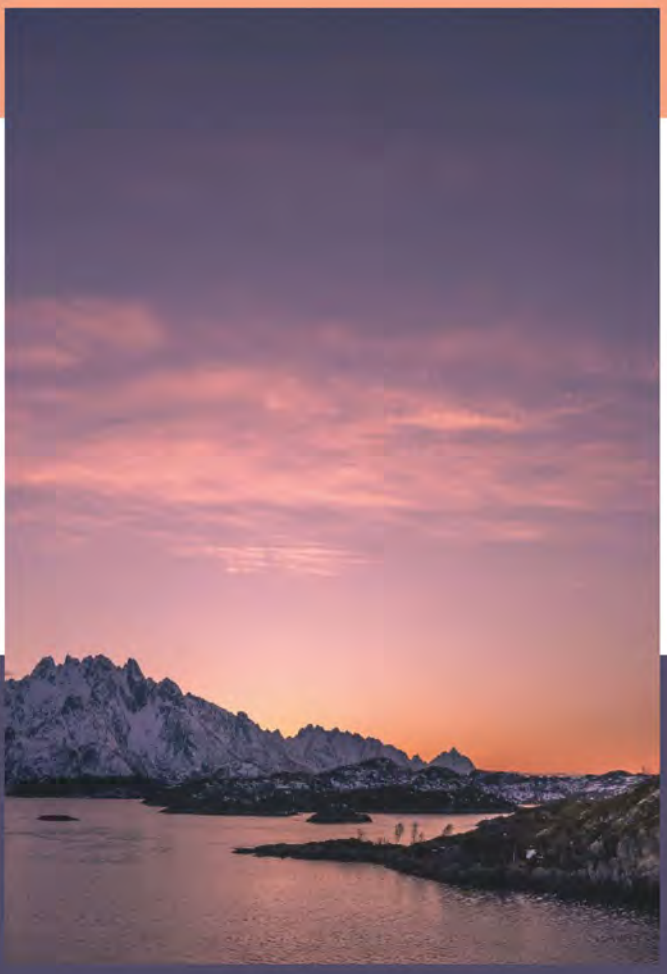
NORDIC LEGAL RESEARCH GROUP

NORDIC LEGAL RESEARCH GROUP ON HEALTH LAW

PATIENT'S CONSENT TO TREATMENT
- A NORDIC PERSPECTIVE ON MEDICAL SELF-DETERMINATION



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PATIENT'S CONSENT TO TREATMENT

A NORDIC PERSPECTIVE ON MEDICAL SELF-DETERMINATION

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The Nordic Legal Research Group ("**NLRG**") was established in 2019, in an ambitious attempt to improve and expand co-operation between the Nordic members of the world's largest law student association, ELSA.
Through the valiant effort of both the coordination team as well as our researchers and editors, we were able to launch the second edition of the NLRG amidst a global pandemic. Despite such arduous times, the team was able to provide prolific work and proved adaptable to fickle circumstances. I offer my everlasting gratitude to you all, both for your dedication to the project and the thoroughness thereof.
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Yours sincerely
Eve Ahonen
Head of Coordination Team

FOREWORD

”Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained.”

Justice Benjamin Cardozo wrote his famous decision in the case of *Schloendorff v Society of New York Hospital* in 1914.[1] The principle of informed consent has ever since become a cornerstone of medical law. Also in the Nordic countries, the patient's rights have been a subject of interest for decades. Each country has also developed its own legislation to ensure that patient's rights are taken into due consideration in medical practice. However, despite common legal tradition, each Nordic country has its own particular features. Therefore, it is interesting to compare the statutes and practices. The present reports cover Denmark, Finland, Norway and Sweden.

The reports of four Nordic student groups of the European Law Students' Association (ELSA) have approached this issue with several interesting research questions. First, they describe the legislative acts that regulate patients' decision-making in each country. Second, they explain which international human rights instruments have a significant influence on the status of a patient in each country. Third, each group has analysed the extent of information that should be disclosed to a patient for a valid consent.

The consent of children and consent for children has then been studied as a separate topic as well as the possibility of a parent to oppose a treatment. In addition, the legal remedies and legal consequences for violating an obligation to provide information about medical treatments are covered in each study report. Finally, the consent procedures in medical emergencies are analysed for all four Nordic countries.

To my knowledge, the four study reports consist of the most extensive comparison of Nordic countries in medical law. As such, the project of ELSA deserves congratulations. Furthermore, the study groups have shown remarkable research skills, which I hope will also result in further studies in related fields.

Even though informed consent of a patient is the basis for the legitimate medical treatment, modern therapies may be complex and decisions can be difficult even for an educated patient. Medical professionals are often busy and there might be little time to discuss all the issues with a patient. However, digital tools may help

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1 Stephen Bolsin and Kym Saunders, 'Informed consent in medical practice' (2012) Trends in Urology & Men's Health 2012:3(5):34-6 <https://wchh.onlinelibrary.wiley.com/doi/pdf/10.1002/tre.288> accessed 25 April 2021.

and give many patients the access to the information that they need for their decision-making.[2] On the other hand, the internet is full of misinformation and it is not easy for a non-professional to differentiate evidence-based data from advertisements.

Therefore, in modern healthcare systems more effort should be aimed at providing patients with up-to-date digital information on their health issues and their possible treatments thereof.

The role of the family is also changing in three important ways. First, urbanisation means that more and more people are living alone. In medical emergencies, there is often no close relative that could participate in the decision-making on a patient's behalf. A care will/advanced directive may help to clarify the wishes of an unconscious or confused person. However, in practice they are rarely available and may be ill suited for the actual treatment situations (especially if they have been drafted some decades earlier).

Second, the relation of the elderly with their children may be remote. Quite often, the old parent has been treated in a nursing home with only occasional visits with the family members, who suddenly are disposed to health issues that they may not be aware of. If the internal discussion within a family is lacking, the consent given by a relative may better reflect the family member's own thoughts than the wishes of the old patient themselves.

Finally, all four country reports cover many different forms of families. Relations start and end bringing sometimes together a group of children who have in addition to the biological parents several stepparents and siblings. It is not rare that the biological parents are not the persons that children turn to in their medical problems. In issues like contraception and abortion, it might be an older sister or stepsister instead of the mother or the father. In addition, immigration is changing the way patients' rights are seen. Some immigrant societies are still very patriarchal and the independent decision-making by the wife or a child may cause problems at home.

Nordic countries have been forerunners in establishing no-fault compensation systems in medical negligence and errors. Therefore, the court cases in compensating medical damages are rather rare. The reports present the existing jurisprudence as well as the practices of supervising authorities that have the power to limit or abolish the professional rights of a physician or nurse.

Movement of labour across borders has brought to Nordic countries healthcare professionals that may have perfect knowledge of current medical practices, but less experience on the expectations of Nordic patients. Sometimes the professionals come from countries that still have autocratic or paternalistic practices in

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[2] Lasse Lehtonen, 'Tulevaisuuden näkymiä' in Lasse Lehtonen, Mirva Lohiniva-Kerkelä, Irma Pahlman (eds), *Terveysoikeus* (Alma Talent 2014) 379–387.

their hospitals. They may have difficulties in following the appropriate information and consent procedures that the patients are used to, especially if their language skills are still developing.

Appropriate information for a patient is not only a legal question. When the patient has been an active participant in the process of selecting their treatment and when they have received appropriate information on their disease and on its treatment options, the treatment compliance is better. Informed consent is thus contributing to better outcomes and to greater patient satisfaction. The patient-centred care was high in the agenda for better healthcare before the COVID-19 pandemic and it is likely to recover when things return to normal.[3]

The issues above are just examples of the new challenges to the principle of informed consent in healthcare. Even though this principle is now over 100 years old, there are always new issues and questions in its applications, when the society and its values change. I am sure that also the future generations of lawyers will find the basic questions in medical law both challenging and interesting. I hope that you will enjoy reading the reports on the present informed consent regulations in Nordic countries, and find them useful to improve further the rights of patients in healthcare.

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[3] Expert panel on Effective Ways of Investing in Health (EXPH): Future EU Agenda on Quality of Healthcare with a special emphasis on Patient Safety (2014) <https://ec.europa.eu/health/sites/health/files/expert_panel/docs/006_safety_quality_of_care_en.pdf> accessed 25 April 2021.

PREFACE

This ELSA Nordic Legal Research Group report on health law examines the current state of *Patient's self-determination in the Nordic countries* of Denmark, Finland, Norway and Sweden. The groups approached the topic from two main perspectives: valid consent and refusal as right. The report has six sections: introduction, four separate national reports and the joint conclusions.
The topic of patient's self-determination intertwines with human rights law. Therefore, the first section of the report is an introductory part to international human rights law on valid consent and refusal as right. This introduction to international law is common to all the national reports.
Each national report will deal with the topic of patient's self-determination as a dogmatic question under their domestic statutory law. International and national case law are also discussed throughout the report, as they highlight the human rights aspect and the legal problems related to patient's self-determination in medical treatments.
Joint conclusions of the report are given in the section VI Conclusions.

Shared structural framework of the national reports

Before reading the quadruple report, readers will benefit from noting the shared structural framework of the national reports. The following overview of the structure applies to each partial report, be it the Danish, Finnish, Norwegian or Swedish one. It is also worth noting, that the reports may be read in any order, as they are simply listed alphabetically; and each report may be read as a standalone report.
Each national report answers the same distinct six questions under the same six sections for navigation. **First**, the legal regulation of patient's status; **second**, information as a component for valid consent or refusal in medical law; **third**, forms of patients' consent and refusal; **fourth**, voluntary and competent consent to or refusal of medical interventions; **fifth,** capacity to decide on medical interventions; **sixth,** exception: emergency medical interventions. These sections sum up what is conceptually meant by valid consent and refusal as right, how they are embodied in national laws and how they are interpreted in judicial practice.

Yours sincerely
Authors and editors of the Nordic Legal Research Group 2020/2021

ABBREVIATIONS AND NATIVE WORDS

List of Common Abbreviations

CEDAW	Committee on the Elimination of Discrimination against Women
CoE	Council of Europe
CRC	United Nations Convention on the Rights of the Child
CRPD	Convention on the Rights of Persons with Disabilities
ECtHR	European Court of Human Rights
ECHR	Convention for the Protection of Human Rights and Fundamental Freedoms (also mentioned as the European Convention on Human Rights)
EU	European Union
GDPR	General Data Protection Regulation (EU)
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
UN	United Nations
Oviedo Convention	Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (also mentioned as the Convention on Human Rights and Biomedicine)
WHO	World Health Organization

The Danish report

Native words

Autorisationsloven	Authorization Act
Bekendtgørelse om journalføring i sundhedssystemet	Ministerial order on journaling in the healthcare system
Bekendtgørelse om kosmetisk kirurgi	Ministerial order on cosmetic surgery
Forældremyndighedsloven	Parental Responsibility Act
Forvaltningsloven	Public Administrative Act
Lov om klage- og erstatningsadgang inden for sundhedsvæsenet	Complaints and Compensation Act
Lov om patienters retsstilling	Patient's Legal Status Act

Lov om information og samtykke og videregivelse af sundhedsoplysninger	Law on information and consent and on the disclosure of health information
Straffeloven	Criminal Code
Styrelsen for patientklager	Board for Board for patient's complaints (Agency for Patient Safety)
Sundhedsloven	Health Act
Østre Landsret	Eastern High Court

The Finnish report

Abbreviations

Dnro	*diaarinumero*, record number allocated to an appeal
EOA	*Eduskunnan oikeusasiamies*, Parliamentary Ombudsman
EOAK	*Eduskunnan oikeusasiamiehen kanslia*, Office of the Parliamentary Ombudsman
HAO	*hallinto-oikeus*, administrative court
HE	*hallituksen esitys*, government proposal
KHO	*korkein hallinto-oikeus*, Finnish Supreme Administrative Court
KKO	*korkein oikeus*, Finnish Supreme Court
STM	Ministry of Social Affairs and Health
Valvira	National Supervisory Authority for Welfare and Health

Native words

Hallituksen esitys	government proposal
Harkittu suostumus	considered consent
Korkein hallinto-oikeus	Finnish Supreme Administrative Court
Lastensuojelulaki	Child Welfare Act
Mielenterveyslaki	Mental Health Act
OmaKanta	My Kanta, patient record access system for patients
Potilaan itsemääräämisoikeus	patient's right to self-determination
Suomen perustuslaki	Finnish Constitution
Terveydenhuoltolaki	Health Care Act
Tietosuojavaltuutettu	data protection ombudsman

The Norwegian report

Abbreviations

Bvl	*Lov om barneverntjenester,* Child Welfare Act
FARV	*forstå, anerkjenne, resonnere, ta et valg;* understand, recognise, reflect, make a decision
Ot.Prp	*Odelstingsproposisjon*, government proposal
Pbrl	*Lov om pasient- og brukerrettigheter*, Patient and User Rights Act

Native words

Anerkjenne	recognise
Forstå	understand
Fylkesnemda	county board
Helsedirektoratet	Norwegian Directorate of Health
Høyesterett	Supreme Court
Legalitetsprinsipe	principle of legality
Lov om barneverntjenester	Child Welfare Act
Lov om etablering og gjennomføring av psykisk helsevernt	Mental Health Care Act
Lov om helsepersonell	Health Personnel Act
Lov om humanmedisinsk bruk av bioteknologi	Biotechnology Act
Lov om kommunale helse- og omsorgstjenester	Health and Care Services Act
Lov om pasient- og brukerrettigheter	Patient and User Rights Act
Lov om spesialhelsetjenester	Specialist Health Services Act
Lov om styrking av menneskerettighetes stilling i norsk rett	Human Rights Act
Resonnere	reflect
Ta et valg	make a decision

The Swedish report

Abbreviations

DO	*discrimination ombudsman,* equality ombudsman
FB	*Föräldrabalken,* Parental Code
HMSA	Health and Medical Service Act
IoG	Instruments of Government

IVO	*Inspektionen för vård och omsorg,* Health and Social Care Inspectorate
JO	*justitieombudsmannen,* parliamentary ombudsman
OSL	Public Access to Information and Secrecy Act
PA	*Patientlag,* Patient Act
PC	Parental Code
PDA	Patient Data Act
PSA	Patient Safety Act

Native words

Brottsbalken	Penal Code
Diskrimineringslagen	Discrimination Act
Discrimination Ombudsman	equality ombudsman
Försäkringskassan	social insurance agency
Förtroendenämnd / Patientnämnd	patient advisory committee
Förvaltare	administrator
God man	special representative
Hälso- och sjukvårdslag	Health and Medical Service Act
Inspektionen för vård och omsorg	Health and Social Care Inspectorate
Kommuner	municipalities
Lag med instruktion för Riksdagensombudsmän	Instructions for the Parliamentary Ombudsman Act
Lag med särskilda bestämmelser om vård av unga	Care of Young Persons Act
Lagen om avtal och andra rättshandlingar på förmögenhetsrättens område	Contracts Act
Lag om psykiatrisk tvångsvård	Compulsory Psychiatric Care Act
Lag om transplantation m.m.	Transplantation Act
Offentlighets- och sekretesslagen	Public Access to Information and Secrecy Act
Föräldrabalken	Parental Code
Patientdatalag	Patient Data Act
Patientlag	Patient Act
Patientsäkerhetslagen	Patient Safety Act
Regeringsformen	Instruments of Government
Regioner	country councils
Smittskyddslag	Disease Control Act
Socialstyrelsen	national board of health and welfare
Socialnämnden	social welfare committee
Socialtjänsten	social services
Steriliseringslag	Sterilisation Act

Chapter I:
Introduction:
International Human Rights Law in Healthcare

1. Introduction to valid consent and refusal as a right

The right to valid consent and refusal in medical settings is considered a fundamental human right. Its reach and content can be derived from multiple conventions and surmised from different articles in the European Convention of Human Rights. However, it can be a challenging term to place directly, as it is built from multiple components spread throughout many conventions, which are legally binding to different levels. The following sections 1 to 4 will provide the definition of the term 'valid consent and refusal' and explore its meaning as related to the international legal framework. The discussion will begin with a general overview of the concept, its history, and the most relevant conventions from a Nordic legal perspective.

1.1. How was the concept of valid consent and refusal developed?

The concept of patient consent dates back as far as to ancient Greece. We see in Plato's work Laws that he specifically describes how a doctor should not prescribe a patient treatment before the patient is 'convinced'. Although one can discuss whether the use of the word 'convinced' implies that the patient will not have access to the full scope of information, the concept can be nuanced when it is held in comparison to the equivalent rule regarding slaves. Here he says that slaves' doctors shall decide for themselves and never speak to the slaves individually about how to treat them. As such, it would follow that there is a level of autonomy for the freemen.[1] However, the notion of consent in medical affairs had not been discussed thoroughly in modern Europe until the 20th century. While in the United States of America a more thorough discussion began in the 18th century, it did not reach across the Atlantic until centuries later.[2] The main catalyst for this paradigm shift and the following discussion were the atrocities that occurred during the two world wars. World War II and the treatment of the concentration camp prisoners, in particular, invigorated this discussion. From

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1 Nir Eyal, 'Informed Consent, the idea of consent' <https://plato.stanford.edu/entries/informed-consent/#IdeCon> accessed 19 September 2020.

2 Vito Mallard, 'The origin of informed consent' (2005) Acta otorhinolaryngologica Italica: organo ufficiale della Societa italiana di otorinolaringologia e chirurgia cervico-facciale 312.

this came what is referred to as the Nuremberg Code in 1947, which came out of the Nuremberg trials, where amongst others, Nazi physicians were tried for their research on prisoners. From this the concept of a patient's right to be informed and give their consent was given a much bigger importance in the discussion surrounding medical practices in Europe. The Nuremberg Code highlights the importance of a patient's autonomy and right to choose what happens to their body, in addition to research in general striving to limit the amount of suffering and to be for the greater good of society.

1.2. Valid consent and refusal in modern international law

The rights of patients when undergoing medical treatment are regulated in several international conventions. For Nordic countries, the most relevant are the European Convention on Human Rights (ECHR) and the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (the Oviedo Convention). The ECHR was drafted by the Council of Europe (CoE) in 1949. Sir David Maxwell-Fyfe was a prosecutor at the Nuremberg Trials, and played a large role in drafting the ECHR. The ECHR contains many of the rights in the Universal Declaration of Human Rights. In addition, the ECHR defines how the enforcing mechanism, the European Court of Human Rights (ECtHR) operates. The CoE has since the 1980s worked especially with promoting human rights within the medical field. In 1985, they created the Ad Hoc Committee of Experts on Bioethics that were mainly tasked with looking at the prospective legal vacuums that would appear with the rapid development of the biomedical area.[3] This committee was in 1990 instructed to prepare a draft convention with protocols that would complement and elaborate on the ECHR, specifically in relation to biomedical sciences. In April 1997, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine was opened for signature in Oviedo, Spain. This convention, hereafter referred to as the Oviedo Convention, is the only legally binding transnational instrument that relates to the protection of human rights in the biomedical field. It entered into force in December 1999, and currently 35 countries have signed the convention. Throughout this convention, the point of informed consent is reiterated. Informed consent is a necessity for every medical intervention mentioned in the convention. Article 5 states: "An intervention in the health field may only be carried out after the person concerned has given free and informed

[3] Roberto Andorno, 'The Oviedo Convention: a European legal framework at the intersection of human rights and health law' (2005) Journal of international biotechnology law 133-143.

consent to it," after receiving "appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks". According to article 23 of the Convention, Member States are required to "provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles" of the Convention.
Another important convention relating to informed consent is the Convention on the Rights of Persons with Disabilities (hereinafter CRPD). This convention states in article 25 that Member States shall "(r)equire health professionals to provide care of the same quality to persons with disabilities as to others, including on the basis of free and informed consent". This is of special importance as people with disabilities have often been disenfranchised and paternalised when it comes to healthcare. What exactly informed consent looks like in regard to intellectual and physical disabilities can vary and will be discussed later in this paper. The concept of valid consent and refusal necessitates some level of understanding from the patient's perspective. Therefore, the term 'valid consent' is somewhat of a shorthand for a more complex set of requirements. This entails that the patient must be able to provide informed, competent and voluntary consent to constitute valid consent. The requirements of each of these specifications will be discussed in depth later in this paper.

1.3. Which right in the ECHR enshrines the right to valid consent and refusal?

There is no specific article in the ECHR that grants a person the right to valid consent and refusal; however, it is generally accepted as a human right. Therefore, this begs the question of which right it is that enshrines the right to valid consent and refusal. Several rights may seem like they would encompass consent and refusal, so it can be challenging to understand which one specifically should be applied to such cases. Some of the rights that relate to consent are (but are not limited to):

- Article 2 – right to life – this right affords patients the right to be both informed of the best treatment to preserve life, as well as the choice of how to conduct the treatment.
- Article 3 – right to not be subject to torture or degrading treatment – this right gives the patient the right to refuse treatment they believe will not be beneficial, and where the harmful effects of the treatment are perceived to outweigh the benefit.
- Article 5 – right to liberty – this right affords patients the right to refuse to be held in medical facilities against their will, and can relate especially to mental health patients where unlawful imprisonment has historically been an issue of concern.

- Article 8 – right to privacy – the right to privacy means that patients have the right to refuse medical intervention for personal reasons, in addition to the right to utilise medical practices in accordance with their own private sphere.
- Article 9 – right to freedom of religion – this right gives the patients the right to practice their religion how they believe and to live in accordance with these religious choices. Such practices can sometimes be at odds with medical practices, such as blood transfusions or abortions.
- Right to health - though there is no right to health in the ECHR, this has been discussed in various cases as a right that falls under article 2. Various legal scholars have discussed whether this should be an independent right in the convention.[4] [5]

Different rights have been used in different cases in relation to valid consent, to suit the individual case. Examples of this will be provided throughout the paper.

1.4. How is the right to valid consent and refusal dependent on its implementation in the national legal framework?

The European Human Rights Charter binds the European Member States together and forms a moral backbone of the legal state. However, European countries are still divided by several issues, such as social, ethical and religious beliefs.[6] This can be seen by several European countries having differing reservations to the Oviedo Convention. For instance, Germany believes that it is too lax in some areas, whereas the United Kingdom has the diametrically opposite opinion to this. Still, the Oviedo Convention is a large step towards a more cohesive set of minimum requirements in the legal field. The function of the ECtHR is to hold Member States to the convention and ensure that it is implemented correctly. However, the Oviedo Convention has no such "watchdog". The ECtHR are not mandated to make their rulings with influence from the Oviedo Convention.[7] However, the EHRC is mandated to give advisory opinions on the Oviedo Convention.[8] The importance of the Oviedo Convention for the specific question of valid consent is clear, so how can it be ensured it is correctly implemented by the Member States? The connection between the Oviedo Convention and the ECHR has been discussed thoroughly by academics, and some argue that they

4 European Court of Human Rights, Thematic Report, Health-related issues in the case law of the European Court of Human Rights (2015).

5 Tamara K. Hervey and Jean V. McHale, *European Union Health Law: Themes and implications* (Cambridge University Press 2015) 156-183.

6 Vera L. Raposo and Eduardo Osuna, 'European convention of human rights and biomedicine' in Roy G. Beran (ed), *Legal and Forensic Medicine* (Springer 2013) 1405-1423.

7 ECHR, art 32.

8 ibid, art 29.

should be interpreted in unison.[9] The Oviedo Convention has been referred to in different cases, such as in the case of *Glass v United Kingdom*.[10] However, the Court has based its merits and decisions exclusively on the ECHR. Not all European countries have ratified the Oviedo Convention, whilst many, as mentioned, have made reservations or declarations to it. The Oviedo Convention has a different mechanism than the ECHR, which is completely binding on the Member States. At the same time, both instruments were created under the unity of the Council of Europe. The countries that have ratified and implemented the Oviedo Convention are legally expected to comply with it. When interpreting the two different conventions, legislators must harmonise them in order to comply with the obligations set in either. This also shows that the understanding of ECHR cannot differ from the Oviedo Convention, as it may result in unclear and arbitrary situations for the Member States. Therefore, at some point, there should be a harmonisation between them, even though the Court does not explicitly refer to it in its cases. The relation between the ECHR and the CRPD is also of interest. As mentioned, the ECtHR only has jurisdiction within the ECHR. This has been upheld by not interpreting the provisions of the Oviedo Convention strictly in its case law, as well as by constructing its own understanding on the rights of people with disabilities. The Court has referred to Recommendation No R (99) 4 of the Committee of Ministers to Member States on Principles Concerning the Legal Protection of Incapable Adults. The Council of Europe has also recommended its Member States to ratify and comply with the CRPD. The recommendation is considered soft law, but it also shows how the Council of Europe strives for harmonisation of the conventions. When analysing and understanding the topic, it is therefore appropriate to interpret the conventions in light of each other.

2. When does human rights law regard consent and refusal as informed?

This research question discusses informed consent and refusal in human rights law. The focus is on the themes of criteria for informed consent and refusal, standard of information disclosure regarding the patient's right to medical information and patient's right to refuse receiving medical information. A medical intervention performed without a properly obtained informed consent can be

9 Francesco Seatzu, 'The Experience of the European Court of Human Rights with the European Convention on Human Rights and Biomedicine' (2015) Utrecht J Int'l \& Eur L 5.

10 European Court of Human Rights, Research Report, Bioethics and the case law of the Court (2012).

considered a violation of human freedom and dignity.[11] Human rights legislation and case law have shown that a consent or refusal is considered informed when the patient has received as much information as an average or hypothetically reasonable patient would need to receive to make a competent decision regarding a medical intervention. This includes having had time and a chance to elaborate on the consequences of the intervention e.g. in their health, private circumstances and family life.[12] The patient's need for information in their particular situation is in the focus of the criteria of informed consent and refusal. In accordance with the respect of autonomy of the patient, they also have the right to refuse receiving medical information.[13]

2.1. Informed consent and refusal and standard of information disclosure

A free and informed consent or refusal has been considered an informed, voluntary and competent act. In order to be able to consent to a medical intervention, the patient must in advance receive information that is relevant for the purpose and nature of the intervention, as well as information on the consequences and risks of the intervention.[14] A free and informed consent may be express, verbal, written, or implied. Article 5 of the Oviedo Convention does not require any particular form, but in invasive acts or treatments, a specific, expressed consent may be needed. In less invasive, routine medical acts, an implied consent may be considered appropriate if the patient has received sufficient information about the intervention. A consent or refusal is regarded free and informed if it is based on objective information from the responsible healthcare professional as to the nature and the potential consequences of the planned intervention or of its alternatives, in the absence of any pressure from anyone.[15]

The information must be provided in a sufficiently clear and suitably worded manner, so that the patient understands the information and thus has an actual chance to assess the necessity or usefulness of the aim and methods of the intervention against its risks and the discomfort or pain it will cause.[16] The facts that the patient is informed of must be relevant for the intervention, such as the purpose, nature and consequences of the intervention and the risks involved, and

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11 *I.G. and others v Slovakia* App no 15966/04 (ECtHR, 29 April 2013).

12 Alasdair Maclean, *Autonomy, Informed Consent and Medical Law - A Relational Challenge* (2009) 251-252; Yana Litins´ka, *Assessing capacity to decide on medical treatment - On human rights and the use of medical knowledge in the laws of England, Russia and Sweden* (Uppsala university 2018) 369-370.

13 Litins'ka, 'Assessing capacity to decide on medical treatment' (n 10) 239.

14 ibid 172-173.

15 Council of Europe, Explanatory Report to the Oviedo Convention, European Treaty Series No 164, 7.

16 ibid.

the information must be provided to a sufficient extent.[17] The patient is to receive information on inherent risks as well risks related to the individual characteristics of each patient, and the requests for more information from the patient must be answered adequately.[18]

As stated earlier, disclosure of information by healthcare professionals and understanding of the disclosed information by a patient are the key elements of an informed consent or refusal.[19] However, providing an extensive list of any medical, legal or social consequences of a proposed medical intervention is likely not possible, but legal scholars have pointed out different standards for providing adequate information. The current standard of disclosure focuses on the patient's needs, which implies that the patient should be in control of the information they would like to receive (the reasonable patient standard) instead of what information an 'ordinary' doctor would disclose to a patient (the reasonable doctor standard).[20] According to the reasonable doctor standard, the healthcare professionals are to provide as much information they consider reasonable, whereas the reasonable patient standard implies that the healthcare professionals must provide as much information as an average or hypothetically, reasonable patient would need to receive in order to make a competent choice.[21] Maclean has argued in accordance with the reasonable patient standard that the term informed consent implies that the focus of the interaction should be disclosure of information by the healthcare professionals to the patient. This emphasises the fact that the patient's need for information to be able to make an informed consent or refusal is crucial for the concept of informed consent and refusal in theory and in practice.[22]

2.1.1. The right to refuse receiving medical information

The patient's right to refuse treatment and medical interventions is one of the general principles of medical law.[23] As stated earlier, the patient is entitled to know any information collected about their health as well as the diagnosis, prognosis or any other relevant fact in order to make an informed consent regarding future medical interventions or the refusal of these. The patient's right to know is closely related to the patient's right not to know. The patient's right to refuse receiving medical information is codified in article 2 paragraph 2 of the Oviedo

17 ibid.
18 ibid.
19 Litins'ka (n 10) 29.
20 ibid 238-239.
21 ibid 369-370.
22 Maclean (n 10) 41.
23 Litins'ka, 'Assessing capacity to decide on medical treatment' (n 10) 68.

Convention,[24] and article 10 of the Oviedo Convention is relevant for the patient's right to refuse receiving medical information, as it sets out rules regarding private life and right to information.[25] The patient may wish to be unaware of certain aspects of their health for any personal reasons, and the wishes of individuals to not be informed must be respected.[26] Despite the request of the patient to not receive information, the healthcare professionals must seek their consent to any intervention proposed to the patient.[27] The patient's consent or refusal is valid even if they have exercised their right not to know certain facts concerning their health.[28]

In certain instances, the right to know or to not to know may be restricted in the patient's own interest. It may be vitally important for the patient to receive medical information despite their clear wish to not to in order to take possible preventive measures, or in case their medical condition poses a risk to others in addition to the patient. In exceptional cases, a doctor's duty to provide care as codified in article 4 of the Oviedo Convention might conflict with the patient's right not to know. The last paragraph of article 10 of the Oviedo Convention enables that in certain cases domestic law may restrict the right to know or not to know in the interests of the patient's health. Domestic law may even justify the doctor withholding part of the information or disclosing it with circumspection ("therapeutic necessity").[29]

2.2. Informed consent and refusal in human rights legislation and case law: An overview

An individual's right to self-determination is codified in the WHO Declaration on the Promotion of Patients' Rights in Europe, and several of the already mentioned principles regarding informed consent and refusal have been codified in the Declaration. The rights of patients with regard to consent have been laid down in chapter 3 of the Declaration. According to chapter 3 of the Declaration, an informed consent of the patient is a prerequisite for any medical intervention. The patient's right to be fully informed about their health status, diagnosis, prognosis, proposed and alternative medical procedures and its risks and benefits is also stipulated in the Declaration. The patient's right to refuse or to halt a medical intervention is stipulated in chapter 3 of the Declaration, in which it is stated that

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24 Council of Europe, Explanatory Report to the Oviedo Convention, European Treaty Series No 164, 11.

25 Litins'ka, 'Assessing capacity to decide on medical treatment' (n 10) 172-173.

26 Council of Europe, Explanatory Report to the Oviedo Convention, European Treaty Series No 164, 11.

27 ibid 7.

28 ibid 11-12.

29 ibid.

the implications of refusing or halting such an intervention must be carefully explained to the patient by the healthcare professionals.[30]

The principle according to which a person has to give the necessary consent for treatment expressly and in advance, except in emergencies, is also stipulated in the Oviedo Convention. A medical intervention may only be carried out after the patient has given free and informed consent to it, after having beforehand received appropriate information regarding the purpose and nature of the intervention as well as its consequences and risks. This has been codified as a rule in article 5 of the Convention. The rule is a clear indication of a patient's autonomy in relationship with healthcare professionals, and the term medical intervention covers all medical procedures. Article 5 is considered an expression of restraining the paternalist approaches, which may ignore the wishes of the patient regarding a medical intervention.[31]

Informed consent and refusal in healthcare with regard to women, children and persons with mental illnesses has been stipulated in certain international treaties. According to General Recommendation No 24 adopted by the Committee on the Elimination of Discrimination against Women (CEDAW) States parties are required to ensure that women can exercise their right to an informed consent in healthcare. The principle of informed consent of persons that are unable to give their consent has been codified in the Oviedo Convention. The treatment of persons unable to give their consent, such as children and people with mental illnesses, may be carried out only if it could produce real and direct benefit to their health.[32] In general, mental capacity is not necessarily required for making valid healthcare decisions. The Convention on the Rights of Persons with Disabilities guarantees everyone the capacity to have rights as well as to exercise them.[33] Article 25 of the Convention requires medical treatment to be provided based on free and informed consent of the patient on an equal basis with others and without the interference of a substitute decision-maker.[34] In certain situations, non-consensual medical treatment is allowed in case it is carried out in accordance with the law, which is stated in article 8 in the Oviedo Convention. In an emergency,[35] any medically necessary intervention may be carried out immediately for the benefit of the patient. Patients with a serious mental disorder

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30 World Health Organization: A declaration of the promotion of patients' rights in Europe, ch 1-3.

31 Council of Europe, Explanatory Report to the Oviedo Convention, European Treaty Series No 164, 6.

32 Details of Treaty No 164: Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, summary.

33 Litins'ka, 'Assessing capacity to decide on medical treatment' (n 10) 127-128.

34 ibid 155.

35 ECtHR's assessment of what constitutes an emergency situation, see for example *V.C. v Slovakia* App no 18968/07 (ECtHR, 8 November 2011).

may be subjected to an intervention aimed at treating their mental disorder without their consent only if serious harm is likely to result to their health without the treatment in question, as laid down in article 7 in the Oviedo Convention.
The ECHR is essential for the study of informed consent and refusal in human rights law. According to the ECtHR, the Contracting States have a positive obligation to protect patients from infringement of their rights protected by the Convention in the field of medical treatment and otherwise. Thus, the Court may hold a State responsible for the breaches of the articles of the Convention even if private healthcare professionals bring about the violations.[36]
Several articles of the Convention are relevant for the topic of informed consent and refusal. Article 3 of the Convention guarantees freedom from torture and inhuman or degrading treatment or punishment and prevents the State parties from imposing such treatment. Article 8 of the Convention protects everyone's right to private life, which public authorities must not interfere with unless the interference is in accordance with law, pursues legitimate interests and is necessary in a democratic society. Article 8 also encompasses the physical integrity of a person.[37] Informed consent has been the subject of several cases examined by the ECtHR, and in most cases where the Court has found that there has been a breach in the Contracting State's obligations regarding medical treatment of patients; the Court has often concluded breaches in at least articles 3 and 8. In *Ioniţă v Romania*, the ECtHR found a violation of the procedural aspect of article 2 (right to life). The national courts had found no medical negligence even though the healthcare professionals had failed e.g. to obtain an informed written consent required for the operation from the parents of the patient in question, despite the fact that such consent was required in the national law.[38]
In the ECtHR case law, in order for a consent to be valid it has to be informed and voluntarily provided by a capable person competent to decide.[39] A parent or representative can and in some cases should consent for a minor.[40] To be able to provide an informed consent or refusal with regard to a medical intervention, the patient shall receive sufficient and truthful information about the medical intervention as well as its purposes, possible risks, prognosis, and alternative ways of dealing with the medical issue in question.[41] The healthcare professionals are expected to establish a dialogue with the patient instead of providing an extensive number of technical details.[42] The ECtHR case law has also shown that the circumstances must be optimal for the patient and they should be free from pain,

36 Litins'ka, 'Assessing capacity to decide on medical treatment' (n 10) 159-160.
37 *Konovalova v Russia* App no 37873/04 (ECtHR 16 February 2015) para 40.
38 *Ioniţă v Romania* App no 81270/12 (ECtHR, 10 January 2017) para 16.
39 Litins'ka, 'Assessing capacity to decide on medical treatment' (n 10) 28.
40 *I.G.* (n 9).
41 Litins'ka, 'Assessing capacity to decide on medical treatment' (n 10) 28.
42 ibid 239.

discomfort and psychological pressure to be able to take an informed decision regarding a medical intervention.[43]

It has been concluded in the ECtHR case law that an informed consent from the patient is needed not only for medical intervention but also for participation in clinical teaching.[44] In *Konovalova v Russia*, the applicant argued that the presence of the public (i.e. medical students) during the delivery of her child constituted an interference with her article 8 rights, and that the interference was not lawful, as she had not given written consent to it. The case law stated that Konovalova had learnt of the participation of medical students in her labour the day before the birth of her child, between two sessions of drug-induced sleep and after extreme stress and fatigue due to prolonged contractions. The Court concluded that there had been a breach of article 8, because it was unclear whether Konovalova was given any choice regarding the participation of students and whether, in the circumstances of an ongoing childbirth, she was at all capable of making an intelligible informed decision.[45]

2.2.1. Case study: the lack of informed consent and forced sterilisation of Roma women in Slovakia

In the cases of *V.C. v Slovakia*, *N.B. v Slovakia,* and *I.G. and others v Slovakia*, the ECtHR held that the Slovak government had violated articles 3 and 8 of the Convention because the three Roma applicants had been sterilised in public hospitals during or after childbirth without their informed consent. The Court held that the sterilisations of N.B., I.G. and M.K. were not a life-saving intervention, in which case the interventions could have been considered justified. Informed consent was not obtained from the applicants or their legal guardians prior to the sterilisation, which was required in national law as well as international human rights law, as shown earlier in this chapter. Other common facts in the cases are incorrect, insufficient and incomprehensible information that was disclosed to the applicants about their health and the health of their child; inquiries for their consent in circumstances that influenced the cognitive abilities of the applicants and that left no time for elaboration on the consequences of the sterilisation; the lack of consent from the parents or representatives of the minor applicants; as well as harsh social consequences of infertility that the applicants faced after the forced sterilisations. The Court also concluded that the State also failed to comply with their positive obligation under article 8 because the healthcare professionals had not provided the applicants with information about the means of protecting their reproductive health, including information on the characteristics

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43 *Konovalova* (n 35).

44 Declaration on the Promotion of Patients' Rights in Europe, para 3.9.

45 *Konovalova* (n 35) para 47.

and consequences of sterilisation and alternative methods of contraception. The circumstances under which they had been sterilised had excluded the possibility of giving full and informed consent to the procedure.[46]

V.C. had been subjected to a forced sterilisation during the delivery of her second child in a public hospital. Because the healthcare professionals told her that having one more child would be fatal either for her or the child that she was about to deliver, she told the personnel to do what they wanted to do after they requested for her consent to sterilisation. In fear of fatal consequences, she signed a note indicating that she requested sterilisation, despite the fact that she did not understand the meaning of the word. Thus, V.C. had practically no options but to consent to the sterilisation in a situation where her recognition and cognitive abilities were influenced by the ongoing labour and pain. Because of the forced sterilisation, V.C. became traumatised, ostracised by her community and divorced by her husband due to her infertility.[47]

The Court found that the approach of the healthcare personnel was not compatible with the principles of respect for human dignity and human freedom as codified in the ECHR, and that the personnel displayed gross disregard for V.C.'s right to autonomy and choice as a patient. V.C. was a mentally competent adult patient and therefore her informed consent was a prerequisite for the sterilisation. No medical emergency could justify her lack of consent. The Court pointed out that V.C. was not fully informed about her health status, the proposed procedure and the alternatives to it. As she was asked to consent to sterilisation while in labour, the circumstances did not allow her to take a decision of her free will, to consider all of the relevant issues or to reflect the implications and discuss the matter with her partner. The healthcare professionals also failed to disclose information in a manner that she would understand. As sterilisation without her full and informed consent violated V.C.'s right to respect for private and family life, the Court concluded a breach of article 8 of the Convention. The treatment she received constituted a violation of article 3 of the Convention.

In *N.B. v Slovakia*, the applicant N.B. was administered premedication prior to the caesarean section, which resulted in her feeling intoxicated. She was then presented with three pieces of paper, but she had neither the strength nor the will to ask what the documents contained. She recalled a doctor telling her that her child would die if she did not sign the papers, and a healthcare professional taking her hand to help to sign the papers. N.B. was sterilised during the caesarean section without recording the sterilisation. At the time of the sterilisation, N.B. was 17 years old, and her mother, as her legal guardian, was not asked to give her consent to the sterilisation, which was required in the Slovakian law.[48]

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46 *I.G.* (n 9).

47 *V.C. v Slovakia* App no 18968/07 (ECtHR, 8 November 2011).

48 *N.B. v Slovakia* App no 29518/10 (ECtHR, 12 September 2012).

In the case of *I.G. and others v Slovakia*, I.G. and M.K. were underage minors who were sterilised during childbirth without the consent of their legal guardians. They argued for the Court that neither they nor their parents were informed of the sterilisation prior to the procedure nor did they give a written consent to the intervention. M.K. and her parents found lout that she had been sterilised after the intervention had taken place, whereas I.G. discovered that was been sterilised three years later upon examination of her medical documents at the hospital. In its assessment, the Court took into account that learning that they had been sterilised without their or their guardians' prior informed consent left the applicants feeling debased and humiliated. As in the rest of the abovementioned cases, the Court acknowledged the applicants' experiences that the inability to bear children had led to the fall of their social status in their communities as well as relationship issues and divorce.

In the cases of *N.B. v Slovakia* and *I.G. and others v Slovakia,* the case law states numerous factors that would have justified the need for informed consent from the patients or their legal guardians and which should have been taken into account by the healthcare professionals. Analogically, the cases provide an informative overview of circumstances in which healthcare professionals must obtain an informed consent before a medical intervention. In its assessment, the Court took into account e.g. the nature of the intervention, the circumstances during the interventions at the hospital, the young age of the applicants and even the fact that they belonged to a vulnerable population group. Therefore, it is possible to conclude that for example when the nature of the intervention is likely irreversible and has profound social consequences, it is uncertain whether the patient is in the very circumstances capable and truly able to consider the consequences of the intervention. When the patient is a minor, the healthcare professionals should exercise additional caution in assessing whether or not the patient has given their consent and whether or not the consent can truly be considered informed. A realistic possibility to give their informed consent or refusal should be granted to anyone despite ethnicity, but as shown in the cases of the Roma women, the information should be presented in a manner, which is comprehensible for the patient in question, and the socio-cultural consequences should have been considered before the medical procedures. Accordingly, the Court concluded that the obligations of the healthcare professionals are not fulfilled by merely obtaining a consent, but the consent has to be thoroughly considered and the impacts of the intervention need to be assessed from the viewpoint of the patient and their personal and social circumstances as a whole.

3. Voluntary consent and refusal in human rights law

Voluntary consent of the patient is essential and must be respected at all times. Not only is the concept of voluntary consent a well-established rule at the European level but it has also been widely recognised at international level.[49] As stated in article 5 of the Oviedo Convention, an intervention can only be carried out once the patient concerned has given voluntary and informed consent to it. The concept of voluntary consent can be explained in a rather simple way; it refers to the autonomy of the patient in their relations with healthcare professionals. The interests and welfare of the patient must prevail over the sole interest of society or science,[50] keeping in mind there are some limitations to this rule. Parties to the Oviedo Convention must protect the dignity and identity of the patients and guarantee respect for their integrity as well as other rights and freedoms with regard to the application of medicine and biology.[51]

In order to determine whether consent is considered voluntary, first the patient must have the freedom to give or to refuse their consent to any intervention.[52] Intervention in this regard refers to all medical procedures, such as preventive care, diagnosis, treatment, rehabilitation or research.[53] Second, voluntary consent must be obtained without any kind of influence, duress or coercion.[54] Third, the patient concerned has generally the right to withdraw their consent freely at any time once fully informed of the consequences of such decision.[55]

3.1. Freedom to decide

Valid consent derives its nature from the principle of autonomy, also known as self-determination, which in turn forms the core of medical ethics.[56] In medical law, autonomy refers to the freedom of action by a patient on a self-decided plan and guarantees the right of a patient to make personal decisions.[57] The ECtHR has pointed out that the patient is the principal party in the decision-making process and their voluntary consent must remain at its heart – even where the patient

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49 Council of Europe, Explanatory Report to the Oviedo Convention, European Treaty Series No 164, 6.

50 Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (adopted 4 April 1997, entered into force 1 December 1999) (Oviedo Convention) Art 2.

51 Oviedo Convention Art 1.

52 Council of Europe, Explanatory Report to the Oviedo Convention, European Treaty Series No 164, 6.

53 ibid.

54 ibid.

55 Council of Europe, Conference Publication (Minsk, 8 December 2017) 29.

56 ibid 27.

57 ibid 27.

is unable to express their wishes.[58] Instead of being only an expression of will, a process allows the patient to make a free choice regarding the planned medical intervention.[59] Voluntary consent can be either expressed or implied and can be given either verbally or in a written form. Expressed specific consent has to be obtained in certain cases, for example when participating in research or removal of body parts for transplantation purposes.[60]

3.2. Refusal of a treatment

One of the greatest dilemmas healthcare professionals have to deal with occurs when a patient refuses a recommended medical treatment, especially when the treatment is considered by the healthcare professionals to be necessary in order to sustain life and health.[61] When a patient decides to refuse a recommended medical intervention, respect for the patient and their rights must be guaranteed and protected at all times. Furthermore, the ECtHR has recognised the individual's right to refuse any treatment, which could prolong their life.[62] Patients or their legal guardians do reserve the right to make decisions about their care, even if the decision is contrary to medical advice.[63] For example, in *Glass v United Kingdom* the Court ruled that a doctor's decision to treat a severely disabled child contrary to parent's expressed wishes and without the opportunity for judicial review violated article 8 of the ECHR.[64]Patient's refusal to a treatment is normally expressed in written form but this is not a requirement. What is required is that the doctor or healthcare personnel is obliged to fully explain in detail all possible consequences of the patient's refusal.[65]

3.3. Issue of abuse

In general, voluntary consent is always required and a patient cannot be forced to undergo a medical intervention against their own will. A compulsory medical

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58 *Lambert and Others v France* App no 46043/14 (ECtHR, 25 June 2015) para 178.

59 Text in (n 53) 7.

60 Council of Europe, Explanatory Report to the Oviedo Convention, European Treaty Series No 164, 6.

61 Stephanie Cooper, 'Taking No for an Answer: Refusal of Life-Sustaining Treatment' (2010) Virtual Mentor.

62 *Lambert* (n 56) para 180; *Pretty v The United Kingdom* App no 2346/02 (ECtHR, 29 April 2002) para 63.

63 Terri D'Arrigo, 'Look for reasons if patients refuse advice' (2014) Patient Communication < https://acpinternist.org/archives/2014/02/informed-refusal.htm> accessed 13 March 2021.

64 Council of Europe, 'Guide on Article 8 of the European Convention on Human Rights' (2020) 30.

65 Council of Europe, Conference Publication (Minsk, 8 December 2017) 30.

intervention, even if it is of minor nature or importance, is considered as an interference with the right to respect for private life.[66] Furthermore, forced examination of a patient amounts to an interference with the right to respect for private life as guaranteed in article 8(1) of the ECHR.[67] Although forced medical interventions constitute a breach of human rights, there are cases in which such interference can be justified. Such interference violates the rights of the patient unless it is in accordance with the law, pursues a legitimate aim under article 8(2) of the ECHR and is deemed necessary in a democratic society in order to achieve the aim in question.[68] Thus, it is the role of the Court to decide whether such interference is proportional to the legitimate aims pursued. In *Juhnke v Turkey*, the Court found that a gynaecological examination imposed on a patient without her voluntary consent violated article 8 of the ECHR as such an examination was not in accordance with domestic law or deemed necessary in a democratic society.[69] In a similar case, *Y.F. v Turkey*, the Court ruled that a forced gynaecological examination on a detainee against her voluntary consent did violate article 8 of the ECHR, as there were no grounds, no medical necessity nor any circumstances defined by law for such an interference to be justified.[70] Furthermore, as the Court found that the interference was not in accordance with law, there were no reasons to examine whether the interference in question pursued a legitimate aim or was necessary in a democratic society.[71]

3.4. Issue of undue influence

The concept of voluntary consent assumes that the patient should not be subjected to any kind of unreasonable influence or pressure.[72] For example, even the slightest pressure to a patient in a vulnerable position can be considered as if the patient had been forced into giving consent against their own free will.[73] When there is a trusting relationship between the patient and the healthcare professional asking for the consent, pressure can also be a factor in such situations. This can easily happen when the healthcare professional performing the tests is the same person requesting the patient's consent.[74] Once a patient has given their consent to a certain test to be performed, the patient might feel pressured to stick with

66 *X v Austria* App no 8278/78 (Commission Decision, 13 December 1979) para 3.
67 *Matter v Slovakia* App no 31534/96 (ECtHR, 5 July 1999) para 64; *Salvetti v Italy* App no 42197/98 (ECtHR, 9 July 2002).
68 ibid.
69 *Juhnke v Turkey* App no 52515/99 (ECtHR, 13 August 2008) paras 80-82.
70 *Y.F. v Turkey* App no 24209/94 (ECtHR, 22 October 2003) paras 41-43.
71 *Y.F.* (n 71) para 44.
72 Council of Europe, Conference Publication (Minsk, 8 December 2017) 7.
73 ibid.
74 ibid.

the given consent for possible additional tests if these are conducted by the same healthcare professional. In case there is a need for further examinations or tests, the patient ought to be given a chance to express their consent to these additional interventions. Otherwise, such practice could be seen as a violation of the patient's rights.

3.5. Withdrawal of consent

Article 5 of the Oviedo Convention also stipulates that the patient have the right to withdraw their consent freely at any given time. Professional standards, obligations and rules of conduct applied in these kinds of cases may oblige the doctor or healthcare professionals to continue with a particular treatment or test in order to avoid serious endangerment to the health of the patient.[75] This can raise an issue especially in situations in which the intervention by healthcare professionals has already begun and it is impossible to stop or reverse the effects, and doing so would put the life or health of the patient in danger.[76] Thus, in some situations the doctor or healthcare professionals may be obliged to continue with the intervention regardless of the patient's withdrawal of consent.

3.5.1. Voluntary withdrawal from medical research

The concept of voluntary withdrawal from medical research or studies is rather recent and has not yet been mentioned in many reports related to the field.[77] The concept emphasises the individual's consent being voluntary without any kind of coercion, influence or pressure from the researcher or on their behalf.[78] In other words, everything is based on the patient's voluntary and own choice to participate in the medical research. In case an individual has agreed to be a research subject, they must be provided with the opportunity to exercise their free power of choice to withdraw from the medical research.[79] In order to protect a research subject from exploitation, they are under no obligation to participate in an experiment or medical research if they decide not to participate and are free to withdraw their consent at any time.[80]

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75 ibid 29.
76 ibid 7.
77 Fida K. Dankar et al, 'Informed Consent in Biomedical Research' (2019) Computational and Structural Biotechnology Journal, vol 17 467.
78 ibid.
79 ibid 464-465.
80 ibid 465.

3.6. Voluntary consent from a human rights perspective

From a human rights approach, the lack of properly obtained voluntary consent can become a crucial element when determining whether a particular case demonstrates evidence of violations of human rights treaties.[81] If medical assistance or intervention is provided within the principle of legality and the framework of a certain law that is in line with the requirements of international human rights treaties and is carried out for the purposes of protecting health, it is the task of the court to ensure that such assistance or intervention was medically necessary and thus respecting the rights of the patient.[82] When courts are asked to give decisions on matters regarding voluntary consent, not only do they rely on domestic law but also emphasise international standards as well as regional human rights legislation. Under the EU law, the requirement of voluntary consent is a fundamental principle aimed at ensuring respect for the right to personal integrity.[83] This is guaranteed in article 3(1) of the Charter of Fundamental Rights of the EU stating that everyone has the right to respect for their physical and mental integrity. According to article 3(2)(a) of the Charter, in the fields of medicine and biology, the free consent of the patient must be respected in particular. Furthermore, the most common articles of the ECHR that are related to legal disputes about voluntary consent are article 3 of the ECHR on prohibiting torture and inhuman or degrading treatment or punishment and article 8 of the ECHR on the right to respect for private and family life. When determining whether consent has been given voluntarily, one has to take into account the interests of the patient. In *Gard and Others v The United Kingdom*, the legal issue concerned whether the hospital had blocked life-sustaining treatment against expressed parental decision. The Court decided that the withdrawal of treatment from a terminally ill infant against the wishes of his parents did not violate article 8 of the ECHR as there would have been a significant harm to the child and thus to his best interests had the treatment been carried out.[84] Significant about this case is the fact that several consultations with healthcare professionals were conducted regarding the intervention and that the legal framework was considered appropriate, unlike in *Glass v United Kingdom* as seen above. In *Bataliny v Russia*, a patient at a psychiatric hospital was used as a test subject for a new drug solely for the interests of medical research instead of taking into account the interests of the patient. The ECtHR ruled that it is unacceptable to conduct such research without the voluntary consent of the patient, and stated that the treatment of the

81 Council of Europe, Conference Publication (Minsk, 8 December 2017) 11.
82 ibid 13.
83 ibid 10.
84 *Gard and Others v The United Kingdom* App no 39793/17 (ECtHR, 27 June 2017) paras 109-124.

patient was deemed inhuman and degrading, thus violating article 3 of the ECHR.[85]

3.7. Limitations to the principle of voluntary consent

Although the principle of voluntary consent constitutes a general rule, there are situations in which this rule may be subject to certain limitations.[86] As expressed in article 8(2) of the ECHR, the limitations must be in accordance with applicable law, serve a legitimate purpose and be necessary in a democratic society especially in the interests for the protection of the health of others. In addition, article 8 of the Oviedo Convention provides an exception to the general rule and states that if in case of an emergency the appropriate consent cannot be obtained, medically necessary interventions can be carried out immediately.

3.7.1. Limitations to the general rule

There are situations in which the Court has ruled that relatively minor medical tests of compulsory nature can be proportionate and as such, the interference does not violate article 8 of the ECHR even without voluntary consent of the patient.[87] As stated in *Solomakhin v Ukraine* on compulsory vaccinations, the Court ruled that the interference with a patient's physical integrity can be justified by the public health considerations and be necessary in order to control the spreading of infectious diseases.[88] In the case of *Boffa and Others v San Marino*, the proportionality of the pursued aim was questioned, and the Court reasoned that a large-scale vaccination campaign obliges individuals to put the general interest of the society above personal interests as long as their own life is not in danger.[89] In both of the above-mentioned cases, the balance was determined between the patient's personal integrity and the public interest of protecting health of the whole population, and thus the Court found no violations of article 8 of the ECHR. In *Acmanne and Others v Belgium*, the Court had to establish whether Belgian domestic law requiring children to undergo X-ray examinations in order to prevent tuberculosis was in breach of article 8 of the ECHR. The Court ruled that the domestic law did not breach article 8, as the article does not provide an unlimited right for an individual to do with one's body as they please and the intervention was conducted in the interests for the protection of the society.[90]

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85 *Bataliny v Russia* App no 10060/07 (ECtHR, 23 July 2015) paras 110-113.
86 Council of Europe, Conference Publication (Minsk, 8 December 2017) 30.
87 Council of Europe, 'Guide on Article 8 of the European Convention on Human Rights' (2020) 29.
88 *Solomakhin v Ukraine* App no 24429/03 (ECtHR, 24 September 2012) para 36.
89 *Boffa and 13 Others v San Marino* App no 26536/95 (Commission Decision, 15 January 1998).
90 Council of Europe, Conference Publication (Minsk, 8 December 2017) 31.

3.7.2. Emergency situations

If the patient is not able to express their voluntary consent in case of an emergency, article 8 of the Oviedo Convention states that any medically necessary intervention can be carried out immediately (without obtaining consent) for the benefit of the health of the patient. In such situations, the doctor or healthcare professional has to make the decision and act in the interests of the patient.[91] In emergencies, previously expressed wishes of the patient must be taken into account as provided in article 9 of the Oviedo Convention. For example, even if a patient is in a coma or has been in an accident, the healthcare professionals are obliged to make every reasonable effort to determine what the patient would want or what they have previously expressed.[92] Despite this, previously expressed wishes can be ignored for example in such cases if the wishes were expressed a long time ago before the intervention and medical practices as well as science have since progressed.[93] Let us assume a patient has foreseen that they might not be able to give their voluntary consent, for example in the event of dementia or Alzheimer's disease, and thus has expressed their wishes previously, the practitioner should in general be satisfied with the wishes of the patient and apply them in the present situation.[94] What makes these kinds of situations problematic is the fact that the medical field has probably evolved drastically since expressing the wishes, and thus there might be an innovative treatment available, which had not been discovered at the time of expressing the wishes. Although the patient has the last word, this could be an example of a situation where the practitioner possibly would have to determine what would be the best solution for the patient. Of course, there is no clear-cut answer and like in all medical cases, a balance between the patient's interests and respect of the patient's human rights always has to be ascertained.

4. Competent consent or refusal

The question about consent also heavily relies on the competence of the person. The principles of free and informed consent presuppose a competent patient, who has the mental means to comprehend the information. In many circumstances, the patient concerned is not able to understand the severity of a situation,

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91 Council of Europe, Explanatory Report to the Oviedo Convention, European Treaty Series No 164, 9.
92 ibid 10.
93 ibid 11.
94 ibid.

and or has no understanding of the world. This state of mind can be either momentary or innate. The following exclusively focuses on treatment, and not euthanasia.

4.1. General provisions

Questions and rights regarding a patient's competence are regulated in several international human rights charters. These include the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights (ICESCR), the CRPD and the United Nations Convention on the Rights of the Child (CRC). The European legislation mainly consists of the Oviedo Convention and the ECHR.
From a European and Nordic perspective, the focus will be on the European conventions and the CRPD. These are highly relevant, and the most detailed framework in regards of medical competence. Concerning children's right to consent, the CRC is of great importance.

4.2. Definition of a competent patient

As discussed earlier, free and informed consent is an established human right. However, for this rule to apply, the patient must be capable of giving such a consent. It is already presumed in the rules of consent and mentioned in the different conventions. In order to understand when a patient has the right to consent, it is important to have a full overview on the main legal traits of personal competence.
This part will focus on competent adult patients. Specific questions regarding children will be discussed in chapter 4.5.
There is no explicit definition of a competent patient in the three conventions. Article 6 of the Oviedo Convention only mentions the protection of persons not able to consent. The ECHR mentions nothing regarding this issue, and this is because the law on medical consent is interpreted within the general human rights articles. The reason why the state of a non-competent patient has not been described thoroughly can be explained in two ways: the definition of a person with disabilities or a person not able to consent is a highly controversial topic. It is subject to social and cultural development, which is the reason this term is in constant change.[95] At the same time, competence is to be defined by national law.[96]

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[95] Litins'ka, 'Assessing capacity to decide on medical treatment' (n 10) 118.
[96] Art 6(3) of the Oviedo Convention.

However, the Oviedo Convention mentions reasons as to why a patient might not be able to consent.[97] It is stated that the cause must be a "mental disability, a disease or for similar reasons". A mental disability would be defined in national law, as mentioned above. The CRPD attempts to define a disability in a rather broad and vague manner.[98] For the sake of European and global legal harmonisation, it would be ideal for national legislators to use international classification standards when determining mental disabilities in a legal context. The same would apply for diseases, while 'similar reasons' is supposed to cover all circumstances which originally do not qualify within the first categories, but after an assessment still is eligible to this rule.[99]

The questions remain if national legislators are bound to certain guidelines when determining which dysfunctions, diseases, or characteristics are sufficient for a patient to be deprived of their self-determination.

For Nordic legislators, case law from the ECtHR is of high relevance. In the case of *Arskaya v Ukraine*, the Court discussed the patient's competence to consent in relation to article 2 – right of life in the ECHR. The patient had died during a medical malpractice and one of the questions was whether the healthcare professionals had conducted the appropriate measures to determine the patient's competence. The Court stated, "As noted above, despite S. showing symptoms of a mental disorder, the doctors took those refusals at face value without putting in question S.'s capacity to take rational decisions concerning his treatment. […] From the standpoint of article 2 of the Convention a clear stance on this issue was necessary at that time in order to remove the risk that the patient had made his decision without a full understanding of what was involved." [100]

The Court refers to the patient's ability to make a rational decision, who can fully understand his medical condition. This can be understood as an underlining of the criteria stated in the Oviedo Convention. At the same time, it also narrows down the understanding of these. There are different stages and complexities to a mental disability. A person with mental disabilities under protection can be fully able to understand the reality and the gravity of the medical procedure. Therefore, decision-making capacity is a constant concept and applies in all circumstances.

This understanding has been underlined in Recommendation on Principles Concerning the Legal Protection of Incapable Adults.[101] The Recommendation goes into detail about the rights of people with disabilities. The recommendation is

97 ibid.

98 Art 1(2) of the CRPD.

99 Council of Europe, Explanatory Report to the Oviedo Convention, European Treaty Series No 164, para 43.

100 *Arskaya v Ukraine* App no 45076/05 (ECtHR, 5 December 2013) paras 87-88.

101 Council of Europe Committee of Ministers, Recommendation No R (99) 4.

soft law; hence, the Member States are not obligated to follow it directly. However, the Court has referred to the Recommendation in its case law, for instance in *Shtukaturov v Russia*. This illustrates the significance of the document and makes the definition of decision-making capacity accessible and available for national legislators.

According to the Recommendation Principle 1 – Scope of application, an incapable adult is defined as "by reason of an impairment or insufficiency of their personal faculties, are incapable of making, in an autonomous way, decisions concerning any or all of their personal or economic affairs, or understanding, expressing or acting upon such decisions, and who consequently cannot protect their interests."

It is also specified in Principle 22 – consent that if a person under protection is capable of giving a free and informed consent, this must be attained before a medical procedure. This must be understood in light of Principle 3 – maximum preservation of capacity, where it is recognised that there are different levels to capacity. The level of competence may change from time to time.

Being under protection, which means that the person has been removed of their legal capacity, is not enough to define the lack of rational decision-making competence. According to the Recommendation, a measure of protection does not automatically deprive the patient of abilities to consent to or refuse from a medical intervention. [102] The same understanding has been reflected by the Committee of CRPD and ECtHR (the Court held that a legal incapable person could still be able to form an understanding of their situation and circumstances). [103][104]

Case law from the ECtHR and other soft law uphold that every case and every patient must undergo an individual assessment. It is not enough for courts or healthcare professionals to determine a person's capacity exclusively on their mental disability or illness. Their level of understanding must be examined. This means that there is no objective understanding of what capacity is; there are only guidelines in determining when a person's decisions are based on a rational thought-process.

There is naturally a connection between a free consent and a competent consent. A patient may refuse treatment even if it is strongly recommended. The refusal should not automatically be viewed as the patient not being able to make rational decisions. Indeed, an individual assessment should be made. If the patient seems to take their decisions on a rational basis, but the outcome is object to mixed opinions, they are considered capable. Controversial opinions are not eligible for

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102 Council of Europe Committee of Ministers, Recommendation No R (99) 4, principle 22.

103 General Comment No 1 (2014), Committee on the Rights of Persons with Disabilities, para 8, 29f, 41.

104 *Shtukaturov v Russia* App no 44009/05 (27 March 2008); *Stanev v Bulgaria* App no 36760/06 (17 January 2012); *A.N. v Lithuania* App no 17280/08 (31 May 2016).

incapability, as demonstrated in the case of *Jehovah's witnesses of Moscow v Russia*. However, if a patient has a history of hallucinations and a wrong understanding of the reality, their opinion may be understood as being non-rational in this sense. The concept of individual assessment of rational decision-making capacity applies to not only mental disabilities, but also illnesses and similar circumstances[105]. Although the mentioned case law and documents regard mental disabilities, it would lead to technical difficulties and contradictions if the rules were not the same in deciding a patient´s capacity. An example of a disease where an individual assessment could be relevant is if the patient is in a temporary vegetative state or has suffered brain damage. Many somatic diseases have an impact on the mental abilities; thus, the outcome of such conditions intertwine with each other.

One specific question that could fall under the scope of 'similar reasons' is if the patient is under the influence of alcohol. It also raises the question if the mental disability or the patient not making rational decisions are object to certain time perspectives. The conventions do not give any advice on the matter, and it is indeed reliant on an individual assessment of the patient. However, a momentary 'incapability' cannot be enough for the patient to be declared incapable. The crucial part is whether the patient can make a decision at the time of treatment. If the intoxicated person needs treatment, it will rather fall under the scope of lawful non-consented treatment. If the intoxication is recurring, then it might be classified as a mental disability. Regardless, an individual examination would be necessary.

The findings above show that the mere classification and diagnosis of impairment is not decisive of a patient's decision-making capacity. Healthcare professionals must perform an individual assessment of the patient in question and decide their capacity case by case.

The results of an individual assessment must not be dichotomous; there is a spectrum between capacity and incapacity. The healthcare professionals must determine to what extent the person is able to understand the situation and include the patient in the decision-making accordingly.[106] These principles are mentioned in the case of *A.N. v Lithuania*.[107]

4.3. Requirements of an individual assessment

In the medical field, four standards are recognised in assessing a patient´s competence. First, the patient must be able to understand the information given. Second, the patient must retain the information. Third, the patient must be able to

105 Art 6(3) of the Oviedo Convention.
106 ibid.
107 *A.N.* (n 102) para 124.

weigh and reason the information. Lastly, the patient must make a voluntary decision. These are not legal requirements, but helpful guidelines for the assessment. [108]

The concept of informed consent is also a guideline for determining whether the individual assessment indeed was satisfactory. For a person to have a full understanding of the circumstances, the patient must be informed in a way, which is tailored for them.

The principle of maximum preservation of legal capacity shows that the information provided must have an actual outreach to the person.[109] A patient with hearing disabilities must be informed in sign language, and a patient with cognitive challenges might need explanations though pictures and videos. The presence of informed consent can be seen throughout in CRPD, for instance in article 9 about accessibility and article 12 about freedom of expression. They may not refer to medical consent but show a pattern throughout the convention. The information must be accessible for the patient. In the case of *Arskaya v Ukraine*, the Court explains that regardless of the patient's mental disorder, sufficient information was not provided. The patient had a wrong understanding of his health, and healthcare professionals did not correct him.[110]

During the assessment, a patient's previously expressed consent should be considered, even if they at the time of medical treatment are considered incapable. This is enshrined in article 9 in the Oviedo Convention. This relates to the concept of relative capability; there are different degrees of dysfunctions. The article does not specify how far healthcare professionals must go to attain information about the patient´s will, but a minimum requirement could be to ask relatives or a proxy. For further elaboration, please see the discussion in chapter 3.7.2.

There may be different approaches to how the assessment may be performed, and by whom. The general rule is to establish a right understanding of the patient's decision-making capacity. For diseases and disabilities, a medical doctor or a psychiatrist would be the most suitable assessors. Since the goal is to have, a professional to assess the patient, one could think of the scenario of nurses or other qualified healthcare professionals performing the assessment. This can only be accepted if the professional has the expertise to make such decisions and is in line with the general provisions laid down in this chapter. It would also be beneficial if the doctor has observed and treated the patient for a while, as it would result in a more correct assessment.

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108 Priscilla Alderson, 'Competent children? Minors' consent to healthcare treatment and research' (2007) vol 65/11 Social Science & Medicine 2272.

109 Council of Europe Committee of Ministers, Recommendation No R (99) 4, principle 3.

110 *Arskaya* (n 98) para 89.

4.4. The use of proxies in medical treatment

According to the Oviedo Convention, a proxy can consent to medical treatment if the patient suffers from an impairment.[111] A proxy may be the representative of the patient or any other authority by national law. As observed in the report, legal incapacity does not deprive the patient of the right to consent to medical treatment. The use of a proxy would therefore only be necessary if the patient is deemed incapable of making a decision after an individual assessment. Concerning decision-making, the patient must be included according to their level of their understanding.

Following the conventions as well as ECtHR case law, the general rules of free and informed consent also apply mutatis mutandis to proxies and legal representatives.

Since the patient's wishes and desires before they became incapable must be considered according to the Oviedo Convention article 9 as mentioned in chapter 4.3, certain obligations may be reflected upon proxies. The proxies must take all decisions in the interest of the patient. Having personal knowledge of the patient also means having to consider what they might have wanted. This also means that healthcare professionals may consult the proxy about the patient's personal life, as well as the patient themselves, to determine their capability.

4.5. Children's consent

According to the Oviedo Convention, a child's incapability is determined in domestic law. [112] This differs within the Contracting States and varies from the age of 14-18. Article 1 of the CRC expresses that a child is anyone under the age of 18. The Convention has not specified anything regarding medical capability, so it is left upon Member States to determine.

A child is always represented by a proxy in a legal context. The proxy is normally the child's parents. It could also be another representative by law, usually a foster parent or the child welfare pedagogue.[113]

There are four recognised levels of decision-making for children.[114] These consist of the rights to be informed, to express an informed view, the expressed view being taken into account, and lastly being the main decider. The CRC openly recognises the three first levels.[115] Accordingly, the Convention does not directly recognise a child's right to be the main decider. However, the Committee on the

111 Art 6(3) of the Oviedo Convention.
112 Art 6(2) of the Oviedo Convention.
113 Art 3(2) of the Oviedo Convention; art 5 of the CRC.
114 Alderson (n 106).
115 Arts 12 and 13 of the CRC.

Rights of the Child has upheld that consent from adolescents must be obtained, regardless if the parents must give consent or not.[116] National legislation may give children the right to be the main decider from a certain age, especially adolescents.

The child's opinion must be heard in proportion to their age and maturity.[117] This also relates to informed consent, where the child must be explained the circumstances in a way that is understandable to them. This differs depending on their age. The parents' understanding of their child's maturity may be important. It lies in the nature of the case that parents often have more insight in their child's cognitive level. Regardless, healthcare professionals should have a separate conversation with the child to determine their rational decision-making capacity.

Paediatricians may use pictures, leaflets and cartoons to explain the medical procedure in line with the principles of informed consent.[118]

The best interest of the child must be the primary condition.[119] When parents and healthcare professionals are deciding on a medical procedure, it must be for the sole benefit of the child. The child's right to be heard may collide with the best interest of the child. A younger child may express a certain maturity and understanding, but still refuse the treatment for different reasons. Some might be scared, which would usually be the case for younger children. The reason for refusal must be uncovered in order to determine whether the child is expressing themselves with a rational mind. The older and/or mature a child is, the more their refusal would be acceptable.

Children with disabilities have been mentioned in the three conventions.[120] It is upheld that State Parties meet their needs. It also relates to the definition of capability in chapter 4.2, where an individual assessment is made to determine the patient's competence. The same would apply to children with disabilities, when a more thorough examination may take place because children are constantly changing and developing, which makes it difficult to determine how the disability affects the child's rational thinking.

4.6. Non-consented medical treatment

In certain circumstances, a medical intervention without consent may be performed without breaching international law. These include but are not limited to emergency treatments, as explained in chapter 3.7.2. An unlawful treatment is considered torture in the CRPD; however, it is not clear whether it would qualify

116 General Comment No 20, Committee on the Rights of the Child, para 39.
117 Art 6(3) of the Oviedo Convention; art 12 of the CRC.
118 Alderson (n 106).
119 Art 3 of the CRC.
120 Art 23 of the CRC; art 6 of the Oviedo Convention; art 7 of the CRPD.

as torture under the ECHR.[121] Regardless, non-consented treatments must be avoided for the sake of human integrity.

[121] Litins'ka, 'Assessing capacity to decide on medical treatment' (n 10) 115.

Chapter II:
Report from Denmark

1. Legal regulation of patient's status

1.1. What are the legislative acts that regulate the issues of patients' decision-making in your country?

Many different legislative acts regulate the patients' decision-making in Denmark, but the Health Act[1] is the main one. The previous patient's legal status Act[2] is now a part of chapter 3 in the Health Act, which regulates the patients' rights. In connection to the preparation of the Health Act,[3] the Minister of Health stated the significance of one main health act. He states that the purpose of one main act is to create transparency and an overview of the rules for the sake of citizens, authorities, and society as whole. Because of the health sector playing a major economic and political role in Denmark, the Danish parliament finds it necessary to make frequent legislative changes.[4]
The healthcare system in Denmark is characterised by the professional activity of health workers. The public healthcare system is free for patients and financed through tax, which can explain why Denmark has some of the world's highest tax rates. The basis of the healthcare system is regulated in the Health Act, but future regulatory issues of the healthcare system are not suitable to be determined in a political forum such as the Danish parliament, but rather left to the Minister of Health. The Danish Agency for Patient Safety and the Danish Health and Medicines Authority have professional expertise in the field of health. They issue instructions and guidelines to the healthcare workers. Some guidelines have a medical purpose and are often issued with reference to the Authorization Act's provision on care and conscientiousness[5] which is a law contributing to the understanding of the health workers rights.

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1 Sundhedsloven (Health Act) Ministerial Order No 903 of 26 August 2019.
2 Lov om patienters retsstilling (Patient's Legal Status Act) 1997/2 LSF 15.
3 Folketings Tidende 2004-05, tillæg A, 3148.
4 Mette Hartlev, Ulla Hybel, Peter Bak Mortensen: *Sundhed og Jura – Sundhedsretlige perspektiver på sundhedsvæsen, sundhedspersoner og patientrettigheder, published by Jurist- og Økonomforbundets Forla*g (2nd edn, 2017) 44.
5 Autorisationsloven (Authorization Act) Ministerial Order No 731 of 8 July 2019.

Some guidelines are related to the health workers, but others are more closely related to patients' legal rights. An example is the guidance on information and consent and on the disclosure of health information.[6]

Although this document has the character of guidance and is less valuable than the Health Act as a legal source value, it still has an important legal source value, because this guidance largely reproduces the comments within the law proposal of the law on the legal status of patients.[7] As previously mentioned, the law on the legal status of patient's is now a part of the Health Act from 2019, which explains why this guidance still has a legal source value.

In summary, it can be said that the guidelines are often a starting point for the Danish Health and Medicines Authority and the Danish Agency for Patient Safety's perception of what it takes to comply with section 17 of the Authorization Act on care and conscientiousness.

In practice, the health worker proposes a treatment to the patient and goes ahead if the patient agrees to accept the treatment. If the public health worker starts a treatment, in Danish administrative law, this is seen as an administrative decision. This type of decision is made in connection with the public sector's services and is thus not subject to the Public Administrative Act's[8] requirements for legal decisions. However, some types of decisions within the healthcare system are considered so intrusive in the patient's life that the decision must be characterised as a legal activity and the protection principles of the Public Administration Act are applied. This applies, among other things, to decisions on the use of coercion, etc., which will be discussed later on.

In Denmark, there is not much of a difference between the patient's decision-making related to treatment in the private or the public sector. It can be said that the general principles in the Authorization Act of care and conscientiousness and the Health Act are legal sources, which applies in both the private and public sector. The only difference in Denmark is that, in the private sector treatments are not free, whereas they are free in the public sector.

Besides the mentioned legislative acts, guidelines and administrative decisions, as a precedent, the decisions from the Danish courts can have legal source value. In Danish law, the courts are only rarely used in conflicts regarding a patient's health decisions.[9] This can be explained by the fact that the health system in Denmark is an administrative system that decides whether patients' rights have been fulfilled or whether there is a basis for financial compensation. These administrative

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6 Vejledning om information og samtykke og om videregivelse af helbredsoplysninger (Guidance on information and consent and on the disclosure of health information) 9 guideline no 161 of 16 September 1998.

7 The Patient's Legal Status Act (n 2).

8 Forvaltningsloven (Public Administrative Act) Ministerial Order No 433 of 22 April 2014.

9 Hartlev et al (n 4) 44.

decisions are important in the understanding of patients' rights of decision-making.

1.2. What international human rights instruments have a significant influence on the status of a patient in your country? Why did the influence of these instruments (or norms) become significant in your legal system?

Historically the health law has emerged in close interaction with human rights. See for example article 8 of the ECHR regarding the right to a private and healthy life.[10] Therefore, it is not surprising that international sources of health law become significant in the Danish legal system as human rights become universal. There are different types of international rules. Some are binding on the participating States, while others are of a more indicative nature. Both the organisation and the standard of healthcare in the different countries can be very different. Therefore, even though several international sets of rules have been formulated, it has been difficult to gather many people to establish binding international rules and regulations for the healthcare system. Today, it is becoming more common for patients to seek healthcare in other countries, especially in the EU. Therefore, in recent years there has been an increasing need to establish universal standards and agreements across borders in the EU and internationally.[11]

Regarding the binding documents relevant to healthcare must the ECHR[12] be mentioned, which by law in 1992 was incorporated as part of Danish law. The convention contained provisions on the right to private life and the right to family life. Citizens from Denmark and other European countries that are a part of the ECHR can lodge a complaint against Denmark for human rights violations with the European Court of Human Rights (ECtHR).[13]

The first international agreement on patients' rights, which is generally binding at the international level, is the Council of Europe's Convention for the Protection of Human Rights (Bioethics Convention).[14] Denmark ratified the convention in 1999. This convention has not been incorporated into Danish law as is the case with the ECHR, but the ratification of the convention entails an obligation for the State to ensure that Danish legislation and administrative practice do not contravene the provisions of the convention. It follows from the Convention on Bioethics article 28 that the ECtHR has the power to issue advisory opinions on the interpretation of the Convention.

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10 Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR).

11 Hartlev et al (n 1).

12 ECHR (n 10).

13 ibid, Protocol no 16.

14 Convention for the protection of Human Rights and Dignity of the Human Being regarding the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Convention on Human Rights and Biomedicine).

Several UN conventions also play an important role in patient's rights. The UN Convention on Economic, Social and Cultural Rights[15] protects, among other things, the right to a healthy life. Both the Convention on the Rights of the Child[16] and the Convention on the Rights of Women[17] contain provisions that affect children's rights as patients and women's right to a healthy life, including reproductive rights. Finally, the UN Convention on the Rights of Persons with Disabilities[18] also has a say in health law. These conventions combine human law and health, but they will not be analysed into further detail.
Besides the international conventions, there are a lot of international recommendations, declarations, guidelines etc. in health law. These are often referred to as soft law, understanding in the sense that they have a guiding character and as such have a certain significance in the definition and application of national health law.[19] These will not be mentioned into further detail in this article.

1.3. What is the legal status of a patient in relation to their decision-making?

1.3.1. Do patients have justiciable rights?

It is a fundamental principle in human rights law that the individual has the personal freedom and right to make decisions regarding their own life. This also applies in health law, where the patient's right to self-determination is protected through the requirement for informed consent in connection with professional health treatment. The right to self-determination applies to any interaction between patients and the health service. However, the scope and regulation of the right to self-determination may differ depending on the type of treatment. Health treatments involve the patient's body and will often involve interventions in relation to the body in the form of examinations, operations, and medical treatments. Many of these interventions could constitute violations in the Danish Criminal Code[20] if they were performed in a context other than healthcare and outside the healthcare system. However, it is important to mention that if a patient agrees to a treatment, it cannot be against the Criminal Code. If the treatment is performed without the patient's consent, it is not considered a criminal offence.

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15 International Covenant on Economic, Social and Cultural Rights (ICESCR).
16 Convention on the Rights of the Child (CRC).
17 Convention on the Elimination of All Forms of Discrimination against Women, New York, 18 December 1979.
18 Convention on the Rights of Persons with Disabilities (CRPD).
19 Hartlev et al (n 4) 47.
20 Staffeloven (Criminal Code) Ministerial Order No 976 of 17 September 2019.

1.3.2. What legal remedies are available to patients in your legal system if the violation of the regulation on patient's self-determination (consent) takes place?

The Health Act's provisions on informed consent give patients a legal claim as a basis for taking a position on initiating or continuing treatment. Health workers have a duty to provide guidance on appeal options if the patient so requests. This applies in any case to health workers who are employed by public administrative authorities, cf section 7 subsection 1 of the Public Administration Act.[21] The Complaints and Compensation Act[22] gives the patient that wishes to complain about the treatment-taking place without consent, the opportunity to choose between two public authorities as the appeal body: the Danish Agency for Patient Safety and the Health Service's Disciplinary Board.

Competencies of the Agency for Patient Safety and the Health Service's Disciplinary Board regarding complaints from the patients are identical, except that only the Agency for Patient Safety can process complaints about access to documents. Before the Danish Agency for Patient Safety processes a complaint about the health service's health workers activities and treatments, the agency must offer the patient a dialogue with the region.[23] The purpose of local dialogue is to rectify misunderstandings and errors and to investigate whether the issue can be resolved with, for example, an apology, a single explanation, or information that procedures are being changed.

It is up to the patient to decide if the patient wants to accept the offer of local dialogue. The dialogue may lead the patient to drop, maintain or change the complaint. If the dialogue process is not completed within 4 weeks, the region must send the complaint to the Patient Safety Agency, which will begin processing the complaint.

On the other hand, the Health Service's Disciplinary Board is a board that, through sanctions, disciplines or punishes health workers who do not live up to the professional standard that must be expected. The Disciplinary Board can only decide on sanctions if there is a complaint from a patient or a report from the Danish Agency for Patient Safety or the Danish Health and Medicines Authority. Most cases dealt with by the board are complaints from patients regarding lacking informed consent. The board for patients' complaints annual report from 2019 states that there were 2.769 compensation cases in 2019. In 2018, it was 2.432.[24]

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21 Forvaltningsloven (Public Administrative Act) Ministerial Order No 433 of 22 April 2014.

22 The Complaints and Compensation Act (Lov om klage- og erstatningsadgang inden for sundhedsvæsenet), Ministerial Order No 995 of 14 June 2018.

23 ibid.

24 Styrelsen for patientklager (The board for patient's complaints), Annual report March 2019, 9.

The patient's complaint is the condition for the Disciplinary Board to investigate and decide whether a health worker has acted in violation of the health law.
The Disciplinary Board deals with complaints from patients about the health workers' activities and treatments covered by the chapters 4-7 and 9 of the Health Act on informed consent and liability for loss. The Board's competence is limited negatively, as the Board is not competent to process complaints for which a special right of appeal is prescribed in the legislation. The Disciplinary Board deals with complaints about the health workers' activities carried out by authorised health professionals, cf section 2, subsection 1 of the Complaints and Compensation Act.
The Board may decide that the case is so serious that there is a basis for emphasising the health workers to be more careful and conscientious in the future work. The Board may also request the Prosecution Service to consider prosecuting if the Board finds that there is a reasonable suspicion that the health worker has been guilty of gross or repeated negligence, cf section 75 of the Authorization Act. The Prosecution Service may after this take into account whether it should start a case referring to the Danish Criminal Code.
The Board's administrative decisions are final, as they cannot be brought to another administrative authority, cf section 11, subsection 3 of the Act on access to complaints and compensation within the healthcare system. Finally, the Board's decisions can be tried in the Danish courts in the form of recognition proceedings against the Board.

2. Information as a component for valid consent or refusal in medical interventions

2.1. What information shall be disclosed to a patient? Who has the obligation to inform?

According to section 16, subsection 1 of the Health Act, a patient has the right to information regarding their health and treatment options. Information regarding their treatment options includes knowledge of complications and potential side effects.
The specific legal requirements as to what constitutes informed consent are found in section 4 in the Ministry of Health's Ministerial Order No 359 from 4 April.[25] They require the healthcare worker involved to disclose the information as soon as treatment becomes an option. Neither the act nor the ministerial order

[25] Lov om information og samtykke og videregivelse af sundhedsoplysninger (Law on information and consent and on the disclosure of health information) Ministerial Order No 359 of 4 April 2019.

requires the information disclosure to be done by a doctor, as it simply refers to the healthcare worker. According to the ministerial order, the information should always include a detailed walkthrough of preventative action, treatment of the ailment, different kinds of treatments and their potential side effects, and what the consequences of non-treatment would entail. According to the Health Act section 16, subsection 4, 2nd part, there is an extra responsibility on the healthcare worker if the treatment involves an increased chance of serious side effects or complications.

2.2. How detailed and specific should the information be? Is it acceptable to provide information in broad terms?

As mentioned previously, the information required to make an informed decision should be as specific as possible, while still being understandable to the patient. Information regarding potential treatments does not mean treatments that can only be obtained in another country, which was decided by the Danish Supreme Court of Justice of 24 January 2017.[26] The case was about a hospital in Greenland, that did not inform a patient about a potential cancer screening, as the screening itself was not possible in Greenland and required a special reference to get in Denmark, which the patient did not qualify for. The Greenlandic health act is identical to the Danish health act when it comes to the type of information that a patient is entitled to, and the judgement therefore creates precedence. In addition, patients are only required to be informed about medicinally responsible treatments, which means there is no legal necessity to inform the patient of alternative medicine or treatments. Regarding experimental treatments healthcare worker only needs to inform the patient if the provider finds a reason to attempt it. If an experimental treatment is chosen, then the patient must be explicitly informed about every potential side effect and complication, even if the complications can seem small or insignificant.

2.3. How should information be provided in general? Are there specific requirements for information disclosure for children, persons with disabilities and persons who do not speak the majority language?

According to the Health Act section 16, subsection 3, information should always be presented in a way that is easy to understand, and special consideration is required if the patient is not conscious about their legal rights regarding

[26] Danish Supreme Court, decision U 2017.1280 H, Case no 31/2016, 1st department.

healthcare.[27] This also means that the relevant information should omit as many medical terms as possible as the healthcare workers should assume that the patient does not have any prior knowledge.[28]
If the patient does not speak the majority language, extra care needs to be taken to ensure that the patient is fully aware of the information they are being given. Furthermore, there is a general rule that if the patient asks any follow-up questions these should of course always be answered. Likewise, if the patient is asking the healthcare worker for an explanation regarding a particular term, these should also be explained. Finally, it is a requirement that written material is always accompanied by an oral explanation, and that written material does not deviate from the received explanation.

2.3.1. Specifically regarding children

Regarding information to children, the law has a few stipulations. First, the law requires that a patient beneath the age of 15 be informed to whatever degree the healthcare worker deems necessary, however the final medical decision is made by the patient's legal guardian or caretaker, cf the Health Act, section 17, subsection 1. If the patient is above the age of 15, they are allowed to make their own decisions; however, in order for the consent to be informed, the legal guardian also needs to receive the same information as the patient, cf the Health Act section 17, subsection 1, part 2.
There are however two circumstances where a healthcare worker can refrain from fully informing either the patient, or their legal guardian, even if the patient is over the age of 15, and younger than 18. If the healthcare worker deems the information harmful to the patient, or the patient is deemed unable to understand the consequences of their consent, the healthcare worker is able to let the final decision defer to the legal guardian. Likewise, a healthcare worker can keep certain information away from a patient's legal guardian, if the healthcare worker thinks that it will cause the patient great harm. The latter exception requires legal basis, and is found among other places, in the Health Act, section 99, subsection 2 and deals with circumstances regarding abortions for minor. Furthermore, among patients aged 15-18 the legal guardian does not have a right to information about the patient, if the treatment concerns sexually transmitted diseases or birth control as well as abortion.[29]

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27 Vejledning om information og samtykke og om videregivelse af helbredsoplysninger (Guidance on information and consent and on the disclosure of health information) guideline no 161 of 16 September 1998.

28 ibid.

29 Hartlev et al (n 4) 293.

2.3.2. Overruling the consent of the legal guardian

The legal guardian needs to make an informed decision about the child's medical care, but if the legal guardian makes a decision that puts the child's health at risk, then the healthcare worker can petition the Children & Youth Administration at their local Danish county.[30] The county can then make a legal decision on behalf of the child, but only if the life of the child is directly at risk, or if there is a great risk of permanent disability. If there is a pressing need for medical intervention, then the healthcare worker is legally allowed to make decisions on behalf of the child, however these are subject to scrutiny following the procedure.

2.3.3. Regarding adults who are permanently unable to consent

If a patient permanently has lost the ability to consent, either because of a disability or a disease then their closest family members is the one who consents to medical procedures. If the patient is under guardianship, the legal guardian makes the decision. When healthcare workers must decide if a patient is unable to consent, the law requires them to determine if the patient is able to reason and make reasonable decisions.[31]

2.4. Can a patient refuse medical information? What are the legal consequences of refusal?

2.4.1. Can a patient refuse being informed about specific medical intervention?

A patient can refuse medical information at any time or at any point during the treatment, cf the Health Act, section 16, subsection 2. However, this is expounded upon in the guidance,[32] where it is made clear that any form of refusal by the patient must be unambiguous and clear. Furthermore, the right to not be informed is a right bestowed upon the patient, which means that only the patient themselves can invoke the right.[33]
If the medical procedure is a purely cosmetic, then a patient cannot refuse to be informed, as under Danish law it is illegal to perform cosmetic procedures on a

30 Text in (n 27).
31 ibid.
32 ibid.
33 Hartlev et al (n 4) 293.

patient that has not been adequately informed, cf ministerial order regarding cosmetic surgery, section 28.[34] If a patient has declined to be informed about medical procedures, it must be written down in the patient journal, cf ministerial order regarding journaling in the healthcare system, section 13, subsection 3.[35] The note in the journal must include both the patient's refusal and which part of the information disclosure the patient refused. Thus, from the ministerial order it can be inferred that a patient is able to decline information regarding both specific parts of their treatment, and entire treatment courses.

2.5. Is a patient always required to be informed about their health issues? Are there exceptions?

The Health Act does not entail a provision that allows the healthcare worker to determine on their own if a patient can handle knowing about their own health.[36] If a patient does not wish to be informed about the status of their health, they need to say so explicitly, as per the discussion in section 2.4. If a patient does not wish to be informed, their consent is still considered informed, as they have made the active choice regarding their care.[37]

If a healthcare worker is in doubt as to whether a patient wishes to be informed about a potential issue, and/or abnormality regarding their health, the healthcare worker is required to at the very least ask the patient if they wish to know more.[38] Furthermore, it has been found by the Danish Agency for Patient Complaints, now known as the Agency for Patient Safety that it is in violation of norms to not inform a patient immediately after the discovery of cancer during a surgery, even if the cancer has yet to be identified as malignant or provide any kind of symptom.[39] In the specific case, it was argued that the patient's right to know everything about their health should be of utmost importance, even if the patient is elderly and the non-malignant cancer is yet to provide any kind of discomfort.[40]

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34 Bekendtgørelse om kosmetisk kirurgi (Ministerial order on cosmetic surgery) No 834 of 27 June 2014.

35 Bekendtgørelse om journalføring i sundhedssystemet (Ministerial order on journaling in the healthcare system) No 530 of 24 May 2018.

36 Text in (n 27).

37 ibid.

38 Helle Bødker Madsen, *Sundhedsret* (Djøf Forlag, 4th edn, 2018) 222.

39 Danish Agency for Patient Complaints, decision in case no 9914402.

40 ibid.

2.6. What is the legal status of family or other close ones in questions of information disclosure?

As discussed previously in question 2.3, family members to a patient are important when it comes to information disclosure for patients who are younger than 18. If the patient is beneath the age of 18, then the healthcare worker needs to not only disclose information to the patient, but also to whomever is the legal guardian of the patient, cf the Health Act, section 17, subsection 1. Aside from situations described in the law, where due to the patient's age and/or health another person needs to be informed about the patient's health and treatments, family or close ones are not privy to any kind of information. Healthcare workers are bound by a duty of confidentiality and that includes information disclosure to the patient's family or other close ones. The duty of confidentiality is of course only relevant as far as the patient has not already explicitly given the healthcare worker their consent, cf the Health Act, section 43, subsection 1. If the healthcare worker finds it necessary to disclose information about a patient, and the patient refuses to consent, then the healthcare worker can be allowed under certain circumstances, if for instance there is a request by the police as part of an official investigation. Likewise, if it is deemed a necessity for the safety of the patient or the healthcare worker, then disclosures can happen, cf the Health Act, section 43, subsection 2.

If a patient dies then the privacy protections in the Health Act no longer applies as strictly, and family members are therefore able to request information about the deceased and its' disease using the provision in the Health Act that concerns access to documents, cf the Health Act, section 45. According to the established guidelines for handling confidentiality regarding close ones or family members, information regarding a patient's health is something that a patient is always entitled to have. This means it is forbidden for a healthcare worker to have a private conversation with a close one or family member unless the patient very explicitly consents.[41]

Finally, due to the nature of certain mental and/or physical illnesses it is impossible and not in the patient's interest at all, to keep information from being disclosed to family members or close ones. This includes diseases such a later-stage dementia, chronic mental illness, or the final stages of seriously debilitating disease.[42]

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41 Vejledning om sundhedspersoners tavshedspligt (Guideline on healthcare workers duty on confidentiality), guideline no 9494 of 4 July 2002.

42 ibid.

2.7. What are the legal remedies and/or legal consequences for violating an obligation to provide information about medical treatments?

If a healthcare worker violates the obligation to provide information about medical treatments, a patient has the right to complain about the hospital or healthcare provider by going to the Danish Patient Safety Authority. Following a government decision in 2018, the Danish Agency for Patient Complaints was created, and intended to take over parts of the complaints process, including cases concerning the violation of the duty to inform.

However, it is reserved only for the patient itself and family members or close ones are not able to submit a complaint unless the patient is a minor in which case the legal guardian has the right to submit a complaint. Finally, family members or close ones can submit a complaint if the patient has either died or become incompetent due to the procedure.

If a patient or anyone otherwise empowered wishes to submit a complaint to the Danish Agency for Patient Complaints, there are certain requirements regarding the time passed since the violation occurred. There is a general statute of limitations of 2 years from when the patient was informed about the error and an absolute limit of 5 years after the violation, cf the Complaints and Compensation Act, section 4 a.[43]

If the Danish Agency for Patient Complaints finds that the hospital has violated any of the rules in the Health Act's chapters 4-9, it will inform the management at the place of the treatment. As discussed in section 1.3 of this article the decisions made by the Danish Agency for Patient Complaints are final and cannot be appealed to another administrative agency, cf the Complaints and Compensation Act, section 11, subsection 3.

The law does not cover situations where a healthcare worker has violated the rules regarding informed consent unless the violation later led to an injury.[44] However according to legal theory, since it would be exceedingly difficult for a patient to retrieve the necessary evidence regarding their lack of informed consent a rule has developed within case law. If a patient can prove that they did not receive adequate information about a procedure, possible complication, or side effect, then there is a presumption that the lack of information was the cause of the injury. One such example of this presumption is a case decided by the Danish Eastern High Court on 31 October 1990.[45] In the case, a woman was paralysed following chiropractic treatment. The court found that while the treatment had relatively low risk, the chiropractor had failed in adequately informing the patient

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43 Lov om klage- og erstatningsadgang inden for sundhedsvæsenet (Complaints and Compensation Act), Ministerial Order No 995 of 14 June 2018.

44 Madsen (n 38) 554.

45 Østre Landsret (Eastern High Court) UfR 1991, 774.

prior to the treatment, by not mentioning the associated risks. The chiropractor had not given the patient an opportunity to decline the treatment and was subsequently required to pay damages.
The presumption has however been modified to include the caveat that the healthcare worker needs to have committed a clear violation of the duty to inform and the information has to be of importance to the final decision of the patient.[46] If a healthcare worker causes an injury in the way described above, the patient is entitled to financial compensation as described in the Liability Act, section 26.

3. Forms of patients' consent or refusal

3.1. In what forms can a patient consent to – or refuse of – medical treatment?

3.1.1. Written and oral consent or refusal

According to the principle of autonomy, the patient is the only one to decide whether to receive medical treatment. This principle, as seen in section 1.2, is based on the belief that patients are autonomous and deserve respect for their individual dignity and integrity.[47] This principle is today found in the Health Act section 15, which states that no treatment may start or continue without the patient being informed and consenting to treatment, unless otherwise exempted by law or regulation according to national law in general or by the Health Act section 17-19.
In accordance with section 15, subsection 3 in the Health Act, consent is given based on adequate information provided by the healthcare worker, cf section 16. The informed consent or refusal can be given according to chapter 3 in the Health Act, in a written or oral form, or in some circumstances as tacit consent. The patient can withdraw their consent at any time, cf section 15, subsection 2. The consent is only valid towards the current treatment; cf the ministerial order on information and consent and on the disclosure of health information section 3. Consent can be explicit or non-explicit. The explicit consent is seen as conscious and concrete consent. If the consent is not explicit, it is considered tacit consent.
While the consent of the patient is enormously important, it has certain limitations. As an example, a patient cannot consent to treatment that will or can harm themselves through irresponsible operations or euthanasia, cf the Criminal Code

46 ibid 555.
47 Law proposal No L15 of 26 March 1998, FT 1998-98, 2nd collection.

section 240. Furthermore, all healthcare workers are obliged to treat patients in a caring and conscientious way, cf the Authorization Act section 17.[48]
As an exception to the Health Act section 15 on informed consent, section 17 regulates minors' possibility to consent to a medical treatment. Section 18 regulates those patients who are not able to give informed consent. In those cases where an immediate treatment is necessary, the section 19 can be used to continue a treatment without consent. A patient who is 15 years old can give an informed consent to a medical, biological or genetic treatment by themselves, cf section 17, subsection 1 and 3. This informed consent cannot be given without the legal guardian being informed in the same way as the minor and is a part of the minor's decision, cf section 17, subsection 2.
Another exception to the Health Act section 15 is section 18, which regulates those who permanently lack the ability to give informed consent, cf section 14. In this case, the next of kin as in parents, siblings, children, or nearest family member may provide the necessary informed consent. If the patient is under guardianship, which covers the patient's personal matter, cf the Guardianship Act section 5,[49] then the guardian may provide the informed consent. If the patient has submitted a future power of attorney statement, which includes personal matters and health conditions, the future representative may provide the informed consent. The informed consent may only be given when the patient has been included into the assessment of the treatment and has been provided the same information as the guardian, parent, next of kin or future representative, if the information and process does not harm the patient, cf the Health Act section 20, subsection 1. Furthermore, the patient's opinion towards the treatment must be included in the assessment when relevant.
If the healthcare worker assesses that the next of kin, guardian, or future representative manage the informed consent in a way that obviously will harm the patient or the result of the treatment, the healthcare worker can decide to carry out the treatment if the Danish Agency for Patient Safety consents, cf section 18, subsection 4. Should a patient who permanently lacks the ability to provide informed consent have no immediate contact, guardian, or future representative, it is up to the healthcare worker to decide if they should carry on the treatment or not. Only a healthcare worker who has knowledge of the treatment and has not previously participated in or must participate in the treatment of the patient, cf section 18, subsection 2 can take this decision. If the healthcare worker assesses that the treatment is of a less invasive nature, then the healthcare worker may decide, without a second opinion, to carry out or proceed the treatment cf section 18, subsection 3.

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48 Authorization Act (n 5).
49 Ministerial Order No 1015 of 20 August 2007 on guardianship.

In situations where a patient is a minor, has temporarily or permanently lost the ability to give informed consent, is in a situation where immediate treatment is necessary for the patient's survival or in the longer term to improve a patient's chance of survival or secure a significantly better outcome of the treatment, the healthcare worker is allowed to intervene and treat the patient.[50] A healthcare worker is also permitted to continue a treatment without the informed consent from the patient, next of kin, guardian, or future representative, provided the circumstances above are fulfilled.

3.1.2. When can consent or refusal be implied?

According to the Health Act section 15 an informed consent can be given not only oral or in written form, but also as tacit consent. If the consent is not explicit, it is considered tacit consent. Here the patient's action and signals will be interpreted as a consent or refusal. Through the patient's actions, a consent can be implied when the patients signal with hands, head, and eyes or behave in a way that indicates consent. The consent will only be valid if the healthcare workers are without any doubt that the patient is providing the informed consent through their actions as stated in the guideline from 1998.[51]
In the case where a patient is not able to provide a consent or refusal due to a critical accident, the healthcare worker can use an assumed consent, where they assume the patient wants the healthcare worker to try to save them.[52] It can also be used when the doctor asks the patient to remove a shirt to be able to listen to the lungs. When the patient removes the shirt, the patient consents to the treatment. The same happens when the patient consents to the nurse taking a blood sample.

3.2. Withholding or withdrawing consent

A patient can at any point withdraw their informed consent, cf the Health Act section 15, subsection 2 given, according to section 15, subsection 1, if the patient's medical information has not been forwarded to other relevant healthcare workers.[53]
An exception to this is section 24a in the Health Act, which states that no healthcare worker is allowed to accept a withdrawal of a consent if this means that the patient's life-prolonging treatment will stop and result in the patient dying. Unless the patient's death was unavoidable. It is up to the healthcare worker

50 Health Act, s 19.
51 Text in (n 27).
52 Hartlev et al (n 4) 199.
53 Text in (n 27).

to assess if the withdrawal of the consent would kill the patient and thereby be against the healthcare workers ethical perception. If this is the case the healthcare worker is not obliged to accept the withdrawal of consent but is obliged to refer the patient to a healthcare worker that is able to accept the patient's wish, cf the Health Act, section 24 a.

4. Voluntary and competent consent to or refusal of medical interventions

4.1. When can consent to or refusal of medical intervention be regarded as involuntary?

In the general remarks to the previous version of the Health Act it states that, the Health Act does not regulate those cases where the health workers uses force to treat a patient, if the patient is a minor[54] or permanently lacks the ability to provide an informed consent.[55] If a person lacks the ability to give informed consent for the reasons outlined above, the law does not regulate the use of force against patients who lack the ability to consent, when it comes to somatic medicine.[56]

If a competent patient decides not to receive medical treatment, then the health worker is obligated to respect this decision and a treatment is therefore not possible. There would be cases where a health worker assesses that the patient is in such a need of medical intervention, that forcing the patient or threatening with force, might be the only means to save the patient's life or health. This drastic intervention may only be done if there is a clear legal basis, due to the far-reaching encroachment on personal freedom, which is a fundamental human right. If this is done with a sufficient clear legal basis, it might give the health worker immunity from criminal prosecution, cf the Criminal Code section 13 and section 14.[57] The provision is based on an emergency law consideration and applies in situations where the patient lacks the ability to give informed consent and urgent treatment is necessary for the patient's survival, or that the chance of this is significantly improved and where it is therefore not possible to obtain consent from relatives or guardians. It applies to both emergency law and emergency defence that these provisions only allow the application of coercion in completely extraordinary situations, which means that they cannot be used as a legal basis in everyday cases.

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54 Ministerial Order No 359 of 4 April 2019 on information and consent and on the disclosure of health information, s 17.

55 ibid, s 18.

56 Hartlev et al (n 4).

57 ibid.

When a patient is providing an informed consent, these following conditions must be met. The patient must be able to manage to give consent also known as decision-making competence, the patient must have adequate information provided by the healthcare worker and the patient must be able to act voluntarily.[58]
For a consent or refusal to be regarded as involuntary, the patient must have been forced to consent or refuse medical intervention. However, it can also be forced if a healthcare worker persuades a patient by sweet-talking them into giving informed consent or by leaving out information that the patient should have had. The consent can be assessed as affected by the healthcare workers and therefore not the patient's own. An informed consent that is given under pressure force or fraud is not legal.[59]
Using force on a patient can be seen in different ways by verbal force also known as hidden force, or physical force, also known as qualified coercion. Where the physical force is obvious, the hidden force is more difficult to detect. It can include situations where a patient feels forced to take their medicine, or when a child has to do something that they do not want to, and the healthcare worker in both cases illegally threatens with force, unless they are immune according to the Criminal Code section 13 and section 14 about emergency situations.

4.2. What are the legal consequences of consent or refusal being involuntary?

When a consent or refusal is involuntary, it is not legal and any treatment that is done not based on a consent will be considered as force, as mentioned above. The treatment against the patient's will may, depending on the circumstances, be both punishable and punitive, unless there are special rules on compulsory treatment, as in the Act on Detention and Other Compulsion in Psychiatry[60] and the Act on Measures against Communicable Diseases.[61]
Since there are no lex specialis regarding compensation when a patient has been forced to receive a treatment, the general rules of the Complaints and Compensations Act section 19,[62] subsection 1 is used. This opportunity to seek compensation is used when a patient has been harmed or died during a treatment, and not because the patient has been forced to receive the treatment. The compensation is given to the patient or those who are left behind in case the injury killed

58 Hartlev et al (n 4) 170.
59 Text in (n 27).
60 Ministerial Order No 403 of 26 June 1998.
61 Ministerial Order No 114 of 21 March 1979 on amending various laws on the Interior and Area of the Ministry of Health.
62 Ministerial Order No 995 of 14 June 2018 on complaints and compensation in healthcare.

the patient. If treatment takes place without consent, then the patient can appeal within the Danish appeal system as mentioned above in section 1.3.

5. Capacity to decide on medical interventions

5.1. Competence of adult patients

5.1.1. Are there any criteria for recognising that adult patients are not able to consent to or refuse medical interventions? What are these?

For a patient to be considered unable to provide an informed consent, the patient must lack the ability to make a reasonable informed decision permanently or temporarily. Lack of this ability can be caused by lack of mental or physical development, either born with or acquired with time, old age, disease or for other reasons.[63] Patients with chronic mental illness and long-term mentally ill patients will often be categorised as patients unable to provide an informed consent.[64] The crucial part is if the patients can relate reasonably to the proposed treatment and the received information. In practice, the health worker assesses whether the patient has understood the information provided and should therefore not be given when the patient is affected by medication that may obscure judgment or understanding.[65]

5.1.2. Who decides that an adult patient is incapable of making healthcare decisions?

As stated above in section 1 about human rights influencing Danish health law, patients have a right to decide by themselves if they want to receive treatment and other healthcare decisions. In cases where a patient is not able to provide the necessary consent and therefore not able to decide if they want to receive the treatment suggested by the healthcare workers, a parent, guardian or next kin decides whether the patient should receive the treatment, cf the Health Act section 14. The patients who are not able to provide informed consent can be, as mentioned in section 5.1.1, people who lack the ability to comprehend the information due to mental illness or dementia and if they have no one to decide for them, then the healthcare workers have to decide on behalf of the patient, cf the Health Act sections 17-19.

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63 Guidance of the 9, 16 September 1998 no 161 on information and consent on the disclosure of health information, s 2.2.

64 ibid.

65 Guide for Hospitals in the region of Northern Jutland on informed consent to receive treatment (23 April 2019).

When reviewing the Health Act, it is nowhere stated how the health worker must define whether a patient is able to give consent. As the act covers permanent and temporary cases of inability to make decisions, it can be difficult for health workers in the situation to make a momentary assessment of the patient's abilities with which it may be necessary to involve family or other medical expertise to get a correct assessment of the patient's ability. Often will this expert be the chief physician at the hospital if the patient is receiving treatment at a hospital.[66]

5.1.3. Who decides that an incapable adult needs treatment?

In the case that the patient is not able to provide an informed consent and does not have a next of kin, the health worker can decide if the patient is in need or not of medical treatment and what kind of treatment, cf the Health Act section 18, subsection 2 and subsection 4.

5.1.4. What are the legal consequences of incapacitation? Can a patient be forced into treatment?

Can a patient be forced into treatment?
In certain scenarios, the patient can be forced to receive treatment. According to the Health Act section 18 subsection 4 the assigned health worker can decide to continue the treatment if the person assesses that the next of kin, guardian etc. is handling the patient's consent in a manner that is harmful to the patient. The patient can also be forced to receive medical treatment if they are unconscious and the health worker assess that they are in a need of immediate help, cf the Health Act section 19.
Even though a health worker may decide that it is necessary to force the patient to receive treatment, the patient must still be informed and the patient's consent or lack of so, still have to be taken into consideration before the health worker decides whether or not to use force, cf the Health Act section 20. This section illustrates the importance and balance that the health worker must be able to perform on one hand the patient's consent and on the other hand, the patient's health.

Shall healthcare personnel refuse to provide treatment that an incapable patient wants and needs?
As it appears in section 21 of the Health Act, the health worker is obliged to obtain consent in accordance with sections 15-17 and 18, subsection 1. There

[66] Hartlev et al (n 4)

must be a connection to treatment from other health workers according to section 18, subsection 2, that there is acceptance from the Danish Agency for Patient Safety pursuant to section 18, subsection 3 and that the patient is informed and involved in the discussions of the treatment pursuant to section 20. However, the Health Act does not state how these obligations are to be performed. The health worker is obliged to help the patient due to the duty of care and at the same time, the health worker must use the treatment that is least intrusive towards the patient according to the Health Act section 27B[67] and has the fewest side effects and risks.
A health worker can in some cases refuse to help a patient or carry out a treatment because of ethical perception cf section 24, subsection 3 in the Health Act and section 42 in the Authorization Act.[68] A health worker can refuse to continue or start a treatment if a patient refuses to accept blood and it is against the health workers ethical principle to carry out the treatment without extra blood. In other cases, health workers may apply for exemptions from assisting the patient with forester reduction if this is contrary to the health worker's ethical or religious beliefs cf section 102 in the Health Act. Although these exceptions exist, professional opinion is no more important than the duty of care.[69]

5.2. Competence of a child

5.2.1. When can a child consent to or refuse medical treatment? Are there any established criteria for assessing ability to decide on medical treatment for children? Who decides that a child is incapable of making healthcare decisions?

Children under the age of 18 are under parental responsibility in Denmark, cf the Parental Responsibility Act section 1.[70] The holder of the parental responsibility can make decisions regarding the child's personal matters, cf the Parental Responsibility Act section 2, subsection 1. It also appears in the Health Act's section 17, subsection 1 that children under the age of 15 cannot consent or refuse treatment by themselves. From the same section, it states that children above the age of 15 can consent or refuse treatment by themselves, but the holder of the parental responsibility should be involved and have information about the treatment. However, it is the holder of parental responsibility who can consent to or refuse treatment and receive information on behalf of the child if the child is

67 Health Act (n 1).
68 Authorization Act (5).
69 ibid.
70 Forældremyndighedsloven (Parental Responsibility Act), Ministerial Order No 1820 of 23 December 2015.

under the age of 15.[71] The holder of parental responsibility is obligated to take care of the child and in relation to health treatment; this means that the parent is obligated to ensure that the child receives the necessary treatment.

5.2.2. Who decides that a legally incapable child needs treatment?

If there is joint custody, it generally follows from the Parental Responsibility Act section 1, subsection 1, that significant decisions concerning the child's circumstances require agreement between the parents. Contrarily, it follows that non-essential decisions do not require agreement between the parents and can be made by one parent. Certain conditions that must be considered so intrusive for the child that both parents must agree on it, which follows from the Parental Responsibility Act.
This general starting point about the parental authority's responsibility to act appears in the Parental Responsibility Act section 2, subsection 1, but is only applicable until the patient turns 15, cf the Health Act, section 17, subsection 1. Although a young patient can consent to treatment by themselves, the holder of parental responsibility must also have information in accordance with section 16 of the Health Act and be involved in the young patient's decision in accordance with section 17, subsection. 1. The holder of parental responsibility still has a duty of care towards the young patient according to the Parental Responsibility Act section 2, subsection 1, and it must be possible for the parental authority to carry out this duty of care if, for example, there is a need for follow-up in the home. The parental authority must be involved in decisions concerning treatment. However, if there is a disagreement between a young patient and their legal guardian, the young patient has the final decision-making power.

5.2.3. Can a child that refuses medical treatment be forced to undergo treatment anyway? In what cases?

If a young patient has had their consent competence disregarded and offers physical resistance to treatment or examination, the question is whether force can be used to carry out the treatment or examination. In relation to children under the age of 15, there is no legal basis for the use of force in the Health Act. There is disagreement in legal theory as to whether the Parental Responsibility Act section 2, subsection 1, contains a legal basis for the holder of parental responsibility, which can be delegated to the health personnel. In the case of a child under the age of 15, there may be a legal basis in the Parental Responsibility Act section 2, subsection 1, but it is unclear whether this legal basis can be used if a young

[71] Parental Responsibility Act, s 2, subs 1.

person over the age of 15 has been deprived of their consent competence, and resists treatment. If the rules for adult patients over 18 years applies, the Parental Responsibility Act section 2, subsection 1, does not apply and there is no legal basis for the use of force.

Caroline Adolphsen and Eva Naur Jensen distinguish between young people over the age of 15, who are very immature, but who become consent-competent later in life and the young people over the age of 15, who have a disability and who will be unable to consent even as adults.[72] The authors state in relation to the first group, that it will be problematic if these young patients are not protected from their lack of judgment until they become sufficiently mature. They state that these young patients should be placed as if they were under 15 years of age. However, matters are different when it comes to the other group mentioned. In principle, it would be questionable to extend the period during which the parent can make decisions on their behalf, as this is a group that might not be in a position to give consent.

An extension of the period where the legal guardian can consent on behalf of the young patient cannot be justified by the fact that this period is only temporary. If these patients, in relation to the use of force, are to be asked as adult patients, there will be no access to use force in the event of resistance. Although it is worrying, to extend the period during which the young patient is dependent on the consent of the holder of parental responsibility. On the other hand, it is problematic to regard these young patients as adults, as the consequence will be that some of the weakest patients will refuse treatment and it will not be possible to treat these patients. The authors state that it will be in the best interests of young patients with permanent disabilities, that these in relation to the use of force are placed as children under 15 years of age, as otherwise it can have serious consequences for the young and problematic to treat the two groups of young patients differently.[73]

It is unclear how the legal position is in relation to the use of force, and there is no administrative practice in Denmark in this field of law. The unclear legal situation is inappropriate when it is first brought into play considered that the use of force was an infringement of personal freedom and that the lack of regulation and guidelines can mean that the permanently incompetent young patients do not receive treatment at all.

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72 Caroline Adolphsen and Eva Naur Jensen, 'Use of Force for Medical Purposes – A Danish Perspective' (2015) European Journal of Health Law, vol 22, no 4, 377.

73 ibid.

5.2.4. Can a legally incapable child receive treatment when guardians oppose it? In cases where the guardians of the child do not agree on the need to have a medical intervention, who decides?

If the legal guardian disagrees with the patient on non-material decisions, it is unclear from the wording of the Parental Responsibility Act whether one parent can still decide, as is the case if the other parent had not objected. Thus, it is also unclear whether there is a valid consent to treatment if one of the parents opposes. In these situations, one must distinguish between cohabiting parents and parents living separately. This is done to avoid conflict and confusion around the child's daily life, which could arise if both parents want to make different decisions about the child's medical care. The resident parent has the overall competence to make decisions about matters surrounding the child's daily life in their place of residence. The resident parent's opinion must thus carry more weight in these conflicts and disagreements over treatment. Thus, in these situations, the resident parent has the last word.[74]
If there is disagreement between the parents about a material decision regarding treatment that requires the consent of both parents, the necessary consent to treatment is not given until both agree, cf Health Act section 15, subsection 1. If the child suffers from a life-threatening illness or an illness that exposes the child to a significant and permanent disability, and the parents do not want to consent to treatment, it follows from the Health Act section 63, that the Children & Youth administration in the municipality in question, may decide to carry out treatment without consent from the parents. Whether an illness is life threatening or exposes the child to a significant and permanent disability, is a medical assessment in the specific case, and requires approval from the doctor in charge of treatment. In the case of a situation where the parent does not generally look after the child's interests and provide for treatment, there may be measures taken by the social authorities that result in placement outside the home in the end.

6. Exception: Emergency medical interventions

6.1. How is provision of medical treatment in cases of medical emergency regulated in your country?

For almost every type of medical treatment there needs to be informed consent from the patient. If there is no consent, then the treatment could be considered a violent attack or the inflicting of grievous harm on the patient. However, certain situations necessitate immediate medical intervention where time will be of the

[74] ibid.

essence and to save a patient from either death or disfigurement the healthcare worker must act with haste.
The legal basis for this kind of treatment is found in the Health Act section 19, which allows a healthcare worker to initiate treatment if the patient is temporarily incapacitated, however this only applies on situations where the patient would otherwise die, or the quality of the treatment would worsen if it were not started immediately. The same applies to patients who are below 15 years of age, if there is need for urgent care and there is no time to wait for the consent from the legal guardian. In these cases, a doctor also has a duty to treat the patient and can potentially be sanctioned under the Authorization Act if they do not initiate treatment.
The Health Act section 19 regulates instances where there are immediate needs, and the patient is incapacitated. This provision applies to patients who would otherwise be able to make their own decisions and who are temporarily unable, and in urgent matters applies to the able and unable equally. The provision thus implies that outside of urgent care situations, there is no legal basis for treating the temporarily incapacitated, if they are otherwise able to make their own medical decisions.

6.2. Is there any legal definition of emergency care?

In the Authorization Act section 42, subsection 1, there is a duty of care that every doctor is obligated to honour. The duty only applies to situations where medical intervention or treatment is urgently needed. That provision is supposed to supplement the provision in the Criminal Code section 253, wherein any person can be punished for not acting or offering assistance, if another person is in danger and the helper will not be putting themselves in danger.
While the Authorization Act does not contain a specific description of emergency care, it does list the situations where a doctor is not allowed not to act, or they will face punishment. Those specific situations are poisoning, major bleeding, choking or births where a midwife is not available. One such example of an emergency is from the Eastern High Court on 12 May 1965,[75] where a physician was charged with breach of the Medical Act section 7.[76] In the case, the chief physician of a hospital received a phone call at home from the hospital, claiming that a patient was choking in the psychiatric department. The chief physician declined to return to the hospital, instead stating that the nearby anaesthesiologist in the building nearby would be better suited to treat the emergency. The physician was acquitted, as the duty of care was seen to be about ensuring the patient's

[75] Østre Landsret (Eastern High Court), UfR 1965.750 Ø, Case no 115/1965.
[76] Authorization Act (n 5) s 42.

best possible chance of recovery, which could best be ensured by contacting the anaesthesiologist and initiating immediate treatment.
While this case is somewhat old, it still shows that even if choking is considered an emergency and requiring treatment, there is not a strict duty placed onto any singular doctor, if they can argue that the patient would have a better chance of recovery if someone else handles the treatment.
While the above-mentioned situations are considered dangerous, the list is not exhaustive, and the law simply lists them as examples. The reason for these examples is found in the fact that the law is trying to balance two of the principles mentioned above in section 1. Those principles being the right to bodily autonomy and the right to life. There is no definitive answer to the balance of these principles, thus the emergency care only applies in certain situations.
In the legal theory, it has been concluded that the duty to provide medical care only extends as far as necessary to avoid imminent harm, and the doctor is under no obligation to provide the patient any kind of treatment beyond that.[77]
An important addition is the fact that the law only requires the doctor to act if there is no one else providing medical care for the patient. Furthermore, the provision in the Authorization Act only applies if somebody requests medical care for the patient, however the request is equally valid if it comes from an eyewitness, a relative to the patient, or the patient themselves.

77 Madsen (n 38) 136.

Chapter III:
Report from Finland

1. Legal regulation of patient's status

1.1. What are the legislative acts that regulate the issues of patients' decision-making in your country?

The most essential Act that regulates patients' decision-making is the Act on the Status and Rights of Patients (785/1992) (Patient's Rights Act). According to article 1, the Act shall apply to the status and rights of patients in healthcare and medical care. The Act applies to everyone regardless of the nature of the illness or the patient's age. Therefore, the scope of the Act is broad. The Act is applied particularly when the patient's treatment is voluntary. However, the Act may be interpreted in cases of involuntary treatment as well. Thus, the scope of the Patient's Rights Act should be interpreted as substantially as possible.[1]
Healthcare professionals must acknowledge the provisions regarding patients' rights.[2] Under article 15 of the Health Care Professionals (559/1994), the professionals are ought to adapt generally accepted and empirically justified methods, in accordance with their training. In addition, healthcare professionals must estimate the benefits of their professional activity to the patient and its potential disadvantages.
Under article 6 of the Patient's Rights Act, the patient must be cared for in mutual understanding with the patient. If the patient refuses a certain treatment or measure, they have to be cared for, as far as possible, in another medically acceptable way. Under article 6 of the Patient's Rights Act, if a major patient, due to mental illness or for other reason, cannot decide on the treatment, the legal representative, a family member, or other close person of the patient must be heard before making an important decision concerning the treatment. This must be done in order to assess what kind of treatment would be in accordance with the patient's will. Alternatively, if the latter procedure is not achievable, the patient must be given a treatment that is deemed to be in accordance with their personal interests. Hence, it is a strong premise that the patient receives their treatment voluntarily. The grounds for this principle are set in the Finnish Constitution (731/1999). According to article 7, everyone has the right to life, personal liberty, integrity and security. It prohibits the violation of personal integrity of the individual nor

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1 Lasse Lehtonen, Mirva Lohiniva-Kerkelä and Irma Pahlman, *Terveysoikeus* (Alma Talent Oy 2015) 161.
2 ibid 148–149.

shall anyone be deprived of liberty arbitrarily or without a reason prescribed by an act. The lawfulness of other cases on deprivation of liberty may be submitted for review by a court of law. The rights of individuals deprived of their liberty shall be guaranteed by an act.

Furthermore, under article 10 of the Constitution, everyone's private life is guaranteed. Everyone is eligible to decide independently whether to utilise healthcare services or not.[3] Nonetheless, under certain circumstances, a patient could be treated involuntarily. When necessary to do so, the justified acts or treatments are mentioned under the Mental Health Act (1116/1990), the Communicable Diseases Act (1227/2016) and the Substance Abuse Act (41/1986). In addition, there are specific regulations that are applicable to minors. For more information, regarding children's rights in the healthcare system, please study chapter 5.2 of this Research (competence of a child).

The decision to treat the patient without their consent must be well considered and justified. The measure must be proportionate and necessary. Additionally, the self-imposed or other optional means must be proven inadequate.[4] Further, the coercive measure may be acceptable for safety reasons as well.[5] The involuntarily treated patient must be able to oppose the decision by effective remedies. Moreover, the patient must have an opportunity for a fair trial.[6] For example, under article 24 of the Mental Health Act, an appeal may be lodged before the Finnish Administrative Court on the decision of a hospital physician to order a person to treatment or to continue treatment against the person's will.

Under article 22 of the Mental Health Act, a patient's right to self-determination and other fundamental rights may be limited in virtue of the provisions only to the extent that is necessary for the treatment of the illness or the person's safety. The measures shall be undertaken as safely as possible and with respect for the patient's dignity. When choosing and determining the extent of a limitation on the right of self-determination, special attention shall be paid to the criteria for the patient's hospitalisation. Thus, the patient's will is essential even when the treatment is given regardless of the patient's consent.

If there is an obvious risk of the spread of a generally hazardous communicable disease or a disease that is justifiably suspected of being generally hazardous, the patient may be isolated or ordered to quarantine under articles 60 or 63 of the Communicable Diseases Act. Under article 68, the quarantine or isolation must be carried out in a way that does not needlessly restrict the person's rights. The isolation requires an administrative decision in order to ensure that the patient

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3 Kaarlo Tuori and Toomas Kotkas, *Sosiaalioikeus* (5th edn, 2016) 507–508.

4 ibid 513-514.

5 Hallituksen esitys mielenterveyslaiksi HE 201/1989 (Government Proposal for the Mental Health Act) 22.

6 Lehtonen et al (n 1) 335.

has all the rights guaranteed by law. Isolation or quarantine may be constituted by the patient's consent as well.[7] Therefore, even a national compelling reason cannot automatically override the most fundamental rights such as treating a patient with mutual understanding.

1.2. What international human rights instruments have a significant influence on the status of a patient in your country? Why did the influence of these instruments (or norms) become significant in your legal system?

The Finnish legal framework has evolved in coordination with the developments in human rights, such as the enactment of the Convention on Human Rights and Biomedicine (the Oviedo Convention). It had a major impact on e.g. the Act of the Medical Use of Human Organs and Tissues. After its amendment, the removal of a person's organs has been permitted unless it has been explicitly prohibited by the person themselves while still being legally competent. Additionally, the Oviedo Convention pushed for legislation regarding medical research.[8]
The United Nations Convention on Civil and Political Rights (ICCPR) and the ICESCR have both influenced the legislation on the Finnish healthcare system. For instance, there is a substantial connection between the principal of the Welfare State and the ICESCR. Article 12 of the ICESCR is an excellent archetype to illustrate the suitable implementation of the social rights in the Member States.[9] Under article 12, the Parties must recognise everyone's right to the enjoyment of the highest attainable standard of physical and mental health. This requires i.e. the prevention, treatment and control of epidemic, endemic, occupational and other diseases in accordance with the Subparagraph 2(c).
The ECHR establishes e.g. the right to liberty, private and family life. In the praxis of the European Court of Human Rights (ECtHR), the procedures concerning the involuntary mental treatment in Finland have been reprimanded. The Court has not expressed any need to increase the quality of the treatment itself.[10] However, the Court has addressed the procedural rights especially in the case of *X v Finland* App no 34806/04 (ECtHR, 3 July 2012). The person had been assessed in a psychiatric hospital due to criminal conduct. In the process, the person had no independent right to require autonomous medical review. The Court declared that Finland had breached articles 5(1) and 8(1) of the Convention.

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7 Hallituksen esitys tartuntatautilaiksi ja eräiksi siihen liittyviksi laeiksi HE 13/2016 vp (Government Proposal for the Communicable Diseases Act) 55.
8 Liisa Nieminen, *Terveys ihmisoikeuskysymyksenä* (Suomalainen Lakimiesyhdistys 2015) 53–54.
9 ibid 39, 42-43.
10 ibid 115.

Hence, the Mental Health Act was amended and nowadays this procedural right is recognised.[11]

The Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (the Patient Directive) establishes the possibility for patients to receive cross-border healthcare. In Finland, this Directive is implemented in the Finnish legislation through the Act on Cross-Border Health Care (1201/2013).[12] Under article 6, if an insured person in another EU Member State seeks treatment in Finland, the local authority must provide these services for the person without any discrimination. Consequently, treatment must be provided on equal grounds vis-à-vis everyone regardless of whether an individual resides in Finland or not.

1.3. What is the legal status of a patient in relation to their decision-making?

Under article 19 of the Finnish Constitution, the public authorities shall guarantee everyone adequate social, health and medical services and promote the health of the population. Additionally, under article 21, everyone has the right to have their case dealt with appropriately and without undue delay by a legally competent court of law or other authority, as well as to have a decision pertaining to their rights or obligations reviewed by a court of law or other independent organ for the administration of justice.

Provisions concerning the publicity of proceedings, the right to be heard, the right to receive a reasoned decision and the right to appeal, as well as the other guarantees of a fair trial and good governance shall be laid down by an act. Under article 22, the public authorities shall guarantee the observance of basic rights, liberties and human rights.

For the patient, article 19 of the Constitution establishes the right to access to healthcare. The patient has, further, the right to choose where to receive the healthcare services, if certain conditions are met. Those conditions are determined in articles 47 and 48 of the Healthcare Act (1326/2010).[13] For instance, under article 47, individuals have the right to choose from which of the health centre units operating in their municipality they seek healthcare services.

Under article 6 of the Patient's Rights Act, the treatment should be constituted by the patient's consent. However, occasionally the patient may disagree with the decisions regarding the organised treatment. Thus, the Patient's Rights Act provides for certain remedies for the patient. One of those is the right to object or make a complaint to the Regional State Administrative Agency. Under article 10,

11 Tuori and Kotkas (n 3) 560-561.
12 Nieminen (n 8) 212.
13 Lehtonen et al (n 1) 175.

a patient who is not satisfied with the healthcare or medical care and the related treatment received by them, has the right to submit an objection on the matter to the director responsible for healthcare in the healthcare unit in question. A decision on the objection has to be given within a reasonable time from the submission of the objection. Submitting an objection does not restrict the right of a patient to appeal to the authorities controlling healthcare or medical care concerning the care or related treatment received by the patient.

If the patient still feels unsatisfied after receiving the response to the objection, article 10a of the Patient's Rights Act includes the right for the patient to complain to the Regional State Administrative Agency. Nonetheless, the complaint cannot nullify or amend any medical decisions or establish any right to e.g. a certain operation. The complaint is an instrument for those situations when a patient suspects that there has been for example a violation of the legislation or that the medical staff have acted *ultra vires*. The complaint may be addressed to the supreme overseers of legality, the Parliamentary Ombudsman or the Chancellor of Justice.[14] However, the official supervisory authorities of the healthcare system and the professionals are the Regional State Administrative Agencies and the National Supervisory Authority for Welfare and Health (Valvira).[15]

The right to appeal to the administrative court requires that the patient have been given an administrative decision. In practice, this means that the patient is ordered to receive treatment involuntarily e.g. under article 11 of the Mental Health Act.[16] Thus, the complaint is an important remedy for the patient. The procedure of the complaint at the supervisory authority is regulated in the Administrative Procedure Act (434/2003). First, the supervisory authority is entitled to provide administrative guidance. The supervisory authority may, under article 53c, draw the attention of the supervised entity to the requirements of good administration or inform the supervised entity of the authority's understanding of lawful conduct. Second, if this is not found sufficient in view of the circumstances influencing the overall assessment of the matter, the supervised entity may be given an admonition. The resolution to the complaint must be proportional. Should the case be preferred to be tried in the criminal procedure, the authority must transfer the case to the competent authority in question.[17]

In order to provide adequate healthcare services, public authorities must secure the quality of healthcare professionals. In fact, the most essential element is that the patient can trust in the competence of the professionals. The very existence of the required trust is related to supervision and its efficacy.[18] In Finland, Valvira

14 Heikki Kulla, *Hallintomenettelyn perusteet* (10th edn, Alma Talent Oy 2018) 376, 381–382.
15 Lehtonen et al (n 1) 153.
16 Tuori and Kotkas (n 3) 700.
17 Kulla (n 14) 379-381.
18 Jonathan Montgomery, *Health Care Law* (2nd edn OUP) 133.

supervises healthcare professionals. The Health Care Professionals Act regulates all measures that can be performed. Under article 1, the purpose of the Act is to promote the safety of the patients and to improve the quality of healthcare services. Therefore, the measures are imposed merely to protect the safety of the patients. If the healthcare professional's conduct requires disciplinary actions, Valvira may either provide administrative guidance or impose more severe measures, e.g. restrictions to professional activity. For compulsory grounds, Valvira may even withdraw the licence to practise the profession for a fixed period of time or until further notice. Generally, the imposed measures are related to health conditions, e.g. mental illnesses or addictions to substances.[19]

The patient may, if considered necessary, appeal to an administrative court in a matter of administrative litigation. An administrative court shall consider as a matter of administrative litigation any dispute that 1) is provided by law for a decision as a matter of administrative litigation; 2) concerns a payment liability governed by public law; 3) concerns some other interest, right or obligation arising from a legal relationship governed by public law; or 4) concerns an administrative contract.[20] A matter shall nevertheless not be considered a matter of administrative litigation if an administrative decision or a decision issued on a material appeal can be made on the subject.

In the Finnish Supreme Administrative Court's (*Korkein hallinto-oikeus*, KHO) case KHO 2002:21, the municipal authority was obliged to compensate for all the operational costs incurred. The municipal authority had organised the patient's treatment at the hospital X. Nonetheless, the patient argued that the adequate treatment had been omitted at the above-mentioned hospital. Ultimately, the patient had obtained the imperative operation at the private hospital Z. Consequently, the municipal authority reckoned that it was not liable to reimburse the costs incurred at the hospital Z. However, the Supreme Administrative Court declared that the patient had not received the necessary treatment at the hospital X, which should have been organised by the municipal authority. Accordingly, the patient had had to purchase the surgical treatment that she *de facto* had needed. Hence, the municipal authority was compelled to reimburse the patient's operational costs at the hospital Z as well.

19 Lehtonen et al (n 1) 153, 155-156; Tuori and Kotkas (n 3) 823.

20 Administrative Judicial Procedure Act, art 20.

2. Information as a component for valid consent or refusal in medical interventions

In Finland, patients' right to self-determination derives its legitimacy from multiple interrelating sources, such as international human rights obligations, the Finnish Constitution, healthcare regulations and the general principles of medical law. In medical care, valid consent is a precondition for the patient's self-determination to take place. Valid consent is at hand when four factors are present: 1) the patient must have the capacity to give consent, 2) the patient must be acting voluntarily, 3) the patient must be informed sufficiently, and 4) the patient must understand the said information.[21] This is also known as the informed consent doctrine and the following section will focus specifically on the role of information as a component for valid consent.

2.1. What information shall be disclosed to a patient? Who have the obligation to inform?

The main provision of interest concerning patients' right to be informed can be found in the Patient's Rights Act, article 5(1). It stipulates that 'a patient shall be given information about their state of health, the significance of the treatment, various alternative forms of treatment and their effects as well as about other factors related to the patients' treatment that are significant when decisions are made on the treatment given to them'. The purpose of providing the information is essential to guarantee that the patient is able to consider whether to consent to a treatment or not. The list of the information to be provided continues on the law drafting material, where it is specified that before beginning any treatment, an explanation of the treatment's extent, risk factors, complications, the likelihood of failure and what would happen if the treatment is waived, shall be disclosed to the patient.[22]

The obligation to inform is set to healthcare professionals, who are defined in article 2 of the Health Care Professionals Act. Essentially, the definition includes licensed professionals, authorised professionals and professionals with protected occupational titles within the health and medical care. Although the right to be informed is a derivative of the patient's self-determination, at the same time it serves an important role in promoting a relationship of trust between the healthcare personnel and the patient, another general principle of medical law. As a result, healthcare professionals are required to disclose information on their

21 Tuori and Kotkas (n 3) 519.

22 Hallituksen esitys eduskunnalle laiksi potilaan asemasta ja oikeuksista HE 185/1991 vp (Government Proposal for the Act on the Status and Rights of Patients) 15.

own initiative.[23] The obligation to inform is supported by another obligation set to healthcare professionals, namely by the obligation to 'take account of the provisions concerning patients' rights' (article 15(2) of the Health Care Professionals Act).

2.2. How detailed and specific should the information be? Is it acceptable to provide information in broad terms?

Under article 5(2) of the Patient's Right Act, healthcare professionals should try to deliver the information in such a way that the patient can understand it. Usage of professional medical language is not advised, since it cannot be assumed that a patient can fully understand it.[24] The list of what information shall be disclosed to a patient is quite long, but it is not exhaustive and the regulation leaves room for the case-by-case consideration. First, any significant factor relating to the treatment shall be disclosed. When it comes to risk factors, such as the likelihood of failure and complications, the importance of specific and detailed information is highlighted. Obviously, the information must be based on facts and should be given in an honest manner.[25]

Second, the scope of the required information is also shaped by the patient's right to self-determination because the patient has to be treated in mutual understanding with them. Some patients may prefer the use of medical terms when speaking with them and some patients may prefer the information to be put in a very simple and general manner, so the used language must be adjusted according to the patient's preferences and capacity. It is noteworthy that the law does not prescribe any such obligation that would require that all available information must be disclosed to a patient. It is permissible to disclose the information even in a vague manner if the patient understands the relevant pieces of information. The healthcare professional is competent to decide how much information is sufficient to give to the patient.[26]

The way the regulation handles information disclosure can be described as a communication-based approach even if the healthcare professionals are obliged to take the initiative. It emphasises a continual communication between the healthcare personnel and the patient, which promotes mutual understanding. In this sense, the content of the obligation to inform takes shape during the communication process and it is decided on a case-by-case basis regarding how broad

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23 ibid.

24 ibid.

25 Irma Pahlman, *Asiakastietojen käsittely, salassapito ja asiakkaan tiedonsaantioikeus sosiaali- ja terveydenhuollossa* (Edita 2010) 62–63.

26 Irma Pahlman, 'Potilaan itsemääräämisoikeus' (Edita Prima Oy 2003) 201.

or specific the provided information should be. Instead of a paternalistic approach where the law or the healthcare professionals dictate which information and the scope of said information must be disclosed, the communication-based approach takes into consideration the patients' needs and autonomy.[27]

2.3. How should the information be provided in general? Are there specific requirements for information disclosure for children, persons with disabilities and persons who do not speak the majority language?

In general, the information should be provided by the healthcare professionals on their own initiative, before the treatment and in a way in which the patient is able to understand the given information. When disclosing information, the following factors must be taken into consideration: the patient's age, education, native language and other characteristics of the individual.[28]
In principle, mature children and persons with disabilities can exercise their right to self-determination and make autonomous decisions when certain conditions are met. Consequently, the opinion of a minor as a patient on a treatment measure has to be assessed if it is possible with regard to their age or level of development. If a minor can decide on the treatment given to them, they have to be treated in mutual understanding with them. However, if the minor cannot decide on the treatment given to them, they have to be treated in mutual understanding with their guardian or legal representative, although the opinion of the patient should also be taken into consideration, if possible.[29] Healthcare professionals consider on a case-by-case basis whether a minor is capable of making their own decisions regarding their treatment (there is no set age limit after which the child can exercise the right to self-determination). Crucial in this aspect is whether the child is capable of understanding the consequences of consenting to or refusing treatment and how it might affect their health.[30]
The content and extent of the consent of minors, who are deemed self-determined, are the same as with adult patients. The mutual understanding of both the parent and minor patient and the grounds for such a decision must be recorded within the patient journals. Minors who are not considered self-determined are still entitled to receive information about their health and treatment in accordance with their age and development.[31]

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27 Ilpo Paaso, Potilaan tiedonsaantioikeus terveydenhuollossa (WSOY Lakitieto 2001) 147.
28 HE 185/1991 (n 215).
29 Laki potilaan asemasta ja oikeuksista 785/1992 (Act on the Status and Rights of Patients) art 7.
30 HE 185/1991 (n 215).
31 Suvianna Hakalehto and Irma Pahlman, *Lapsen oikeudet terveydenhuollossa*, (Kauppakamari 2018) 291-293.

If an adult patient is unable to decide on their treatment because of their mental disability, mental disorder or other such reason, then their legal representative, family member or other close person is entitled to receive information regarding the patient's state of health that may be required to enable that person to express an opinion and give their consent.[32] The wording of the provision limits the information disclosure to what is necessary in order to express an opinion and give consent. Even when the patient is not fully capable of understanding the decisions made regarding their treatment, there is almost never any reason to leave the patient completely without such information, because of the importance that is put on the opinion forming and decision-making of patients.[33]
Finland has two national languages, Finnish and Swedish, and in addition, there are several minority languages such as Sami and sign language. The legislation and provisions pertaining to language issues are manifold, so only a general overview is possible in the context of this paper. Public healthcare units are considered a municipal authority and thus the question of what national language is used in the healthcare unit and in what language the patient is treated depends in general on whether the municipality in question is monolingual (Finnish or Swedish) or bilingual (article 9 of the Language Act (423/2003)).[34] Because of the patient's right to receive information, which includes the requirement that the patient understands said information, the Patient's Right Act has a provision in case of a situation where the healthcare professional does not know the language used by the patient or if the patient because of a sensory handicap or speech defect cannot be understood. Under article 5(2) of the Patient's Rights Act, an interpretation should be provided, if possible.

2.4. Can a patient refuse medical information? What are the legal consequences of refusal?

There are two exceptions to the obligation to inform; the first exception is when the patient refuses to receive information, the second exception is discussed in the following chapter 2.5 of this Research. It is explicitly stated in article 5(1) of the Patient's Rights Act that information shall not be given against the will of the patient. Part of the obligation to inform is that it must be recorded in the patient journals how the obligation was fulfilled. If the patient refuses to receive medical information, this fact must also be recorded in the patient journals.[35] Because the patient can always refuse to receive information, no matter how important such information is, it has been proposed in the legal literature by Irma Pahlman that

32 Patient's Rights Act, art 9(1).
33 Paaso (n 26) 290-293.
34 ibid 177.
35 Decree of the Ministry of Social Affairs and Health on Patient Journals (298/2009) art 18(2).

the use of the term "informed consent" can be misleading in the Finnish context since in practice, a valid consent can be given without the patient receiving any information. Instead, she suggests the term "considered consent" (*harkittu suostumus*) would be more appropriate in this context.[36]

2.5. Is a patient always required to be informed about their health issues? Are there exceptions?

The second exception for the obligation to inform can be found under article 5(1) of the Patient's Rights Act: when it is obvious that giving the information would cause a serious hazard to the life or health of the patient, then the information shall not be provided. If information is not given to the patient, it is crucial that the information and the reason for such a decision are recorded in the patient journals, the same way as mentioned previously in chapter 2.4. This provision must be interpreted very restrictively because it goes against the general principles of patient autonomy and the right to be informed. Thus, a mere suspicion of the potential harm information disclosure might cause is not enough, the harm must be evident.[37] A situation that might fall under this provision is a patient having a severe depression and there is a risk of suicide, yet, even then, it does not mean that the patient is denied all information. It is also possible to provide information later when the patient's condition has improved.[38]
The situation can also be such that the patient is not able to receive information and express their will in an emergency due to unconsciousness or other reasons. In these situations, when the patient's life or health is at risk, under article 8 of the Patient's Rights Act, the patient must still be given necessary emergency treatment and 'if the patient has earlier steadfastly and competently expressed their will concerning their treatment, they must not be given a treatment that is against their will.'

2.6. What is the legal status of family or other close ones in questions of information disclosure?

In regard to the information contained in the patient journals, which are confidential, the main rule is that family and other close ones are considered a third party, and thus they are not automatically entitled to receive any information without explicit consent from the patient. The scope of what information shall

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36 Pahlman, 'Asiakastietojen käsittely, salassapito ja asiakkaan tiedonsaantioikeus sosiaali- ja terveydenhuollossa' (n 24) 60.
37 HE 185/1991 15.
38 Lehtonen et al (n 1) 191.

be considered part of patient journals should be interpreted broadly.[39] It is specifically stated that the healthcare professionals and other persons working in a healthcare unit are not allowed to give the information contained in the patient journals to outsiders without written consent by the patient (article 13(2) of the Patient's Rights Act). However, it has been postulated in the legal literature that the existence of a written consent does not mean that the third party may receive any information they wish to know from the patient journals, but rather that healthcare personnel's obligation to maintain secrecy is set aside.[40]

Sometimes patients are not able to exercise their right to self-determination or express their will, so it is important to ensure their interests are still taken properly into consideration. That is why opinions from the family and other close ones can prove to be valuable in sorting out the will of the patient. For such situations, there are provisions in the Patient's Rights Act that confer the right to receive necessary information regarding the patient's state of health, so that a legal representative, family or other close person is able to express their opinion (see article 9(1) of the Patient's Rights Act).[41] Family and other close ones in this context refer mainly to spouse, children, parents, siblings, partner or other person, who lives permanently with the patient. A legal representative is either a guardian, next friend or a representative.[42] One instance where the patient's written consent is not needed is when a patient is not able to decide on their treatment due to a mental health disorder, mental disability or other such reason (article 6(2) of the Patient's Rights Act). Another instance is a patient receiving treatment because of unconsciousness or other comparable reason (article 13 of the Patient's Rights Act). It is noteworthy that the right of a third party to receive information is not absolute or limitless. The provision regarding an unconscious patient also stipulates that if there is a reason to believe that the patient would forbid information disclosure to their family members or other close persons, then the information shall not be disclosed.

Minor patients, who are deemed self-determined and capable of deciding of their own treatment, have a right to forbid providing their guardian or other legal representatives with information on their state of health and care under article 9(2) of the Patient's Rights Act. This right should be explained to the patient and a record must be made to the patient journals about their opinion on the subject.[43] When the minor is not deemed self-determined, their guardian or legal representative has the right to receive information about the patient's state of health,

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39 Paula Ilveskivi, *Potilaan oikeusasema tiedonsaantioikeuden näkökulmasta* (Hakapaino Oy 1998) 103.
40 ibid 104.
41 ibid 104-105.
42 HE 185/1991 (n 215) 17.
43 Hakalehto and Pahlman (n 30) 293.

treatment and patient journals under article 9(3) of the Patient's Rights Act, although the patient's individual interest might limit this right in some cases.

2.7. What are the legal remedies and/or legal consequences for violating an obligation to provide information about medical treatments?

When a patient is provided with information about their treatment and state of health during their medical treatment, it is considered as an administrative activity, which means there is no possibility to appeal to an administrative court, as would be the case with an administrative decision. In the case of violation of the obligation to provide information about medical treatments, the primary remedy is to submit an objection to the director responsible for healthcare in the healthcare unit in question according to article 10 of the Patient's Rights Act. If the response to the objection is unsatisfactory, a complaint may be lodged as prescribed in article 10a of the Patient's Rights Act. Additionally, the Patient Ombudsman is an advisory body, who, for instance, gives advice on the application of the Patient's Rights Act.[44] For a more in-depth discussion of the legal remedies available to patients, see chapter 1.3.
The situation is different when it comes to patient records, which are considered 'personal data' and for which the EU General Data Protection Regulation (GDPR) thus applies.[45] Article 15 of the GDPR provides Right of access by the data subject. The national data protection officer, the Data Protection Ombudsman (*tietosuojavaltuutettu*) monitors the compliance of the GDPR and Data Protection Act (1050/2018), the latter being the Finnish law, which specifies and supplements the GDPR and its national application. If a patient is unable to exercise their right to access their patient journals, they may, under article 21(1) of the Data Protection Act, 'refer the matter to the Data Protection Ombudsman for consideration'. Consequently, under article 25(1) of the Patient's Rights Act, a decision of the Data Protection Ombudsman may be appealed against to an administrative court.

3. Forms of patients' consent or refusal

The patient's right to self-determination includes the patient's right to accept or refuse treatment. As mentioned in chapter 1.1., this right is regulated under article

44 Ilveskivi (n 37) 128-129.
45 Valvira, Processing of patient and personal data <https://www.valvira.fi/terveydenhuolto/hyva-ammatinharjoittaminen/salassapito/potilastietojen_kasittely> accessed 11 November 2020.

6 of the Patient's Rights Act, according to which the patient's consent is a prerequisite for the permissibility of a treatment.[46] Therefore, all treatments must take place in agreement with the patient. The Act does not, however, specify the form or the means in which the patient shall give consent and therefore it must be judged on a case-by-case basis, taking into account the nature of the treatment, the extent to which the integrity of the person is compromised and the specific circumstances.[47]

3.1. In what forms can a patient consent to – or refuse of – medical treatment?

The patient's consent can be explicit or tacit, and in deciding which type of consent is needed, the invasiveness of the treatment is assessed. The government proposal considering this distinction provides unclear information; on the one hand, it states that consent can be tacit in situations where the patient is treated for a minor sub-measure of a treatment, and on the other hand, it implies that the treatment itself must be minor.[48] Regarding the importance that a sub-measure holds for the overall treatment, it may seem relevant to interpret the article in light of the latter distinction.

Accordingly, Pahlman argues that the intention of the legislature has been to draw the line to a minor treatment rather than to a minor sub-measure.[49] This interpretation is also supported by Lahti, according to whom explicit consent cannot be considered legally necessary in the case of a harmless or low-risk measure.[50] Although the view was expressed before the Patient's Rights Act, it should be given importance on the grounds of the content of the patient's right to self-determination, which has largely depended on customary law and medical practice.

The more treatment options there are and the more serious the issue of patient integrity is, the more important it is to ensure explicit consent.[51] Such consent may be either oral or written. When it is apparent for the patient what a routine treatment contains and the mentioned treatment is non-invasive, explicit consent is not necessary.[52] In this case, the patient's tacit consent is detectable from their behaviour.

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46 Pahlman, 'Potilaan itsemääräämisoikeus' (n 25) 192.

47 Lehtonen et al (n 1) 196.

48 HE 185/1991 16.

49 Pahlman, 'Potilaan itsemääräämisoikeus' (n 25) 194.

50 Raimo Lahti, 'Minkälainen riski on ilmoitettava potilaalle hänen kysymättä?', Sairaala 10/1971, 452–454.

51 Merja Turunen, *Täysi-ikäisen potilaan itsemääräämisoikeus ja sen rajoittamisedellytykset somaattisessa hoidossa* (University of Lapland 2018) 13.

52 Lehtonen et al (n 1) 196.

3.1.1. Oral consent

Oral consent contributes to preventing the bureaucratisation of healthcare.[53] Generally, it is also the most efficient way of giving explicit consent.[54] Oral consent can be given in its simplest form by saying "yes". The demarcation between oral and tacit consent is not always clear. For example, a nod of the head is construed conceptually as oral consent despite its non-verbal form.[55] Oral consent can be seen as the standard form of the patient's consent and it functions in situations that are more serious than minor procedures allowing a tacit consent, but not serious and possibly arguable enough in order to require written consent. Despite the consent not being provided in a written form, the relevant information concerning the treatments and examinations is recorded in the patient journals.[56]

3.1.2. Written consent

If the law requires written consent, the healthcare professional cannot deviate from it, and the patient shall consent to the treatment with a signature. Due to the disadvantages outweighing the benefits of written consent, its field of application is limited.[57] Therefore, it is mainly necessary when there is a reason to suspect that there would be subsequent difficulties in proving the existence of consent.[58] Written consent has been considered potentially to undermine the level of oral information given to the patient and to act as a formality that may not have any real content. Written consent also does not guarantee that the patient will understand the content, significance, and risks of the treatment.[59]
Written consent can be required, for example, when prescribing medicine. This came into question in the decision of the Parliamentary Ombudsman of Finland concerning the use of an anticancer medicine called Avastin as an ophthalmic medicine. The medicine was used off-label, i.e. for another use than that described in the product's summary.[60] The Ombudsman emphasised that if a doctor intends to prescribe a medicine off-label, they must tell the patient that it is a question of prescribing the medicine for a use other than the one mentioned in

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53 Salla Lötjönen, '*Loukatun suostumuksesta potilaan itsemääräämisoikeuteen*', Lakimies 7–8/2004, 1398–1420, 1410.
54 Irma Pahlman, '*Potilaan itsemääräämisoikeus ja hoitotestamentti*', Lakimies 6/1997, 815–835.
55 Lehtonen et al (n 1) 195.
56 ibid.
57 ibid 198.
58 HE 185/1991 (n 215) 16.
59 Lehtonen et al (n 1) 198.
60 Parliamentary Ombudsman's decision, EOA Dnro 3603/2/2013.

the medicinal product's summary approved by the marketing authorisation authority. The doctor should also explain to the patient the therapeutic reasons why they are prescribing off-label medicine and such a statement should be given to the patient in writing in accordance with the Patient's Rights Act.
Furthermore, the Ombudsman stated that if a patient refuses to use Avastin off-label, to which they are entitled due to the right to self-determination, the patient could not be left without a treatment, which would be an unlawful act. It was also stressed that when prescribing Avastin off-label, the physician's responsibility for the treatment and the obligation to inform the patient in writing are emphasised. Consequently, off-label use of the drug requires informed, written consent from the patient.[61]
Other measures that require written consent include e.g. abortion, castration, sterilisation and the removal of organs and tissues for medical purposes and participation in medical research or as a patient in the training of healthcare staff.[62] Such treatments and measures affect physical integrity to such an extent that the obtaining of the written consent is justified for the legal protection of both the patient and the healthcare professional.

3.1.3. Tacit consent

Despite the preparatory work of the Patient's Rights Act not defining the term minor procedure or treatment, some characteristics can be found:

- Interference with the patient's personal integrity is not significant;
- The patient is able to understand through visual observations what kind of treatment they are receiving (in case of a visually limited patient, the healthcare professional verbally explains the treatment); and
- The patient by their behaviour shows to understands the situation and cooperates with the healthcare professional.[63]

Pahlman has listed examples of situations that fulfil the three characteristics and fall in the category of minor medical treatments that can be carried out after a tacit consent is given: making a wound dressing, suturing or skin gluing a wound, removing a mole and draining an abscess.[64] Such examples can be considered as minor procedures that do not constitute a more serious sub-treatment, as the

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61 Annual Report by the Parliamentary Ombudsman, <https://www.oikeusasiamies.fi/documents/20184/42383/2013-fi> 226, accessed 13 March 2021.

62 Tuula Suhonen, *Potilaan suostumus tutkimus- ja hoitotoimenpiteisiin ja potilaan oikeus kieltäytyä hoidosta* (2012) Opuslex <https://www.opuslex.fi/artikkelit/perhe-ja-perinto/potilaan-suostumus-tutkimus-ja-hoitotoimenpiteisiin-ja-potilaan-oikeus-kieltaytya-hoidosta/> accessed 13 March 2021.

63 Pahlman, 'Potilaan itsemääräämisoikeus' (n 25) 195-196.

64 Lehtonen et al (n 1) 197.

effects and risks are small and the bodily and personal integrity are not significantly affected. In a situation where a healthcare professional treats a patient who walks in and tells about a speck in their eye, sits down and patiently waits for the treatment, the healthcare professional can treat the patient without an explicit consent due to the patient's behaviour.

3.2. Withholding or withdrawing consent

A patient may refuse at any stage the treatment or procedure planned for them, including treatments that have already started. A patient can also agree to treatment after consideration, even if they have initially refused it.[65] Article 6 of the Patient's Rights Act also states that if a patient refuses a certain treatment or measure, they have to be treated, as far as possible, in another medically acceptable way in mutual understanding with them.[66] The patient also has the right to make decisions that may harm their health or life and the healthcare professionals must respect the decisions of the patient.[67] However, the decision to implement treatment is always made by a healthcare professional and while the patient has the right to refuse the proposed treatment, they will take the responsibility for the refusal, and treatment is continued in another medically acceptable way when possible.[68]

The definition of patient's consent includes both positive and negative consent, i.e. refusal.[69] Thus, it seems consistent that the patient's refusal can be either explicit or tacit. The refusal is then recorded in a reliable manner in the patient journals.[70]

3.3. Patient journals

The Patient's Rights Act provides that the healthcare professionals shall record the information necessary for the arranging, planning, providing and monitoring of care and treatment for a patient in the patient documents.[71] On the other hand, the Decree of the Ministry of Social Affairs and Health on Patient Journals provides that information on service events should include, to the necessary extent,

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65 Suhonen (n 60).

66 Act on the Status and Rights of Patients, art 6.

67 Valvira, Itsemääräämisoikeus, <https://www.valvira.fi/terveydenhuolto/potilaan-asema-ja-oikeudet-oikeudet/potilaan-itsemaaraamisoikeus> accessed 15 September 2020.

68 Potilaan oikeudet. Potilaan itsemääräämisoikeus: suostumus ja yhteisymmärrys, <https://www.ppshp.fi/Potilaille-ja-laheisille/Hoidon-laatu-ja-turvallisuus/Potilaan-itsemaaraamisoikeus/Pages/default.aspx> accessed 14 September 2020.

69 Lehtonen et al (n 1).

70 Decree of the Ministry of Social Affairs and Health on Patient Journals (298/2009), art 18.

71 Act on the Status and Rights of Patients, art 12.1.

the reason for the visit, preliminary information, current status, observations, examination findings, problems, diagnosis or health risks, conclusions, treatment planning, implementation and follow-up, disease course and final statement.[72] Therefore, the wording of the Patient's Rights Act (interpreted in the light of the mentioned article of the Decree), does not provide exhaustive guidance on to what extent the relevant information gathered during examination and treatment sessions should be recorded. As from each such session the relevant information should be recorded, it seems reasonable to exercise case-by-case consideration and in minor cases, a summary of the treatment or examination is sufficient to ensure good treatment of the patient, whereas, in contradictory or atypical cases, a more thorough recording is needed. The Minister of Social Affairs and Health, according to which the more difficult and critical the patient's situation or the more significant the treatment decision is, the more precise and detailed the recording to the patient journal should be, supports this view.[73]

As mentioned in chapter 3.2, the patient's consent or refusal is found in the patient journals as well, since it is required to treat the patient in an agreement with them, and document the outcomes of relevant conversations with the patient.[74] Records of the patient journals should adequately reflect the rationale for the diagnosis, treatment chosen and treatment decisions made. The choice of examination and treatment methods with different effects and risks must be marked to show the reasons for the chosen method. The rationale for each procedure should be clearly defined in patient journals.[75] However, the Parliamentary Ombudsman has found that the patient journals are often completely devoid of records of discussions with the patient about their care and the views expressed by the patient.[76] These types of shortcomings are serious, as the main purpose of the patient journals is to ensure good patient care. If the journals lack the patient's view of the treatment or care, which the patient wishes to receive for example in the future, it can have serious consequences in situations where the patient is unable to provide their view later because of a mental disturbance, intellectual disability or other similar reasons.

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72 Decree of the Ministry of Social Affairs and Health on Patient Journals (298/2009), art 11.

73 Potilasasiakirjojen laatiminen ja käsittely. STM julkaisuja 2012:4, 45. <http://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/72897/URN%3ANBN%3Afife201504225719.pdf> accessed 15 July 2020.

74 Miia Soininen, 'Miten kirjaan, jos potilas kieltäytyy hoidosta?', Lääkärilehti 46/2017, <https://www.laakarilehti.fi/ajassa/ajankohtaista/miten-kirjaan-jos-potilas-kieltaytyy-hoidosta/> accessed 14 September 2020.

75 Decree of the Ministry of Social Affairs and Health on Patient Journals (298/2009), art 12.

76 Parliamentary Ombudsman's decision, EOA Dnro 2828/2/07, <https://www.eduskunta.fi/triphome/bin/thw.cgi/trip/?${APPL}=ereoapaa&${BASE}=ereoapaa&${THWIDS}=0.13/1600276273_9395&${TRIPPIFE}=PDF.pdf> accessed 16 September 2020.

The Decision 3892/4/15 of the Parliamentary Ombudsman concerned both insufficient patient journals, as well as obtaining the patient's informed consent. The patient had undergone plastic breast surgery and according to the patient journals, the patient's breasts were photographed six times during the treatment period. However, the patient journals' records were incomplete in the light of the Patient's Rights Act and the Decree on Patient Journals, as the reasons for the photograph and the patient's consent to be photographed were not fully recorded.[77]

Based on expert opinions, photographing the breasts can be considered to be justified and in itself in accordance with the treatment practice. However, in this case, the patient was probably not told clearly enough about the purpose or significance of the photography in her treatment. As a result, the patient felt that she did not receive sufficient information about the treatment and was unable to influence the treatment decisions in such a way that would reassure her that the treatment was carried out in mutual agreement with her. The details of the treatment and the importance of related measures, such as photographing, should have been discussed in more detail with her. It follows from article 6 of the Patient's Rights Act, that the photographing of the patient would have required her informed consent and that the patient had also the right to refuse being photographed. The patient complained to the Parliamentary Ombudsman, who considered that the procedure for photographing the patient was incorrect and that the entries in the patient journals were incomplete.[78]

3.4. Advance directive

The advance directive is always recorded in the patient journals, too, and it can be given explicitly - either orally or in writing. Through the advance directive, the patient continues to exercise the right to self-determination even after they are unable to decide on the treatment in accordance with the Patient's Rights Act.[79] In the advance directive, the patient may refuse life-prolonging treatment in a situation where it is likely only to prolong the suffering. On the other hand, the patient can also express their wishes regarding active treatment. Refusal or hope for active treatment expressed in the advance directive is binding on the healthcare professionals and guides the decisions of the patient's relatives unless

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77 Parliamentary Ombudsman's decision, EOA Dnro 3892/4/15, <https://www.eduskunta.fi/triphome/bin/thw.cgi/trip/?${APPL}=ereoapaa&${BASE}=ereoapaa&${THWIDS}=0.33/1600292733_32009&${TRIPPIFE}=PDF.pdf> accessed 11 September 2020.

78 ibid.

79 Lääkäriliitto, Lääkärin etiikka, <https://www.laakariliitto.fi/site/assets/files/5164/laakarin_etiikka_2013.pdf> accessed 11 September 2020.

there is a justified reason to assume that the patient's will has changed.[80] The advance directive is not only essential in end-of-life care, but it can also come into question in situations where the patient is not able to express their will regarding the treatment, for example, because of unconsciousness. However, the role of advance directive is especially emphasised concerning important treatment decisions and measures, which characteristically deeply intervene with the patient's integrity and impose a statistical risk of injury, disability or death.[81]

The advance directive does not have any strict form, but the patient can decide how they want to express their wishes for future treatment. Like in the case of withholding or withdrawing consent, the patient always has the right to explicitly change or withdraw the advance directive, which is recorded in the patient journal with information indicating whether the patient has been informed of the consequences of complying with the will.[82] Article 8 of the Patient's Rights Act provides that necessary treatment to ward off a hazard cannot be given to a patient, who steadfastly and competently expressed their will concerning the given treatment.[83] However, if the advance directive was created a long time ago, the healthcare professional needs to consider whether the patient's will might differ and whether they are aware of the updated information regarding possible treatments.[84] In an active and surprising situation, it might also be difficult to know about an existing advance directive and the healthcare professionals might be obliged to act against it. In such situations, it might also be difficult to interpret the patient's intention, in comparison to an advance directive created together with a healthcare professional because of a terminal illness.

The *My Kanta* service is the recommendable platform to store the advance directive. It is a nationwide service where both public and private healthcare providers can record information for example regarding the medical examination results and healthcare-related entries.[85] However, it is argued that healthcare professionals may not have all the necessary information about the content of the *My Kanta* service, and may not know what information is stored in the Patient Data Repository, from where *My Kanta* service retrieves the information.[86] Nevertheless, this service exists and is actively used.[87]

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80 ibid.

81 Lehtonen et al (n 1).

82 Sosiaali- ja terveysministeriö, 'Potilasasiakirjojen laatiminen ja käsittely' <http://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/72897/URN%3ANBN%3Afi-fe201504225719.pdf> accessed 11 September 2020.

83 Act on the Status and Rights of Patients, art 8.

84 Lääkäriliitto (n 77).

85 My Kanta pages, <https://www.kanta.fi/en/my-kanta-pages> accessed 11 November 2020.

86 Sari Kauppinen and Marita Kokkonen, *Terveydenhuollon ammattilaisten Omakanta-palveluun ohjaamisen haasteet* (Laurea University of Applied Sciences 2017) 6-7.

87 Kanta: Omakannan käyttö kuukausittain, viim 12 kk,

4. Voluntary and competent consent to or refusal of medical interventions

4.1. The essence of the right to self-determination

The question of self-determination is ultimately about the protection of the weaker party. First, the right to self-determination is a basic concept that includes the right to liberty and equality, and the prohibition of discrimination. Second, it includes the right to privacy and personal integrity. Third, it includes the right to competence.[88] An individual may lack the right to self-determination for two reasons; either they do not have the freedom to determine because other people dictate them or they are not capable of doing it themselves.[89] There is no real right to self-determination unless a person understands their interests and acts in accordance with them.[90]

Every patient-doctor relationship is a matter of the patient's integrity and interference, as well as respect for the patient as a subject. Subjectivity means that, as a rule, decisions are made by the individual. The patient exercises their right to self-determination as consent to treatment or research in accordance with the informed consent doctrine. The respect for the right to self-determination must be implemented as far as possible. Legally, the doctor decides whether to treat the patient or not and how to treat the patient. The patient's right to consent or refuse treatment limits the doctor's right. This means that the patient also bears partial responsibility for the decisions about individual care. The exception to this is the doctor's decision on involuntary treatment.[91]

4.2. Legitimate and unjustified paternalism

The concept of self-determination means that the individual is free to make decisions for themselves. Other persons may influence the actual exercise of a patient's right to self-determination. Relatives, close ones, legal representatives and healthcare professionals may knowingly or unintentionally impede the patient's train of free and autonomous thoughts and decision-making.[92]

<https://www.kanta.fi/documents/20143/129708/Omakannan+k%C3%A4ytt%C3%B6+12kk.jpg/036b798c-1739-8343-72b9-1ccaed7094bd?t=1528379440769> accessed 13 November 2020.

88 Pahlman, 'Potilaan itsemääräämisoikeus' (n 25) 182-183; Lehtonen et al (n 1) 194.

89 Juha Räikkä, 'Johdanto' in Veikko Launis and Juha Räikkä (eds): *Itsemääräämisoikeus* (University of Turku 1993) 3–11; Pahlman, 'Potilaan itsemääräämisoikeus' (n 25) 170.

90 Pahlman, 'Potilaan itsemääräämisoikeus' (n 25) 171.

91 ibid 121, 183, 188, 191; Lehtonen et al (n 1) 194–195.

92 Räikkä (n 87) 3–11; Pahlman, 'Potilaan itsemääräämisoikeus' (n 25) 170.

The infringement of the right to self-determination can be either legitimate or unjustified. The legitimate intervention refers to situations where an individual's choices are unreasonable and harm the individual's health to the extent that the legislator has considered it possible to restrict the individual's right to self-determination.[93]

In that way, the right to self-determination is not absolute but can be limited. Paternalism is about narrowing a patient's right to self-determination for the benefit of the patient. The legal basis, in this case, is the right to prohibit the patient from causing harm to themselves. The legitimate paternalism thus means ignoring the patient's right to self-determination and making decisions for the benefit of the patient when the person exercising paternalism has a legal right to violate the autonomy of another person or the person's condition is one of those listed below.

1) The patient has never had the right to self-determination within the meaning of the Patient's Rights Act,
2) The patient's right to self-determination is temporarily removed from them and there is medical evidence of this, or
3) The patient has permanently lost the right to self-determination.

The legitimate paternalism is used in situations 1-3 by healthcare professionals, guardians and legal representatives.[94] The Mental Health Act, the Act on Social Work with Substance Abusers (41/1986), the Communicable Diseases Act and the Act on Special Care for the Mentally Handicapped (519/1977) contain provisions concerning the authorisation to treat a person against their will.

As stated earlier, the right to self-determination must be respected as far as possible. The institutions cannot guarantee that the patient is self-determined. The patient's self-determination is built, verified, and realised in an interactive patient-physician relationship. The core of the doctrine of medical consent is adequate information, an adequate understanding of it and considered consent as a process.[95] However, the patient's right to self-determination is not actualised if the healthcare professionals do not respect the patient's wishes.

There is an imbalance of power between the patient and the doctor. The physician has the expert power based on the knowledge and clinical experience, as well as the power to decide in individual cases how healthcare resources are allocated. The patient may even directly or indirectly state that the doctor can make decisions on their behalf. In these situations, paternalism is based on trust. A doctor has a duty to think about the patient's best interests and to act in accordance with them.[96] However, it is essential for the doctor to be aware of this imbalance. For

93 Pahlman, 'Potilaan itsemääräämisoikeus' (n 25) 171.
94 ibid 181–182.
95 ibid 241.
96 ibid 172, 179.

example, a patient may comply with a doctor's advice because of their authority, and in the worst-case scenario, the patient does not dare to express their own will.

The right to self-determination essentially includes the idea of a person's independence and authenticity.[97] Especially when treating elderly patients, the doctor should ensure that the patient has expressed their own will regarding the treatment and not the will of outsiders, such as relatives' will. The consent of deputy decision-makers only becomes relevant in situations where the patient is unable to exercise their sovereignty over an important treatment decision. Merely a patient's age alone is therefore not a sufficient justification for not ascertaining the patient's own will if that is otherwise possible.[98]

Medical research should be emphatically based on genuine voluntariness. A mere consent to research is not in itself sufficient but does in addition require the creation of conditions for real voluntariness. This means that the subject is not pressured in any way to give consent and is sufficiently informed and is given time to consider the decision. In addition to the patient-physician relationship, voluntariness can also be affected by many other factors, such as the supervisor or teacher-student setup. Other influencing factors may include, for example, the ability to access surgery more quickly.[99] In case a person is vulnerable, special attention should be paid to determine the patient's will when making treatment decisions or giving consent to research.

4.3. What are the conditions for valid consent or refusal?

The Patient's Rights Act regulates patient's right to self-determination. Based on article 6; '(t)he patient has to be cared for in mutual understanding with them.' The legally valid consent of the individual cannot be replaced by the good purpose of the medical procedure or the medical assessment that the procedure is in the best interests of the patient[100]. Although the physician makes a valid decision based on knowledge and experience, every decision made on behalf of the other in the name of health is value-based. Only the patient knows their perceptions of quality and value of life. Therefore, the treatment is always chosen according to the patient's needs in mutual understanding.[101] As a rule, the patient's

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97 Juhani Pietarinen, 'Itsemääräämisoikeus' in Veikko Launis and Juha Räikkä (eds): *Itsemääräämisoikeus* (University of Turku 1993) 22–23.

98 Lehtonen et al (n 1) 206.

99 Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, ch 64; Salla Lötjönen, *Lääketieteellinen tutkimus ihmisillä* (Forum Iuris 2004) 124-127.

100 Pahlman, 'Potilaan itsemääräämisoikeus' (n 219) 191; Lehtonen et al (n 1) 195.

101 Samuli Saarni (ed), *Lääkärin etiikka* (7th edn, Suomen lääkäriliitto 2013) 15.

consent is required for all medical interventions and it is a precondition for the lawfulness of the treatment.[102]

The concept of self-determination requires the simultaneity of three different factors: voluntariness, competence and knowledge.[103] However, the Patient's Rights Act is not fully committed to these elements. The exercise of the right to self-determination presupposes a person's competence, which means the ability to understand the meaning of treatment or refusal of treatment and its health effects. According to the general principles of law, voluntary, non-coercive opinion forming and decision-making are the starting points for this.[104] Despite that, it is essential to note that the patient is not required to have legal capacity. The key is that they can understand aspects that are adequate for the treatment and the research. The doctor will decide if the patient can determine their own treatment. A patient can also consent or refuse treatment even after they have refused to receive the information. Therefore, consent should be intentional rather than knowledge-based. The underlying principle of the doctrine of consent is autonomy, which is repeatedly implemented at different stages of the process.[105]

A competence can be divided into general and situation-specific competence. General competence means that a person is able to form relatively consistent perceptions of themselves and their surrounding reality. Situational competence thus means the ability to make a considered decision in each situation. Even if a person is generally capable of making decisions, some factors related to that particular situation can cause the person to be incapable of making a decision. The reason may be, for example, a strong fear or a lack of information about the situation.[106] When questioning a patient's competence, it is essential that the physician assess whether the patient lacks general or only situational competence. If, for example, a patient is unable to exercise their sovereignty due to panic the urgency of the decisions and the patient's condition should be assessed. Whenever possible, the physician should wait for the patient to calm down so that the treatment decisions can be made with mutual understanding.

For the patient to be able to make independent choices between different research and treatment options, it is the physician's responsibility to present all the sensible methods, their benefits and drawbacks. While patient autonomy is a core human rights principle, it does not diminish the physician's responsibility when making decisions regarding a treatment. The danger of over-emphasising the

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102 Inkeri Anttila, '*Tarvitseeko lääkäri tehtävän suorittamiseen potilaan suostumuksen?*', Lakimies 1944, 29–30; HE 185/1991 (n 215) 16.

103 Lehtonen, Lohiniva-Kerkelä, Pahlman (n 1) 195.

104 ibid; Pahlman, 'Potilaan itsemääräämisoikeus' (n 25) 183, 188.

105 Pahlman, 'Potilaan itsemääräämisoikeus' (n 25) 188–189, 214, 220.

106 Pietarinen (n 95) 17–22.

right to self-determination is that an uncertain physician shifts the responsibility for the choice on the patient.[107]

If the patient refuses a certain treatment or measure, they must be cared for, as far as possible, in another medically acceptable way in mutual understanding with them (article 6 of the Patient's Rights Act). The patient's right to self-determination means that they can refuse any treatment that has already been planned or started. The right to refuse a treatment also applies to situations, which result in the patient's death, serious injury, serious illness or risk of such illness.[108] By nature, self-determination allows a person to live and act by their individual perceptions, beliefs and values.[109]

Although a patient cannot be left untreated because of their refusal, the patient is not entitled to request a particular type of treatment. The doctor decides on the treatment in accordance with article 22 of the Health Care Professionals Act. The same applies to medical research. The doctor decides on the patient's examination and the need for an examination. Even in these situations, the patient always has the right to refuse the treatment that has been provided by a doctor.[110] If the doctor and the patient cannot agree on the treatment or its necessity, another doctor can be consulted.[111]

Do Not Resuscitate (DNR) is an important treatment decision that is always made individually for each patient. The decision is based on a medical assessment of the patient's condition and prognosis that are based on the physician's education and experience. The patient's age or diagnosis are not critical in the decision. The DNR decision should primarily be made by a doctor and a patient with one accord. The DNR decision can also be discussed with the patient's relative or another close person with the patient's consent. In principle, however, the patient's relative or other close person is an outsider. If a patient is unable to take a position on their care, a patient's treatment demands approval of the patient's legal representative, a close relative or another close person as provided in article 6 of the Patient's Rights Act. When the patient is no longer able to decide and assess their situation, the decision to discontinue the active treatment is ultimately at the discretion of the physician. When the physician considers that it is not in the patient's interest to continue the treatment, active treatments are stopped, even if the person in the position of deputy decision-maker requires further treatment. The consensus requirement is based on the best interests of the patient.[112]

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107 Anttila (n 100); Saarni (n 99).

108 HE 185/1991 16; Pahlman, 'Potilaan itsemääräämisoikeus' (n 25) 214–215; Lehtonen et al (n 1) 199.

109 Saarni (n 99) 27–28.

110 HE 185/1991 16; Pahlman, 'Potilaan itsemääräämisoikeus' (n 25) 217; Lehtonen et al (n 1) 195.

111 Saarni (n 99) 16.

112 Lehtonen et al (n 1) 206–207.

The Convention on Human Rights and Biomedicine (SopS 23–24/2010, later Biomedical Convention) came into effect in Finland on 1 March 2010. The purpose of the Biomedicine Convention is to protect the dignity of the people and to guarantee, without any discrimination, that everyone's integrity and other rights and fundamental freedoms are respected in the field of biology and medical applications. The Convention emphasises the individual's right to self-determination. The consent requirement related to medical research is defined in article 6 of the Medical Research Act (488/1999). A consent to research is considered to require stricter criteria than the consent to treatment. In a treatment relationship, the purpose of the procedure is to determine, maintain, or improve the patient's health. In a research relationship, the purpose of the measure is, in part or in full, to increase scientific knowledge. The problem can also be formed by the fact that today tissues and embryos do not only concern scientific but also commercial interest. The current informed consent model does not provide any legal protection for the donors if tissue samples or embryos are used against their will. Therefore, consent to research must be explicit and documented.[113]

4.4. What are the powers of the patient's representative?

A legal representative, a family member or other close person of the patient has to be heard before making an important decision concerning a treatment that would be in accordance with the patient's will, if an adult patient is incapable of deciding on their treatment because of mental disturbance, mental retardation or for some other reason. If this matter cannot be assessed, the patient must be treated in a way that can be considered to be in accordance with the individual's personal interests (article 6 of the Patient's Rights Act). The patient's legal representative, a close relative or other close person, must therefore approve important treatment decisions. A consent should take into account the patient's previously expressed will. If the patient has not expressed a will for a treatment, the treatment should be based on the best interest of the patient.[114]
When the persons are heard as deputy decision-makers, relatives do not take precedence. The person who best knows the patient's will, their personal views and the things they would prioritise, is placed in a consultative position. The role of the respondent is to bring out information about the patient's personal convictions and their way of life, as well as their previous attitude towards different situations.[115]

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113 Lötjönen, 'Lääketieteellinen tutkimus ihmisillä' (n 51) 176–177; Laura Walin, '*Kun suostumus ei riitä – kudosnäytteen ja alkion luovuttajan oikeusaseman tarkastelua*', Lakimies 5/2008, 776-777.

114 HE 185/1991 17.

115 Lehtonen et al (n 1) 199–200.

The guardian or other legal representative shall not have the right to refuse any care, which may be required to avert a threat to the patient's life or health (article 9 of the Patient's Rights Act). The same applies to any research in a similar situation. The article prevents situations of abuse of decision-making power, where the decision-making is influenced by, for example, and the interests of the heir or the religious beliefs of the relative, which differ from the patient's own beliefs. In the last resort, it is a medical question of what is meant by a treatment necessary for life or health.[116]

4.5. What are the legal consequences of missing consent?

There are no sanctions in the Patient's Rights Act for missing consent. The legal situation is different between medical procedures and medical research. The Medical Research Act stipulates that examining a patient without their consent is a punishable act (article 6). If medical research is conducted without the patient's consent, the court may impose a fine for the act (article 27). The legal situation can be considered unsatisfactory. The patient's consent to care can be neglected without a fine, but failure to consent to a medical examination is sanctioned.[117]
The patient receives legal protection via an objection procedure and an administrative complaint. If the healthcare professional has acted incorrectly or negligently, this may result in administrative control, a written warning, a restriction or withdrawal of professional practice rights. In matters concerning disciplinary proceedings, the Health Care Supervisory Board (Valvira) deals with restrictions and removal of rights. There is also a sanction for breach of duty under the Penal Code. Injuries to the patient are compensated in accordance with the Patient Injuries Act (585/1986).[118]
In Finland, the Parliamentary Ombudsman has objected to improper procedures by doctors and hospital districts who have carried out procedures without the patient's consent. In the ECtHR practice, medical procedures performed without the consent of the patient or legal support have been considered as violations of article 8 of the ECHR for which the patient must be compensated financially[119]. The Court has drawn attention to whether the procedure caused the appellant fear, anxiety or feelings of inferiority. Because of the complaints, patients have

116 Pahlman, 'Potilaan itsemääräämisoikeus' (n 25) 227.
117 ibid 198.
118 Hallituksen esitys eduskunnalle laiksi terveydenhuollon ammattihenkilöistä annetun lain muuttamisesta HE 347/2014 vp (Government Proposal on Changing the Health Care Professionals Act) 7.
119 *X v Finland* App no 34806/04 (ECtHR, 3 July 2012); *Y.F. v Turkey* App no 24209/94 (ECtHR, 22 July 2012); *Glass v the United Kingdom* App no 61827/00 (ECtHR, 9 March 2012); *M.A.K. and R.K. v the United Kingdom* App nos 45901/05 and 40146/06 (ECtHR, 23 March 2012).

received compensation from hospital districts for violating their right to self-determination.[120]

5. Capacity to decide on medical interventions

5.1. Competence of adult patients

The right to patient's self-determination has been recognised as a basic right in the Finnish Constitution, as well as in human rights conventions ratified by Finland, as one of the important rights that must be honoured as far as possible. It is a matter of protecting the weaker party as well as the right of an individual to make unrestricted choices.[121] Article 6.2 of the Patient's Rights Act mentions the conditions when a patient is not competent to exercise the right to self-determination and is able to make decisions regarding their own healthcare. These are mental disturbance, intellectual disability and other possible conditions determined by a doctor such as long-term unconsciousness. In other words, for a patient to be able to exercise the right to self-determination, competence is demanded. The competence is defined as the ability to think, to want and to make decisions concerning oneself, but also as the ability to understand the impact of the treatment or the refusal as well as the impact on one's state of health. The criteria for competence are the ability to understand the procedure, the possible effects, the meaning as well as the content of the consent.[122] The right to self-determination sets patient's consent as the prerequisite for treatments' permissibility[123] since a patient must be treated in consensus with them.[124] Legally sufficient consent consists of adequate ability on determination, adequate knowledge and voluntariness.[125] Adequate knowledge is part of a doctor's responsibilities since they are obliged to give information about the treatment, the state of health of the patient and the effect of the treatments on the patients' health, in a way in which the patient easily understands the received information.[126]
The patient's competence on exercising the right to self-determination is not tied with one's competence before the law, but the sufficient ability to make decisions, which is an unconditional requirement to a legally sufficient consent, is. This means that even a person who is not capable of taking certain legal actions

120 Annual Report by the Parliamentary Ombudsman, EOAK 09.10.2013 Dnro 673/4/12, 73-74; Decision of the Parliamentary Ombudsman, EOA 22.8.2013 Dnro 2803/4/12.
121 Lehtonen et al (n 1).
122 Irma Pahlman, *Potilaan itsemääräämisoikeus ja hoitotestamentti*, Lakimies, 6/1997, 820.
123 HE 185/1991 16.
124 Act on the Status and Rights of Patients, art 6.1.
125 Mirva Lohiniva-Kerkelä, *Terveydenhuollon juridiikka* (Helsinki Talentum 2007) 113.
126 ibid 113; Act on the Status and Rights of Patients, art 5.

may still be capable of deciding on their own healthcare. Due to which, even a person who suffers from dementia or from a mental disability, may have sufficient ability to consent to treatment when these prerequisites are met. The Deputy Parliamentary Ombudsman stated in its recent decision that an over 80 year old elderly, who lived in a treatment facility due to their severe dementia, was still able to express their wills and desires.[127] There is no official routine according to which a patient's ability to self-determination could be assessed[128] but the competence; sufficient knowledge and voluntariness are the prerequisites for a patient's self-determination.[129] All of them must be fulfilled at the same time.
When the patient does not meet the criteria for competence, they cannot exercise the right to self-determination by themselves. The doctor, who decides whether the adult patient is able to exercise the right to self-determination in accordance with the law, assesses the valid competence.[130]

5.1.1. Incapable adult patient in need of treatment

When a patient is incapable of making healthcare decisions themselves, the patient's legal representatives, such as a person authorised by the patient or a close relative, must be heard so the patient's will and what treatment best responds to the patient's volition, may be figured out.[131] Even during the treatment of a patient who is incapable of exercising the right to self-determination, their personal beliefs and matters, which they prefer, shall be taken into account. This means that the patient's treatment must be pursued in such a way, as the patient would generally decide if they could decide about their own treatment.[132] Because article 6.1 of the Patient's Rights Act states that the patient must be treated in consensus with them, in situations where the patient does not hold the capacity to self-determination on their own medical treatment, the medical interventions must be made in consensus with the legal representative or a relative.
When a patient is not capable of exercising their right to self-determination on medical treatment, the healthcare proxy decides together with the doctor on the suitable treatment. However, the proxies have limited power on making healthcare decisions due to the fact that the decisions on medical interventions do have a higher threshold than, for example, decisions on monetary transactions since medical care is a question of personal integrity. When the patient has an

127 Decision of the Parliamentary Ombudsman EOAK 3513/2020, 14.
128 Anna Mäki-Petäjä-Leinonen, *Vanhuusoikeuden perusteet* (Alma Talent Oy 2017) 230–231.
129 ibid; Lehtonen et al (n 1) 195.
130 Mäki-Petäjä-Leinonen (n 126) 230–231; Lehtonen et al (n 1) 199.
131 Act on the Status and Rights of Patients, art 6.2.
132 ibid; HE 185/1991 17.

adequate advanced directive, it primarily removes the possibility of the legal representative to intervene in the medical treatment. On those occasions, the legal representative only has the role of a clarifier of the will. Also, when giving their consent on medical treatment, they must take into consideration any prior will that the patient has stated even when not being written on an advanced directive, as well as the best interest of the patient.

5.1.2. Forced treatment

Due to the right to self-determination being a constitutional right, there must be valid legal grounds in order to intervene.[133] The Mental Health Act, Communicable Diseases Act and Child Welfare Act (417/2007) (*Lov om barneverntjenester*, hereinafter Bvl), are the Acts including such paragraphs in which a patient's right to self-determination may be overridden and the patient may be forced into treatment. Already in the preparatory materials for the Mental Health Act, the need for a specific prerequisite for forced treatment has been acknowledged.[134] The prerequisites are: 1) the person has been diagnosed with a mental illness, 2) the person is in need of treatment for the illness and without that treatment, it would get considerably worse or severely endangers the patient's or others health or safety, and 3) all other mental health services are incapable or inadequate.[135] All three criteria must be fulfilled so that the treatment could be ordered against the patient's will.

Since Finland has ratified the ECHR, the Convention functions as a part of the Finnish domestic law, which therefore also must be taken into consideration when assessing the national regulations. According to article 5(1) of the Convention, everyone has the right to liberty and this liberty may not be deprived without being in accordance with a procedure described by the law. Article 5(1)(e) acknowledges the prevention of spreading infectious diseases, persons of unsound mind, alcoholics, drug addicts and vagrants being situations in which a person's liberty may be lawfully deprived.

Forced treatments may, however, only be exercised in hospitals. According to a Finnish Supreme Administrative Court's judgment given in 2006,[136] the Court stated that since the patient was transferred from a hospital to a rehabilitation centre, located outside the hospital, and later on transferred back home, the forced treatment had ceased the day the patient had left the hospital, despite still being a hospital patient and receiving treatment.

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133 Suomen perustuslaki 731/1999 (The Finnish Constitution) art 7.
134 The Government's Proposal to Parliament for the Mental Health Act, HE 201/89 vp 15.
135 The Mental Health Act (1116/1990) art 8.
136 KHO 2006:85.

5.1.3. To what extent can a patient refuse a treatment?

Despite the fact that the patient is being treated in consensus with them, the patient's right to self-determination does not mean that they can demand that a certain procedure is to be conducted, but rather means that they have the right to accept or decline from a medical treatment or procedure.[137] That is to say, the doctors hold an exclusive right to make decisions concerning the examinations and the content of medical treatment.[138] Patients do not hold any right on demanding certain treatments or examinations,[139] so the healthcare personnel may refuse to give the treatment that the patient wants, especially when finding it unnecessary. When a patient denies contacting their family members or legal representative and as a result, any information on their background cannot be received, or legal representative cannot be contacted for further information, the question about the right to self-determination rises again. In a situation where the patient's will is being complied with but they do not receive the treatment, the doctor could be held accountable for the act of negligence.

As mentioned before, a patient who is not capable of exercising the right to self-determination is treated in consensus with their legal representative. When the legal representative denies treatment, the patient shall be treated, where possible, in some other medically acceptable way. It is to be noted that the legal representative does not have the right to deny any treatment necessary to prevent danger to the patient's health or life. In addition, when the legal representatives of a patient outlook on the treatment deviates from one another, the patient is treated in a way that is in their best interest.[140]

As said, a self-determinant patient has the right to decline from any treatment, planned or already ongoing, due to the voluntary nature of the consent. The right to declination goes as far as the right to decline from treatment, without which the patient would die, which could lead to severe trauma, severe illness, or the possibility for one. If a patient refuses the treatment, they will not be left untreated, but they must be treated in consensus with other medically acceptable ways. The doctor will be obliged to inform the patient on how their health and life might be affected if they decline from treatment.

An incompetent patient may withdraw their consent at any point if it goes in line with their interest. Eventually, however, the doctor makes an objective assessment of what the best and the most beneficial treatment for the patient in the situation is.[141] A competent patient's right to self-determination extends as far as

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137 Pahlman, 'Potilaan itsemääräämisoikeus' (n 25).

138 Laki terveydenhuollon ammattihenkilöistä 1994/559 (Act on Health Care Professionals) art 22.

139 Lehtonen et al (n 1).

140 Act on the Status and Rights of Patients, art 6.3.

141 Hakalehto and Pahlman (n 30) 285–287.

refusing from treatment even in situations where the treatment would negatively affect their health or even cause their death.
According to the Finnish legislation, when the patient's will is unknown, and cannot be resolved, for example, due to the patient's unconsciousness, the doctor is obligated to give the treatment, if deemed necessary, in order to protect the patient's life or health. The healthcare professionals thus cannot refuse from giving necessary treatment to the patient.

5.2. Competence of a child

5.2.1. When can a child consent to or refuse medical treatment? Are there any established criteria for assessing ability to decide on medical treatment for children?

Article 4 of the Act on Child Custody and Right of Access states that parents or legal guardians of the child have the right to decide on medical treatment for the child. As already mentioned in chapter 5.1.1., the capability to make decisions concerning one's medical care is not attached to their competence before the law but on their general competence, such as the ability to think and make decisions regarding themselves, which also applies to minors. Furthermore, according to article 7 of the Patient's Rights Act, a minor patient must be cared for in consensus with the minor themselves, concerning their age and the level of development. Thus, a minor may be capable of deciding on their own treatment without the need for influence or consent from the parents. Minor patients' ability to influence on decisions concerning themselves may be divided into three categories: 1) self-determination, in which the patient's consent is enough for legal capability, 2) parents' consent is needed, and 3) minor's opinion must be heard, and the opinion taken into consideration in accordance with their age and level of development.[142]
The minor has the right to self-determination when the doctor finds them being capable of understanding the procedure and its effects. When this is the case, the patient is being treated in consensus with themselves, not with the parents, even if they disagree. A doctor is the one who makes the assessment without any external impacts, and the consideration must be made separately with each treatment.
The patient's age, as well as their level of development, affects the decision whether or not the minor patient is capable of exercising the right to self-determination, and the nature of the procedure must be taken into consideration as

[142] Anna-Kaisa Aaltonen, 'Lapsioikeus ja lapsen oikeus tuomioistuimessa' (Edilex 2009) 241–242.

well.[143] A 12-year-old may always be considered as sufficiently capable to have the right to self-determination.[144] However, the will of under 12-year-olds must be taken into consideration as well, if they contest the treatment.[145] Another possible age-limit for exercising the right to self-determination has been found to be the age of 15, due to the criminal liability age according to the Finnish Criminal Law and the medical examinations legislation, which both set 15 years as the age limit.[146] However, there is no set age to when a minor is capable of exercising the right to self-determination in medical treatment and it is always an overall assessment.

As part of the assessment, the doctor also evaluates the interaction between the doctor and the patient, the minor's individual factors, as well as the entire family's values and factors affecting their background.[147] For more, the minor must have appropriate knowledge on treatment options and the possible effects of those. Based on that knowledge the patient should have the possibility to consider the options and effects with care and express their will without any outside coercion or pressure.[148]

In the decision given by the Parliamentary Ombudsman of Finland in 2015, he emphasised that there is no set age in legislation when evaluating a minor's capability for exercising the right to self-determination, but the crucial element in the assessment is whether the patient is able to understand the effects of the treatment and of declining from it. The patient's maturity is one of the criteria among with their level of development and the possible risks of the operation.[149] In literature the criteria for a minor being capable to exercise the right to self-determination are described as following; they are mature enough to consider the treatment, they have had enough information on different treatments and their effects, they have considered the issue with care and the minor has stated their will and opinion without any pressure or coercion.[150] As seen, although there are no set criteria for the assessment of a minor and their right to self-determination,

143 HE 185/1991 18.

144 ibid 17.

145 Anja Hannuniemi, 'Alaikäisen oikeudellisesta asemasta terveydenhuollossa', Lakimies 6/1997, 842.

146 Kirsi Pollari, 'Lapsen asema potilasasiamiesten työssä – lapsen oikeus osallistua ja tulla kuulluksi', Lapsiasiavaltuutetun toimiston julkaisuja 2011:9, 14.

147 Kirsi Pollari, 'Lapsipotilaan päätöksentekokyky ja sen arviointi' (Doctoral thesis, University of Lapland 2019).

148 Kirsi Pollari and Mirva Lohiniva-Kerkelä, 'Ketä kuullaan – Kuka päättää? Alaikäisen osallisuus ja itsemääräämisoikeus terveyden- ja sairaanhoidossa' in Suvianna Hakalehto-Wainio and Liisa Nieminen (eds), *Lapsioikeus murroksessa* (Lakimiesliiton kustannus 2013) 287.

149 Decision of the Parliamentary Ombudsman, EOA 11.6.2015 Dnro 61/4/15.

150 Markku Helin, Alaikäisen oikeudet potilaana in Koivisto (ed), *Potilaan oikeudet ja potilasasiamiestoiminta*, (Suomen Kuntaliiton julkaisu 1994) 92.

they nevertheless are similar in the legal praxis, literature and in legal preparatory works.

There might rise conflicts on the interest of the child and their right to self-determination. The minor's competence in self-determination must be assessed on whether the child's opinion can be argued objectively. A child's full right to self-determination, thus, would mean that they have the right to decide matters concerning them in contradiction to their benefit.[151]

A minors' will, when competent, may not be confined because the parents have a different view on how the treatment should be conducted. As mentioned, minors deemed competent in this regard are to be treated equally to self-determinant adults.

When the child is competent, they may decide on declining a treatment just as self-determinant adult patients may. However, they must understand the effects of declining the treatment on their health. In this situation, the patient must be treated in another medically acceptable way in consensus with the patient.

5.2.2. Who decides that a legally incapable child needs treatment?

When a minor is incapable of deciding about their own medical treatment, they are treated in consensus with the parents or a legal guardian.[152] When the child has two parents, both of them must make the decision together.[153] In the judgement of the Administrative Court of Finland from 2003, the Court ruled that both parents' approval for therapy was necessary and that when the parents are disagreeing on the treatment, the treatment cannot be given as an agreement between the other parent and a doctor.[154] In a Supreme Court judgment, the Court argued that circumcision was a medical procedure that requires both of the parents' consent. When the father of the child had made the decision by himself for cultural and not medical reasons, it was an act, which was punishable as an assault.[155] When the doctor was in a justified belief that both of the parents' had given the permission, he could not be punished for an assault.[156]

However, before the parent makes the decision on the medical treatment given to the minor, the child must be heard and their opinion and wishes have to be taken into consideration.[157] According to the legal framework, it is mandatory to take into consideration the child's opinion due to the principle according to

151 Pollari, 'Lapsen asema potilasasiamiesten työssä' (n 145) 13.

152 Act on the Status and Rights of Patients, art 7; Laki lapsen huollosta ja tapaamisoikeudesta 361/1983 (Act on Child Custody and Right of Access) art 4.

153 The Finnish Act on Child Custody and Right of Access, art 5.1.

154 HAO 2 8.11.2003 T 93/0837.

155 KKO 2016:25, paras 22-23, 33.

156 ibid para 40.

157 Act on Child Custody and Right of Access, art 4.2.

which parents must gradually give more and more independence to the child and thus secure the child's growth towards adulthood.[158]

In a recent decision given by the Deputy Parliamentary Ombudsman of Finland, she stated that treatment given to a seven-year-old who was in foster care should have been done in consensus with the biological parents and child welfare services. When the doctor who had treated the child and prescribed medication to him, had argued that the parents of the child should not be informed of the treatment, the Deputy Parliamentary Ombudsman found this to be illegal, since a minor who is not capable of exercising the right to self-determination must be treated in consensus with their parents.[159] In case a child is placed in foster care, the decision on their healthcare should be made together with the parents and child protective services.[160] Despite the right to self-determination being a primary ethical principle, a complex question on a minor patient's right to self-determination and the patient's advantage emerges when the child suffers from substance abuse. Intoxication affects the patient's ability to make decisions regarding themselves and in these situations, the doctor needs to assess whether or not to contact the parents. In these situations, the doctor assesses the situation based on the doctor-client confidentiality, trust, as well as based on building a treatment relationship.[161] Because the parents' presence has proven to have positive effects on treating a minor's substance abuse problems, it does weigh in during the consideration. However, if the minor declines on contacting the parents, it does create a complex issue due to the law obligating doctors to inform the Child Protective Services on matters which seriously dangers the minor's development,[162] who then have the authority to contact the child's parents.[163] Most of the time, it is also justified for the doctor to inform the parents about substance abuse even without consent.

158 Government proposal, HE 224/1982 vp 14.

159 Decision of the Parliamentary Ombudsman EOAK 4.9.2020 Dnro 7210/2019.

160 Lastensuojelulaki 417/2007 (Child Welfare Act) art 45.3.

161 Suomen Lääkäriliitto, 'Potilaan päihdeongelma', <https://www.laakariliitto.fi/laakarinetiikka/mielenterveys-ja-paihdepotilaat/potilaan-paihdeongelma/> accessed 9 September 2020.

162 Child Welfare Act, ch 3, art 25.

163 Janne Aer, *Lastensuojeluoikeus: Lapsi- ja perhekohtaisen lastensuojelun oikeudelliset perusteet* (Sanoma Pro 2012) 52.

5.2.3. Can a child that refuses medical treatment be forced to undergo treatment anyway? In what cases?

As mentioned earlier, when a legally incapable child refuses or contests a treatment, their opinion must be taken into consideration. A child who is resisting the treatment should not be treated involuntarily.[164]
A minor patient may also be ordered to forced treatment by a decision made by a doctor when suffering from an intellectual disability or mental illness.[165] A minor may be ordered into forced treatment with or without the parents' consent. Although, the parents' must be given a chance to be heard when possible, either orally or in writing.

5.2.4. Can a legally incapable child receive treatment when the guardians oppose it? In cases where the guardians of the child do not agree on the need to have a medical intervention, who decides?

Parents or legal guardians of a minor do not have the right to forbid necessary treatment for the minor's health or life. These include treatments which when left undone, could lead to causing an injury, such as plastering a fracture; or surgery for a fracture, which when left undone, may lead to a permanent defect on the position of the patient's bone. The aforementioned is an example of the treatment necessary for the patient's health. Necessary treatment for a patient's life would be, for example, blood transfer or surgery.
If a legal guardian or parents of the minor refuse treatment, which according to medical professionals would be necessary for the health and life of the patient, the child may be taken into custody and an organ corresponding to social welfare would give the consent to the treatment.
In a judgment given by the Supreme Administrative Court of Finland in 1991, in which the minor had leukaemia and was in need for immediate blood transfer, which both parents of the minor objected to, the Court adjudicated that the child could be taken into custody and be hospitalised so the treatment could be accomplished.[166] In another similar judgment, the Supreme Administrative Court adjudicated that a child suffering from lymphoma could be taken into custody since the minor's parents refused on giving blood products for the child. The Court stated that it was a necessary action to prevent danger to the child's life or health.[167]

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164 ibid; Anja Hannuniemi, 'Alaikäisen oikeudellisesta asemasta terveydenhuollossa', Lakimies 6/1997 842.
165 Mielenterveyslaki 1116/1990 (Mental Health Act) art 8.2.
166 KHO 9.8.1991 T 2542.
167 KHO 10.3.2000/530.

As mentioned, both of the minor's parents need to consent to medical treatment for the child. However, if one of the parents is being hindered due to illness or for other reasons and thus cannot participate in the decision making and delaying the decision would cause harm to the minor, a decision must be made with only one of the parents.[168] However, the exception does not apply when the decision has a crucial impact on the future of the child. This kind of crucial impact would be, for example, a difficult surgery or medical treatment due to a severe condition.[169] When the question is more about ordinary healthcare for example, which is exercised in healthcare centres rather than in a hospital, both parents' consent is not necessary.[170] However, when different examinations and treatments are in question, the situation is entirely different and especially when one of the parents denies a treatment, such treatment cannot be provided for the minor.
In the Supreme Court's decision in 2016, the Court adjudicated that a circumcision for some other reason than a medical one was to be viewed as a matter in which both parents' consent was necessary.[171]

6. Exception: Emergency medical interventions

6.1. Introduction

As mentioned before, the right to self-determination is one of the fundamental principles of medical ethics in Finland.[172] As it refers to the treatment of patients in accordance with their will and wishes, this principle extends to emergency medical interventions as well. Emergency medical interventions, however, form an exception to the rule due to unusual circumstances of the treatment. It is not always possible to get informed consent from the patient or even acquire their wishes regarding treatment.
This section will cover the current legislation in Finland regarding emergency medical interventions, consent as a legal instrument and the wishes of the patient. Moreover, the current regulatory challenges and the definition of 'emergency medical intervention' will be covered in this section as well. Legislation, academic articles, books and official Ministry of Social Affairs and Health guidelines will be used.

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168 Act on Child Custody and Right of Access, art 5.2.
169 Hallituksen esitys Eduskunnalle laeiksi lapsen huollosta ja tapaamisoikeudesta ja holhouslain muuttamisesta sekä niihin liittyvien lakien muuttamisesta HE 224/1982 vp (Government's Proposal to Parliament for the Law on Child Custody and Access Rights and Amendments to the Guardianship Act amending the related laws) 14.
170 Tapio Räty, 'Alaikäisen oikeudellisesta asemasta terveydenhuollossa', Lakimies 6/1997, 1211.
171 KKO 2016:25.
172 Valvira (n 65).

6.2. Current legislation in Finland

The Patient's Rights Act regulates emergency medical interventions and consent.[173] Article 8 of the Patient's Rights Act regulates emergency treatments. According to this article, 'a patient has to be given treatment necessary to ward off a hazard imperilling their life or health even in case it is not possible to assess the patient's will because of unconsciousness or other reasons'. However, if the patient has expressed their will earlier steadfastly and competently, they must not receive any treatment that goes against their will. Therefore, the patient's wishes must be respected concerning emergency treatment and intensive care.[174] There must always be medical reasons for the treatment.

It is not in the patient's best interest to give treatment if it is not medically reasonable.[175] According to a government proposal, article 8 of the Patient's Rights Act is meant to be applied in instances where the patient's wishes cannot be inquired and the need for treatment is urgent. Postponing medical treatment would be harmful to the patient's health or even lead to death.[176] It is noteworthy that a suicide attempt should not be interpreted as a patient's rejection of the treatment.

Article 50 of the Health Care Act (1326/2010) defines emergency medical treatment as 'involving an injury, a sudden onset of an illness, an exacerbation or a long-term illness, or a deterioration of functional ability where immediate intervention is required and where treatment cannot be postponed without risking of worsening the condition or further injury.'[177]

6.3. Current regulatory challenges

Medical care, including emergency medical treatment, should align with the patient's wishes or expected wishes. There are certain instances where the issue of consent and emergency medical care come up frequently, for example in childbirth and in end-of-life -treatments. A global pandemic such as Covid-19 has also shown that the doctors must prioritise between patients if there are not enough supplies or beds for all. There is also a separate issue of emergency care in clinical medical trials.

When a patient is close to dying, one of the most important aims of treatment is to alleviate pain and suffering. Often it is medically sensible to stop treatment

173 Act on the Status and Rights of Patient (785/1992).
174 Saarni (n 99) 121.
175 ibid.
176 HE 185/1991.
177 Terveydenhuoltolaki 1326/2010 (Health Care Act).

since emergency medical care is highly invasive to the body. If the patient is not conscious, their relatives or close ones must be notified of the situation.[178] According to article 6 of the Medical Research Act, 'if a person taking part in a clinical trial on medicinal products is not able to give consent on taking part in the trial, the person may not -- be research subject unless the person's close relative or another person closely connected with the person or their legal representative, after having been informed about the nature, meaning, effects and risks of the clinical trial, gives consent to taking part in the trial. The consent must be in accordance with the research subject's supposed will.' Thus, it is equally important to respect the wishes of a person who is part of a clinical trial.
Obstetric violence is a term used to define violence against women during childbirth. According to World Health Organization (WHO), it is the 'appropriation of a woman's body and the reproductive process by health personnel, in the form of dehumanising treatment, abusive medicalisation and pathologising of natural processes, involving a woman's loss of autonomy and of the capacity to freely make her own decisions about her body and her sexuality, which has negative consequences for a woman's quality of life.'[179] Obstetric violence might manifest itself through violation of consent or going against the will of the patient.[180] Even though childbirth might sometimes lead to an emergency, there is usually time to ask for the mother's consent or wishes.

6.4. Conclusion

Emergency medical interventions pose a challenge to the traditional notion of informed consent in medicine. As the right to self-determination is one of the key principles of medical ethics, it must be taken into consideration during emergency medical interventions despite the obvious time constraints due to the nature of emergencies. It is not always possible to get informed consent from the patient or even from close family. The Patient's Rights Act regulates emergency medical interventions, as well as consent, and article 8 of the Act considers emergency medical interventions. However, it must be noted that if the patient has specifically expressed their will earlier, they must not receive treatment against their will. According to the government proposal regarding article 8 of the Patient's Rights Act, this article should be applied when the patient's consent and/or wishes cannot be inquired and lack of treatment would be harmful or lead to the patient's death.

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178 Suomen Tehohoitoyhdistys, Suomen Tehohoitoyhdistyksen Eettiset Ohjeet (2019) 10.

179 World Health Organization, Organic Law on Women's Right to a Violence-Free Life, art 15(13).

180 Saara Jämes, '*Potilaan itsemääräämisoikeus synnyttäjän oikeutena*', <https://sjlaw.fi/potilaan-itsemaaraamisoikeus-synnytyksessa/> accessed 10 September 2020.

There are certain situations where the issue of consent and emergency medical interventions cause issues for medical professionals. For example, childbirth and end-of-life treatments. Recently, the Covid-19 pandemic has demonstrated that doctors must prioritise between patients due to lack of resources. Moreover, childbirth has led to issues known as 'obstetric violence'. This term is used to define violence against women during childbirth when their will is not respected due to lack of consent.

Overall, emergency medical interventions form an important exception to the principle of self-determination and informed consent. Due to the fast-paced nature of emergency medicine, it is not always feasible to ask for the patient's consent. However, this does not mean that the patients' wishes and will should not be respected.

Chapter IV:
Report from Norway

1. Legal regulation of patient's status

The essentiality of consent is a reflection of the conditions to prevent patients' integrity breach. The right to self-determinate the extent of medical intervention protects the legal sphere of all citizens. Patient's decision-making is hereby a safeguard to withhold the principle of legality. As a result, consent functions as a prerequisite to receive healthcare – healthcare simply cannot be given without consent. Healthcare has a wide range of scope. This report will primarily discuss patients' consensual status from a medical standpoint. In spring 1999, the Norwegian health legislation underwent the biggest reform of that century. Four new legislations were created to regulate the medical field. This health-reform clarified the legal statuses of medical interventions, the goal being to improve welfare. The four mentioned laws were the Norwegian Health Personnel Act,[1] the Norwegian Patient and User Rights Act,[2] the Norwegian Specialist Health Services Act,[3] and the Norwegian Mental Health Care Act.[4] These new laws collectively created a new framework for Norwegian health law. In the later years more specific legislation were rectified, e.g. the Norwegian Biotechnology Act,[5] and the Norwegian Health and Care Services Act.[6]

1.1. What are the legislative acts that regulate the issues of patients' decision-making in your country?

1.1.1. The Health Personnel Act

After the health reform, the four new laws are the main regulations in the field of healthcare. The Health Personnel Act is the framework for health professionals' duties when executing medical care. This law regulates their confidentiality, authorisation, scheme for reporting medical arrangements and general rules for professionally sound conduct. Furthermore, the Health Personnel Act is mainly created to ensure the public confidence in the healthcare system. Another goal was to ensure that the personnel is subject to clarified rules when exercising their

1 Lov om helsepersonell (Health Personnel Act 1999).
2 Lov om pasient- og brukerrettigheter (Patient and User Rights Act 1999).
3 Lov om spesialhelsetjenester (Specialist Health Services Act 1999).
4 Lov om etablering og gjennomføring av psykisk helsevernt (Mental Health Care Act 1999).
5 Lov om humanmedisinsk bruk av bioteknologi (Biotechnology Act 2003).
6 Lov om kommunale helse- og omsorgstjenester (Health and Care Services Act 2011).

profession. They still have to follow the Working Environment Act (2005) in work settings, but the Health Personnel Act has additional specified laws in order to guide health professionals in the field of medicine. This creates a favourable structure, so that the necessary aspects of healthcare are intact despite the general working environment concerns.

1.1.2. The Patient and User Rights Act

To protect the users of health services from partiality and to engage their rights to receive and refuse treatment and care are regulated in the Patient and User Rights Act (*Lov om pasient- og brukerrettigheter*, hereinafter Pbrl). This act preserves equal rights for all based on maintaining respect for live, integrity and dignity. This law does not discriminate between the persons receiving healthcare. Each citizen has the right to receive medical assistance regardless of ethnic backgrounds, sex, social status, and economic standards.[7] It is the duty of the healthcare professionals to perform medical assistance. The Pbrl served all the same rights.

1.1.3. The Specialist Health Services Act

The purpose of having a Specialist Health Services Act is to maintain integrity in smaller, more specific parts of the healthcare system. This would also be the motive behind the Mental Health Care Act. Every field has their own challenges and having regulatory principles for each will judicially make the system structured. The Specialist Health Services Act primarily regulated the healthcare system when combating diseases, injury and disabilities while contributing to quality, equality, availability and adaptability in performing specialist heath treatments.[8] These services will not exclude medical care; however, it is not the primary motive.

1.1.4. The Mental Care Health Act

The Mental Health Care Act has the main purpose of protecting the implementation of such in a responsible manner. In addition, the given care should be in

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7 IS-8/2015 Patient and User Rights Act, with comments <https://www.helsedirektoratet.no/rundskriv/pasient-og-brukerrettighetsloven-med-kommentarer > accessed 28 November 2020.

8 IS-5/2013 Special Health Services Act, with comments <https://www.helsedirektoratet.no/rundskriv/spesialisthelsetjenesteloven-med-kommentarer/Spesialisthelsetjenesteloven-med-kommentarer-IS-5-2013.pdf> accessed 28 November 2020.

accordance with human rights and basic principles of legal security.[9] This regulation is one of few that legalises force in order to practice healthcare towards patients; however, it is explicitly given that force should be limited.[10] The patient's personal and physical integrity should be respected at all times. The Mental Health Care Act is considered to be in accordance with Norway's international obligations.[11]

1.2. What international human rights instruments have a significant influence on the status of a patient in your country? Why did the influence of these instruments become significant in your legal system?

The Norwegian healthcare law is inspired by several international human rights instruments. It is not coincidental that the implementation on human rights regulations in Norwegian law and the health reform was done at the same time.[12] The health reform had its baseline from the international human rights conventions. These are the ECHR, the ICCPR and the ICESCR. The CRC was also implemented into national law on later events.[13] Adaptation of these particular conventions resulted in making several changes to national regulations, especially the healthcare system. Hereafter, the principle of precedence was introduced; when in conflict, the international human rights protocols precede against other legislations.

In addition, the World Health Organization's declaration heavily influences Norwegian healthcare regulations. The Declaration on the Promotion of Patients' Rights in Europe is not directly implemented as the conventions mentioned above.[14] However, these acts are used as directions in current legislation. The declaration regulates the patient's integrity, as well as the right to receive adequate information about the treatments they receive. The same range of incorporation in national legislation goes for the Ljubljana Charter on Reforming Health Care.[15] This charter gives great detailed regulations on the systematic function on healthcare systems in Europe. However, the Oviedo Convention was ratified by

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9 IS-9/2012 Mental Health Care Act, with comments <https://www.helsedirektoratet.no/rundskriv/psykisk-helsevernloven-med-kommentarer> accessed 28 November 2020.

10 Mental Health Care Act s 1-1 (1).

11 Proposition from the Odelsting (*Odelstingsproposisjon*, hereinafter Ot.Prp) No 11 (1998-1999) ch 4; Ot.Prp No 65 (2005-2006) ch 3; Proposition from the Storting (hereinafter Prop) 78 L (2015-2016) ch 8.4.

12 Lov om styrking av menneskerettighetenes stilling i norsk rett (Human Rights Act 1999).

13 Aslak Syse, *Pasient- og brukerrettighetsloven med kommentarer* (4th edn, Gyldendal Norsk Forlag 2015) 63.

14 World Health Organization, Declaration on the Promotion of Patients' Rights in Europe (1994).

15 World Health Organization, Ljubljana Charter on Reforming Health Care (1996).

Norway in 2006 and consist of strict regulatory principles in biomedical research on humans.[16] It also reaffirms how to treat patients in accordance with human rights.
Overall, the international human rights instruments have a great influence on the national legislation and will often emphasise the international law obligations.[17]

1.3. Do patients have legal rights to decide about their treatment?

The core of patients' right to self-determinate lies in the concept of consent. Thus, their autonomy will be respected. Consent also secures the patients' right to co-determination. When co-determining, the patient is choosing to undergo the treatments suggested by health professionals. In order to give consent, the patient must have formal legal capacity as well as the ability to understand the consequences of giving consent. Their mental and/or physical ability to reflect upon the consequences of refusing medical help refers to the concept of competence to give consent. Their capability to intake the necessary information should be intact, cf the Pbrl section 4-3.[18] Every person above the age of 16 has consenting competence. Exceptionally this may not be the case if the patient is clearly not able to understand the consequence of giving consent. The lack of competence can be caused by physical or mental disability, senile dementia or other psychological deficiencies. The main assessment for medical practitioners will be to determine the individuals' consenting competence. *Helsedirektoratet* (the Norwegian Directorate of Health) evaluates the patient's capacity of making an informed decision that is not clearly affected by a medical condition.[19] Health personnel utilise the tool 'FARV' when determining a patient's consenting competence. If a patient is able to rationally understand (*forstå*), recognise (*anerkjenne*), reflect (*resonnere*) and make a decision (*ta et valg*) based on the provided information, they have consenting competence. The FARV-method was developed through empirical research, case law and general medical ethics. The method is a supplement designed to ensure that the evaluation of the patient is exclusive and comprehensive. As previously mentioned, there is a complete framework for retrieving valid consent; this will be discussed further in chapter 4. On a day-to-day basis, everyone makes consensual acknowledgements freely, but Norwegian health law requires consenting competence. It would be difficult to create a bal-

16 The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (1996).
17 Syse (n 13) 65.
18 Patient and User Rights Act (1999).
19 IS -9/2012 Mental Health Care Act, with comments < https://www.helsedirektoratet.no/rundskriv/psykisk-helsevernloven-med-kommentarer > accessed 28 August 2020.

ance between the patient's autonomy and their right to healthcare without constructed guidelines. Consent is the primary term to engage healthcare, therefore it is of the utmost importance to clarify whether the patient has consenting competence or not. However, the validity of competently given consent can still be doubted if there is a lack of information. Without having sufficient knowledge of what the patient is agreeing to, the consent will be invalid - it is a necessary criterion for consent.[20]

1.3.1. What are the legal remedies when the right to self-determination is violated?

An overall understanding of the consent criterion can be derived from a coherent analysis of the Pbrl and the Penal Code. There is a connection between the extent of the treatment and the consensual requirements. The more advanced invasions will require equally strict demanding forms of consent.[21] The Penal Code sections 274, 280 and 281 regulate mainly assault and battery. However, they can be used analogically to describe health law principles. The more physically endangering diagnostic acts or treatments require consent of higher quality and clarity. Treatments that cause significant pain require written consent. When turning the viewpoint around, in order for healthcare personnel to have their execution of work be non-punitive, the collected consent must be explicit, cf the Penal Code section 276. This is when, as mentioned above, the procedure is extensively invasive or painful. The Supreme Court's appraisal on this matter should be noted here.[22] A 77-year-old woman experienced physical and mental affliction after a doctor did a gynaecological exam without her explicit consent. The doctor informed the patient about the full health check that she had consented to, but she was not made aware of the gynaecological test in particular. The doctor presumed there was consent when she agreed to the full body check. The Supreme Court found that a gynaecological examination composes a physically and mentally burdening treatment. Consent through passivity will not be adequate. This distinction of severity in treatments is also firmly established in the Mental Health Care Act.[23]

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20 Henriette Sinding Aasen, *Pasienters rett til selvbestemmelse ved medisinsk behandling* (1st edn, Fagbokforlaget 2000) 347.

21 ibid.

22 Rt. 1984, 22.

23 Mental Health Care Act s 4-4 (2); Ot.Prp No 12 (1998-99) 133.

2. Information as a component for valid consent or refusal in medical interventions

2.1. What information shall be disclosed to a patient? Who has the obligation to inform?

Information is a necessary condition to exercise both the right to participation and to be able to give valid consent to healthcare. A valid consent must be an informed consent. Information, consent, voluntariness, participation, self-determination and autonomy are closely linked and are central to our Western legal tradition. Therefore, medical treatment and medical procedures must also be based on this.

The Pbrl section 3-2 states the main rule for a patient or user's right to information.[24] According to paragraph 1 of the same section, the patient shall have the information that is "necessary" to obtain an insight into their health condition and the content of the healthcare. The patient shall also be informed of possible risks and side effects.

The expression "necessary information" states that the patient must have received sufficient information about the purpose, methods, expected benefits and possible dangers associated with the procedure.[25] The section 3-2 shall ensure that the patient receives the necessary information to gain insight into their health condition and the content of the healthcare, meaning the treatment, nursing, care, diagnostics or examination offered and provided, and about the results of examinations and assessments of the health condition. In the case of untried or new treatments, the duty to provide information stiffens, especially in relation to informing the patient about the risks (see chapter 2.7).[26]

The person who provides health and care services, is obligated to provide information to the person who is entitled to it in accordance with the rules in the Pbrl sections 3-2 and 3-4. The right corresponds with the duty to provide necessary information, cf the Health Personnel Act section 10 and the Special Health Services Act section 3-11. All health personnel who provide healthcare to the patient are therefore obliged to provide information to the patient.[27] In health institutions, the person designated by the health institution is overall responsible for providing information.[28]

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24 Patient and User Rights Act s 1-3(a) and (f).
25 Health Personnel Act s 10.
26 Ot.Prp No 12 (1998–1999) 132.
27 Health Personnel Act s 3; Patient and User Rights Act s 1-3(e).
28 Health Personnel Act s 10.

2.2. How detailed and specific should the information be? Is it acceptable to provide information in broad terms?

There are various considerations behind the duty to provide information: the consideration that the patient should be able to give a valid consent *before* the treatment, and the consideration that the patient should be able to safeguard their interests *during* and *after* the treatment. The right to receive information must be adapted to the nature of the situation, which is pointed out in the preparatory work for the Pbrl: 'However, the information requirement must be adapted to the situation. In special situations such as emergency admissions and in immediate emergencies, it is therefore sufficient to inform about the measure, possibly serious complications and risks. The information requirement thus coincides with the requirement for informed consent in section 4-1.[29]

In addition to the section 3-2 paragraph 1 about providing the information that is "necessary", there are also listed requirements for what information is to be disclosed, if certain scenarios occur, in the sections fourth to seventh paragraph: If the patient or user is injured or has serious complications, the patient or user should be informed. At the same time, information shall be provided on the right to apply for compensation from the Norwegian Patient Injury Compensation, the right to contact the patient and user ombudsman and the right to request the supervisory authority to assess any breach of duty pursuant to section 7-4.

If the patient or user suffers injury or serious complications, and the outcome is unexpected based on foreseeable risk, the patient or user must also be informed of what measures the health and care service will implement to ensure that a similar incident does not occur again.

If the injury or complication as mentioned in the fifth paragraph is very serious, the patient or user shall be offered a meeting with the health and care service as soon as possible after the incident and no later than ten days after the incident. Such meetings seek to provide the patient or user with information pursuant to the fourth and fifth paragraphs, as well as answers to questions related to the incident and the further follow-up thereof. In the event of death because of a serious incident, the next of kin shall be offered a similar meeting.

Should the patient sustain any significant injuries as a result of their treatment, they are entitled to be informed of such, if reasonably feasible. The trust aspect is therefore important both before, throughout and after the treatment. The patient must have opportunities to look after her own interests even after the treatment has ended.

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[29] Ot.Prp No 12 (1998-1999) 130.

2.3. How should information be provided in general? Are there specific requirements for information disclosure for children, persons with disabilities and persons who do not speak the majority language?

The question of how information should be provided – or the form thereof – follows from the Pbrl section 3-5. It is required that the information is adapted to the qualifications of the individual recipient, such as age, maturity, experience and cultural and linguistic background. The information shall be provided in a considerate manner. As far as possible, health personnel shall ensure that the patient has understood the contents and significance of the information. This can also mean the use of an interpreter. It is the person who provides healthcare, who is responsible for arranging the dissemination of the information or ensuring that this is done.[30]

The information can be communicated in writing or orally, but because it should be adapted to the patient, it is not necessarily correct to give the patient a comprehensive standard form that covers all possible risks. Too comprehensive information can work against its purpose.[31] The main point is that the patient receives enough information to accept the healthcare/give a valid consent.

2.4. Can a patient refuse medical information? What are the legal consequences of refusal?

The Pbrl section 3-2 paragraph 2 states that the patient may refuse to receive information. Accordingly, information shall not be given against the expressed will of the patient. This is based on the right to autonomy and self-determination, which includes the right to refuse to receive information. Healthcare professionals must respect the patient's wish not to be informed. However, the right to refuse to receive information cannot apply without exceptions.

Only if it is necessary to prevent the harmful effects of the healthcare, or law, the patient must be informed against their will. The assessment of whether it is "necessary in order to prevent harmful effects" for the patient herself or others may indicate that the patient should be informed even if the patient does not wish so. There may also be another legal basis, for informing a patient against her will. For example, the due diligence requirement that applies to health personnel in section 4 of the Health personnel Act, and the requirement for informed consent, will often mean that healthcare cannot be provided if information is not provided. Healthcare is dependent on consent. A term for a valid consent, cf section 4-1, is that that the patient must have received "necessary information about their

30 Anna Kjersti Befring, *Helserett i et nøtteskall* (Gyldendal 2019).

31 Therese Eriksen, *Rettslig ansvar for medisinsk behandling ut gyldig rettsgrunnlag* (Universitetet i Oslo 2016) 16.

state of health and the content of the healthcare" (see chapters 3 and 4 of the report).[32]
Shall a patient refuse to receive information; one must establish to the patient whether a situation may arise where the information would be vital for further opportunities to provide healthcare.
In situations where information is not provided to the patient, this shall be justified and recorded in the medical record, cf section 3-5 paragraph 3, the Health Personnel Act, and the Patient Record Regulations section 7. The legal consequences of the patient refusing the information may be that it becomes important in the context of supervision and tort law, cf the Patient Injury Act.[33]

2.5. Is a patient always required to be informed about their health issues? Are there exceptions?

With regard to the time at which the information is to be provided, the Norwegian Directorate of Health assumes that the health service and health personnel emphasise the purpose for which the information is to be provided. The health service must therefore organise its activities so that patients and users experience openness about their health status and topical care throughout the treatment, and that they receive good and sufficient information about the incident at an early stage after an incident has occurred. It must be seen in connection with how the information is to be provided and must be adapted to the individual patient / user's individual requirements (see chapter 2.4).[34]
Section 3-2 paragraph 3 of the Patient and Users Rights Act is an exception to the patient's right to be informed. Information may be omitted if it is "urgently necessary" to avoid danger to life or serious health damage to the patient.
However, there is a high threshold for failing to provide information based on emergency law considerations. In the preparatory work, an example case is one where a very serious somatic disease has been diagnosed at the same time as the patient is in a mentally unstable period. If the patient becomes aware of the serious diagnosis at such a time, it may involve danger to the patient's life or danger to the patient's serious health damage.[35]
Information may also be omitted if it is "clearly inadvisable" for the sake of persons close to the patient to provide such information. When it comes to protecting the patient's close ones by failing to inform the patient, more is required than

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32 The Norwegian Directorate of Health's circular on requirements for the professional practice of health personnel (28 June 2018).
33 Patient Injury Act s 2 para 3.
34 The Norwegian Directorate of Health's circular on the Patient and User Rights Act with comments (1 April 2015).
35 Ot.Prp No 12 (1998-1999) 93, 129.

unfortunate consequences. According to the preparatory work, there must be a real danger of significant or substantial consequences.[36]

2.6. What is the legal status of family or other close ones in questions of information disclosure?

The legal starting point can be said to be the duty of confidentiality of health personnel pursuant to the Health Personnel Act section 21, cf the Pbrl section 3-6. The main rule is that health personnel and other employees in the health and care service must prevent unauthorised persons from gaining access to information about a person's physical or medical conditions, or other personal conditions that they have received or are entrusted with.[37]

Relatives have been more actively involved in patient care in recent years. However, the precondition that this is in line with patients' wishes and interests must be met. Exceptionally, information may thus be communicated to the patient's next of kin, cf the Pbrl section 3-3. That is if the patient consents thereto or circumstances justify it. The patient's next of kin shall then receive information concerning the patient's health condition and the healthcare that is being provided.[38] This, in turn, is based on the premise that relatives look after the patient's interests. The scope of the consent determines what the relatives are entitled to know. The provision only gives the "next of kin" the right to information. Health personnel therefore do not need to inform all relatives listed in section 1-3 letter b.

In other words, it is assumed in principle that the patient must consent to the disclosure to others, i.e. family or other close relatives, of information about their state of health. Irrespective of consent, family or close ones have the right to information to the extent "the circumstances so require".

In situations where it is not possible to obtain the patient's consent due to unconsciousness or mental disorders of various kinds, and of a transient nature, family and close relatives will also have the right to information. It is assumed that the patient would have wanted information to be communicated to the next of kin. The more serious the patient's condition, the greater effort may be required by healthcare professionals to inform relatives.[39]

In section 3-3 second paragraph, it is stated that if the patient is over 16 years of age and "obviously incapable" of safeguarding their own interests, both the patient and their next of kin are entitled to information pursuant to the provisions of section 3-2. This may be the case when the patient due to a physical or mental

36 ibid.
37 Health Personnel Act s 21.
38 Patient and User Rights Act s 3-3 para 1.
39 Text in (n 32).

disorder, senile dementia or mental retardation, in no way is able to safeguard their own interests.
For children, i.e. minors, there are specific descriptions of requirements for information dissemination in section 3-4. If the patient is under 16 years of age, both the patient and their parents or other persons with parental responsibility shall be informed. If the patient is between 12 and 16 years of age, information shall not be given to their parents or other persons with parental responsibility, when the patient, for reasons that should be respected, does not wish them to receive such information.
However, information that is necessary to fulfil parental responsibility shall be given to parents or other persons with parental responsibility when the patient is under 18 years of age. If the child welfare service has taken a child under 16 years of age into care pursuant to section 4-6 second paragraph, and 4-8 or 4-12 of the Bvl, paragraphs 1-3 shall apply correspondingly to the child welfare service.

2.7. What are the legal remedies and/or legal consequences for violating an obligation to provide information about medical treatments?

The duty to provide information shall enable the patient to cooperate and participate in the decision-making process. The patient is deprived of the right to look after their own interests, if they do not receive the necessary information. In that case, it would be contrary to both the principle of voluntariness and self-determination.
Chapter 11 of the Health Personnel Act contains reactions in case of violation of the provisions of the law. The counterweight is largely the rules included in the Pbrl*,* chapter 7 paragraph 1. The chapter deals with the patient's rights to complain in the event of, among other things, a breach of the rules in chapter 3 regarding right to participation and information.
The consequences for healthcare professionals can include anything from a warning, revocation or suspension of authorisation, license or specialist approval or punishment under the Penal Code. However, the most common in practice is that the patient is awarded compensation under the Patient Injury Act.[40] The health service and health personnel may be held liable for damages due to lack of information about risks. This may occur when the injury is caused despite the treatment or intervention being performed correctly enough, but the patient would not have consented to the intervention (with associated risks) if she had received correct information.[41]

[40] Syse (n 13) 331.
[41] ibid.

This was clarified in a judgment from the Norwegian Supreme Court with reference to a case concerning a young man who lost his sexual function after a back operation.[42] The risk of such an injury was approx. 5 percent, but he was not informed of this before the operation. The Supreme Court agreed that there was a duty to provide information, cf the current section 3-2, but the majority believed that the patient would still follow the doctor's advice to have surgery. He was therefore denied compensation.

In another judgment from the Supreme Court, the duty to provide information was somewhat extended.[43] The majority stated that the patient probably had to be informed of "predominantly probable consequences". The patient was not awarded compensation.

In the Judgment HR-2017-687-A, a patient had been informed that he had a slightly higher risk of future heart disease than the average for his age group, but he was not informed further about this risk or how he should deal with symptoms of heart attack. About three months later, he had a heart attack. The Supreme Court concluded that the lack of information from the doctor was no "failure" and did not provide a basis for patient injury compensation, cf the Patient Injuries Act section 2 paragraph 1(a). The duty to inform about possible risk factors had to be assessed in light of the fact that the risk of heart disease in the immediate time after the examination was very small. This premise was continued in another Judgement (HR-2020-1332-A).

3. Forms of patients' consent or refusal

3.1. In what forms can a patient consent to – or refuse of – medical treatment?

According to the Norwegian principle of legality, any intervention against the individual, also within the healthcare system, requires a valid legal basis. Such legal basis can be either law or the individual's consent. Through consent, a patient can give health personnel admission to perform actions that would otherwise have to be perceived as breaches of integrity. A patient's right to refuse, or consent to, medical treatment is regulated by section 4-1 of the Patients' Rights Act. According to section 4-1, 'healthcare may only be provided with the patient's consent', unless legal authority exists or there are other valid legal grounds for providing healthcare without consent. In order for the consent to be valid, the

42 Rt. 1998, 1538.
43 Rt. 1993, 1169.

patient must have "received the necessary information concerning his health condition and the content of the healthcare", cf the Patients' Rights Act section 4-1 paragraph 1.

The requirements regarding the form of the consent are specified in section 4-2 of the Patients' Rights Act. Section 4-2 states that consent may be given "explicitly or tacitly". The meaning of "explicitly" is not further defined in Norwegian law, however a natural understanding of the wording indicates that the patient's wishes must be clearly stated, without any doubt, either in writing or orally. According to general Norwegian contract law, an oral consent will normally be equated with a written consent.[44] Oral consents are mostly used as a legal basis for medical treatment in Norway. The consent is communicated through verbal approval from the patient to the health personnel conducting the medical treatment. In certain situations with a special need for notoriety however, a written consent may be required in order to prove that a voluntary consent was given. For measures of a more intrusive nature, there are stricter requirements in different Norwegian regulations to make sure that the patients really want the treatment, cf Ot.Prp No 12 (1998-99) p 132 and section 4-3 of the Patients' Rights Act. Examples of such situations, where a written consent is required, are section 1 of the Sterilization Act of 1977, section 5-4 of the Biotechnology Act and section 1 of the Transplantation Act. These are all examples of comprehensive and intrusive procedures. The more intrusive the measure, the stricter the requirements for an informed consent from the patient.

A consent to or refusal of medical treatment can also be given tacitly, cf section 4-2 of the Patients' Rights Act. Section 4-2 stipulates that a tacit consent is considered to have been given if it is "probable, based on the patient's conduction and all other circumstances, that they accept the healthcare". The patient must have had the opportunity to assess their situation and made a choice that is expressed through the conclusive behaviour.[45] One example could be that the patient shows up at the doctor's office, which must be regarded as tacit consent for the doctor to carry out necessary examinations to be able to diagnose the patient. In another example, a patient swallows a contrast medium for an X-ray examination. If the patient after receiving sufficient information, cf section 3-2 of the patients' Rights Act and have had the opportunity to participate, cf section 3-1 of the Patients' Rights Act, and does not oppose the measure, the health personnel must assume that there is a tacit consent. However, if the medical intervention is particularly painful, intrusive or may pose a risk to the patient, healthcare personnel have a duty to ensure that the consent also covers this situation. This

44 Syse (n 13) 394.
45 ibid 407.

follows indirectly from the due diligence principle in section 4 of Act of 2 July 1999 No 64 relating to Health Personnel.

Another form of consent is hypothetical or presumed consent.[46] A hypothetical consent means that health personnel assumes that the patient wants the medical treatment, even though they have not given a tacit or explicit consent to the procedure. This must be based on an assessment of how an average, sensible person would act, think or reflect. The health personnel must then act based on a constructed scenario that the patient would have consented to the medical treatment. An example of the use of hypothetical consent as a legal basis for a medical procedure is Rt 1998 p 1531 (the case of Cauda Equina). In this case, the injured party endured a surgical procedure. During the operation, nerves in the lower back were damaged, which affected his sexual function. He was not granted damages, because the treatment was considered to be adequate and the risk acceptable. The Supreme Court stated that the patient had not been given enough information regarding the procedure. However, the court found that the patient would have undergone the surgery, even if he had been given the necessary information regarding the risks of the surgery. Hypothetical consent was considered a valid legal basis for medical intervention. Other examples of hypothetical consent can be found in the Patients' Rights Act and the Transplantation Act.[47]

For patients who are unable to give a valid consent on their own behalf, a consent or refusal can be expressed through a representative.[48] Such a representative could be family members or health personnel, who have to contemplate what the patient would have wanted if the patient were competent to give their consent. This would be relevant in situations e.g. where the patient suffers from dementia or is mentally disabled.

3.2. Withholding or withdrawing consent

The Supreme Court has stated that '[t]he right to self-determination also includes making decisions regarding your own health, which from a professional point of view are not very rational or even are directly harmful for the patient.[49] A patient may withdraw or withhold their consent implicitly or explicitly. The health personnel shall then give the necessary information to the patient regarding the diagnostic consequences of not going through with the treatment, cf the Patient's Rights Act section 4-1, paragraph 2. A withholding or withdrawing of the consent can be done by the patient at any point of the examination or treatment, and does

46 Ot.Prp No 12 (1998-99) 81.
47 Patient's Rights Act, s 4-6(2); Transplantation Act, s 2(2).
48 Patients' Rights Act ss 4-7, 4-4, 4-5, 4-6.
49 Rt. 2010, 612.

not have to be explicit.[50] There could be a number of different reasons as to why a patient decides to withdraw or withhold a consent. Painful examinations or stressful psychiatric treatment can make the patient change their mind regarding the future benefits of completing the examination or treatment. The consequences of the treatment were more difficult to bear than expected. In such situations, health personnel shall ensure the patient that consent to such treatment will have positive consequences, and make sure that the consent is not withdrawn due to "ailments of the moment", cf Ot.Prp No 12 (1998-99). It is important that the health personnel provide necessary care to the patient, as well as understanding of the unpleasant and painful situation, to encourage them to continue with their original plan of treatment. Information about the consequences of withdrawing consent could make the patient change their mind. If the patient still wants to withdraw the consent, this must also be respected. However, the duty of health personnel to save lives will always be prioritised if there is ever a conflict with the patient's right to self-determination, cf the Patient's Rights Act section 4-9.

4. Voluntary and competent consent to or refusal of medical interventions

4.1. When can consent to or refusal of medical intervention be regarded as involuntary?

Healthcare shall take place on a voluntary basis, based on the consent from the patient, cf section 4-1 of the Patient's Rights Act. All relevant health measures in relation to examination, treatment and care require that the patient agrees and consents. The patient must give their consent in a process that is not characterised by coercion or duress. All health personnel must be aware of how the situation may be perceived by the patient. In many situations, one's position as health personnel gives an authority and respect that may influence the patient's decision. If so, the consent might be considered involuntary.

An important part of a voluntary consent is that the patient is accurately informed, cf the Patient's Rights Act section 3-2, which has been examined earlier in section 2 of the Norwegian national report. Another requirement for a voluntary consent is that the patient is competent to give a consent, cf section 4-3 of the Patient's Right Act. When a patient is not competent to give their consent, the consent cannot be counted as voluntary. The patient must have an understanding of what they consent to, as well as being able to make contemplated

[50] Syse (n 13) 406.

decisions regarding examination and treatments. Section 4-3 of the Patient's Rights Act states that persons of 'full legal age and legal capacity' and 'minors over 16 years of age' are competent to give their consent to or refusal of medical interventions, unless "special provisions or the nature of the measure dictate otherwise. In Norway, the "full legal age" is 18 years old. Furthermore section 4-3 paragraph 2 stipulates that the competence to give consent may cease to apply wholly or partly if the patient 'on account of physical or mental disorder, senile dementia or mental retardation, is clearly incapable of understanding what the consent entails. The decision is made by the health personnel. Health personnel shall 'do their best to enable the patient themselves to consent to healthcare, cf section 3-5', cf section 4-3 paragraph 3 of the Patient's Rights Act.

4.2. What are the legal consequences of consent or refusal being involuntary?

If a consent to or refusal of medical treatment is involuntary, it is also considered invalid, cf section 4-1 of the Patient's Rights Act. In principle, the patient is not bound by an invalid consent.[51] A medical intervention the patient has agreed to base on an invalid consent can hardly be remedied. Impunity only applies as long as the medical intervention is within the boundaries of the consent. For example, if a patient has taken medication for an illness on the advice of health personnel, despite the fact that they were made aware of a side effect, which could be characterised as an offence, the health personnel cannot be penalised for the offence. The patient may however have a claim for compensation against the health personnel or the hospital, cf the Norwegian Patient Injuries Act section 2 and 3.
In addition to claim for damages, the health personnel may also be penalised by the provisions of the Norwegian Penal Code regarding violations of the body and other unlawful attacks on personal freedom. However, according to the Attorney General and the Supreme Courts' assessment in specific cases, the provisions of the Penal Code will generally not be natural to use when an intervention takes place in the patient's best interests.[52] It is rare that a criminal case is brought against health personnel who has not intentionally harmed patients.[53] Other means of reactions will be more appropriate, such as compensation or reactions from the supervisory authorities according to chapter 11 of the Health Personnel Act.
Medical treatment with an involuntary consent is illegal and may be in violation of the responsible conduct requirement in section 4 of the Health Personnel Act.

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51 Syse (n 13) 391.
52 Syse (n 13) 391; Rundskriv RA-2001-5, 2.
53 Aslak Syse, Reidun Førde, Olav Helge Førde, *Medisinske feil*, (Heftet 2000) 36.

According to section 4 of the Health Personnel Act, health personnel shall 'conduct their work in accordance with the requirements to professional responsibility and diligent care that can be expected based on their qualifications, the nature of their work and the situation in general'. The assessment of whether the medical treatment is considered irresponsible conduct is made based on the individual situation and which alternative options the health personnel had at the time. If the treatment is irresponsible and in violation with section 4, the health personnel could e.g. get a warning, cf section 56, revoked authorisation, licence or certificate of completion of specialist training, cf section 57, a suspension, cf section 58, or a punishment according to section 67.

5. Capacity to decide on medical interventions

5.1. Competence of adult patients

5.1.1. Are there any criteria for recognising that adult patients are not able to consent to or refuse medical interventions? What are these?

If you are going to provide healthcare in Norway, there must exist a legal basis. The patient's right of self-determination can be seen as an expression of the person's autonomy, and that is why an intervention in a patient's self-determination normally requires use of law, which means that a valid legal basis is required (*legalitetsprinsipp*, principle of legality). Today this legal requirement is constitutional.[54] The Pbrl § 4-1 contains the main rule for consent. The statutory provision shows that healthcare only can be provided with the patients consent, unless there exists a statutory authority/provision or another valid legal basis to provide healthcare without consent.

The ability to consent shall not, however, be considered as a trait the patient has or does not have in general, but an assessment of whether the patient comprehends what the consent includes in the concrete situation of the patient's current medical intervention.[55] Such an understanding of the consent capability term is important for the legal system, because it makes it possible for other considerations to be crucial in a decision of whether a current legal provision can be used or not. Examples of such legal provisions are the mental healthcare act and the infection control act. In the situations that these acts regulate, it is important both

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54 Anne Kjersti Befring, *Helserett og helsetjenesten* in *Sentrale helserettslige emner,* (Anne Kjersti Befring, Morten Kjelland, Aslak Syse eds, Oslo 2016) 21.

55 Jan Fridthjof Bernt, *Tvangsmedisinering i psykisk helsevern- virkelighetsforståelse, rettferdiggjøring og rettssikkerhet* in *Selvbestemmelse og tvang i helse- og omsorgstjenesten,* (Bjørn Henning Østenstad, Caroline Adolphsen, Eva Naur, Henriette Sinding Aasen eds, Bergen 2018) 266.

for the safety of society and for the safety of the patient, that it is possible to make decisions on her behalf.
"Healthcare" is defined as actions that have preventive, diagnostic, treating, health-preserving, rehabilitative or nursing purposes performed by healthcare personnel, cf Pbrl § 1-3 c.
In Pbrl § 4-3's second paragraph it is stated that 'the competence to consent can lapse completely or partly if the patient clearly due to physical or mental disruptions, senile dementia or mental retardation is not able to comprehend what the consent includes.'
The criteria determines that adult patients are not able to consent to or refuse medical interventions if they lack the ability to 'comprehend what the consent includes'. However, this decision shall be made for the individual healthcare measure, and only after the healthcare personnel have provided the best conditions possible for the patient to consent themselves, cf Pbrl § 4-3 paragraph 3. In the acts preparatory works it is explained more detailed how the healthcare professionals are supposed to go forward when they decide whether an adult is able to consent or not. The healthcare personnel must consider in which areas it is inadvisable that the current patient has the competence to consent. Should the patient be unable to give their well-informed consent, this implies that they are unable to fully grasp the repercussions of their treatment. In turn, this means that they are unable to truly provide positive consent as required by law. Furthermore, the preparatory works state that there must be a reason for the patient losing their consent competence. It is only where the patient due to mental illness, physical or mental disruptions, senile dementia or mental retardation can lose their competence to consent.[56]

5.1.2. Who decides that an adult patient is incapable of making healthcare decisions?

When adults are unable to take care of themselves or refuse to receive daily medical help or refuse to consent to this help, it is primarily the nursing staff, without any legal education, that are supposed to consider if this help should be given regardless of the patient's resistance.[57]
This is also stated in Pbrl § 4-3 paragraph 3, where it is stated that persons who provide healthcare decide whether the patient lacks the competence to consent.

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56 Ot.Prp No 12 (1998-1999) to § 4-3.
57 Eva Naur, *Samarbejde eller juridisk bindende samtykke* in *Selvbestemmelse og tvang i helse- og omsorgstjenesten,* (Bjørn Henning Østenstad, Caroline Adolphsen, Eva Naur, Henriette Sinding Aasen eds, Bergen 2018) 57.

The healthcare personnel shall make the decision based on the patient's age, mental state, maturity and experience, and must provide the best possible conditions so that the patient can agree to the healthcare, cf Pbrl § 3-5.

5.1.3. Who decides that an incapable adult needs treatment?

Pbrl § 4-6 paragraph 1 states that persons who "provide healthcare" make the decision of whether healthcare should be provided. However, the healthcare can only be intrusive to a small degree with regard to extent and duration. In the provision's second paragraph it appears that healthcare which for the patient is intrusive to a high degree, can be given if it is considered to be in the patients best interest, and it is most likely that the patient would have given their consent, if they were able to. In other words, the health professionals have to familiarise themselves with the patients' needs to a certain extent.[58] Furthermore, in these situations, Pbrl § 4-6 states that information from the patient's closest relatives, considering what the patient would have wanted, shall be obtained when possible.

5.1.4. What are the legal consequences of incapacitation?

If a patient is incapacitated after the Guardianship Act § 22 paragraph 3, the patient shall as far as possible consent to the treatment herself. If this is not possible, the guardian can consent on behalf of the patient.
The Health Personnel Act § 7 regulates the health personnel's duty and right to give immediate help to a patient that is in an acute emergency and it is assumed that the help is urgently needed. This statutory provision also imposes health personnel to provide help if the patient is unable to give consent or opposes this help.[59] However, there are some situations where the patient has a right to refuse healthcare, even when this is not in their own best interest. In Norwegian law, this is regulated in Pbrl § 4-9.
The first exception is regulated in paragraph 1. The patient can refuse to receive blood or blood products or refuse to interrupt an ongoing hunger strike due to serious belief. It follows from the act's preparatory works that this means that the health personnel have no right to intervene with forceful treatment, even if the patient might die because of their decision. However, if the current health personnel cannot accept to treat the patient under these conditions, the patient can be referred to other health personnel.[60]

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58 Ot.Prp No 12 (1998-1999) to § 4-6.
59 Helsedirektoratet om Pbrl § 4-9.
60 Ot.Prp No 12 (1998-1999) to § 4-9.

The other exception is regulated in paragraph 2. A dying patient has the right to refuse life-prolonging treatment. In addition, if the patient is unable to convey her wishes, the health personnel shall abstain from treatment if the patient's closest relatives announces corresponding wishes and the health personnel after an independent evaluation also finds this to be the patient's wish and that this wish clearly should be respected. Although health personnel has a duty to respect the patient's wishes, pain can be relieved with medication. The refusal applies only to the treatment itself, not nursing and care.[61]

It appears that health personnel shall make sure that patients mentioned in paragraphs 1 and 2 are over 18 years of age and have not been deprived of their legal capacity on the personal area, and that the person concerned has gotten satisfactory information and understands the consequences of the treatment refusal.[62]

If the current patient is not covered by any of the exceptions in Pbrl § 4-9, the mental healthcare act makes it possible for health personnel to execute healthcare by force in some cases. This is regulated in § 4-4 of the same act. Healthcare personnel can force a patient into treatment, if the patient lacks the competence to consent, as defined in the Pbrl as mentioned earlier. Furthermore § 4-4 states that the 'treatment' of the patient must 'conform to professionally recognised psychiatric method and sound clinical practice'.

It is clear that healthcare personnel cannot refuse to give a patient the treatment that the patient *needs*. But as mentioned, there are situations where what the patient *wants*, regardless of what is in their best interest, must be followed due to certain legal terms. The healthcare personnel's possible desire to refuse to provide medical treatment is simply not a practical question. It is the patients right, based on their self-determination, to make the decision of whether they want the medical treatment. This is the clear starting point. However, when it comes to life-saving treatment, the duty to save life will go ahead of self-determination.[63] This is what Pbrl § 4-9 regulates.

However, a patient is never obligated to seek healthcare. For example, in Norway it has been discussed whether women giving birth, for the sake of their child's best interests, shall have a duty to seek professional healthcare. Today such a legal basis does not exist in Norway. Women can choose to give birth at home, even when healthcare professionals find this to med indefensible. However, if this leads to an urgent need for help, the healthcare professionals will give immediate healthcare based on the Health Personnel Act § 7, as mentioned.

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61 ibid.

62 Pbrl § 4-9, para 3.

63 Health Personnel Act § 7.

5.2. Competence of a child

5.2.1. When can a child consent to or refuse medical treatment? Are there any established criteria for assessing ability to decide on medical treatment for children? Who decides that a child is incapable of making healthcare decisions?

In the patient and user rights code § 4-3 paragraph b and c it holds that children between the age of 16 and 18 years old have competence to consent, unless it is otherwise noted in any special legal regulations or it follows from nature of the measure. Furthermore, children between the ages 12 and 16 have competence to consent with regard to healthcare which their guardians are not informed about, cf § 3-4 paragraphs 2-3, or it follows from the nature of the measure. In the preparatory works of Prop 75 L (2016-2017), it is stated that in the evaluation of whether the guardians shall be informed or not, there shall be an evaluation of what is in the child's best interest.

The criteria for assessing the ability to decide on medical treatment for children are the same as for adults, where the ability to consent will lapse if the child completely or partly clearly due to physical or mental disruptions, senile dementia or mental retardation is unable to comprehend what the consent entails.

Consent on behalf of a child is regulated in the patient at user rights code § 4-4. Both guardians have the right to consent on behalf of children under the age of 16. However, this does not apply for patients between the age of 12 and 16 years old who have the right to consent, cf § 4-3 paragraph 1(c). Furthermore, it is sufficient that only one of the child's guardians consents to the healthcare, which the health specialists find necessary to avoid harm to the child. If the child welfare services have taken over the responsibility of a child under the age of 16, cf the Bvl,[64] § 4-8 and § 4-12, they have the authority to consent to healthcare on behalf of the child. When the child turns 7 or when a younger child has the means to form their own views on what the consent involves, the guardian must provide the child with information and the possibility to state their opinion on the matter. For children aged between 16 and 18 years, the guardians have the right to on behalf of the child if the child is legally incapable of doing so. The decision of whether a child is capable to consent is made by health professionals.[65] This means that before the child turns 16, it is normally the guardian's responsibility to make the decision for the child's healthcare. However, after the age of 12 the same rules for adult applies,[66] and health professionals must consider the child's capability to consent in the situations listed in (b) and (c) of the same paragraph.

64 Lov om barneverntjenester (Child Welfare Act 1992).
65 The Patient and User Rights Act, § 4-3 para 2.
66 ibid.

5.2.2. Who decides that a legally incapable child needs treatment?

Normally health professionals will give incapable children healthcare with the consent of their parents, cf the Pbrl § 4-4. However, healthcare professionals have a duty to give children instant help if that is "urgently needed", cf the Health Personnel Act § 7. The rules of Norwegian childcare code only come into use if both parents, or one of the parents if that parent has the parental responsibility alone, opposes that necessary healthcare be given to the child. Furthermore, the county board can consent on behalf of the child if 'there is reason to believe' that a child suffers from 'a life threatening or other serious illness or injury'. They may decide that the child – with help from the childcare services – will get examined by a doctor or brought to a hospital for examinations if the child's parents does not ensure that the child receives the examination or the treatment needed, cf Bvl § 4-10

5.2.3. Can a child that refuses medical treatment be forced to undergo treatment anyway? In what cases?

Until the child turns 12, the child is incapable of giving consent and will therefore undergo treatment even if it refuses, when that medical treatment is in the child's best interest, cf the Health Personnel Act § 7.
In Norway, the capability to consent is related to age limits. In the Pbrl, the age is established at 16, but if the child has turned 12 years and does not agree with the medical measure, the question about establishing mental healthcare shall be brought to the Control Commission.
When the patient is between 16 and 18 years old and considered capable of giving consent, the patient has the right to oppose to treatment, because of their self-determination. The Pbrl does not give relatives the possibility to participate in these decisions. However, if the patient is legally incapable a guardian can consent on behalf of the patient, cf the Pbrl § 4-5.

5.2.4. Can a legally incapable child receive treatment when guardians oppose it? In cases where the guardians of the child do not agree on the need to have a medical intervention, who decides?

According to the Bvl § 4-10 a legally incapable child can receive treatment when guardians oppose it. However, before this can happen certain conditions must be met. First, there must be a "reason to believe" that the child is suffering from a "life threatening or other serious illness". If this is the case, the child shall be brought to a doctor or a hospital for examination. If the child's condition needs treatment, it may be decided that the child will be treated at a hospital or at home.

This statutory provision entails a limitation of the general parental responsibility, and can be perceived as particularly intrusive. However, as stated in the preparatory work, a decision under § 4-10 does not imply that the child protective services takes over the parental responsibility in general. Though this may be relevant in some of these cases, which is regulated in § 4-12 of the Act.
Where the provisions conditions are met, § 4-10 clearly states that decisions on medical examination and/or treatment shall be decided by the "*fylkesnemda*" (county board). The county board consist of "one or more leaders that meets the requirements for judges", "a selection of professionals" and "a general membership committee", cf § 7-2 of the Bvl. That a County Board makes these decisions contributes to both the welfare of the child and their parents, which is particularly important in a decision as intrusive as this one. This is further the aim of the County Board's decision, to make the case processing both "reassuring, fast and trustworthy" for the parties involved, cf § 7-3.

6. Exception: Emergency medical interventions

6.1. Introduction

Norwegian health law consists of four primary rules to regulate emergency medical interventions. One being directed to the health personnel's duties. According to the Health Personnel Act, section 7, health practitioners are obligated to provide immediate medical care when it is intrusively necessary.[67] The Specialist Health Services Act section 3-1 states that hospitals and birthing homes are obligated to receive patients in emergencies.[68] Through these provisions, there is no specific reference to patients' rights to acclaim such treatment. Furthermore, the second rule in emergency medical care are such rights. The Pbrl section 2-1 (a) and (b) describes the patients' right to receive corresponding treatment to their emergency diagnosis.[69] This provision is straightforward. Patients in need of urgent medical care have the right to receive it immediately. The third rule for emergency healthcare is, according to the Health Personnel Act section 7, a patient's obligation to receive the emergency care as provided. The prerequisite about consent will therefore deviate. At the same time, patients do not get the right to free choice of hospital, cf the Pbrl section 2-4 – this is the fourth provision.
In order to perform emergency medical care with the framework as mentioned above, the needed help should be characterised as "invasively necessary". Cases

67 Health Personnel Act (1999).
68 Specialist Health Services Act (1999).
69 Patient and User Rights Act (1999).

categorised as such may be e.g. when saving a life in general and preventing deterioration of serious conditions. This wording is prevailed in practice as strict, especially when defying patients' rights.[70] It is the health practitioners' duty to examine the range of necessity in every specific situation. They have to conclude whether there is reason to provide emergency care. When in doubt, they are obligated to make a full diagnosis of the patient. However, if professionals are misinformed about the emergency status, it will still be non-punitive for them to act accordingly, cf the Health Personnel Act section 7 (2). That does not take away their accountability fully. The rules and health workers' duties are to be seen somewhat proportional.

6.2. Statutory principles

The importance of consent in Norwegian health law has been ascertained throughout this report. As mentioned in 6.1 emergency medical care compose an exception to the prerequisite of consent. This is reasoned in the fact that it can be physically or technically impossible to retrieve consent when in an urgent medical state. If the patient is e.g. unconscious, opposes absolute vital help, underage or psychical deficient, it would not be efficient to wait for consent in order to implement emergency medical care. Thus, there is an opening in the legal system to invade patients' right to refuse medical treatment.[71] Their right to negative self-determination lapses in order to protect their vital health. Intervening with human rights needs proper regulation to preserve the state of justice. Similar provisions are to be found in the Mental Health Care Act, Act relating to control of communicable diseases of 1994 and the Act relating to social services of 1991 that disregards consent.

6.2.1. Protection of health and life

To protect life and health is a moral obligation for medical personnel. One should not kill, and they will be legally punished if such action takes place. In addition, this concept serves the base for the right of emergency medical healthcare. Anyhow, prioritising human dignity is not always that straight forward. When addressing cases of abortion, the foetus' right to live falls behind in the process. At the same time, health practitioners cannot force a person into donating organs in order to save another life.[72] The restrictions in emergency circumstances are still

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70 Anne Kjersti Befring and Bente Ohnstad, *Helsepersonelloven med kommentarer* (1st edn, Fagbokforlaget 2001) 66.

71 Sinding Aasen (n 20) 473.

72 ibid 474; Act relating to transplantation, hospital autopsies and the donation of bodies etc (1973).

present. The matter in question will be to define where the limit for emergency healthcare is set. Whenever a person (in the Norwegian territory, cf the Pbrl section 1-3) is in urgent need of medical attention, this should be provided. It should be given as soon as possible.[73] Having that as a baseline for all medical help, the obligation to receive such strengthens with the necessity of it. The health personnel should assist to their achievable potential.[74] This aspect is reasoned in the more economical and efficiency-oriented principles of the medical system.[75] If they are unable to provide a certain type of treatments, they are obligated to transfer the patient to somewhere this can be provided. The quality of treatment is set to the standard of 'professionally sound effort', cf the Health Personnel Act section 4. The right to assert emergency care ceases as soon as the danger for life is surpassed or when there is nothing that (further) can be medically done. What type of care is given should also be equivalent to the injury or illness. Emergency care is characterised as an intrusive matter when life-threatening circumstances occur and patients' autonomous rights are reduced. Hence, this type of care is also limited to the degree of necessity. Beyond the urgency, there is no requirement for health personnel to act further. As previously mentioned, hospitals and birthing homes are required to take in patients that are in emergency circumstances. This does not mean that all urgent care only should take place in medical facilities. Private practitioners can do this at their own offices. At the same time, when the emergency is of a higher scope e.g. traffic accidents or transport restrictions – health personnel will then need to travel directly to the patient in need. The framework of providing care in emergency care is restrictive and well regulated by law. In certain cases, the assessment of such treatments can be difficult to ratify.

In addition to the provisions mentioned and travaux préparatories, case law has also helped navigate the concept of emergency medical care. More specifically, *Høyesterett* (the Supreme Court) has concluded that the scope and degree of care should be measured individually to each specific case.[76] A woman had received a reduction from the home care system she had before. This did not fulfil her needs of medical assistance. The Supreme Court emphasises that minimum care should be given regardless of the economic solicitude. An overall look at the legislation in the field would result in an understanding that a concluded decision should be taken by health professionals with the framework given by law. If a patient refuses to receive such medical help, health practitioners are still obligated to perform assistance in order to protect the health and life of the patient to that extent it is considered an absolute necessity.

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73 Health Personnel Act s 7.
74 ibid.
75 Prop 91 L (2010-2011) 27.
76 Rt. 1990, 874.

6.3. Refusal in emergency circumstances

The right to provide and receive emergency medical intervention can be repelled if terms in the Pbrl section 4-9 are fulfilled. A person in a medical emergency state can be able to refuse such. Health practitioners cannot intervene further in that particular case even if their condition may cause death. However, the right to refuse emergency medical help concerns mainly those who have serious belief such as political and/or religious motives etc. that blood transfusion should not be received. The regulation also includes emergency medical assistance that may interrupt an active hunger strike.[77] Dying patients can also refuse life-prolonging treatments. If the patient is unable to make a decision, their closest next of kin can decide for them. Health personnel have a duty to fulfil the patient's wish if her wish has been clearly stated before. Patients above the age of 18 that have consenting competence can only conduct this exception for refusal in emergency circumstances. The consequences of not withholding the regulation will often result in an outcome in favour of the patient. For intervention in circumstances that are covered by the said regulation, this will cause a breach in patient's physical integrity, cf the European Court of Human Rights (ECtHR) in the case of *Jehovah' Witnesses of Moscow and Others v Russia*.[78] This principle is also stated in the Constitution of Norway.[79]

To refuse emergency medical assistance by persons mentioned is to prevent personal integrity breach where this exact act of survival might harm their beliefs. In cases of rightful refusal, medical practitioners who abstained from performing care will not be punished. With the knowledge of a patient's views that may give them reason to refuse emergency assistance, the health personnel should not act, even if it will result in the death of a patient.[80]

The right parents have to make decisions on their child's medical care does not change through this exception. However, a child can still receive blood transfusion even when their parents' beliefs differ. This stems from the Pbrl section 4-9 (3) where only persons above the legal age of 18 can decide to refuse emergency medical care. It is also stated in the Health Personnel Act section 7, that necessity of care is enough legal basis to conduct medical care on children, even if parents do not agree. It is punitive for parents to neglect giving their child proper healthcare, cf the Bvl sections 4-10 and 4-11, see chapter 5.2.[81]

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77 Patient and User Rights Act (1999) s 4-9.
78 Syse (n 13).
79 Kongeriket Norges Grunnlov (Constitution of the Kingdom of Norway (1814) § 104.
80 Syse (n 13) 444-445.
81 The Child Welfare Act (1992).

Chapter V:
Report from Sweden

1. Legal regulation of patient's status

1.1. What are the legislative acts that regulate the issues of patients' decision-making in your country?

Within the Swedish healthcare field, issues of patients' decision-making and legal status have long been topics for discussion. In general, the discussions have concerned rights of patients and obligations of healthcare personnel and providers, and in what ways the healthcare personnel and providers could best promote safe and good healthcare while satisfying the principle of patient's participation in the decision-making. In order to understand how the legislative acts regulate and affect patients in their decision-making, a few things should be noted about the Swedish legal sources. There are four central legal sources in Swedish law: legislation, preparatory works, case law, and legal doctrine.[1] The legislation contains mandatory norms and encompasses the constitution, acts of Parliament, ordinances of the Government, and provisions from the authorities.[2] In the Swedish legal order, the constitution is at the top of all the legal sources. The constitution is not a single document but is made up of four fundamental documents. However, for the purposes of this report, the Instruments of Government (1974:152) (*Regeringsformen*, hereinafter the IoG) is of primary importance.

Mainly two provisions in the IoG govern patients' status. According to chapter 2 section 6 of the IoG, 'Everyone shall be protected in their relations with the public institutions against any physical violation […]'. Moreover, chapter 2 section 8 of the IoG states that 'Everyone shall be protected in their relations with the public institutions against deprivations of personal liberty.' The protection derived from chapter 2 section 8 of the IoG encompasses the situation where one is detained against one's will in a hospital or another care facility.[3]

The provisions in the IoG may only be limited by an act of Parliament.[4] Moreover, these limitations may be imposed only to satisfy a purpose in a democratic society and must never go beyond what is necessary with regard to the purpose, which occasioned it.[5] The Health and Medical Service Act (2017:30) (*Hälso- och*

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1 Ulf Bernitz, *Finna rätt: juristens källmaterial och arbetsmetoder* (Norstedts Juridik, 2014) 31–32; Wiweka Warnling-Nerep, *Vad är rätt?* (Norstedts Juridik 2019) 57.

2 Thomas Bull and Fredrik Sterzel, *Regeringsformen: en kommentar* (Studentlitteratur 2015) 180.

3 Henrik Jemsen, *Regeringsformen*, *commentary to Chapter 2 section 8*, Karnov.

4 IoG, ch 2 s 20.

5 ibid, ch 2 s 21.

sjukvårdslag, hereinafter the HMSA) is a central act in the healthcare field. The HMSA is primarily considered a goal legislation, which means that it provides broad and general goals as opposed to actual rules.[6] The provisions in the HMSA are not intended to govern in detail. By way of contrast, a great deal of discretion is left to the county councils (*regioner*) and municipalities (*kommuner*) to coordinate efforts according to regional and local needs.[7] The county councils and municipalities have the main responsibility to provide healthcare. In view of that, it is, ultimately, the responsibility of healthcare providers to ensure that the goals set out in HMSA are met.[8]

In addition to the HMSA, the legislation governing patients' decision-making, includes the Patient Act (2014:821) (*Patientlag*, hereinafter PA). According to the preparatory work of the PA, the act was introduced to strengthen the legal position of patients' and to promote patients' integrity, self-determination and participation.[9] The PA contains provisions on what information patients are entitled to as regards their healthcare, which is essential for their decision-making.[10] Moreover, it contains provisions on the relevance of patients' consent and the possibility for patients to choose healthcare treatment and healthcare facilities.[11] For example, when there are several treatment options that are in accordance with science and proven experience, patients should be given the opportunity to choose the option that they prefer.[12]

The legislation in the healthcare field is, by its very nature, mainly governed by public law. Questions on access to information and confidentiality have traditionally been considered relevant topics within patients' decision-making. These topics are regulated in the Public Access to Information and Secrecy Act (2009:400) (*Offentlighets- och sekretesslagen*, hereinafter the OSL). According to the OSL, disclosure of information is contingent upon patient consent or, alternatively, if it is clear that a patient will not be hurt in any way by virtue of the disclosure of information.[13] However, there are some exceptions to these rules. For instance, chapter 10 section 2 of the OSL states that secrecy does not prevent information being disclosed to another authority if this is necessary in order for the disclosing authority to carry out its own activities.

When a patient is a child, the decision-making is to some extent also regulated by the Parental Code (1949:381) (*Föräldrabalken*, hereinafter the PC). According to

6 Prop 2016/17:43, 72.
7 ibid.
8 Ewa Axelsson, *Patientsäkerhet och kvalitetssäkring i svensk hälso- och sjukvård: En medicinrättslig studie* (Iustus 2011) 89, 93.
9 Prop 2013/14:106, 39.
10 PA, ch 3 s 2-3; s 2.1 below.
11 PA, ch 4.
12 PA, ch 7 s 1.
13 OSL, ch 25 s 1.

the PC, guardians have the right and the obligation to decide in matters concerning a child's personal matters.[14]
A child's perspective in Swedish healthcare is of importance. As will be further discussed in this report, on 1 January 2020 Sweden incorporated the CRC as a domestic law. Accordingly, in recent years, the importance of listening to and accounting for the will of a child has been increasingly emphasised.[15]
Yet another act that indirectly regulates the issues of patients' decision-making is the Discrimination Act (2008:567) (*Diskrimineringslagen*). The act establishes the grounds based on which it is prohibited to discriminate a person, in particular, within healthcare. Provisions of the act concerning inadequate accessibility, direct and indirect discrimination, can be of tremendous importance in healthcare. For instance, these provisions can shape the understanding of when it is acceptable to question if a person has decisional competence, or how information concerning medical intervention should be presented to a person with disability.

1.2. What international human rights instruments have a significant influence on the status of a patient in your country? Why did the influence of these instruments (or norms) become significant in your legal system?

When international instruments are ratified, they do not automatically become part of Swedish law, which is a result that follows from Sweden's dualistic approach to international instruments.[16] Instead, it is required that Sweden implements the international instrument (or norm) at issue into Swedish law for it to have effect. There are three ways for international instruments to affect the domestic law, through (1) transformation, (2) incorporation and (3) treaty conform interpretation.[17] International instruments that Sweden is party to be typically *transformed* in the national system.[18] Transformation means that international norms are implemented in Swedish law by amendments.[19] This is mainly done through altering certain provisions in law or the law as a whole. For example, the CRC provisions on the best interests of a child were transformed in Swedish healthcare legislation for many years, or some of the provisions concerning reasonable accommodation of the CRPD are transformed into Discrimination Act. Moreover, only a few human rights instruments have been incorporated in Swedish law. One of such instruments is the ECHR, which was accepted as a whole as a Swedish law. The ECHR holds a special position in the Swedish legal system.

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14 PC, ch 6 s 11
15 Cf art 12 of the CRC.
16 Ove Bring, *Monism och Dualism*, *Folkrätten i svensk rätt*, (Rebecka Stern and Inger Österdah eds, Liber 2012) 28, 31.
17 ibid.
18 SOU 1974:100, 10–11.
19 ibid 13, 45–46; Bring (n 16) 31.

While, the ECHR does not have constitutional status, its special status is expressed in chapter 2 section 19 of the IoG. According to chapter 2 section 19 of the IoG, 'No act of law or other provision may be adopted which contravenes Sweden's undertakings under the European Convention for the Protection of Human Rights and Fundamental Freedoms.' Article 8 of the ECHR recognises everyone's right to private life. Through case law derived from the European Court of Human Rights (ECtHR) every Member State has obligations not to interfere with medical intervention in other cases then prescribed by law, and only to the extent that is necessary in a democratic society. States also have positive obligations to protect the right to privacy, which means in particular, that States must ensure that private persons, such as private healthcare practitioners or relatives, do not force persons into undesirable healthcare.[20]

In addition, Sweden has incorporated the CRC. The incorporation of the CRC is another exception from the traditional transformation and is of particular importance for a child's status. Although, children's rights were already formulated in the HMSA and the PA,[21] the influence of the CRC is significant in the Swedish legal system. A central principle of the CRC can be found in article 3, which deals with the best interests of the child. The provision clarifies that all municipalities and county councils must always consider the norms that derive from the CRC when they decide on matters related to children.[22] The CRC further clarifies children's rights regarding the obligation of respecting the integrity of children and their evolving capacities.[23] A child's opportunity to independently request healthcare or to refuse healthcare shall depend on the child's age and maturity, the situation and the type of healthcare in question.[24]

As was mentioned above, in Sweden a treaty conform interpretation is also a way in which an international treaty can affect domestic law. When a treaty is ratified, it does not automatically become a domestic law. However, if provisions of domestic law are not very specific, and provisions of a treaty do not directly contradict domestic law, the courts and other authorities are supposed to interpret domestic law in conformity with a treaty manner. This means that if there is a room for seeing the domestic law in light of the treaty, the domestic law can be filled with the international law content. On the other hand, if the domestic law is explicit, or directly contradicts to a convention, there is no room for treaty conform interpretation of domestic law. Therefore, treaty conform interpretation

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20 ECtHR, *X and Y v the Netherlands* App no 8978/80, Judgment of 26 March 1985, para 23; ECtHR, *Storck v Germany* App no 61603/00, Judgment of 16 June 2005, paras 149–150.

21 HMSA, ch 5 s 6-7 of the; PA, ch 1 s 8, ch 3 s 3 and ch 4 s 3.

22 Kavot Zillén, *Barnets bästa i hälso och sjukvården* in *Barnets bästa i hälso och sjukvården* (Karin Åhman, Pernilla Leviner, Kavot Zillén eds, Norstedts Juridik 2020) 255; cf HFD 2015 ref 5.

23 ibid 260.

24 National Board of Health and Welfare, *Din skyldighet att informera och göra patienten delaktig,* 2015, 13; cf PC, ch 6 s 11.

can make many of the relevant human rights conventions directly incorporated or otherwise transformed to domestic law. These include the CRPD, the European Social Charter (revised), and the Convention on Elimination of All Forms of Racial Discrimination and so on.

1.3. What is the legal status of a patient in relation to their decision-making?

The legislative acts regulating healthcare in Sweden are obligations-based, which means that the acts mainly regulate the duties of healthcare providers and healthcare personnel.[25] Hence, the status and rights of a patient are ensured indirectly through the provisions on the obligations of healthcare providers and personnel.

Today, the possibilities available for hearing cases in the courts are rather limited since Swedish law provides few enforceable rights in this regard, such as the right to abortion and the right to sterilisation.[26] Even in these cases, the appellation is not made to court; instead, one submits the complaint to the National Board of Health and Welfare (*Socialstyrelsen*).[27] The possibility to enact right-based legislation concerning patients' status and right to healthcare as enforceable rights has been discussed in the preparatory works of the HMSA. However, the option of having an enforceable right of access to healthcare was not considered a realistic approach.[28] Such a system would, despite it strengthening the position of a patient, conflict with the principle of autonomous governance. That is, the democratic legitimacy for municipalities and county councils to adapt political decisions local circumstances and differing local needs. Instead, it would be up to the court to assess a patient's need for healthcare and the accuracy of the healthcare provided.[29]

Even though there are limited possibilities for hearing cases in courts, there are several options available for submitting complaints about the healthcare provided or about an injury in connection with the healthcare. In the event of dissatisfaction, a patient may submit a complaint directly to the healthcare providers or the

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25 Axelson (n 330) 89.

26 Elisabeth Rynning, *Still No Patients' Act in Sweden – Reasons and Implications* in *Nordic Health Law in a European Context: Welfare State Perspectives on Patiens' Rights and Biomedicine* (Elisabeth Rynning, and Mette Hartlev eds, Liber 2012) 126; Elisabeth Rynning, *Patientens rättsliga ställning – två steg fram och ett tillbaka?* in *Festskrift till Lotta Vahlne Westerhäll*, (Titti Mattsson, Thomas Erhag, Therese Bäckman, Santérus, 2011) 315.

27 ibid.

28 SOU 1997:154, 121–122; SOU 2013:2, 159; Prop 2013/14:106, 41.

29 ibid.

Patient Advisory Committee (*patientnämnd* or, in some municipalities, *förtroendenämnd*).[30] Additionally, patients' complaints can be considered by the Health and Social Care Inspectorate (*Inspektionen för vård och omsorg*, hereinafter IVO). IVO shall consider complaints and make further investigations when a healthcare provider has initially been given the opportunity to fulfil its obligation but has failed to do so.[31] Some of these decisions may open up the possibility of administrative appeals within the system of administrative courts.[32]
Regarding other complaints related to discrimination or criminal acts in connection with healthcare, a patient can turn to the Equality Ombudsman (*Discrimination Ombudsman*, hereinafter the DO) or to the police. Such cases are tried within the system of general courts and can be initiated even without first having received a decision from an authority.[33]

2. Information as a component for valid consent or refusal in medical interventions

2.1. What information shall be disclosed to a patient? Who has the obligation to inform?

The obligations of healthcare personnel to disclose information to a patient is regulated in chapter 3 PA. Pursuant to chapter 2 of the PA, before consenting to the medical treatment, the patient needs to be given information in accordance with chapter 3 of the PA. Chapter 3 sections 1 and 2 of the PA enshrines the obligation of healthcare personnel to disclose the following information to a patient:

- The patient's medical condition;
- Existing methods for medical examination, care, and treatment;
- Available aids for persons with disabilities;
- Time when a patient can expect to be given treatment;
- The expected course of care or treatment;
- Essential risks of complications or side-effects;
- Aftercare;
- Methods to prevent illness or injury;

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30 Lag om stöd vid klagomål mot hälso- och sjukvården (Act on Support with Complaints against Healthcare) (2017:372).

31 Patientsäkerhetslagen (Patient Safety Act 2010:659) ch 7 s 10, 11 and 12.

32 Vårdhandboken. *Om patienten inte är nöjd*, 2019 <https://www.vardhandboken.se/arbetssatt-och-ansvar/ansvar-och-regelverk/patientens-rattsliga-stallning/om-patienten-inte-ar-nojd/> accessed 15 August 2020.

33 ibid.

- The possibility to choose treatment options, contact with a permanent doctor and publicly funded healthcare provider;
- The possibility to get a new medical assessment and a permanent contact with a new healthcare provider;
- Healthcare guarantee and
- The possibility to receive information from the Swedish Social Insurance Agency *(försäkringskassan)* regarding healthcare in another country within the European Economic Area (EEA) or Switzerland.

Chapter 6 section 6 of the PSA stipulates that the obligation to inform a patient in accordance with chapter 3 of the PA lie on those who are responsible for the healthcare of the patient. This is to ensure that the information can be individually formulated and thus relevant for the patient's specific circumstances. In addition, the healthcare provider has an obligation to organise the workplace in such a way that the healthcare personnel can fulfil their obligations towards the patient.[34]

2.2. How detailed and specific should the information be? Is it acceptable to provide information in broad terms?

The specificity of information that needs to be provided can vary. The information needs to be individually formulated in a way, which allows a patient to use the information to consent to a medical treatment. The level of detail required when disclosing information depends on the patients' personal circumstances. That is, to what extent they are able to receive and understand the information as well as on the medical condition in question.[35] Generally speaking, the more invasive the treatment option or more critical the condition is, the more important it is for the patient to be aware of all side effects or available treatment options. Receiving information in broad terms can be satisfactory as long as the patient only requires general information to understand adequately their situation and to consent hereto. However, if the circumstances are more complicated or unique in relation to the patient, more specific information needs to be given.[36]

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34 Prop 2013/14:106, 47–48.

35 PA, ch 3 s 6; Socialstyrelsen, *Din skyldighet att informera och göra patienten delaktig*, 2015, 25.

36 Ulrika Sandén, *Sekretess och tystnadsplikt inom offentlig och privat hälso- och sjukvård* (Iustus 2012) 224; Prop 1998/99:4, 49.

2.3. How should information be provided in general? Are there specific requirements for information disclosure for children, persons with disabilities and persons who do not speak the majority language?

As a main rule, the information should be given verbally to a patient.[37] However, according to chapter 3 section 7 paragraph 2 of the PA, if a patient so requests or if the patient's specific circumstances call for it, healthcare personnel must also give the information in writing. A benefit of disclosing information in writing is that it can be difficult to prove that a verbal disclosure has occurred, but proving that written information has in fact been provided is easier.[38]

According to chapter 3 section 7 of the PA healthcare personnel must ensure that the patient understands the disclosed information when possible. This rule is especially relevant for patients with special needs or circumstances. For example, such needs or circumstances could be that the patient is a child, has a disability or has difficulties understanding the language used by healthcare personnel. The information may need to be simplified in order to not overwhelm a patient with complicated words or notions that they may have trouble understanding or comprehending due to various factors, such as age, maturity, language barriers, or problems with memory. Moreover, information may be given in other formats, such as via pictures or videos.[39] In the preparatory works, it is stated that special consideration must be had to the needs of patients that are immigrants, deaf and visually or aurally impaired.[40]

The obligations to adjust the information and ensure that the patient understands it means that there is a duty of healthcare providers and staff to, for example, use interpretation services.[41] It is therefore insufficient simply to disclose information to a patient. Healthcare personnel needs to answer questions a patient might have if it would help with the comprehension of the information necessary for consent to or refusal of medical intervention.[42] Having follow-up meetings to provide feedback and clarification is regarded important to ensure that the patient has received the information in a satisfactory manner.[43]

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37 Cf PA, ch 3 s 7 para 2; Lars-Åke Johnsson, *Patientlagen, commentary to chapter 3 section 7 of the PA* (JUNO 2020).

38 See further Yana Litins'ka, *Assessing capacity to decide on medical treatment - On human rights and the use of medical knowledge in the laws of England, Russia and Sweden* (Uppsala university 2018) 477-478; Jameson Garland, *On Science, Law, and Medicine: The Case of Gender-"normalizing" Interventions on Children Who Are Diagnosed as Different in Sex Development*, (Uppsala university 2016) 314.

39 Socialstyrelsen, *Din skyldighet att informera och göra patienten delaktig* (2015) 35.

40 Prop 1981/82:97, 59.

41 Lena Rönnberg, *Hälso- och sjukvårdsrätt*, (Studentlitteratur 2016) 103.

42 Prop 2013/14:106, 118; Johnsson (n 359).

43 Socialstyrelsen (n 361) 22, 26.

2.4. Can a patient refuse medical information? What are the legal consequences of refusal?

Sometimes, patients do not want to know about their medical conditions, or about the process of treatment, purpose or perspectives of treatment. As a main rule, all patients can refuse medical information according to chapter 3 section 6 of the PA. A patient's refusal is not required to be presented in any specific form; it can be written, verbal or even implied.[44] However, the existence of implied patient refusal cannot be solely based on assumptions made by the healthcare personnel, but rather on knowledge relating to patient's personal opinions and circumstances. The fact that the information might be difficult for the patient to handle can never be a satisfactory reason to withhold information from the patient.[45]

Swedish law in not explicit concerning consequences of refusal obtaining medical information. In the preparatory works to the PA, it is considered that if information that is necessary for making a decision could not be provided, consent is to be regarded as invalid.[46] Since healthcare is only allowed to be provided if the patient has given explicit consent, and the providing information is fundamental to giving consent, it follows that healthcare cannot be provided if the patient has not been properly been informed, unless the opposite is explicitly stated in other regulation.[47] However, what information is necessary for making a decision is unclear and depends on the individual situation of a patient. For instance, in the situations when patients need to follow certain routines as to medication, nutrition, or the medical intervention will be detrimental for patient's life and health, then it is essential that the patient knows what routines to follow. Providing care without disclosing this necessary information will contradict the principles of provision of good care, patient's safety, and legality.

Additionally a patient's refusal can be overruled if other regulations stipulate that the patient needs to receive information.[48] An example of this is in procedures relating to organ donation or sterilisation, where information is a necessary requirement to undergo the procedures.[49] Another example where the rule of the patient's right to refusal of information does not apply is a situation where a patient has a disease listed in the Disease Control Act (2004:168) (*Smittskyddslag*), where the disclosure of information is needed to ensure that the patient does not

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44 Prop 1981/82:97, 59.

45 Rönnberg (n 41) 103; Elisabeth Rynning, *Samtycke till medicinsk vård och behandling. En rättsvetenskaplig studie* (Iustus 1994) 267, 324.

46 Prop 2013/14:106, 119; Garland (n 360) 301; Rynning (n 367) 168.

47 Prop 2013/14:106, 119; ch 4 s 2 of the PA.

48 Prop 1998/99:4, 49.

49 Lag om transplantation m.m. (Transplantation Act) (1995:831) s 10; Steriliseringslag (Sterilisation Act) (1975:580) s 5.

spread a contagious disease. The specific diseases that this applies to are listed in the appendix to the Disease Control Act.

2.5. Is a patient always required to be informed about their health issues? Are there exceptions?

Certain medical conditions may render the patient nonsensical to the world around them. Hence, they would not be in a position to be informed of any further measures. This might be the case if the patient is unconscious or otherwise not able to receive the information due to for instance confusion, pain, or exhaustion.

A healthcare provider can refuse to provide information to a patient in cases concerning confidential information in accordance with the OSL or other cases of professional secrecy. There are two main cases of confidentiality in relation to the patient themselves. The first case concerns situations when someone else has given information about a patient. That is, if the information has been noted in the patient's medical journal and if the disclosure of the information would reveal the identity the information provider and if there is a risk that this person or someone close to them will be subjected to violence or serious harm should the information be conferred to the patient.[50] This case of confidentiality is an exception to the main rule of a patient's right to receive information about their medical condition and should be used restrictively.[51] The purpose of this exception is to protect the provider of the information from reprisals from the patient.[52]

The second case where confidentiality might outweigh the patient's interest of information is when the disclosure of information about a treatment would jeopardise the treatment's purpose and effectiveness.[53] This exception should be also used only in exceptional cases when compelling reasons outweigh the patient's interest in receiving the information.[54]

2.6. What is the legal status of family or other close ones in questions of information disclosure?

When the patient is a child, the legal guardians need to be given the same information as described in section 2.1 above. The legal guardian is in most cases one

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50 Ulrika Sandén, *Sekretess och tystnadsplikt inom offentlig och privat hälso- och sjukvård* (Iustus, 2012) 246–247; PSA, ch 6 s 13; OSL, ch 25 s 7.

51 Sandén (n 50) 253.

52 ibid 247.

53 ibid 242.

54 ibid; Prop 1980/81:28, 28; Prop 1979/80:2, 177–178.

or both of the child's parents.[55] The right of a legal guardian to receive information does preclude the right of the child to receive information. The right of a legal guardian to receive information about their child stems from the responsibility to ensure that the needs of the child are fulfilled regulated in chapter 6 of the FB. A legal guardian has both the right and the responsibility to make decisions about a child. However, as a child matures, child's capacity to make decisions also evolves.

If a patient is unable to receive the information, and if possible, the information should instead be given to a close person.[56] The question of whom the law considers a close person is not clearly defined and needs to be determined on a case by case-basis. Most often, family and other relatives can receive the information, but in some cases, very close friends should also be able to fulfil this role.[57] However, determining who a patient's close persons are can sometimes be challenging for the healthcare personnel. For instance, if the patient is in a state of mind where they cannot comprehend information disclosed to them, they may not be able to inform the healthcare personnel who their close persons are.[58]

2.7. What are the legal remedies and/or legal consequences for violating an obligation to provide information about medical treatments?

The right to information is not a legally enforceable right in Swedish law, which has been criticised.[59] The enforceability of the right to information was addressed when introducing the regulation, but it was stated that the law would serve its purpose better without potentially costly legal proceedings, shifting focus away from the care of the patient.[60] The lack of enforceability of the right to information does not mean that the Swedish system is toothless. There are ways to report specific healthcare personnel to disciplinary boards. The PSA is the main regulation in this regard, containing remedies for patients in healthcare. The act contains rules for IVO, a supervisory body with jurisdiction to oversee all organisations in the healthcare and social care.[61] IVO's supervision concerns all adverse events and injuries in healthcare as well as events that seriously and negatively affect or threaten the patient's autonomy, integrity or legal position – for instance if the patient has not received the information they are entitled to.[62]

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55 Lars-Åke Johnsson, *Patientlagen, commentary to chapter 3 section 3 of the PA* (JUNO 2020).
56 See section 2.5.
57 Prop 2013/14:106, 121.
58 Litins'ka (n 38) 479.
59 Vårdanalys, *Lag utan genomslag* (2017) 11.
60 Prop 2013/14:106, 41.
61 See section 1.3.
62 PSA, ch 7 s 11; Riksrevisionen, RIR 2015:12, *Patientsäkerhet – har staten gett tillräckliga förutsättningar för en hög patientsäkerhet?* (2015) 51.

There are also ways for patients to receive compensation if they have been mistreated in their healthcare. The available remedies in terms of compensation are most frequently paid out due to bodily harm or pecuniary damage, such as loss of income. However, there is also a possibility for the patient to be compensated for non-material damage pursuant to chapter 3 section 4 of the Tort Liability Act (1972:207) (*Skadeståndslag*). This section provides a possibility to receive compensation in cases where a breach of the rights in the ECHR has occurred. The provision is intended as a last resort when no other methods of compensation are available to ensure access to an effective remedy in accordance with article 13 of the ECHR.[63]

3. Forms of patients' consent or refusal

3.1. In what forms can a patient consent to – or refuse of – medical treatment?

Swedish general healthcare legislation, such as the HMSA, the PA, and the PSA do not establish requirements concerning the form of consent to or refusal of treatment. In the preparatory works to chapter 4 section 2 of the PA, many consultative bodies were determined that a formalised system of consent was not desirable.[64] According to the consultative bodies, a written consent does not imply any guarantee that a patient has received the necessary information required and it does not offer a guarantee that a patient understands the possible consequences of the planned healthcare measure. There is also a risk that the handling and administration of the documents on consent may require extra resources.[65] Therefore, the general rule is that consent can be provided in any form. Although the form of consent is not generally regulated, in some legislative acts, the forms of a patient's consent and refusal have been specified.[66] For example, in the legislation on transplantation, it is specified that consent to taking biological material from a living donor shall be obtained in written form.[67]

3.2. Withholding or withdrawing consent

A patient may withdraw their consent at any time, according to chapter 4 section 2 of the PA. If a patient decides to refrain from certain healthcare measures, the

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63 Bertil Bengtsson, *Skadestånd vid överträdelse av Europakonventionen — den nya lagstiftningen* (SvJT 2018) 104–105.

64 Prop 2013/14:106, 55–56.

65 ibid.

66 Rynning (n 26) 177; Prop 1981/82:97, 117–118.

67 Transplantation Act (n 371) s 6; Rynning (n 367) 177.

patient must initially be informed of the consequences of receiving healthcare and the consequences of refusing healthcare.[68] In addition to the requirement of providing information, there is an obligation under chapter 3 section 6 of the Patient Data Act (2008:355) (*Patientdatalag,* hereinafter the PDA) to document a patient's refusal to receive certain healthcare, in the medical journal.

4. Voluntary consent to or refusal of medical interventions

4.1. When can consent to or refusal of medical intervention be regarded as involuntary?

Consent to or refusal of medical intervention can be regarded as involuntary for different reasons. One particular reason is forced intervention. Every citizen has constitutional protection against forced bodily intervention in relation to the public authorities according to chapter 2 section 6 of the IoG. No one can consent to give up one's constitutional rights.[69] The protection against forced intervention applies to everyone, including people with reduced decision-making abilities, e.g. persons with dementia.[70] Hence, if a person with diminished mental abilities explicitly refuses to undergo medical care or treatment, and is forced into the intervention, an intervention shall be considered as a forced act.[71]
What is forced intervention? Medical interventions carried out when a person objects it are to be considered as forced.[72] However, the constitutionally based prohibition of forced intervention is interpreted even broader by the Parliamentary Ombudsman (*justitieombudsmannen*, hereinafter the JO), and the JO's approach is supported in the legal doctrine.[73] The JO considers that forced interventions encompass both interventions carried out with physical force against the wishes of a person and interventions carried out with mentally perceived force, even though the person may actually have consented.[74] Examples of such mentally perceived force include threats of sanctions or due to behaviour of representatives of public authorities when patients perceive a threat they do not have

68 Prop 2013/14:106 p 57; SOU 2013:2, 176; National Board of Health and Welfare, *Din skyldighet att informera och göra patienten delaktig* (2015) 12–13.
69 Litins'ka (n 38) 458.
70 Yana Litins'ka, *To force or not to force: protecting the lives of persons with dementia who refuse care* in *Vänbok till Sverker Scheutz: om rätt – och att undervisa rätt*, (Hans Eklund, Lotta Lerwall, Anna-Sara Lind eds, Iustus 2020) 468.
71 ibid.
72 Litins'ka, 'Assessing capacity to decide on medical treatment' (n 38) 458.
73 ibid 458–459.
74 Cf ibid, 458, fn 1569.

a real choice, but must consent to interventions.[75] In all these cases, it will be considered that the intervention is forced.

In some cases, it can be difficult to draw the line between coercion and consent given voluntarily. This is exemplified in JO 479-2010 (decision of 26 April 2010), where the admissibility of so-called random drug tests at a high school was discussed. The students were free to participate in submitting urine samples when they were asked to. Routines were set to ensure that the students' participation was, in the true sense, voluntary and that the students did not feel pressured to submit a test. According to the routines, all students should have signed an agreement that they agree to be included in a group of students from whom the school randomly selected students to take drug tests. Furthermore, students who have been selected should have been informed at the time of the test that the drug test is voluntary and that the students can refrain from participating. In this decision, the JO considered that interventions were voluntary. In JO 2050-2018 (decision of 4 June 2020), the JO criticised the fact that some regions set requirements for regular urine tests, performed under supervision, as a precondition for receiving certain treatment. The JO emphasised that undue pressure may not occur in relation to the tests and that the interventions must be genuinely voluntary. In order for consent to be truly voluntary, it is required that information about intervention is made clear for a person. It is also essential that it is straightforward for a person what alternatives to act they have, and that undue pressure to act in a specific way or manipulate with information is not applied.[76]Additionally, in JO 2089-2016 (decision of 27 February 2018), JO criticised the circumstances associated with performing drug tests without voluntary consent. There was no real alternative to refraining from performing a drug test, as a refusal would be equated with a positive result.

In certain cases, receiving consent to or refusal of medical intervention is not possible. Does it mean that if consent is absent, the intervention is always forced? In Swedish law the answer to this question is no. To clarify why, the concept of the *hypothetical consent* or *refusal* may be helpful.[77] Hypothetical consent means that in certain situations it is presumed that a patient who is not able to communicate would consent to intervention. A typical example is a situation when a person has a heart attack on a street and collapses. In this case, it is presumed that a person consents to further measures to save their life, and that a person consents

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75 ibid 459; JK 2418-16-41 decision on 16 December 2016; JO 2089-2016 decision on 27 February 2018; JO 5705-2014 decision on 30 June 2016; JO 6442-2014 decision on 30 June 2016; Rynning (n 26) 331.

76 ibid 342; cf JO:s ämbetsberättelse 1984/85, 227–233.

77 Rynning (n 26) 325.

to intervention (provides hypothetical consent), unless the presumption of consent is rebutted.[78] Typically, hypothetical consent is presumed within somatic care, and hypothetical refusal is presumed in psychiatric care.[79]
Coercion may also occur in relations between private parties, for example, between patients and their relatives.[80] These relations are not regulated by the IoG, which only governs the relations where at least one part is a representative of authorities. A patient may, due to undue influence, consent to a medical measure and – in some circumstances – such consent will be considered involuntary. Undue influence refers to situations where consent is given after receiving false information or pressure in the form of threats of violence or other sanctions.[81] For instance, undue influence may appear in situations of organ-donation, sterilisation, or abortion.[82] It is difficult to recognise such situations, since undue influence often occur within the private sphere.[83] For the moment, the judicial practice regarding undue influence is scarce.

4.2. What are the legal consequences of consent or refusal being involuntary?

In general, the legal consequence of consent or refusal being involuntary is that the consent will be considered invalid. In turn, the invalidation of consent means that any medical care or treatment, based on the consent in question, is unlawful.[84] The consent must be valid at the time when the treatment takes place; otherwise, the healthcare personnel may not use the consent as a ground of discharge to carry out the treatment.[85] In the absence of consent, a patient may have the right to claim the liability of the healthcare personnel. The available legal sanctions in this regard can be divided into three categories: (1) disciplinary liability, (2) penal liability, and (3) liability in tort.[86] The difference between the sanctions systems is attributable to the conditions that led to the lack of consent, as well as to differences in intent and negligence.[87]
Disciplinary sanctions may be imposed when healthcare personnel commit professional faults, which are primarily regulated in the PSA. The disciplinary sanctions that may be imposed are a probationary period of three years under chapter

78 ibid 108, 325; Yana Litins'ka, *Samtycke och beslutskompetens i vården* in *Medicinsk rätt* (Kavot Zillén, Titto Mattsson, Santa Slokenberga eds, Nordstedts Juridik 2020) 93–94.
79 Litins'ka, 'Assessing capacity to decide on medical treatment' (n 38) 460, 508.
80 Rynning (n 26) 342.
81 ibid 341.
82 ibid 434.
83 ibid 343.
84 ibid 407.
85 ibid 331.
86 ibid 408.
87 ibid 409.

8 section 1 of the PSA and a revocation of medical license according to chapter 8 section 3 of the PAL. Moreover, healthcare providers have an obligation to report to IVO if a patient is at risk of injury, or if damage was inflicted, according to chapter 3 section 5 of the PSA. This obligation to report is referred to as *lex Maria*.[88] When IVO receives a report, they can initiate an investigation. IVO can, based on the results of the investigation, require the healthcare providers to remedy the deficiencies.[89] Furthermore, according to section 6 of the Instructions for the Parliamentary Ombudsman Act (1986:765) (*lag med instruktion för Riksdagensombudsmän*), JO may report to IVO regarding disciplinary sanctions.

Additionally, medical care and treatment performed without valid consent can in theory lead to penal liability. However, the question has never reached the courtroom.[90] In this context, such medical care and treatment might constitute, *inter alia,* battery, unlawful detention and duress under the Penal Code (1962:700) (*Brottsbalken*).[91] On the other hand, exception from the requirement of consent may be found in chapter 24 section 4 of the Penal Code, which governs actions performed out of necessity. Accordingly, healthcare personnel may be exempt from penal liability if the medical care and treatment was performed in a situation of emergency.[92]

From a civil law perspective, no binding consent can arise if the consent has been obtained through the coercion or undue influence, under sections 28, 29, and 31 of the Contracts Act (1915:216) (l*agen om avtal och andra rättshandlingar på förmögenhetsrättens område*). Therefore, liability in tort may arise as a legal consequence.[93]

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88 IVO, *Anmäl vårdskada - lex Maria*, 2019 <https://www.ivo.se/anmala-och-rapportera/anmala-och-rapportera-som-yrkesverksam/anmal-vardskada---lex-maria/> accessed 11 November 2020.

89 ibid.

90 Rynning (n 26) 508.

91 ibid 429.

92 ibid 507.

93 ibid 440–441.

5. Capacity to decide on medical interventions

5.1. Competence of adult patients

5.1.1. Are there any criteria for recognising that adult patients are not able to consent to or refuse medical interventions? What are these?

The terms 'competence' and 'capacity' are often used synonymously. Two definitions of the terms will be used in this text; the first being what will be referred to as 'decisional competence' and the second being what will be referred to as 'legal competence'. In this text, decisional competence will be understood as abilities that an individual possesses to make a decision.[94] Legal competence will be understood as the authority to make valid decisions.[95] A legal system may recognise various thresholds for legal authority to make valid decisions (legal competence) – for instance, age or decisional competence.[96] The decisional competence and legal competence of adult patients will be investigated in regards to three situations: (1) where a patient consents to treatment, (2) where a patient refuses treatment and (3) where a patient's decision to consent or refuse intervention is absent. Emergency situations will be considered in section 6.

The explicit requirement of obtaining consent prior to medical treatment is laid down in chapter 4 section 2 of the PA. Although it is not directly expressed in the PA, the preparatory works stipulate that consent is not valid unless prior and necessary information has been provided to the patient.[97] While disclosure of information is presented as a necessary requirement of valid consent, it is not addressed to what degree comprehension of the information by a patient is required.[98] In the preparatory works of the PA, the government addressed the question whether the issue of decisional competence should be explicitly regulated. However, due to the complexity of the issue, the Government decided to leave it until the results of a special investigation became available.[99] Thus, the PA does not regulate how the decisional competence of a patient affects their legal competence.

94 Litins'ka, 'Assessing capacity to decide on medical treatment' (n 38) 31.
95 ibid.
96 ibid 34.
97 Prop 2013/14:106, 119.
98 ibid 48; Litins'ka, 'Assessing capacity to decide on medical treatment' (n 38) 474.
99 Prop 2013/14:106, 61

5.1.2. Who decides that an adult patient is incapable of making healthcare decisions?

In the PA, the duty of healthcare personnel to obtain consent and provide necessary information to the patient prior to treatment is explicitly affirmed. Healthcare personnel should, as far as possible, ensure that the patient has understood the information provided in chapter 3 section 7 of the PA. However, there is no explicit obligation to assess a patient's competence within the Swedish legal system, nor is it established who has the authority to make such an assessment.[100] Since there is no support in law for healthcare personnel to assess competence, it is questionable whether such an action is in line with the principle of legality, as expressed in chapter 1 section 1 paragraph 3 IoG. Deciding that an adult is incapable is an exercise of public power and since this power is not rooted in legislation, doing such an assessment without the consent of a patient is prohibited.[101]

5.1.3. Who decides that an incapable adult needs treatment?

In Sweden, the possibility to declare an adult as fully legally incompetent was abolished in 1989.[102] The possibility to declare an adult fully legally incompetent was then replaced by two, less intrusive, alternative measures of guardianship. These measures are the appointment of an administrator (*förvaltare*) or a special representative (*god man*) in accordance with chapter 11 sections 4 and 7 of the PC. An administrator and special representative only have power concerning civil relations, such as buying or selling property. An administrator and special representative may be assigned to monitor an incapable adult's personal interests.[103] However, an administrator and special representative do not have legal competence to make decisions for the individual's healthcare.[104] In a situation where an incapable adult patient consents to treatment, complementing consent from a special representative or administrator may, however, be taken into consideration and result in valid consent.[105] However, when a patient refuses treatment, consent from an administrator or special representative cannot overrule that refusal,

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100 Litins'ka, 'Assessing capacity to decide on medical treatment' (n 38) 545.

101 ibid 453–455.

102 Lag om ändring i föräldrabalken (Act on Amending the Family Code) (1988:1251).

103 PC, ch 12 s 2.

104 Elisabeth Rynning, *Rättssäkerhet och rättsskydd i vården av icke beslutskompetenta vuxna* in *Rättssäkerhetsfrågor inom socialrätten*, (Vahlne Westerhäll ed, Norstedts Juridik 2002) 267; Prop 1987/88:124, 172; SOU 2015:80, 411.

105 Rynning (n 26) 302.

as they do not have the legal competence to consent to treatment against the will of the patient.[106]

While no formal decisional competence is given to relatives of a patient, they presumably have knowledge about the patient's wishes and preferences, which may be helpful in determining what the individual would have wanted in a given situation. Thus, relatives can be helpful for healthcare personnel when determining the will of a patient.[107] To summarise, administrators, special representatives and relatives do not have any legal competence to make decisions for an incapable adult. However, their opinions may be regarded to some extent when healthcare personnel attempts to establish the will of a patient. In Swedish law, a patient decides.

5.1.4. What are the legal consequences of incapacitation?

Chapter 2 section 6 of the IoG, stipulates that 'everyone shall be protected in their relations with the public institutions against any physical violation'. The notion of physical violation is very broad[108] and covers even minor interventions, such as vaccination and blood sampling as well as similar interventions.[109] Thus, it is clear that medical interventions are included within the scope of protection under the provision. As previously mentioned, the protection in chapter 2 section 6 of the IoG may be limited in law.[110]

For medical interventions, this means that measures cannot be forcibly given against the will of a patient unless there is an explicit exception in law.[111] Since neither the PA nor any other act authorises the use of force in relation to most of somatic treatments, it is, as a rule, not legally possible to force a patient to medical treatment. In this regard, it is not essential whether a patient is legally capable to make a decision or not.[112] Therefore, a refusal to undergo medical treatment by a decisional incompetent adult shall be respected and, if they consent to medical care, consent should be seen as valid, unless it is forced (see section 4.1 and 2.4).[113]

106 SOU 2015:80, 412.
107 ibid 412.
108 See section 4.1.
109 Prop 2013/14:106, 56.
110 IoG, ch 2 s 21 and 22.
111 Prop 2013/14:106, 56.
112 Litins'ka, 'Assessing capacity to decide on medical treatment' (n 38) 490.
113 ibid 468; SOU 1988:7, 105–106.

5.2. Competence of a child

5.2.1. When can a child consent to or refuse medical treatment? Are there any established criteria for assessing ability to decide on medical treatment for children?

In Swedish law, the general rule is that children can make decisions (have legal competence) about their medical treatment when they are deemed to have decisional competence to decide on a particular intervention.[114] The rule has some exceptions. For example, even children that have decisional competence cannot decide on sterilisation.[115] Healthcare personnel are responsible to make assessments regarding children's decisional capacity on a case-by-case basis. This assessment may be complex since many circumstances influence children's abilities to make decisions. Such factors can include age, maturity, the nature and urgency of the planned medical treatment.[116] Different medical interventions may require various levels of decisional competence depending on the complexity of the intervention and the children's previous experience with such interventions.[117] Central criteria for the assessment of the ability to decide on medical treatment for children are, for instance, understanding relevant information for intervention and considering the consequences of their decisions.[118] The legal acts do not directly establish whether guardians should be involved in the assessment of decisional capacity. However, in the preparatory works and other supplementary sources, involvement of guardians in assessment is considered desirable, unless it would contradict best interests of the child.[119]

When a child is legally competent, it should not always be necessary to establish the opinion of a guardian. Nonetheless, guardians can continue to be involved in decision-making concerning a competent child[120]

Swedish legal sources provide some guidance as to the level of decisional competence of children for making healthcare decisions. According to preparatory works, children can normally consent to medical examination at the age of 12.[121] Moreover, children are normally able to consent to medical interventions by the age of 15.[122] These presumptions of decisional competence are rebuttable, which

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114 FB ch 4 s 1-3; Prop 2013/14:106, 67.

115 Steriliseringslag (Sterilisation Act) (1975:580) s 2-3.

116 Prop 2013/14:106, 120.

117 ibid 67; Socialstyrelsen, *Bedömning av barns mognad för delaktighet, Kunskapsstöd för socialtjänsten, hälso- och sjukvården samt tandvården* (2015) 14.

118 ibid.

119 ibid.

120 ibid; Rynning (n 26) 286.

121 Prop 2013/14:106, 66; SOU 2013:2,190.

122 Prop 2013/14:106, 66; SOU 2013:2, 189; JO 1975/76, 244.

means that the decisional competence to refuse or consent to specific treatment might not be confirmed in an individual case.
The possibility for children to make decisions regarding medical treatment does not exempt guardians of their obligations to make and be involved in decisions for their child.[123] A child is only supposed to be granted legal competence regarding decisions that they are deemed mature enough to make.

5.2.2. Who decides that a legally incapable child needs treatment?

The authority and duty to make decisions that affect a child's personal affairs, including medical treatment, is generally assigned to the child's legal guardian, chapter 6 section 11 of the PC. In cases where a child has two legal guardians, chapter 6 section 13 of the PC establishes that decisions should be made jointly. Thus, legal guardians have legal competence to refuse or consent to medical treatment for their children if children are incompetent to decide. Even though a child may not have reached the necessary requirements to have full legal competence, legal guardians and healthcare providers and personnel are obliged to take the views of the child into consideration when making decisions in accordance with chapter 4 section 3 of the PA and article 12 the CRC.

5.2.3. Can a child that refuses medical treatment be forced to undergo treatment anyway? In what cases?

In accordance with FB, guardians have the right to consent to treatment for the child. As was mentioned in the previous section however, chapter 2 section 6 RF prohibits the authorities to physically violate persons, unless law provides for an exception. An example of such an exception – when the use of force is authorised – is compulsory psychiatric treatment in accordance with the Compulsory Psychiatric Care Act (1991:112852) *(lag om psykiatrisk tvångsvård*). However, as to somatic treatment, the exceptions are not explicitly made in the acts of parliament, which may make it questionable whether healthcare personnel, considered representatives of authorities, may force a child into treatment.[124]
Although the use of force in relation to children is not regulated, force is applied in practice. Kindström Dahlin provides examples of such practices in terms of legal guardians holding their small children during vaccination, regardless of refusal.[125] In this example, the legal guardians are not representatives of public authorities and, as such, the prohibition of chapter 2 section 6 of the IoG is not

123 Prop 2013/14:106, 120.
124 Moa Kindström Dahlin, *Att tvinga ett barn – om barns rättigheter i hälso- och sjukvården och behovet av en tydligare tvångsvårdslagstiftning* (Förvaltningsrättslig tidskrift 2016) 270–272.
125 ibid 270.

applicable. It follows that when children resist treatment, guardians should have some leeway to use force in order to enable medical treatment, as long as the force remains within the boundaries of the so-called the disciplinary[126] and criminal provisions on, inter alia, abuse, unlawful coercion or unlawful deprivation of liberty.[127] In relation to healthcare personnel, a child is protected from the use of force through the aforementioned chapter 2 article 6 of the IoG. This provision leaves little room for the healthcare personnel to use force when a child is resisting interventions.
To summarise, if a child resists treatment, only guardians have some limited possibilities to use force. Healthcare personnel d0 not have the right to use force when providing treatment to a child, regardless if the child is incapable of giving consent. Yet, this does not mean that healthcare personnel will be criminally liable for the use of force against incapable children.[128] The limited legal possibilities for healthcare personnel to lawfully use force, in situations where a child refuses treatment, can be criticised for being insufficiently precise in order to safeguard that children's needs for healthcare are ensured.[129]

5.2.4. Can a legally incapable child receive treatment when guardians oppose it? In cases where the guardians of the child do not agree on the need to have a medical intervention, who decides?

Well-being of children in Sweden is ensured in particular through social services (*socialtjänsten)*.[130] According to chapter 6 section 13a of the PC, the Social Welfare Committee (*socialnämnden)* can decide that an action may proceed without consent of one of the guardians, if it is in accordance with the best interests of the child. However, most actions concerning somatic care are not part of this exception. Moreover, this exception should be used restrictively and only where there is a clear and distinct need for care in the individual case.[131]
If both guardians disagree concerning somatic care, section 2 of the Care of Young Persons Act (1990:52) (*lag med särskilda bestämmelser om vård av unga*) authorises compulsory care measures by the Social Services in cases where there are real, significant and specific risks to the child's health or development. The criteria for risk in the Care of Young Persons Act means that children cannot be taken from their family for receiving treatment that is potentially beneficial for them, such as vaccination.[132] However, in cases where children are in life-threatening

126 FB, ch 6 s 1
127 Kindström Dahlin (n 123) 272.
128 NJA 2018, 1051.
129 Litins'ka, 'Samtycke och beslutskompetens i vården" (n 78) 99.
130 Kindström Dahlin (n 123) 249.
131 Prop 2011/12:53, 27; HFD 2015 ref 5.
132 Litins'ka, 'Samtycke och beslutskompetens i vården' (n 78) 99.

situations, and the guardian refuses treatment, the social services may take a child into their care and authorise the treatment.[133]

6. Exception: Emergency Medical Interventions

6.1. How is the provision of medical treatment in cases of medical emergency regulated in your country?

As stated above, a patient's consent is a necessary requirement for healthcare personnel to perform their duties in relation to a patient.[134] Chapter 4 section 4 of the PA provides an exception from the main rule in chapter 4 section 2, enabling healthcare personnel to act without consent in certain emergencies. According to the provision, a patient should receive healthcare that is needed to avert an imminent danger that acutely and seriously threatens a patient's life or health, if patients cannot be investigated because of unconsciousness or for other reasons.

The abovementioned provision means that the risk to a patient's life must be considered imminent in order to provide healthcare under this exception.[135] When this is no longer the case, care can no longer be provided pursuant to the provision, even if the patient is still unable to express their will. The provision will not be applied in situations where there is a constant need for healthcare, but no imminent threat to the patient's life is present.

In order for medical interventions in accordance with chapter 4 section 4 of the PA to be carried out, a patient should also not be able to express their will. The preparatory works provide several examples of when patients are unable to express wishes, such examples include when a person is in medical shock, under influence of substances, or otherwise unconscious.[136]

Even the Penal Code contains the provisions concerning releasing from criminal liability in cases of emergency. The Penal Code provisions on emergency have been interpreted as an acute situation of a temporary nature, in which a person inflicts harm to protected rights and interests to save other, more important rights and interests.[137] The provisions can mean that in order to save life and health, a healthcare professional can inflict harm to such values as a patient's right to privacy without being criminally liable. Consequently, there may be situations in which healthcare providers can medically intervene despite the patient not

133 Care of Young Persons Act, s 1-2.
134 PA, ch 4 s 2.
135 Prop 2013/14:106, 120.
136 ibid 60.
137 Petter Asp, Magnus Ulväng and Nils Jareborg, *Kriminalrättens grunder,* (Iustus, 2013)241; Nils Jareborg, *Allmän kriminalrätt* (Iustus 2001) 263.

consenting, or even actively refusing the intervention.[138] The preparatory works give examples of situations in which the provision is applicable, such as cases where a patient is unconscious and an imminent threat to the patient's life or well-being is present.[139]

The discussion above indicates that there is a certain overlap between chapter 4 section 4 of the PA and chapter 24 section 4 of the Penal Code. The main difference between the two provisions is that the PA's main purpose is to codify the duties of healthcare personnel. The mentioned above provision of the Penal Code only regulates situations in which medical personnel cannot be criminally prosecuted due to acting out of necessity.

6.2. Legal definition of emergency care

Swedish law contains no explicit definition of emergency care; however, the provisions allow deducing when care without explicit consent can be provided. As mentioned above, in accordance with the PA, emergency care can be considered as care that is necessary to avert an imminent danger that acutely and seriously threatens a patient's life or health. Therefore, what can be understood as emergency care includes both danger to life and health, but the danger should be serious and acute to classify care as emergency. This definition does not coincide with criminal law definition of as to releasing from liability in cases of emergency (see discussion in the section above); it might not necessarily coincide with the definition of emergency care in medical practice.

[138] ibid 224.
[139] ibid.

Chapter VI:
Conclusion

1. Legal regulation of patient's status

Nordic countries have been cooperating since the 14th century and the Kalmar Union, when the Nordic countries as we know them today came together due to Queen Margaret I of Denmark's announcement. Although, at the time all the regions held tight on their own legislation and governments, the cohesion on the Nordic countries' legislation dates back to the times of the Kalmar Union. Finland was at the time part of Sweden, and Denmark was the ruler of Norway and Iceland. Part of still existing Finnish legislation, dating back to 1734, when Finland was part of Sweden, providing the reason that Finnish and Swedish legislations are still today quite alike. Even though Finland was part of the Russian Empire, it never implemented the Russian civil law (Svod Zakonov 1832) but Finland held its own legislation from the Swedish time. Sweden's' legislation on the other hand, was influenced greatly by Norway and Denmark, thus influencing the way Finnish legislation shaped over the years.
Although Norway and Iceland's legislations are quite independently developed, hundreds of years of history together has developed our thinking and procedures the same way across the Nordic countries, which we may see when comparing these to all other legislations worldwide. Nordic cooperation amongst legislation started in the 20th century, when the Agreement on the Cooperation of Legislation came into force with the Helsinki Agreement.[1] The agreement states that all the Nordic countries commit to accomplish coherent legislation on as many fields of law as possible. The cooperation although has been criticised as weak and non-successful but it indicates the willingness on coherent legislation and simultaneous development on legislative acts as well as legal position across the Nordic countries. Especially in the field of healthcare and biomedicine, the legal cooperation is lacking, mostly due to the legislation being of a later date.
All the Nordic countries are welfare States and are built upon the same principles such as equality and high quality of education but as seen from the report above, legislation has not been accomplished to create as coherent as adequate. However, all the Nordic countries are parties to the same international instruments, such as the ECHR, as well as the ICESCR, all of which play an important role in national legislation and the rights of patients. These conventions aim to more coherent implementation of legislation on the regulated fields. One way or another, these conventions affect national legislation, whether by implementation

[1] SopS (Helsinki Accords) 28/1962

as part of national legislation or by ratifying the conventions. When Norway reformed their entire legislation on health regulations in 1999, they used as the baseline the international human rights convention they are a party to, and took into consideration how to unify international conventions and their national legislation.

2. Information as a component for valid consent or refusal in medical interventions

Despite the fact that informed consent is now-a-days one of the leading principles, and practice in medicine, it is a somewhat an innovation in the Nordics when the principle was acknowledged not until in the 90s. The concept itself however has a significant history, dating back from the early 20th century. In *Schloendorff v Society of New York Hospital*, adjudicated in 1914, the court stated that "every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who perform an operation without his patient's consent, commits an assault, for which he is liable in damages."[2] One of the most well-known cases considering the informed consent has been from the Nuremberg trials in 1947, where the court came up with the so-called Nuremberg code, according to which no one shall be a research subject without a prior given informed consent. For more, the Helsinki Declaration from 1964, which the World Medical Association developed, and which is now seen as the cornerstone document on ethics of human research, was for a long time seen in Finland only as a principle, and not practice,[3] despite it being compromised at the capital of Finland.

The Nordic countries do respect the principle by far today but vary somewhat between the States. Depending on the country, it is either doctors' or healthcare workers' duty to inform the patient on the medical procedure, its risks as well as the possible side effects. Despite the fact that informed consent is demanded before exercising any medical procedure in all of the Nordic countries, the demand on how detailed the information should be, varies from country to country. Danish health law requires that healthcare workers deliver the knowledge on possible complications as well as side effects to the patient[4] but for example, Finnish legislation is broader and states only that risk factors need to be informed.[5]

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2 *Schloendorff v Society of New York Hospital*, 211 NY 125, 105 NE 92 (1914)

3 Paula Kokkonen, 'Informed Consent - A Nordic Perspective' (1993) Medicine and Law Issue 12 583.

4 For more information, see the Danish report chapter 2.1.

5 For more information, see the Finnish report chapter 2.1.

The most specific is the Swedish legislative act, which includes a complete list of the information, which needs to be given to the patient.[6] Finnish and Danish acts have also taken into consideration different languages the patient may speak.[7] Unlike other Nordic countries, Finland has two official languages, as well as several minority languages, which all must be taken into account when disclosing information for patients. Depending on whether the municipality, in which the treatment is given, is bilingual or monolingual, the patient needs to be assisted in their own first language.

When considering the differences whether or not a patient may refuse to receive information on their own medical treatment, the regulations does not vary that much. According to Swedish and Finnish legislation, the patient has always the right to not to hear any information on receiving treatment, which is as well the situation in Norway. In Denmark, the patient has always the right to receive information on the medical procedure, with explicit phrasing. The only exception to the rule is purely cosmetic procedures, where the patient must always receive the medical information.[8] However, it is important to notice that the breach of giving information from a healthcare professional in Sweden is not compensable, which has attracted a lot of critique. In the other countries, the right to information is highly recognised, and when it is breached, the patient has the right to different legal proceedings. When a patient feels the need to complain about their medical treatment, the procedures are quite similar in every Nordic country. There are various administrative bodies that may pass judgment or decide upon a matter. The decisions are generally abided by. Therefore, the first level of jurisdiction is not a court *per se* but an authority. In Norway, a court but also Norwegian Patient Injury Compensation and ombudsman addresses cases where a patient has been injured or faced serious complications. Whereas in Denmark the patient may bring up a case in the Danish Agency for Patient Complaints, and in Finland there is the Patient Ombudsman who is in charge of advising on procedural injustices the patient has experienced. Sweden has disciplinary boards for doctors, which usually grant awards for bodily harm, and pecuniary damages but nothing for the lack of information. The aforementioned legal proceedings in the other countries are not exclusively to compensate the breech on the right on information but rather for all possible breeches.

Since the entire resident population of the Nordic region has been covered with public healthcare, complaint procedures are important means of influencing that. The complaints a patient may present, may be divided into two categories: first, one for complaints regarding their rights, such as consent, and second, the complaints regarding malpractice or damages. The proceedings for compensation are

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6 See the Swedish report chapter 2.1.

7 For more information, see the Danish report chapter 2.3. and the Finnish report chapter 2.3.

8 For more information, see the Danish report chapter 2.4.1.

somewhat similar since administrative bodies and ombudsmen or similar institutions exists throughout the countries, helping patients handle their complaints. All the Nordic countries have as well-established patient insurance schemes to regulate patients' right to monetary compensation where injuries have been inflicted by medical staff, which is beneficial for the patient, creating security.
The difference occurs when in Norway courts play a role in the complaint's procedure, where when the patient's rights are violated; they may submit a complaint to an administrative body, which decision is then admissible in civil court.[9] In other cases, authorities play a big part in Norway, likewise in the rest of the Nordic countries. For more, in Denmark, the National Complaint Board may refer the case to the public prosecutor when the case is particularly serious but an individual does not hold the same right.
Whether it is a court or an authority, the judgment or decisions made by those organs are slow processes, and patients rather use private insurance to receive compensation. Thus, the efficiency of legal security, which every Nordic country has ratified in the ECHR 6(1) and more importantly in the Charter of Fundamental Rights of the European Union article 47 and the right to an effective remedy, is being endangered due to the slow proceedings on authorities. Most visible and predictable reasons for delays are the lack of resources, and the nature of the proceedings. Court proceedings take time due to written and oral proceedings, as well as due to hearings.
Despite the fact that the proceedings are somewhat similar, we are considering whether it would be beneficial to harmonise the complaints proceedings across the Nordic countries. We consider it being troublesome, when Swedish legislation does not recognise a formal right to appeal to neither, judicial or administrative bodies concerning violations of patient's rights, creating a possible threat to legal security. The appealable matters should thus be standardised throughout the Nordics, to secure similar legal state in the countries, so the proceedings could also be harmonised.
What about informing children on their medical treatment? Every nation has their own regulations when it comes to children, when they are mature enough to be seen as capable of deciding on their own medical treatment. Finland is the only Nordic country, which has not imposed a set age for children to be evaluated as capable of deciding on their own medical treatment, but it is an overall assessment of the child's capabilities and overall understanding.[10]
Which is better, may be argued on both sides but it nonetheless affects the obligation on information given to the patient. Since Finland is the odd one out, we will discuss it first. When a child is capable of making their own decisions on

9 For more information, see the Norwegian report chapter 2.7.
10 For more information, see the Finnish report chapter 5.1.1. and 5.2.

their medical treatment, they are treated as adults, and the parent or legal guardian may even be denied access to the room when the child so wishes. Consequently, the child needs to be fully informed on the procedure, as well as the risks so they may make an informed decision. In other situations, e.g. when the patient in Finland does not hold the ability to decide on their own medical treatment or in the rest of the States when the child is not capable of deciding on their own treatment due to their age, the child needs to be informed even when they are not the one making the decision. Additionally, the information should still be disclosed in a manner such that the patient understands it. The differences in the practices are quite significant since on the latter, the child does not need to understand the procedure nor its effects since they are not the ones making the decision. In Sweden, the right to a legal guardian to receive information precludes the child's right on receiving information.[11] In both Norway and Denmark, the child has more weight on their say, since in both countries the child may forbid disclosing information for their parents or legal guardians.[12]

What about adult patients who cannot decide for themselves due to temporary or long-lasting conditions? All the other Nordic countries enable family members to receive information on the patient's condition, except for Finland, where a written consent from the patient is needed for the healthcare personnel to be able to give out any information for family members.[13]

However, in Norway, when the patient is unconscious or for other reasons not capable of exercising decision-making, family and other close relatives are justified to receive information.[14] This nevertheless goes hand in hand with the seriousness of the condition of the patient, and the more serious the condition; the greater effort may be required by the healthcare professionals to inform the relatives.

The same goes in Sweden but the concept of relatives is not clearly defined in legislation, and it needs to be assessed each time, whether someone is a relative.[15] We consider this being troublesome since an overall assessment of their relation must always be clarified. However, the people identified as relatives are usually the same, thus raising a question, wouldn't a simple entry to legislation on definition of relatives simplify the procedure by a lot? The record could be left as open ended so it would leave room for assessment as well. We find this being unnecessary bureaucracy, as we also find the Finnish written consent being. Only

11 For more information, see the Swedish report chapter 2.6.
12 For more information, see the Danish report chapter 2.6. and the Norwegian report chapter 2.6.
13 For more information, see the Finnish report chapter 2.6.
14 For more information, see the Norwegian report chapter 2.6.
15 For more information, see the Danish report chapter 2.6.

a few people, usually lawyers and doctors, do give their written consent on assigning medical information to relatives, and the rest are not aware of the fact that a consent of such needs to be given, due to which it is not adequate practice *per se*.

3. Forms of patient's consent or refusal

When it comes to patients' consenting to medical treatment the principle of autonomy applies throughout the Nordic countries. This means that the patient can decide whether to receive or refuse any medical treatment offered or already started. This is an important principle and underlines the idea that a person who undergoes medical treatment maintains their autonomy towards the society and medical personnel that treats them. All Nordic countries have adopted the same idea, but the name of the concept can vary based on countries and their legislation. In Denmark, this concept is often referred to as "the principle of autonomy" and in other Nordic countries for example in Finland, it is formed in legislations as the "patient's right to self-determination" or "sovereignty". However, the idea remains the same.

Before consenting to any medical treatment, the healthcare personnel must inform the patient to the necessary extent about the possible risks of the treatment or procedure and the possible consequences of the patient refusing the treatment. In other words, the patient's informed consent requires that the patient has been included in the process of treatment assessment. The patient has to be aware of the situation before giving their informed consent.

In all Nordic countries, the patients may give their consent in three different ways – written, oral or tacit. Sometimes the forms of consents are also divided in two categories – explicit consent and tacit consent. Explicit consent contains written and oral consent and is often required in situations where the interventions against the patient's integrity are more serious. In Norway, there is also a fourth type of form to give a consent – hypothetical consent. Hypothetical consent is also referred to as presumed consent and means that healthcare personnel presume based on the patient's behaviour that they want the medical treatment without expressing it explicitly or tacitly.[16]

The purpose of hypothetical consent is however a bit confusing since tacit consent can cover these types of situations in the other Nordic countries. Which also might be why the other Nordic countries have not deemed necessary to include the fourth type of consent in their legislation.

Although the formalised system of consent was not desirable, in some situations the written consent is explicitly required. There are some examples from Finland,

[16] For more information, see the Norwegian report chapter 3.1.

Norway and Sweden's legislation where the written consent is a necessity. The common factor between these situations is the level of seriousness of the intervention. In Sweden, the written consent is needed in the legislation of transplantation. In Finland, these interventions include abortion, castration, sterilisation and removal of organs.

If the patient refuses to receive medical treatment, the health personnel are obliged to treat the patient in some other medically acceptable way. The patient can then decide whether to receive the treatment in question or not. In Finland and Sweden, the standard practice is to record the refusal in a reliable manner in the patient journals.

There are some limitations provided by law that prohibit the patient consenting to medical treatment. For example, in Denmark a patient cannot consent to treatment that will or can harm the patient through irresponsible operations or euthanasia.[17] This kind of provision is usually found in the Criminal law of each Nordic country.

Although the patient's consent is a necessary requirement for the healthcare personnel to perform their duties, there are some exceptions of that rule. These exceptions cover certain situations where the patient itself cannot give a valid informed consent. Certain groups of people are not able to give their independent informed consent. These groups include minors and those who permanently lack the ability to give informed consent. In Nordic countries, the legislation states who is capable of giving informed consent on behalf of these special groups. The legal guardians of minors are eligible to give a consent on behalf of their children. Although there are usually some limitations to that. It is often stated by law that children over a certain age are eligible to give an informed consent by themselves.[18] On behalf of the group of people that permanently lack the ability to give informed consent it is usually the next of kin that has the ability to give the consent instead.

4. Voluntary and competent consent to or refusal of medical interventions

In some situations, consent or refusal of medical intervention can be regarded as involuntary. In all Nordic countries, human rights form a strong legal ground on how people need to be treated. Encroachment on personal freedom can only be done due to clear legal basis. A competent person has the right to decide on their treatment. The patient must give their consent in a process that is not character-

17 For more information, see the Danish report chapter 3.2.

18 For more information, see chapter 5 of the Conclusion.

ised by coercion or duress. The patient must be accurately informed, be competent in giving a consent and have an understanding on what they consent to. In Denmark, the law only allows the application of coercion in completely extraordinary situations, which usually are emergencies.[19]

An involuntary consent or refusal is being given when the patient has been forced. There are different ways to using force, which are verbal force aka hidden force and physical force aka qualified coercion. An informed consent that is given under pressure force or fraud is not legal. The health worker is not allowed to persuade a patient into consenting or refusing treatment. This can happen by sweet-talking or leaving out relevant information, which affects the patient's decision. Hidden force is harder to detect and therefore usually more difficult to stop.

There are some legal consequences on forcing someone to give involuntary consent or refusal. If there are no special rules on compulsory treatment, this act can be both punishable and punitive.

In Finland, the concept of self-determination requires three different factors: voluntariness, competence and knowledge,[20] like in other Nordic countries. The competence can be further divided into general and situation-specific competence. Even if a person is generally capable of making decisions, some factors related to that particular situation can cause the person to be incapable of making a decision. A consent to research is considered to require stricter criteria than the consent to treatment. If a guardian or other legal representative holds the decision-making power, they are not allowed to refuse care, which may be required to avert a threat to the patient's life or health. This prevents the abuse of decision-making power.

In Finland, there is no sanctions in the Patient's rights act for missing a consent. However, the legal situation is different between medical procedure and medical research. The patient's consent to care can be neglected without a fine, but failure to consent to a medical examination is sanctioned. The patient receives legal protection via an objection procedure and an administrative complaint. If the healthcare professional has acted incorrectly or negligently, it may result in administrative control, a written warning, a restriction or withdrawal of professional practice rights. Injuries to the patient are compensated based on the Patient Injuries Act. The healthcare personnel can also be charged for breach of duty in accordance of the Penal Code. In Norway consent may cease to apply wholly or partly for example if the patient is because of physical or mental disorder, has

19 For more information, see the Danish report chapter 4.1.

20 For more information, see the Finnish report chapter 4.3.

senile dementia or is clearly incapable of understanding what the consent entails.[21] When a consent or refusal is involuntary, legal consequences include claim for damages and in some situations, the healthcare personnel may be penalised. The exception is that if the intervention is done in the best interests of the patient, it is hardly punishable. If the situations are considered as irresponsible conduct of the healthcare personnel, they could receive warning, revoked authorisation or punishment. In Sweden, a person who explicitly refuses treatment but has diminished mental abilities has the right to competent refusal of treatment.[22] An intervention is considered as a forced act if that person is being forced into the intervention. In cases where the consent is not available hypothetical consent comes into picture. This means that an absent consent does not mean the consent is involuntary. In certain situations, it is presumed that a patient who is not able to communicate would consent to intervention. In Sweden there is also a situation called an undue influence,[23] which refers to a situation where consent is given after receiving false information or pressure in the form of threats of violence or other sanctions. It might appear in situations like organ-donation, sterilisation and abortion. However, judicial practice in Sweden is still scare regarding undue influence. There are three legal sanctions in Sweden if the consent in found involuntary. These are disciplinary liability, penal liability and liability in tort. These three also found in Norway. Penal liability and liability in tort appear also in Denmark. However, like in Denmark the healthcare personnel might be exempt from penal liability if they perform medical care and treatment in an emergency.

5. Capacity to decide on medical interventions

Differing from all the other Nordic countries, Swedish legislation does not recognise practice where an adult patient is declared fully legally incapable.[24] Meanwhile in the rest of the Nordic countries an adult patient may be declared incapable of deciding on their own medical treatment, and a substitute is assigned to make the decisions on behalf of the patient. In Sweden, less intrusive methods were introduced in 1989. The possibility to declare an adult fully incapable was diminished and administrator and special representative were introduced to monitor an incapable adult's personal interests. However, the aforementioned authorities do not hold the power to conclude any medical decisions for the patient but are strictly there to overlook their best interest. The opinion of those authorities

21 For more information, see the Norwegian report chapter 4.1
22 For more information, see the Swedish report chapter 4.1.
23 ibid.
24 For more information, see the Swedish report chapter 5.1.3.

may however be taken into account, which then may result as valid consent. Consequently, capable or incapable adult patients, the patient is the one making the decision in Sweden. In the other countries, an adult patient may be declared as incapable due to physical or mental disturbance, dementia, or due to otherwise not being able to understand the procedure and the content of the consent.

It is the exact opposite in Denmark, Finland, and Norway, where when the patient has been declared incapable for making decisions on their own healthcare, a parent, relative or other person will be chosen to make those decisions for them.[25] Most of the time it is a close relative since the aim is to treat the patient in a way, which they would have decided themselves, were they capable of deciding it themselves. A temporary incapability, which all the countries recognise, may be caused by unconsciousness, and the substitutes for decision-making may become necessary.

However, in the States where a patient may be declared as incapable, a healthcare worker assesses the situation. According to Danish legislation, it is the chief physician if the patient is being treated at a hospital.[26] In Finland and Norway, the doctor conducting the treatment assesses whether the adult patient is capable of deciding on their own medical treatment.[27]

We consider the Norwegian and Finnish way being the most lucrative out of the four. The treating doctor knows the patient the best since they have been in contact with the patient and may get to know their prior medical history. Therefore, the doctor may assess the best way the patient would want to be treated, or at least has the ability to make an objective assessment based on their medical knowledge. Nevertheless, a patient who should be declared as incapable is not capable of making the best decision for themselves. Incapable patients are usually those suffering from dementia, other mental illnesses or disorders, or those who are intellectually disabled, hence not aware of their own situation and thus may not give an informed decision.

The ages when a minor patient is seen as capable of deciding on their own medical treatment varies significantly between the Nordic countries. According to Norwegian legislation, children aged between 12 and 16, may consent to medical treatment without informing the parents or legal guardians, and a child aged seven or older needs to be informed on the proceeding and given the possibility to state their own opinion. However, under 16-year-olds parents have the right to consent on behalf of the patient. 16-18-year-olds have the competence to act

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25 For more information, see the Danish report chapter 5.1.3., the Finnish report chapter 5.1. and the Norwegian report chapter 5.1.3.

26 For more information, see the Danish report chapter 5.1.2 and 5.2.1.

27 For more information, see the Norwegian report chapter 5.1.2. and 5.2.1. and the Finnish report chapter 5.1. and 5.2.

on their own unless otherwise noted. Swedish legislations preparatory works suggest that 12-year-olds can consent on medical examinations while 15-year-old patients may consent on medical interventions, such as treating an injury or disease.[28] Danish legislation has set a stricter approach when limiting children under the age of 15 from consenting or refusing from any treatment.[29]

As stated above, Finland is the only country out of the Nordic countries, which has not set an age limit on minor patients when they can make decisions by themselves. In Finland, the treating doctor performs an overall assessment based on the age, level of development, and the ability to understand the procedures and the possible outcomes. However, the preparatory work has stated that 12-year-olds are always capable of deciding on their own medical treatment. When the child has been evaluated as capable of making the decision on treatment, they are treated the same as an adult patient would. For example, the minor may ask any detail not to be disclosed with their parents.[30]

The common nominator to all of the States is that in cases where the child is incapable of deciding on their own medical treatment, it is the parents or legal guardians who have the right to decide on behalf of the patient. Despite all the other States circulating on somewhat similar age limits, where are these age limits coming from? One preparatory work in Finland suggested that an age limit should be set, which would be 15 since that is the limit for criminal liability for minors in Finland. Since 12-year-olds are heard on custody arrangements and the opinion must be the deciding one if it does not cause harm or danger for the child, that might be seen as an age when a child has enough understanding on what is the best from them and thus capable of making such decisions on medical treatment as well.

When the child is being treated in consensus with their parents, according to Finnish legislation, as a rule, both parents' permission is needed for the medical procedure, and without one's permission, the treatment may not be performed. However, in Denmark when the child is under 15 years of age, the parent with whom the child is living with, has more weight on their opinion and the residential parent has the last say on completing a medical treatment, whether or not the other parent agrees. In some occasions, both parents must consent on the procedure.[31] As the opposite in Finland, the doctor may not perform any medical interventions when they are not sure whether both parents have given their permission.[32]

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28 For more information, see the Norwegian report chapter 5.2.1.
29 For more information, see the Danish report chapter 5.2.1.
30 For more information, see the Finnish report chapter 5.2.
31 For more information, see the Danish report chapter 5.2.4.
32 For more information, see the Finnish report chapter 5.2.2.

When a parent refuses on treating the minor patient, who is not capable of deciding on their own medical care, and which is necessary due to threat on life or health, all Nordic countries have imposed the possibility for authorities to surpass the parents will. In extreme situations, the child may be taken into custody so the treatment may be performed. In Norway the authority is however the county board, consisting of professionals meeting the requirements for judges, but has the same concept than taking into custody does when fast and trustworthy decisions may be made for reassuring the welfare of the child.
In Finland, there are few recorded cases where the opportunity to take into custody has been exercised, one of which was about religious parents who refused to give necessary blood transfer for the child, without which there would have been a great chance that the child would have passed.

6. Emergency medical interventions

A patient's right to self-determination and an informed consent before a medical procedure is the main rule in all Nordic countries. However, the need for emergency medical intervention forms an exception to that rule in Nordic countries. There are multiple challenges in all Nordic countries when it comes to legislation and consent in emergencies. In most Nordic countries, a patient's consent must be respected but medical care can also be given without consent in emergencies. Therefore, medical intervention is possible without explicit consent from the patient or their legal guardian/next of kin. However, in Norway the requirement of patient's consent is completely excluded in emergencies.[33] Interestingly, in Danish Criminal Law the healthcare personnel can be criminally responsible for not helping a patient that needs emergency care.[34] A doctor must help the patient if somebody requests medical care for the patient and no one else is providing medical care to the patient.
The Nordic countries do not have an explicit definition of emergency care in their legislation. Emergency care is often described through the situation where it is needed. A Patient should receive healthcare that is needed to avert imminent danger that acutely and seriously threatens a patient's life. Emergency situations have to include an imminent danger. If a person is capable of expressing their will then the healthcare personnel must respect it. In most Nordic countries, the danger must compose an imminent risk to the patient's life or health. The situation is not characterised as emergency if it does not compose a risk to the patient's life or health or can result in serious permanent injury. Therefore, not every emergency constitutes the right to perform an emergency intervention.

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33 For more information, see the Norwegian report chapter 6.1 and 6.2.
34 For more information, see the Danish report chapter 6.2.

Overall, if a patient expresses their refusal of care before the medical emergency in a steadfast and competent way, the medical personnel must respect it. In Finland there is an instrument called an advance directive which states the patient's will for any situation. The advance directive does not have any strict form so it can be given either orally or in writing. It is then recorded in the patient journal. It binds the healthcare professionals and the patient's relatives.[35] The patient has always a right to explicitly change or withdraw the advance directive. What makes this problematic is that in some situations it might be difficult to know that there is an existing advance directive and the healthcare personnel might be obliged to act against it.

[35] For more information, see the Finnish report chapter 3.4.

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PATIENT'S CONSENT TO TREATMENT
- A NORDIC PERSPECTIVE ON MEDICAL SELF-DETERMINATION

This comparative report provides a comprehensive insight into patient's self-determination in the Nordic countries (Denmark, Finland, Norway and Sweden). The report focuses on a patient's right to self-determination in the Nordic countries and aims to answer the questions of how issues of valid consent to or refusal of (somatic) medical interventions are regulated in the Nordic countries, and what the current regulatory challenges are.

The report answers a number of questions within a legal framework developed in collaboration with law students and academics. It begins with an introduction to international human rights law in healthcare, followed by each national report about the legal regulation of patient's status and valid consent; including the regulation regarding emergency medical interventions. The report concludes with a comparison and suggestions for improvement of the law.

The Nordic Legal Research Group is a project initiative of four Nordic groups (Denmark, Finland, Norway and Sweden) and of the European Law Students' Association (ELSA) in which 28 students gathered throughout 2020 to write this collective report. While written purely by students, the report is a product of close cooperation with 7 esteemed academics and experts of Nordic health law.

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