**Questionnaire on bioethics and disability**

1. **Please provide information on the legislative and policy framework in place in your country in relation to:**
   1. **Prenatal diagnosis**

According to the Act on Genetic Integrity (Lag om genetisk integritet, 2006:351), all pregnant women shall receive information about prenatal diagnostics, and thereafter decide, in agreement with their physician, if they want to carry out a prenatal analysis or a prenatal genetic analysis. Women above a certain age are usually offered a combined ultrasound and blood test.

* 1. **Disability-related abortion**

According to the Abortion Act (Abortlag, 1974:595), abortion can be carried out without any questions before week 18. From week 18 onwards one can apply to the Legal Advisory Board to have an abortion. Such applications can, if there are exceptional circumstances, usually be warranted up until the first days of week 22.

* 1. **Informed consent to medical treatment and scientific research**

*Informed consent to medical treatment*

According to the act regarding the patient’s position in the Swedish health care system (Patientlag, 2014:821), a patient’s autonomy and integrity shall be respected. Health care must not be given without consent from the patient except when another follows from other law. Before consent is obtained the patient shall be given information about e.g.:

* his or her state of health
* methods for investigation, care and treatment
* tools for people with disabilities
* the expected course of the care or the treatment
* significant risks for complications and side effects

The consent can be withdrawn at any time.

If the patient is a child, its attitude towards the care or the treatment shall as far as possible be clarified and considered in relation to the age and maturity of the child.

If the patient’s own will, because of unconsciousness or some other reason, can’t be investigated, the patient shall receive the care needed to ward off danger which acutely and severely threatens his or her life or health.

According to the Compulsory Mental Health Act (Lag om psykiatrisk tvångsvård, 1991:1128) psychiatric care, under specific circumstances, can be given without consent if the patient, because of a severe mental disorder, has an indispensable need for care which he or she opposes or, because of the patient's mental state, there is well-founded reason to assume that care cannot be given with his or her consent. Such compulsory care is only allowed in order to enable the patient to voluntarily participate in the necessary care. Compulsory measures may only be used if they are in reasonable proportion to the purpose of the measure. Further, compulsive care must not be given if the patient's mental disorder only consists of a developmental disorder.

*Informed consent to scientific research:*

For research carried out in Sweden which involves e.g. physical interventions on research subjects and methods with the purpose of affecting a research person physically or mentally, or which includes an apparent risk of injuring the research subject either physically or mentally, informed consent is regulated in the Ethical Review Act (Lag om etikprövning av forskning som avser människor, 2003:460).

According to the Act, the research subject should be informed about:

* the overall research plan,
* the purpose of the research,
* the methods that will be used,
* the consequences and risks that research can bring,
* who the research leader is,
* voluntary participation in research, and
* the research subject’s right to cancel his or her participation at any time.

Research may only be conducted if the research subject has consented to the research that concerns him or her. A consent only applies if the research person has previously been informed about the research. The consent must be voluntary, explicit and precise to some research and it must be documented.

A consent may be withdrawn at any time with immediate effect.

Research may be carried out without consent if illness, mental disorder, weakened health condition or any other similar condition of the research subject prevents his or her opinion from being obtained. However, in such cases the research may only be conducted under the following conditions:

1. The research can be expected to provide knowledge that cannot be obtained through research with consent; and
2. The research can be expected to lead to direct benefit to the research person

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Even though the condition (2.) is not met, the research may be carried out if

1. the purpose is to contribute to a result that may be of benefit to the research person or someone else suffering from the same or similar illness or disorder; and
2. the research involves a negligible risk of injury and a negligible inconvenience to the research person.

Even in these cases, the research subject as far as possible shall be personally informed about the research. Consultation should take place with his or her immediate relatives. Consultation shall also take place with the person’s legally designated trustee, if the question is included in his or her assignment. The research must not be carried out if the research subject in any form expresses a wish not to participate or if any of those who have been consulted oppose the execution.

The research mentioned in this answer may only be conducted if it has been approved subsequent to an ethical vetting/review by the Swedish Ethical Review Authority.

Such research may only be approved if the relevant information and consent provisions will be complied with or if the conditions for research without consent, as described above, are fulfilled.

If a research subject is in a dependency relationship with the research principal or a researcher or if the research subject can be assumed to have special difficulties in exercising his right, questions of information and consent should be given special attention in the ethics review.

There are corresponding provisions in the field of clinical trials of medicinal products and medical devices, in accordance with applicable EU-law.

* 1. **Protection of persons with disabilities undergoing research**

According to The Ethical Review Act (Lag om etikprövning av forskning som avser människor 2003:460), research which involves e.g. physical interventions on research subjects and methods with the purpose of affecting a research person physically or mentally, or which includes an apparent risk of injuring the research subject either physically or mentally may only be conducted if it has been approved subsequent to an ethical vetting/review by the Swedish Ethical Review Authority.

According to the Act, research may only be approved if it can be carried out with respect for human dignity. Human rights and fundamental freedoms must always be taken into account in the ethics review, while taking into account the interest that new knowledge can be developed through research. The welfare of people should be given priority over the needs of society and science. Research may only be approved if the risks it may pose to the health, safety and personal integrity of research subjects are outweighed by its scientific value. Research may not be approved if the expected result can be achieved in another way that involves less risk to the health, safety and personal integrity of research subjects. Processing of personal data may only be approved if it is necessary for the research to be carried out. Research may only be approved if it is to be carried out by or under the supervision of a researcher who has the necessary scientific competence. Compliance with the law is supervised by Swedish Authorities.

These rules are general. There are no special rules aiming at the protection of persons with disabilities.

* 1. **Euthanasia and assisted suicide**

Euthanasia is in Sweden prohibited by The Swedish Penal Code and thus is not allowed in the Swedish health care system. Assisted suicide may also be regarded as a criminal act depending on the circumstances and is not allowed in Swedish health care.

1. **Please provide any information and statistical data (including surveys, censuses, administrative data, literature, reports, and studies) in relation to:**
   1. **The availability, accessibility and use of prenatal diagnosis**

All pregnant women are offered ultrasound during pregnancy regardless of which region they live in. Most regions also offer KUB-test (combined ultrasound and blood test) to pregnant women in the beginning of their pregnancy. During 2018, 52% of pregnant women had undergone this test.

Non-invasive prenatal testing (NIPT) is also offered to pregnant women after 9 weeks of pregnancy, this is less widely used. In one region (Blekinge) 24% of women had undergone this test in 2018, however in other regions uptake is low. This can be explained by the fact that most regions only offer NIPT testing if results of the KUB-test show increased risk for the foetus.

* 1. **The availability, accessibility and use of disability-related abortion**

Abortion is allowed without a special permit from the National Board of Health and Welfare until the 18th week of pregnancy according to the Abortion Act (Abortlag, 1974:595). After that an application can be sent to the Legal Advisory Board at the National Board of Health and Welfare stating the need for abortion, which usually be warranted up until the first days of week 22. Recent years about 540 applications per year has been granted by the Legal Advisory Board. About 70 % of these were motivated by fetal and congenital anomalies. Totally in Sweden there are about 35 000 – 38 000 abortions each year.

* 1. **The practice of informed consent to medical treatment and scientific research**

There is no easily accessible data on this issue exclusively concerning research which requires consent separated from data on research where consent is not required.

* 1. **The existence of measurements of quality of life which affect both clinical decision-making and health policy**

Measurements of quality of life are often used in studies and analyses which form parts of the basis for decision-making and policy-development. Frequently used measures are e.g. Quality-Adjusted Life Year (QALY) and Disability-Adjusted Life Year (DALY), following WHO standards.

* 1. **The practice of experimental, controversial and/or irreversible treatments**

According to Swedish law, health care professionals are required to carry out their work in accordance with science and proven experience. Clinical research projects are allowed if they have been approved by the Swedish Ethical Review Authority, as described in the answer to question 1d above. If the project concerns clinical trial of medical products it also has to be approved by the Swedish Medical Products Authority. The compliance of the relevant laws is monitored by e.g the Health and Social Care Inspectorate (IVO) and the Swedish Medical Products Authority.

* 1. **The practice of euthanasia and assisted suicide on persons with disabilities**

These practices are not allowed in the Swedish health care system, see the answer on question 1e.

1. **Please provide information on discrimination against persons with disabilities on research involving humans.**

There is no specific information about this issue that we know of.

1. **Please describe how national ethics committees address the rights of persons with disabilities. Please provide information on protocols, guidelines, decisions, investigations or publications in relation to persons with disabilities.**

The Swedish National Council on Medical Ethics regularly analyzes bioethical issues from a human rights perspective. The rights of persons with disabilities is an important perspective which is often considered in the work of the council and in its publications.

According to The Ethical Review Act (Lag om etikprövning av forskning som avser människor 2003:460), research which involves e.g. physical interventions on research subjects and methods with the purpose of affecting a research person physically or mentally, or which includes an apparent risk of injuring the research subject either physically or mentally may only be conducted if it has been approved subsequent to an ethical vetting/review by the Swedish Ethical Review Authority. The prerequisites for such approval are described in the answer to question 1d. These rules are general. There are no special rules aiming at the protection of persons with disabilities. However, according to the Act, if a research subject is in a dependency relationship with the research principal or a researcher or if the research subject can be assumed to have special difficulties in exercising his right, questions of information and consent should be given special attention in the ethics review.

1. **Please describe to what extent and how persons with disabilities are involved in the work of national ethics committees.**

In the Swedish National Council on Medical Ethics persons with disabilities are represented by an expert, nominated by the Swedish Disability Rights Federation.

1. **Please refer to any innovative initiatives that have been taken at the local, regional or national level to promote and ensure the rights of persons with disabilities in bioethical discussions.**

There is no easily accessible data on initiatives taken at local or regional levels. At the national level, the rights of persons with disabilities are promoted e.g. through the participation of the Swedish Disability Rights Federation in the Swedish National Council on Medical Ethics. Disability organizations are regularly invited to leave their opinions on reports and proposals submitted by governmental investigations concerning bioethical issues.