problems do this entail?

SUMMARY Based on the main features of the factual evidence, what are the starting points for the subsequent ethical questions?

Compatibility of the intervention with ethical values

4. **EQUALITY AND FAIRNESS:** Is there a risk that the use of the intervention may affect equal and/or fair access to healthcare resources?
5. **AUTONOMY:** Do patients have the opportunity to understand and be involved in the decisions when intervention is to be used? Does the intervention affect the ability of the patient to exercise self-determination in other situations?
6. **PRIVACY:** How does the intervention impact on the physical and personal integrity of patients and their close relatives?
7. **THIRD PARTY:** How does the intervention affect third parties in terms of equality, fairness, autonomy, privacy, health, and quality of life?

Summary What ethical aspects and potential conflicts of interest or goals of particular importance have been identified?

⁴ Health and quality of life may comprise several different aspects, such as (inspired by the International Classification of Functioning, ICF):

- Subjective well-being in terms of physical and mental health symptoms.
- Functional ability: a person's capacity: A person's capacity to perform a task or action.
- Activity: a person's performance of a task or action.
- Autonomy/self-determination: a person's ability to make their own, structured decisions about their life and thereby control their life in accordance with their own values and preferences.
- Self-esteem/identity: a person's view of themselves and the value they ascribe to themselves.
- Social aspects/participation: a person's involvement in a life situation, for example, the ability to have relationships and be involved in social settings.

Structural and resource factors with ethical implications

8. **Cost-efficiency:** Is there a reasonable balance between intervention costs and patient benefits, reasonable?
9. **RESOURCES AND ORGANISATION:** Are there resource and/or organisational constraints that may affect who has access to the intervention or that may lead to decreased feasibility for other health care, if the intervention is used?
10. **REGULATIONS:** Is there anything in the applicable laws that needs to be considered?

EXECUTIVE SUMMARY What structural and resource issues and conflicts of interests or goals of particular importance have been identified?

Values and special interests

11. **PROFESSIONAL VALUES:** Can values in the relevant healthcare professions affect the use of the intervention, and thus lead to unequal access to it?
12. **SPECIAL INTERESTS:** Are there special interests that may affect the use of the intervention and thus lead to unequal access to it?

EXECUTIVE SUMMARY What ethical aspects and conflicts of interests or goals of particular importance have been identified related to values and special interests?

Research ethical aspects

13. **FURTHER RESEARCH:** If there is no scientific evidence concerning the impact of the intervention, are there ethical and/or methodological difficulties associated with conducting research?
14. **PREVIOUS RESEARCH:** Are there indications that the studies that form the basis of the evaluation have been conducted in a way that involves research ethical problems?

EXECUTIVE SUMMARY What research ethical issues have been identified and what do this entail for further research?

Long-term ethical consequences

15. Long-term consequences: Can the use of the intervention lead to more long-term ethical consequences?

Summary of the ethical aspects

How can the ethical aspects related to the intervention be summarised?

Explanations of guideline questions

Starting points for the identification of ethical aspects

1. Severity level: What is the severity and duration of the condition which the intervention aims to address?

A starting point for the subsequent ethical reasoning is the severity of the condition. It also includes assessing the duration and variability of the condition, that is, whether the condition is temporary, permanent, progressive, regressive, static, intermittent, or continuous. In the case of a severe and long-term condition, it may be appropriate to accept a greater extent of certain ethical problems associated with the intervention that should not be accepted for milder conditions. Likewise, the assessment of the severity is an important part of assessing how the intervention should be prioritised (see question 8 and 9).

The severity level can be assessed using The National Centre for Priorities in Health's model and graded as of low, moderate, high, or very high [3]. It may also suffice to provide a general reflection of the condition's impact on health and quality of life, without specifying a specific level of severity.

2. Health: How does the intervention impact on the health of patients in terms of quality of life and longevity?

Another starting point for some of the subsequent ethical reasoning is what impact the intervention has on health. This issue is usually raised elsewhere in the report, and therefore need not be discussed in detail in the ethics chapter, but it can be useful to summarise this prior to ethical debate. This question determines whether the intervention has an effect on the aim of health care, that is, the health of patients in terms of quality of life and longevity. It should be noted that the concept of health is broad and can include, for example, physical and mental well-being, functional ability, activity, participation, empowerment, and self-esteem.

The question can be based partly on the evidence graded results in SBU's systematic review of clinical outcome measures and the qualitative results of perceptions and experiences in relation to the intervention, if there are included in the report. The assessment of the ethical aspects may also need to be supplemented by an assessment of the effects that were not highlighted in the evidence graded results.

If the effect of the intervention is uncertain, that is, there is an evidence gap, it needs to be assessed whether this involves any ethical issues (please see question 3).

3. Evidence gaps: If there are significant evidence gaps - what does this mean for ethical issues?

If there are significant evidence gaps about the effects of the intervention, it must be asked whether this involves any ethical issues.

What does it mean for the patient group if the effects of the intervention are uncertain? This primarily concern whether there is a risk that patients will be denied an intervention

due to lack of scientific evidence, even though there may be no alternatives with better scientific evidence. Is there reason to offer patients the intervention, despite a lack of scientific evidence? Depending on whether the evidence involves risks or benefits, the inherent uncertainty can be assessed in different ways.

Executive Summary Based on the main elements of the underlying facts, what are the starting points for the subsequent ethical issues?

The intervention's compliance with ethical values

4. Equality and fairness: Are there a risk that the use of the intervention may contribute to an increase in inequality and inequitable access to health care resources?

According to the human dignity principle of the ethical platform, healthcare must not be governed by personal characteristics or societal status [4]. However, healthcare interventions can be prioritised based on characteristics such as biological age if there is a clear connection to the medical benefits of the intervention. According to the Health and Medical Services Act, this involves both the goal of healthcare provision on equal terms, as well as the provision of healthcare with respect for human equality and individual human dignity. This is also supported by the Swedish Discrimination Act and the Convention on the Rights of Persons with Disabilities.

Is there a risk that access to the intervention may be affected by factors that according to the principle of human dignity and anti-discrimination legislation should not govern access to healthcare and treatment? The ethical platform specifies that such factors are an individual's sex, chronological age, social and economic status, previous lifestyle, education, or ability to protect their own interests. The anti-discrimination legislation also includes transgender identity, ethnicity, religion or other belief, disability, and sexual orientation.

Sample questions

- Does the intervention require an orderly social situation or a well-developed social support network to function? Are groups who lack this at a disadvantage?
- Is the intervention associated with costs to be paid by the patient? Does this threaten to disadvantage certain groups?
- Is there a risk that the lack of evidence for some specific groups (e.g., groups based on age, disability, or gender) may lead to these groups not having access to the intervention?
- Is the assessment of the cost-effectiveness of the intervention affected by whether or not the potential of the patient group to contribute to production (indirect costs) is included in the assessment? In this case it is important to clarify this and its ethical significance.

- Does the intervention involve self-care responsibilities being placed on the patient or third party, which for some may be difficult to cope with and thus lead to unequal access to the intervention?
- Can the intervention in any way have a positive impact on equality and fair access to health care?

Statements about the equal treatment of all members our society can be more broadly interpreted to mean that all people in our community should have equal opportunities to function optimally and achieve a more generally good quality of life. The perception of an individual's value should not be influenced by their personal characteristics or societal status Will the intervention potentially affects the status of patients or others, or the perception of their value in society? Some examples of questions to ask in order to make such an assessment can be:

- Does the intervention affect an individuals' appearance, functional ability or potential to contribute to society through work or other activities, in a way that ultimately may be perceived as a devaluation and stigmatisation of the individual?⁵
- Can the patient group or other groups in society perceive that the use of the intervention affects their equal access to opportunities, the perception of their equal value or their experience of themselves as valuable?⁶
- Does the intervention affect the presence of disabilities, i.e., limitations in a person's activity and participation that arise in relation to physical, social and attitude related aspects of the surroundings in which people live and work?⁷
- Are there similar interventions used and accepted in the community which can provide guidance on whether or not this intervention should be used?

5. Autonomy: Do patients have the opportunity to make, participate in or be informed about relevant decisions when the intervention is to be used?

According to the Health and Medical Services Act, , healthcare should be based on respect for patients' autonomy. This means that patients will receive personalised information about their healthcare and that health care should as far as possible, be designed and implemented in consultation with the patient. One basic rule in health care is (if it does not involve involuntary treatment) that the interventions should only be conducted with informed consent from the patient and that the patient is able to make decisions and has the right to decline an intervention, even if the patient is considered to be in need of it. In contrast, the respect for autonomy does not usually mean that the patient has the right to insist a specific treatment or other intervention. If the intervention is being considered for

⁵ An example could be tardive dyskinesias due to side effects from the drug.

⁶ An example could be mutilating or extensive surgery.

⁷ An example could be side effects to a medicinal product, such as daytime sleepiness, inability to drive a car, etc.

children and adolescents, it should be noted that special considerations apply to the participation of children and young people's in decisions. This is described for example in the Patient Act and the Convention on the Rights of the Child (which is now law in Sweden).

For those who are deemed unable to make decisions (temporarily or permanently), there are various approaches to the issue. In some cases, close relatives can be consulted, but it should be emphasised that close relatives normally do not have the right to make decisions in the case of adult patients. Another important aspect may be that the patient should only be presented with relevant alternatives about which can/will make a decision. Can the intervention lead to problems related to respecting informed consent? Some examples of questions to ask for such an assessment are:

- Does the intervention present specific challenges in providing information?
- Is the intervention used in conditions where patients cannot give informed consent due to temporary or permanent lack of decision-making ability?
- To the extent that patients who are unable to make a decision are involved, can their close relatives or other third parties be placed in a difficult decision-making situation if the interventions used?
- Might there be occasions when the acquisition of third-party consent could delay and thereby impair the outcome of the intervention?

If there has been a systematic review of qualitative research on the perceptions and experiences related to these aspects, the discussion should be linked to these results.

6. Integrity: How does the intervention impact on the physical and personal integrity of patients and their close relatives?

According to the Health and Medical Services Act healthcare should be based on respect for the integrity of the patient. This can be linked to patient's right to self-determination since individuals should normally define the boundaries of their own personal integrity (as far as possible). However, it can also be linked to the potential vulnerability of the patient, which requires us to act with caution even in cases where the patient cannot determine or maintain their own boundaries.

Privacy includes a person's physical integrity, which can also be called the person's physical private sphere, as well as an individual's personal integrity. The Physical integrity includes such things as body intervention, intimate interventions, interventions affecting the home environment or the spatial area in the individual's direct vicinity or the handling of private effects. Personal integrity includes, among other things, the handling of sensitive information about the person and their immediate surroundings.

Sample questions

- Does the intervention involve major or minor encroachment of the patient's physical sphere compared to alternative interventions and is this reasonable to achieve the goal of the intervention?
- Does the intervention affect patients' ability to maintain control of sensitive information?
- Are there legal barriers to sharing information that would be in the interest of the patient?
- Does the intervention require the dissemination or retrieval of information concerning patients in addition to that normally carried out in the healthcare sector?
- Does the intervention require collaboration and information sharing with professional groups outside the healthcare sector? Is the handling of sensitive information reasonable, given the goal of the intervention?
- Does the intervention interfere with the physical or personal integrity of third parties?

If there has been a systematic review of qualitative research about perceptions and experiences relating to these aspects, the discussion should be linked to these results.

7. Third party How does the intervention affect third parties?

Effects on the health of third parties in terms of integrity, autonomy, quality of life and longevity should also be assessed. Third parties may refer here to the patient's close relatives, but also includes the impact on other groups in the community as well as society and society at large. What are the positive and negative effects of the intervention in relation to third parties? Some relevant questions to ask in such an evaluation are:

- Does the intervention affect the health of close relatives in terms of integrity, autonomy, quality of life and longevity?
- Does the intervention affect public health in terms of quality of life and longevity?
- How are the advantages and disadvantages that the intervention can lead to for third parties being offset against the effects on patients? Does the patient/patient group or third party have any opportunities to influence this?

Executive Summary What ethical aspects and potential conflicts of interest or goal of particular importance have been identified that relate to ethical values?

§ For example, in connection with home healthcare.

9. Example: When a person is vaccinated against an infectious disease, it affects not only the individual's own risk of becoming sick, but also the risk of others in the community becoming infected, which in the short or long term may affect public health.

Structural and resource factors with ethical implications

8. Cost-efficiency: Is the balance between the costs of the intervention and the benefits to patients reasonable?

According to the cost-effectiveness principle of the ethical platform, there should be a reasonable relationship between an intervention, costs, and its effects. This is always assessed in relation to the intervention that the intervention in question is intended to replace.

It is the responsibility of decision-makers to make this assessment, but the ethical discussion can form the basis for the assessment. What is a reasonable relationship is affected by the needs of the patient group (including the degree of severity of the condition under evaluation, see question 1) set in relation to the alternative cost of using the method? In this context, the health-economic evaluation should also be related to other ethical aspects, especially the needs-solidarity principle. In order to avoid an inefficient allocation of resources, the impact on the various sectors of society should be taken into account in the discussion, not just health care. For methodological guidance on how to make a health-economic evaluation, please refer to the SBU Handbook for the assessment of methods in healthcare [2] and the Dental and Pharmaceutical Benefits Agency on general recommendations on economic evaluations [5].

9. Resources and organisation: Are there any resource and/or organisational constraints that may affect who has access to the intervention or that may result in decreased scope for other healthcare if the intervention is used?

Since the availability of healthcare resources (such as expertise and access to relevant equipment) affects the means to use the intervention, it should be assessed whether any such resource constraints that may affect patients' access to the intervention. Similarly, it should be assessed whether the use could lead to effects in other parts of the health care system that could adversely affect patients' access to healthcare. Examples of questions to ask are:

- Is there equitable access to resources (expertise and equipment) required to use the intervention across the country?
- Can the use of the intervention lead to displacement effects on other equal or more urgent care due to limited equipment or competence resources?
- Can other organisational difficulties in using the intervention lead to inequalities in access to the intervention?

10. Regulations: Is there anything in the applicable laws that needs to be taken into account?

Would the use of the intervention in any respect be contrary to applicable the laws? Or is there any particular aspect of the applicable regulatory framework that needs to be taken into account when using the intervention? It is often not necessary or relevant to refer to or analyse general principles of the applicable regulatory framework; it is usually sufficient, to highlight specific aspects of an ethical nature relevant to the specific area, if any exists.

Executive Summary: What structural and resource aspects and conflicts of interest or goal of particular importance have been identified?

Values and special interests

11. Professional values: Can the values of the relevant healthcare professionals influence the use of the intervention and thus lead to unequal access to it?

In order to be able to use the intervention, it is necessary that the healthcare professionals concerned do not oppose it. If there are values that result in the intervention not being used, it may result in unequal access to it. The values may relate to the actual intervention but may also involve the use of the intervention changing the professional role in a way that the relevant professions oppose. Furthermore, there may be different 'cultures', standards and traditions of doing things in a particular way that vary between different hospitals, healthcare centres and similar institutions.

Are there values within the professions involved in the intervention that could prevent its use? Examples of questions to ask are:

- Are there any values related to the intervention as such?
- Are there values about what the intervention can mean for the role and identity of different professional?
- Can these values be considered reasonable or are they expressions of a way of thinking that only serves the profession itself, and that should rather be opposed to support the introduction of the method?

12. Special interests: Are there special interests which may influence the use of the intervention and thus lead to unequal access to it?

One factor that can affect the use of an intervention is whether there are groups that have special interests linked to the intervention. These groups can be favourably disposed and thus promote a use of the intervention that exceeds what is considered reasonable, given the above assessment. There may also be groups that are negatively disposed to the intervention or interested in alternative interventions being used instead. In this situation, it is important to note that.

the ethical platform for prioritisation takes a stand against healthcare being driven by demand from patients and other groups rather than needs [3,4].

Sample questions

- Are there groups, such as scientific, professional, commercial, religious, cultural or others, that may be affected by or have views on the use of the intervention, based on their interests and values? Are they able to influence the implementation of the intervention?
- Is the use of the intervention driven by demand from patient groups or third parties rather than by an established need?

Summary: What ethical aspects and potential conflicts of interest have been identified relating to values and special interests?

Research ethical research aspects

13. Further research: If there is no scientific evidence on the impact of the intervention, are there ethical and/or methodological problems associated with conducting research to improve the scientific evidence?

If there are significant scientific evidence gaps about the impact of the intervention, the question needs to be asked whether further research can be carried out that provides better scientific evidence. See also the Ethical Review Act and the Declaration of Helsinki.

- Are there ethical difficulties in carrying out future research on the intervention? Examples of this may include:
 - when clinical experience shows that the intervention has an effect on a group which lacks other treatment options and where a study with a control group becomes ethically difficult to carry out,
 - in the case of a vulnerable group or situation which makes the issue difficult to study,
 - when there are specific integrity issues related to conducting research in relation to the evidence gap.

14. Previous research: Are there indications that the studies on which the evaluation is based have been conducted in a way that poses research ethical problems?

It may be necessary to reflect on whether the research on which the assessment is based has been conducted in an ethically acceptable manner. This is particularly relevant if there is any particular aspect that has emerged following a review of the studies. If the research has been conducted in an ethically problematic manner, it may be useful to discuss whether there are other, more acceptable ways of conducting future research (see question 13).

Executive Summary What research ethical problems have been identified and what do these mean for further research?

Long-term ethical consequences

15. Can the use of the intervention have longer-term ethical implications?

Although the answers to the previous questions would indicate that the intervention does not involve any inherent major ethical problems, or that no major problems will arise during the use of the intervention, it may lead to a development which in the longer term leads to problematic ethical consequences. Examples of questions to ask are:

- Is there a risk that the use of the intervention may spread to other areas where it is more problematic or that a potentially problematic expansion of indications is occurring?
- Is there a risk of more far-reaching displacement effects that in turn may affect attitudes toward the intervention or the target patient group (see question 9 which examines this risk in the short term)?
- Is there a risk that the use of the intervention could lead to longer-term problematic attitude changes (compare with questions 4 and 11 which explore this risk in the short-term)?
- Is there a risk that the use of the intervention will lead to a more long-term negative impact on public health or the environment in general (see question 7 which looks at this risk in the short term)?
- Can the use of the intervention or its long-term effects influence the trust in health care?

Summary of the ethical aspects identified

After examining the above questions, it may be useful to make a clear summary of the foremost ethical issues have been identified.

Sometimes it can be helpful to set it up as follows:

- What ethical reasons are there against using the intervention? List these reasons.
- What ethical reasons are there for using the intervention? List these reasons.
- Try to make a balanced overview of the reasons for and against.
- Is it possible to change the intervention, or the circumstances surrounding its use, which would render it possible to deal with potential ethical objections?

As an alternative to a list of arguments for and against, the summary can be made by describing the most important ethical aspects and conflicts of interest that have been identified.

Working with ethical aspects involved in SBU projects

Ethical issues and concerns are taken into account as far back as in the pilot study

As a first step in the work, the project manager should try to identify and describe possible ethical issues and problems regarding the interventions to be reviewed and evaluated as early as the pilot study or start-up phase of the project. The guideline can be used at this point. At this stage consideration should also be given to whether external ethical expertise should be recruited to the project group.

Work on the ethical aspects during the project phase

The work on ethical aspects can be carried out according to the model below. How many of these steps are implemented in an SBU project depends, among other things, on the nature of the ethical aspects identified in the initial phase. The basic level that should always be covered is to have an initial spontaneous discussion, then go through the guideline questions and account for the relevant aspects that have been identified.

- Identification and discussion of relevant ethical aspects
 - Initial spontaneous discussion within the project group
 - Review the questions in the guideline
 - Literature search and study review
 - Collection of experiences from affected parties
 - Any further examination with the support of an ethics expert
- Written summary for the ethics chapter of the report

It is important to identify and describe possible ethical issues and problems surrounding the methods to be evaluated at a relatively early stage of the project process – this is recommended to be performed at one through first project group meetings. Project managers and expert groups should begin work to identify ethical aspects of the a general discussion of which issues may be relevant in relation to the intervention. This step is important in order to avoid the group allowing itself to be overly controlled by issues addressed by questions in the guideline and automatically spend less time on ethical issues that they themselves would have spontaneously identified. The project group then uses the questions to systematically assess whether the first review needs to be supplemented with further ethical questions. Depending on the project, some questions may be particularly relevant, while others may not be at all. The report then presents only the ethical issues that have been considered relevant to the intervention. The process may need to be supplemented later once the scientific data is clarified.

When the project group, using the list, have identified the relevant ethical questions, these are discussed and analysed. At this point it should be considered whether it is sufficient to describe the ethical issues in the ethics chapter of the report in a general way or whether a deeper ethical analysis should be carried out and a professional ethics expert

needs to be engaged (if not already done). There may be a specific question that needs to be analysed or the whole ethical discussion may need to be deepened. It is involved is particularly important when ethical issues of a more important or fundamentally interesting nature are identified. Since SBU has an established collaboration with the Swedish National Medical Council on Ethics (Smer), there is also the possibility in some cases to refer the ethical analysis to this Council [6]. This applies in particular to issues which are relevant to discuss at national level from an overall societal perspective.

In particular, it is important to identify potential conflicts of interest and goals, i.e., difficulties in reconciling various prioritised objectives, or conflicts of interest that may exist between different groups. This can be, for example, patient groups, different professions, relatives, other patient groups, or citizens. The role of SBU is generally not to take a stand on which interests are to have priority, but rather to describe what the conflict is, and which interests need to be balanced.

It can also be useful to conduct a specific structured literature search to find previous ethical analyses, other material of ethical relevance or provide answers to empirical questions that have been raised during the initial stages. This is particularly relevant when an in-depth analysis of one or more specific questions is carried out. For more information on searching for literature relevant to ethical questions, see Droste et al [7].

In some cases, it may also be desirable to gather information on the experiences of affected parties (e.g., patients, care users, government officials or professions not represented in the project group). These experiences can serve as a source of knowledge on how the intervention can affect these parties.

Three levels of ambition in the work on ethical aspects

- **Descriptive level/overview:** Description of potential ethical problems and value conflicts arising from a reviewed intervention.
- **Analytic level:** A review and weighing of various arguments as to how identified ethical and value conflicts should be resolved in the light of ethical theory. Assumes descriptive level/overview.
- **If the recommendation is relevant:** A reasoned opinion regarding the appropriateness of an intervention that takes into account, the ethical analysis in the light of the evidence base and available decision options. Assumes analytical level.

The choice of level of ambition depends on the purpose of the project and the nature of the subject. The guideline can be used to structure the ethical work at all levels of ambition.

As a rule, the third level (recommendation) is not relevant in SBU reports.

However, sometimes a standpoint based on an overall assessment of the appropriateness of the intervention from an ethical point of view may be relevant.

The ethics chapter of the report

The ethical aspects that have been identified as relevant are presented and discussed in the report's chapter on ethical and social aspects; the guideline's explanatory texts can be used for support. It is an advantage if it is clear whether the reasoning in the chapter is based on the project group's own discussions, meetings with affected parties, literature, or another source.

If an in-depth ethical analysis is carried out according to a specific analytical model (e.g., the actor model), this should be made clear in the chapter. Regardless of which model is used, the analysis should be firmly based on the Swedish context and regulations and should be confined to the specific issue. It is important to remember that the conclusions of the analysis should not contain any recommendations and that the final text is to be backed by the entire project group as well as by SBU as a public authority. If the in-depth analysis is very detailed, consider including the text in an appendix to the report. In such cases, the ethics chapter of the report itself may contain a summary of the most important ethical aspects identified.

The report's methodology chapter should briefly describe how work on the ethical aspects has been carried out.

Summary -to consider:

Some important points about ethics in SBU assessments:

- Consider the ethics as early as during the pilot study.
- Early in the project, discuss the ethical aspects that have been spontaneously identified, i.e., *before* the guideline is incorporated into the project.
- Different ethical aspects can be of varied importance in different projects.
- Ethical expertise may be needed to a different extent depending on the complexity of ethical issues.
- If an in-depth ethical analysis is carried out according to a specific analytical model (e.g., the actor model), this should be made clear. Regardless of the model, the analysis should apply to Swedish context and regulations and be limited to the specific question.

Some important points about writing the ethics chapter:

- The guideline does not need to shape the structure of the chapter, but the questions and explanations can be used for support.
- A clear structure with descriptive headings makes the text easier to read.
- Proceed from, or start with, the main results of the evaluation.
- Please report any conflicts of interest and objectives that may exist in the area.
- Please report whether the reasoning in the chapter is based on the project group's discussions, meetings with affected parties, literature that has been identified or from another source.
- The conclusions should not contain any recommendations but should describe ethical problems and other important aspects that have been identified.
- Note that SBU as a public authority endorse the final text.
- In the methodology chapter of the report, describe briefly how the work on the ethical aspects has been carried out.

References

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- 2 SBU Utvärdering av metoder i hälso- och sjukvården: En handbok. x edit. Stockholm: Statens beredning för medicinsk och social utvärdering (SBU); 2020.
- 3 Prioriteringscentrum. Nationell modell för öppna prioriteringar inom hälso- och sjukvård – ett verktyg för rangordning. 3:e upplagan. Rapport 2017:2. Linköping: Prioriteringscentrum.
- 4 Socialdepartementet. Proposition 1996/97:60. Prioriteringar inom hälso- och sjukvården. Stockholm: Socialdepartementet; 1997.
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- 6 Socialdepartementet. Prop. [2009] (10/83) Etisk bedömning av nya metoder i vården. Stockholm: Socialdepartementet; 2009.
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Laws referenced

- HSL, Health and Medical Services Act (2017:30)
- Patient Law (2014:821)
- Law (2018:1197) on the United Nations Convention on the Rights of the Child
- Law (2003:460) on ethical testing of human research

Declarations and conventions

- Declaration of Helsinki World Medical Association Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. *JAMA* 2013;310(20):2191-2194. <https://jamanetwork.com/journals/jama/fullarticle/1760318>
- FN:s konvention om rättigheter för personer med funktionsnedsättning, över- satt till svenska: <https://www.regeringen.se/informationsmaterial/2015/06/konvention-om-rattigheter-for-personer-med-funktionsnedsattning/>