

Appendix 9. Ethical aspects of health and medical care interventions

Guidelines for identification of relevant ethical questions

These guidelines have been compiled as an aid in the process of identifying and reflecting on ethical aspects of systematic assessment of interventions¹ in the health and medical services². The aim is that by addressing the questions in the guideline, the risk of overlooking relevant ethical aspects of specific interventions will be reduced. However, the guidelines do not indicate the standpoint to be taken on the intervention, except in those few cases in which Swedish legislation gives clear directions. Consideration of the questions is intended as one of several steps in work with ethical aspects in SBU's reports. For more information on how the guidance was developed, see the SBU's handbook Assessment of methods in health care (1).

Before going through the questions the project group should discuss which ethical aspects which can be spontaneously identified with respect to the procedure and the patient population. Depending on the project, certain issues may be particularly relevant while others may not be as important.

Effect of the intervention on health
1.* Health: How does the intervention influence the health of the patient in terms of quality of life and longevity (including side effects and other negative secondary effects)?
2. Knowledge gaps: If there is insufficient scientific evidence to support the effect of the intervention, are there ethical and/or methodological obstacles to conducting further research to strengthen the evidence base?
3. Severity of the condition: How serious is the condition which the intervention is intended to target?
4. Third party: How does the intervention affect the health of third parties?
Summary: What is the risk/benefit profile of the intervention (<i>based on the answers to Questions 1-4</i>)?
Compatibility of the intervention with ethical values
5. Equality and justice: Is there a risk that access to the intervention violates the principle of human dignity or current legislation against discrimination?
6. Autonomy: Can the intervention affect the patient's ability to give informed consent or participate in relevant decisions about the application of the intervention?

7. Integrity: How does the intervention affect the physical and personal integrity of the patient and his/her relatives?
8. Cost-effectiveness: Is there a reasonable balance between the cost of the intervention and its effectiveness?
Summary: Is the application of the intervention compatible with current ethical values (based on the answers to questions 5–8)?
Structural factors with ethical implications
9. Resources och organisation: Are there resource and/or organisational limitations which can influence who has access to the intervention or can result in restricted availability of other procedures if the intervention is implemented?
10. Professional values: Can values held by the relevant caring professions influence implementation of the intervention, thereby resulting in unequal access?
11. Special interests: Are there special interests which can influence implementation of the intervention, leading to unequal access?
12. Summary: Is there reason to believe that equal access to the intervention or to other procedures can be hindered because of structural factors (<i>based on the answers to questions 9–11</i>)?
Longterm ethical consequences
Longterm consequences: Can application of the intervention have ethical consequences in the long term?
Summary of the ethical questions
How can the ethical questions related to the intervention be summarised?

¹“Intervention” is used here as a common descriptor for all types of procedures in health and medical services, ranging from diagnostic, medical and nursing methods to organisational changes.

²These guidelines are referred to as follows: Heintz E, Lintamo L, Hultcrantz M, Jacobson S, Levi R, Munthe C, Tranæus S, Östlund P, Sandman L. A framework for systematic identification of relevant ethical aspects of health care technologies – the SBU approach. *Int J Technol Assess Health Care*, 2015;2:1-7.

*It is also important to disclose whether the studies on which the assessment of the effect on health is based have been conducted with an acceptable level of research ethics.

Work with ethical aspects in projects

According to SBU:s manual for assessment of interventions intended for implementation in health and medical services, consideration of ethical aspects should follow the model below [5]. How many of these steps are carried out in an SBU projects is partly due to the nature of the ethical issues identified in the initial stage.

- Identification of relevant ethical aspects
- Analysis and discussion of ethical aspects
 - Literature search and assessment of quality
 - Collection of experiences from interested parties
- Ethical analysis with support of an ethicist
- Summary

As an initial step in ethical evaluation (in the introductory analysis), it is important that at a relatively early stage of the project process – preferably at one of the earliest meetings of the project group – potential ethical issues and objections associated with the intervention should be identified and described. It is primarily at this stage that the present guidelines are intended to be applied. The project leaders and the expert group should begin identifying ethical issues, with a general discussion about questions which may be relevant to the intervention to be assessed. This is an important step, as otherwise the group may be steered directly into the questions addressed by the guidelines and in so doing overlook ethical issues which they would otherwise identify spontaneously. The project group then uses these questions to decide systematically whether the initial consideration of ethical issues needs to be complemented with further questions. Depending on the project, certain questions may be particularly relevant, whereas others may have no relevance at all. Subsequently, the report will present only the questions deemed relevant to the intervention being assessed. As the scientific basis for the intervention is clarified, the process may need to be repeated.

When the project group, with the aid of the list, has identified relevant ethical issues, these questions are discussed and analysed. It should be decided whether a deeper analysis of the ethics should be undertaken with the help of a professional ethicist. This step becomes particularly important in cases where ethical issues of greater importance or of principally interesting character are identified. It is important that the ethical analysis is conducted in dialogue with the expert group, but at the same time it is important to be prepared for the fact that an in-depth analysis by a professional ethicist may suggest a different approach from that taken by the expert group. SBU has an established collaboration with the National Medical-Ethical Council (Statens medicinsk-etiska råd: SMER) and in certain cases the ethical analysis may be referred to the council (2). This applies in particular to questions which are relevant for discussion at the national level.

It may also be useful to undertake a systematic search of the literature for earlier ethical analyses or to find an answer to empirical questions which might have arisen in the introductory analysis. For further information on searching for literature of relevance to ethical evaluation, see Droste et al. (3).

In some cases, it may also be of interest to collect information about the experiences of the personnel groups involved. This will provide a source of knowledge as to how the intervention can affect personnel.

Guidelines for identifying relevant ethical questions: explanations

Effect of the intervention on health

Question 1 – Health: How does the intervention affect the patient's health in terms of quality of life and longevity?

The starting point for the subsequent ethical reasoning is to determine the effect of the intervention on health. The response to this question discloses whether the intervention has an effect on the aims of healthcare, i.e. the health of patients, in the following terms:

- Quality of life (inspired by the International Classification of Functioning, ICF)¹
- Longevity.

¹Quality of life can embrace several different concepts:

- Subjective wellbeing in terms of physical and psychological symptoms.
- Functional capacity and integrity: a person's ability to "manage unaided" without technology, medication, supporting personnel etc, particularly in terms of activity requiring intimate bodily intervention.
- Activity/autonomy/self-determination: a person's ability to make their own structured decisions on their life and thus control it in accordance with their own values and wishes.
- Self- esteem and identity: a person's image of themselves and the value he/she attributes to him/herself.
- Social aspects/participation: a person's ability to form relationships and and to participate in social activities.

The question can be answered partly on the grounds of the evidence-graded results in SBU's systematic overview of clinical outcome measures. Assessment of ethical aspects may also need to be complemented by a qualitative assessment of the effects which are not disclosed in the evidence-graded results. To the extent that surrogate measures are used, an assessment should be made as to how these can be related to longevity and quality of life.

- What positive effects, respectively negative side effects or complications are associated with the intervention? Such an assessment can be based on responses to the following questions:
 - Can the intervention have a harmful effect on the longevity and quality of life of some patients?
 - How many patients must be treated for the intervention to have an effect on one patient? Is it likely that the patients perceive this proportion as reasonable?
 - Who weighs the advantages and disadvantages which the intervention can result in for the patient group? Has the patient or the patient group he/she belongs to any opportunity to influence this?

If the effect of the intervention is uncertain, i.e. knowledge gaps are identified, is it necessary to determine whether it is feasible to conduct further research (see Question 2).

Even if the conclusion drawn from Question 1 is that there is scientific support for the intervention, it should be questioned as to whether there are research ethical objections associated with the studies which provide the scientific basis.

- Are there any ethical objections related to the studies which form the foundation for the conclusions about the effect of the intervention on health? Can this influence the potential for conducting continued ethically acceptable research (see Question 2)?

Question 2 – Knowledge gaps: If the underlying scientific basis for the effect of the intervention is inadequate, are there ethical and/or methodological obstacles to the conduct of further research in order to strengthen the scientific basis?

If in Question 1 it is concluded that there are knowledge gaps, the question must be raised as to whether it is possible to conduct further research in order to strengthen the scientific basis.

- Are there ethical obstacles to the conduct of future research on the intervention? For example:
 - When clinical experience shows that the intervention has an effect on a group for whom there are no treatment alternatives and it would thus be ethically unacceptable to conduct a study in which the comparative group would be denied the procedure,
 - In the case of a vulnerable group of subjects who are difficult to study,
 - Where specific integrity problems would arise if research were to be conducted in relation to the knowledge gap.
- Are there methodological obstacles to conducting further research on the intervention, with the risk that patients will be denied access to an intervention which, despite all objections can have a beneficial effect on the patient's condition?
- What are the consequences for the patient group if the knowledge gap cannot be filled in the future? Primarily, what is the risk that patients are denied an intervention because the scientific support is inadequate, although there is little potential to remedy this situation, and despite the fact that there may not be alternative interventions with better scientific support? Under these conditions, should the procedure be made available to patients despite the inadequate scientific basis?

Question 3 – Severity of the condition: How serious is the condition which the intervention is intended to target?

In order to determine whether the effects of the intervention have an acceptable risk/benefit profile, it is necessary to assess the severity of the condition which the intervention is intended to target. It is also essential for evaluation of the subsequent ethical reasoning. For a serious condition, it can be reasonable to accept certain ethical objections associated with the intervention, whereas such objections would not be considered acceptable for less serious conditions. Similarly, assessment of the severity of the condition can indicate whether there is a genuine patient need or if demand for the intervention is being manipulated (see Question 11 below).

The severity of the condition should be assessed according to the same parameters as the effects of the intervention in Question 1 and can be graded in accordance with the national guidelines from The National Board of Health and Welfare (Socialstyrelsen) as minor, moderate, serious or very serious (4).

Question 4 – Third party: How does the intervention affect the health of third parties?

As well as the risk/benefit profile for the actual patient group, an assessment should be made of how the health of third parties health is affected, in terms of quality of life and longevity. In this context, the third party may comprise primarily the patient's relatives, but should also include the effect on

other groups in society and on society in general. What positive or negative effects respectively does the intervention have on third parties? The following are relevant questions in such an evaluation:

- Does the intervention have an impact on the health of relatives, in terms of quality of life and longevity?
- Does the intervention have an impact on public health, in terms of quality of life and longevity?
- Who is responsible for weighing the potential advantages and disadvantages of the intervention on third parties against the effects on the patients? Has the patient/patient group or third party any opportunity to influence this?

Summary – What is the risk/benefit profile of the intervention (based on the answers to questions 1–4)?

Based on the answers to Questions 1–4, a risk/profile analysis of the intervention should be compiled, with reference to the influence on patients or third parties, the level of evidence and the severity of the condition.

Compatibility of the intervention with ethical values

Question 5 – Equality and justice: Is there a risk that access to the intervention violates the principle of human dignity or current legislation against discrimination?

According to the ethical platform's human dignity principle, provision of treatment shall not be based on consideration of personal characteristics or a person's position in society, unless these have a clear association with the severity of a condition or the effect of an intervention. In the Health and Medical Services Act (HSL), this is expressed partly in that the aim is to provide care on equal grounds and partly in that care shall be provided with respect for the concept of all people being of equal value and for the dignity of the individual. This is also supported by Swedish legislation against discrimination. Is there a risk that access to care is influenced by those factors, which the principle of human dignity and legislation against discrimination specify, should not determine access to care and treatment? The ethical platform specifies these factors as a person's gender, chronological age, social and financial status, earlier lifestyle, education or the ability to safeguard their own interests. The legislation against discrimination also lists transgender identity or expression, ethnicity, religion or other belief, physical disability and sexual orientation.

Examples of questions:

- Does the intervention require a well-ordered social situation or well-developed social support to function? Are groups who lack such support disadvantaged?
- Is the intervention associated with co-payment by the patient? Is there a risk that this will disadvantage certain groups?
- Is there a risk that inadequate evidence with respect to certain groups (e.g. groups based on age, gender, ethnicity, sexual orientation etc) will mean that these groups will not have access to the intervention, despite transferable evidence from other similar groups?
- Is assessment of the cost-effectiveness of the intervention influenced by the ability of the patient group to be productive members of society?

- Does the intervention require the patient or a third party to assume some responsibility for self-care, which for some patients may be difficult to manage, thus leading to unequal access to the intervention?

In Swedish society, the standpoint on equality of treatment is generally given a broad interpretation: that people should have equal opportunity to function and achieve a generally good quality of life in society. Nor should our attitude to human dignity be influenced by personal characteristics or position in society. Can the intervention influence the perception of the patient or other people with respect to the patient's value in society? The following are some examples of questions to aid such an assessment:

- Does the intervention affect the person's appearance, or ability to contribute to society through work or other activity, in such a way that in the long term the intervention can be regarded as belittling or stigmatising?
- Can the patient group or other groups in society form the opinion that implementation of the intervention will have a negative influence on their ability to achieve equality, the attitude to their equal worth or their perception of themselves as worthwhile citizens?
- Are there similar interventions which are in use and accepted in society which can thus give some guidance as to whether or not this intervention should be implemented?

Question 6 – Autonomy: Can the intervention influence the patient's ability to give informed consent or to participate in making relevant decisions about undergoing the procedure?

According to the Health and Medical Services Act, care shall be based on respect for patients' self-determination. This means that patients shall receive individually tailored information about treatment and that as far as possible treatment shall be planned and carried out in consultation with the patient. A basic rule within health and medical services (except in cases of mandatory institutional care) is that procedures may be undertaken only with the informed consent of the patient; patients who are capable of making decisions have the right to refuse treatment, even if health personnel consider treatment to be necessary.

For a patient who is considered to be temporarily or permanently incapable of making a decision, there are several approaches to the question. In certain cases relatives can be consulted, but it must be stressed that relatives do not normally have the right to make decisions on behalf of adult patients. Another important aspect may be that the patient should only be given choices that are relevant and which he or she can/is prepared to decide on. Can the intervention thus lead to problems in respecting informed consent? The following are some examples of questions which might aid in such an assessment:

- Is the intervention associated with special challenges when it comes to providing information?
- Is the intervention carried out under circumstances in which the patient cannot give informed consent because of temporary or permanent inability to make decisions?
- Insofar as it concerns patients who are unable to make decisions, can relatives or another third party find themselves in a difficult decision-making position if the intervention is carried out?

Question 7 – Integrity: How does the intervention impact on the physical and personal integrity of patients and their relatives?

The Health and Medical Services Act states that care shall be based on respect for patient integrity. This can be linked to the patient's right of self-determination, because the boundaries of a person's integrity are usually set by the person themselves (insofar as this is possible). But it can also be linked to the patient's potential vulnerability and this requires us to act with care even in cases where the patient cannot determine or maintain the boundaries themselves.

Integrity embraces a person's physical integrity, which is also referred to as a person's physically private sphere and a person's personal integrity. Physical integrity covers such activity as a surgical operation, intimate interference, encroachment of home space or the spatial sphere around the person, or interfering with personal belongings. Personal integrity covers among other things the handling of sensitive information about the person and their surrounding sphere.

Examples of questions:

- Does the intervention imply major or minor intrusion in the patient's physical sphere in comparison with alternative interventions and is this degree of intrusion warranted, in order to achieve the aim of the intervention?
- Does the intervention impair the patient's ability to maintain control of sensitive information?
- Does the intervention presuppose distribution or collection of information about the patient, apart from what normally occurs within the context of health and medical care?
- Does the intervention presuppose co-operation and sharing of information with professional groups outside health and medical care? Is management of sensitive information reasonable, in relation to the aim of the intervention?
- Does the intervention involve interference with the physical or personal integrity of a third party?

Question 8 – Cost-effectiveness: Is there a reasonable balance between the cost and the effects of the intervention?

According to the cost-effectiveness principle of the ethical platform there shall be a reasonable relationship between the cost of the intervention and its effects. This should be assessed in relation to the current procedure which the intervention under assessment is intended to supersede.

However, there is no definitive answer as to what constitutes a reasonable relationship and according to the platform this assessment shall take into account the gravity of the actual condition (see Question 3). In this context, the health economic assessment shall also be considered in relation to other ethical aspects. In order to avoid ineffective distribution of resources, the effect on different sectors of society should also be taken into consideration in the analysis. Methodological guidelines for conducting a health economic assessment are available in SBU's manual for assessment of methods in health and medical care (1). General advice on economic assessment is provided by the Agency for Dental and Pharmaceutical Benefits (5).

Summary: Is implementation of the intervention compatible with current ethical values (based on the answers to questions 5–8)?

In the light of the answers to questions 5–8, there needs to be an overall determination of the potential application of the intervention in the context of current ethical values and whether certain restrictions for implementation of the intervention should be considered. The following are examples of questions which might be addressed in such a determination:

- Are there strong ethical reasons in support of unrestricted implementation of the intervention within health and medical care?
- Are there reasons to support implementation of the application only after a number of ethical objections have been addressed? If so, which objections and how should they be dealt with? As stated previously, Swedish legislation, declarations, guidelines etc, can offer some guidance.
- Can implementation of the intervention require legislative changes?
- Are there strong ethical objections to implementation of the intervention in health and medical care?

Structural factors with ethical implications

Question 9 – Resources and organisation: Are there resource- or organizational limitations which can influence which patients will have access to the intervention, or can result in other care being limited if the intervention is implemented?

Because the availability of resources for health and medical care (e.g. financial resources, availability of competent personnel and relevant equipment) will affect potential implementation of the intervention, it is necessary to determine whether patient access to the intervention may be affected by limited resources. Moreover, an assessment should be made as to whether implementation of the intervention can have effects on other sections of health and medical care which in turn can have a negative influence on patient access to care. The following are examples of questions which might be considered:

- Are there sufficient resources to allow nationwide implementation of the intervention on an equal basis?
- Can implementation of the intervention result in suppression of other similar or more important care because of limited availability of finances, equipment or competent personnel?
- Can other organisational difficulties in relation to implementation of the intervention result in inequality with respect to access to the intervention?

Question 10 – Professional values: Can the values of medical professionals involved influence implementation of the intervention, thereby resulting in inequality of access by patients?

In order for an intervention to function it is necessary that the health professionals involved do not oppose its use. If there are values which result in the intervention not being used, then this may lead to unequal access to the intervention. The values may be related to the intervention itself, but may even be because implementation of the intervention will change the professional roles in such a way that is unacceptable to the professionals concerned. Do some of the professional groups involved

with the intervention have values which might hinder its application? The following are examples of questions which might be considered:

- Are there values related to the intervention as such?
- Are there values related to the implications of the intervention for the role and identity of different professions?

Question 11 – Special interests: Are there special interests which can influence implementation of the intervention, leading to unequal patient access?

A factor which can influence implementation of an intervention is the presence of groups which have special interests related to the intervention. These groups can have a positive attitude and thereby promote the implementation of an intervention to an extent which is greater than can be regarded as reasonable, given the assessment above. There may also be groups with a negative attitude to the intervention or who are interested in the implementation of alternative procedures instead. In this context, it is important to point out that in the ethical platform for prioritising, a stance is taken against promotion of an intervention by patients and other groups.

Examples of appropriate questions:

- Are there groups, e.g. scientific, professional, commercial, religious, cultural or others, who on the basis of their interests and values can be influenced by, or can have opinions about the implementation of the intervention? Have they the potential to influence implementation of the intervention?
- Is implementation of the intervention being promoted more by patient or third party demand than a demonstrated need?

Summary: Is there reason to believe that equal access to the intervention in question or other interventions may be more difficult because of structural factors (based on the answers to questions 9–11)?

The response to this question summarises whether there are structural factors which may result in unequal access to the intervention or to other care (based on the answers to questions 9–11).

Long-term ethical consequences

Question 12 – Long-term ethical consequences: Can implementation of the intervention have more long-term consequences?

Even if the answers to the above questions indicate that there are no major ethical objections to the intervention, or that no major issues will arise with implementation of the intervention, it may lead to developments which in the longer term can lead to problematic ethical consequences. Below are some examples of questions which might be asked:

- Is there a risk that implementation of the intervention can spread to other areas where it is more problematic, or that there is a gradual shift in indications for the procedure which may become problematic?
- Is there a risk of more serious repressive effects which in turn can influence attitudes to the intervention or the intended patient group (compare with Question 9 which addresses this issue in the short-term)?
- Is there a risk that implementation of the intervention can lead to more long-term problematic changes in attitude (compare with Question 5, which addresses this issue in the short-term)?
- Is there a risk that implementation of the intervention may lead to a more long-term negative effect on public health or on the environment in general (compare with Question 4, where this issue is addressed in the short-term)?
- Can implementation of the intervention, or its long-term effects, adversely influence confidence in the health and medical services?

Summary of the ethical questions

After the above questions have been addressed the ethical issues should be summarized clearly.

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

Depending on the answers to Questions 1-12, a summary of the ethical issues identified can be presented as follows:

- What ethical reasons do not support implementation of the intervention? List these reasons.
- What ethical reasons support implementation of the intervention? List these reasons.
- Is it possible to change the intervention or the conditions associated with its implementation so that the ethical objections can be reconciled?

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