Afbeelding 1: S.Jansma, '*Op zijn 35e moet pensioen*', Zwaag: Vior Webmedia 2016.

DECISION ABOUT LIFE OR DEATH, A MATTER OF ARTIFICIAL INTELLIGENCE?

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Preface

In front of you is the thesis 'Decision about life or death, a matter of artificial intelligence?' I wrote this thesis as part of my second master in Law and Technology. I followed this master at the Tilburg Institute for Law, Technology and Society (TILT) at Tilburg University.

Shortly after Otto, the husband of my cousin Saskia Jansma died, I read an article about the multidomain prognostic model that should help diagnose coma patients. Immediately I asked myself what would have happened if the physicians used the multidomain prognostic model in Otto's case? Otto has also been in a coma thirteen years ago and recovered from it. The research I conducted was complex. This is because coma is generally already a complex concept. To properly understand what exactly coma is and what the multidomain prognostic model does, I had to use knowledge from my familiar discipline, namely law, but also other disciplines such as medical and technical. Also, it is a very broad subject, making it sometimes difficult to define it properly. Ultimately, I succeeded in achieving this result through trial and error.

Hereby, I would like to thank my cousin Saskia for letting me use her situation as inspiration for this thesis. This has enabled me to better relate to the topic. In addition, I want to thank my supervisors M.E. Noorman and C.M.K.C. Cuijpers for the guidance and transfer of their knowledge. I also want to thank my friends and family for their moral support during the writing process.

I hope you enjoy reading this thesis.

H.C.H.L.M. Jansma

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List of abbreviations

AI	Artificial intelligence
DC	Dutch Constitution
DCC	Dutch Civil Code
DOC	Disorder of Consciousness
ECHR	European Convention of Human Rights
ECtHR	European Court of Human Rights
GOS	Glasgow Outcome Scale
MCS	Minimally consciousness state
ML	Machine Learning
MDPM	Multidomain Prognostic Model
PVS	Persistent vegetative state
Re-fMRI	resting-state functional magnetic resonance imaging
RVZ	the Council for Public Health and Care
VS	Vegetative state
WGBO	Dutch Medical Treatment Agreement Act

Chapter 1 Introduction

1.1. The case

Thirteen years ago, Otto (the husband of my niece Saskia), got into a coma. I.e., he had a disorder of consciousness (hereafter: DOC). For five months, Otto was unconscious. When he woke up, he had to learn how to speak and move again. In the beginning, Otto was like a newborn child that could not do anything. But in the end, he learned how to walk again and how to express himself. It was a happy man, but with brain damage. Last September, Otto had to undergo an operation. Unfortunately, something went wrong, and Otto became brain death. Otto died several days later.

The week after his death there was an article published about Chinese neurologists at the Academy of Sciences and the PLA General Hospital in Beijing that developed a multidomain prognostic model (hereafter: MDPM), a machine learning algorithm, that can help physicians to diagnose if someone, who is in a coma (a DOC patient), will wake up again or not.[1] The researchers fed the machine learning algorithm with resting-state functional magnetic resonance imaging (hereafter: re-fMRI), and three clinical characteristics, namely the incidence age, the etiology and duration of the DOC. An algorithm is a mathematical formula with which you can achieve a specific goal. The MDPM combines these data to predict one year-outcomes at the single-subject level.[2] This MDPM can help physicians to understand how likely it is that a particular patient will recover.

When I was reading this article, I thought about what the life of Saskia and Otto would look like if the MDPM already existed thirteen years ago. What if the MDPM would have indicated that waking up again was highly unlikely? What if the physicians told Saskia this outcome and she decided to stop the treatment? That would mean that the thirteen years that Otto spent happily with his family would have been taken from him and his family. If he died thirteen years ago, that would have meant that her children never knew who their father was and that Saskia was not able to get more children with him.

The opposite situation is also possible. What if doctors tell the family members that someone will not wake up again, while the MDPM gives a prognosis that the patient has an opportunity to recover? In that case, the MDPM can contribute in a positive way.

1.2. The problem

The problem within the medical community is that the physicians are unable to estimate whether a patient will recover or not with 100 percent certainty. Therefore, they are unable to meet the expectations of the chronic DOC patients families who want clarity. As a result, the legal, social, economic, and ethical consequences are also enormous.[3] It raises, for example, questions like whether a treatment is meaningless or not? It can be difficult for physicians to predict which patient will recover based on the existing models and methods. This diagnose is mainly based on their observations of the patient's behavior. Therefore, these predictions are subjective and vulnerable to errors. A third of the diagnosis is wrong.[4] As a result, we need

[1] Tangemann 2018.
[2] Ming Song et al. 2018, p. 1.
[3] Ibit, p.1.
[4] Van Daele 2012, p. 11 en 12; Gosseries et al. 2011, p.4; Maassen 2009, p.275.

more accurate and objective methods.[5] New technologies may achieve this. One of these technologies is artificial intelligence.

We live in a century where not only humans make decisions but also computers. The use of Big Data and Artificial intelligence (AI) is on the rise. This means that devices will frequently make decisions or will assist people in making decisions. These technologies can have an influence on the daily life of many people. The new MDPM also assists in making decisions. The MDPM makes a diagnosis that is usually made by physicians themselves. The researchers who developed the MDPM state that with the use of the MDPM, the prediction will be more reliable because the MDPM is much better at analyzing complex biological data than humans. The MDPM looks at the same data sets as the physician but does this much faster and more reliable.[6] The MDPM also can see things that are invisible to human eyes. The neural activities are too numerous and sophisticated to be directly visible to physicians. With the AI system that uses machine-learning algorithms, the MDPM can scrutinize these changing details. Therefore, it can discover previously unknown patterns from past cases.[7]

However, the MDPM also has some downsides. The MDPM is opaque. This means that the researchers cannot find out if the MDPM makes a mistake, and if they do find out, it is not clear what causes the error. The MDPM is also not as objective as we think it is because the researchers program it. They have to make choices during the development of the MDPM. These choices influence the analysis and the outcome of the analysis.[8] The question is also if the accuracy of the MDPM is reliable. The outcome is compared with the original diagnosis. However, we saw that there is a high amount of misdiagnosis. When we compare the MDPM with the initial diagnosis, how do we know this outcome is correct? There is a chance that the initial diagnosis is also incorrect. And if the outcomes differ, which one is right? The one of the MDPM or the initial diagnosis? Lastly, there is also a danger of semi-automated decision-making when the physicians use the MDPM. There is a chance that the physicians rely on the outcome of the MDPM because they do not have the time and skills to evaluate the outcome of the MDPM. In short, the MDPM can contribute to making a better diagnosis, but it also has some downsides. It is important to look closely at the downsides of the MDPM and check whether the benefits outweigh the disadvantages.

There are also points of attention in the legal field when we want to use the MDPM. When there is a prognosis based on the outcome of the MDPM, the physician, in consultation with the family members, has to decide whether to stop the treatment or not. Therefore, the use of the MDPM can have a significant influence on the lives of people. From a legal point of view, the MDPM has an influence on several (fundamental) rights and principles of the patients. The most significant impact of the MDPM is on the private life and protection of physical integrity. These rights are laid down in art. 8 of the European Convention on Human Rights (hereafter: ECHR). The right to private life implies that people can be themselves without prejudice. The right to physical integrity provides the right to repel external influences of the body.[9] The most important principles that underlie these rights are human dignity and personal autonomy. Human dignity means that you have a certain dignity that offers you protection against intrusion from the government of third parties. Personal autonomy is an

[5] Ming Song et al. 2018, p. 2.
[6] Tangemann 2018.
[7] Chen 2018.
[8] Vetzo, Gerards & Nehmelman 2018, p. 53 en 54.
[9] Van Beers 2013; *kamerstukken II*, 1978/79, 15463, 2, p.5.

extension of human dignity, and means that people can freely make their own choices and decide how to organize their own lives.[10]

In the Netherlands, the right to protection of physical integrity is elaborated in art. 11 of the Dutch Constitution (hereafter: DC). Subsequently, art. 11 DC is again elaborated more explicitly in the Dutch Medical Treatment Agreement Act (hereafter: WGBO), which is part of the Dutch Civil Code (hereafter: DCC). The WGBO contains the requirements of informed consent. Art. 7:448 Dutch Civil Code (hereafter DCC) determines that a physician has to provide the patient with information about the nature, risks, and the consequences of the treatment. Based on that information, the patient must approve the intended treatment. i.e., there must be informed consent. Treating without informed consent can be an infringement of the physical integrity of the patient, and therefore, cause an infringement of art. 8 ECHR.[11] The question is whether this information can be provided by the prognosis that the prognostic model gives?[12] The prognosis is the outcome of an algorithm. The physician does not know how the algorithm comes to this prognosis. How can a physician be transparent when he does not know how the MDPM comes to that particular indication? Can a physician meet the requirements of the law when he determines whether the treatment still makes sense based on the new MDPM?[13] If he cannot meet this requirement, this will be an infringement of the physical integrity of the patient and therefore, a violation of art. 8 ECHR. An infringement is only allowed when it is provided by law, in accordance with a purpose mentioned in paragraph 2 of art. 8 ECHR, and when it is necessary in a democratic society. The necessity test means that the infringement needs to be proportional and subsidiary. Especially the necessity test will be the biggest problem when we want to use the MDPM. The use of the model is subsidiary if we can provide sufficient information about the model. Also, the medical decision based on the outcome of the MDPM should be based on shared decision-making.

Thus, if we want to use the MDPM, we need to consider whether, when, and how machines should make decisions about human lives and whose values should guide those decisions. Even though the new MDPM does not directly make a decision about human lives, it does contribute to that decision and thus is relevant from a legal perspective.

1.3 Main research question

The questions and explanations mentioned above lead to the following research question:

'Under which conditions is the use of the MDPM compatible with the right to physical integrity as laid down in art. 8 ECHR and further explained in Dutch legislation regarding medical situations?'

To answer the main question, we first need to answer sub-questions derived from the main. These sub-questions are:

1. How does the MDPM works, what are the advantages and disadvantages of the MDPM, and how can it contribute in making a better diagnosis in comparison with current techniques and their benefits and drawbacks?
2. What is the meaning of art. 8 ECHR and the value of the principles of human dignity and autonomy for the interpretation of art. 8 ECHR?

[10] Vetzo, Gerards & Nehmelman 2018, p. 53 en 54.
[11] EHRM 9 March 2004, (*Glass/VK)*, nr. 61827/00, *NJ* 2005, 14, *EHRC* 2004, 38 (m.nt. A.C. Hendriks).
[12] Legemaate & Widdershoven 2016, p. 169.
[13] Hendriks et al. 2008, p. 2-18.

3. How is the right of physical integrity established in Dutch national legislation?
4. Under what conditions can we use the MDPM in accordance with the law?

1.4. The relevance of the research

The purpose of this research is, to find out if the new MDPM can be used in accordance with the law and what the advantages and disadvantages of the MDPM are. Especially considering that the MDPM can have a significant impact on the lives of patients, it is important to look carefully at the possible disadvantages of the MDPM. Ethics are essential to complete the argumentation about the question if the use of the new MDPM is permissible. This is because law and ethics are closely related. Ethical principles like autonomy and human dignity underlie, for example, human rights like art. 8 ECHR. The legal arguments will not expose all necessary ethical considerations, which makes it essential to examine ethics as well. Therefore, ethics will be used to complete the argumentation.

1.4.1. Practical relevance

The use of the MDPM will take place in the medical industry. Based on the outcome of the MDPM, physicians will advise the family of the patient, what they think is the best thing to do. This research will make clear if the use of the MDPM is in accordance with the law and what the advantages and disadvantages of the use of the MDPM are.

1.4.2. Scientific relevance

With the current techniques, there is still a chance of misdiagnoses. In the documentary 'Uit Coma' professor of neurology Steven Laureys says that we need technologies to help physicians make better decisions.[14] One of these technologies can be the MDPM. I will use the research paper of the researchers who developed the MDPM to determine how the MDPM works in practice. In this paper, the researchers explain how the MDPM works and what the results of the tests they did with the MDPM were.[15]

In my research I will show what the points of attention will be if we want to use the MDPM in practice. I will focus on legal and ethical challenges if we use the MDPM. To determine which (human) rights, (ethical) principles, and guidelines are involved, I will use different literature. Various sources of law will be used like treaties, national law (Dutch), guidelines for professionals, and principles of law. This research will be a critical response to the statements made by the researchers of the MDPM. Therefore, this research is a legal and ethical addition to the point of view of the researchers that only concerns the medical value of the MDPM.

1.5. The scientific and theoretical framework

For the first chapter of this research, I will use a literature research to determine which techniques the physicians already use and why they fall short in making a good diagnosis. I will also use a literature review to determine how the model works and what it's benefits and disadvantages are. Regarding chapter three and four, I will use a rights-dogmatic and legal-theoretical approach to answer the main research question. In dogmatic legal practice, sources of law and literature are sought. There will be an analysis of the (human) rights and (ethical) principles that underlie the rights of the patient that are involved. After this analysis, it will be

[14] www.uitcoma.bnnvara.nl afl. 1.
[15] Ming Song et al. 2018, p. 1-53.

possible to determine whether the use of the MDPM is in accordance with these rights and principles.

1.6. Thesis outline

In chapter two, I will explain what the difference is between the current techniques physicians use and the MDPM. I will discuss how current techniques fall short and indicate if and how the MDPM can improve this. I will also discuss the advantages and disadvantages of the MDPM in this chapter. In the third chapter, I will explore which human rights and (ethical) principles are important if we use the MDPM. In chapter four, I will explain how the right of art. 8 ECHR is elaborated in national law. In chapter five, I will determine under what conditions the MDPM can be used in accordance with the rights explained in chapter 3 and 4. Chapter 6 contains a conclusion.

Chapter 2 Coma and the multidomain prognostic model

In recent years there have been many developments regarding the technologies used in neurology. There is a better understanding of what coma is, and they are increasingly able to make better diagnoses. However, we are not there yet. There is still a large number of misdiagnoses. The researchers stated that this will change with the use of the MDPM. In this chapter I will explain the different levels in consciousness in paragraph 1. This creates a clear picture of what coma is and why it is difficult to make a good diagnosis. In paragraph 2 I will explain which technologies physicians use to make a diagnosis. This makes clear what these technologies fall short of. In paragraph 3 I will explain why we need better techniques. After this, I will explain how the MDPM works in paragraph 4. Next, I will set out the advantages and disadvantages of the MDPM in paragraph 5. Paragraph 6 contains a conclusion.

2.1. Levels of consciousness

The multidomain prognostic model aims to improve the diagnosis of coma patients. But, what is a coma and what does consciousness mean? Consciousness is difficult to understand. There are many different levels of consciousness. These extend from coma to full consciousness.[16]

To clarify the levels, I will use the levels that Professor Steven Laureys uses.[17] According to Laureys, there are three levels of consciousness to distinguish. The first level is brain death. In this case, all functions of the brain are permanently damaged and therefore absent.

The second level is the coma. In this stage, some parts of the brain are damaged. Therefore, the patient is not aware of himself and his environment. The patient does not perform conscious actions, but the reflex activities still function. Only the functions that are the basis of consciousness are intact. The most common definition of a coma is: "*coma is a state of unresponsiveness in which the patient lies with the eyes closed, cannot be aroused, and has no awareness of self and surroundings*. "[18] In contrast to patients in a vegetative state (third level), coma patients do not have episodes of wakefulness and cannot open their eyes.[19] There is a lot of miscommunication about the duration of a coma. Many people think that a coma can last for years, but in reality, a coma lasts a maximum of two to four weeks. After this period, the condition of the patient deteriorates, and he dies, or his health improves and the state of coma changes in the state of the vegetative state.[20]

The third level is the vegetative state (hereafter: VS). In this stage, there is some activity of the brains, and therefore these patients still have a sleep and wake cycle. They can open their eyes from time to time, but they are not aware of their environment and themselves. The patient is awake, but not aware.[21] The duration of this stage can vary. When a patient is in this stage for longer than a month, we call it permanent vegetative state (hereafter: PVS).[22] There are cases where the patient has been in this condition for years. Therefore, difficult ethical questions often arise in this situation. For example, if it is allowed to stop the treatment of the

[16] Van Daele 2012, p. 4; Laureys & Tonini 2009, p. 25.
[17] He is a leading clinician and researcher in the field of neurology of consciousness. He works on the University of Liege and is part of the Coma Science Group. He also has a chair in the European Neurological Society Subcommittee on Coma and disorders of consciousness.[17] Thus, he is a great expert in this field.
[18] Van Daele 2012, p. 11; Laureys et al. 2004, p. 538.
[19] Laureys et al. 2004, p. 538.
[20] Van Daele 2012, p. 11; Laureys & Tonini 2009, p. 22.
[21] Van Daele 2012, p. 11; Racine 2010, p. 146.
[22] Van Daele 2012, p. 4 en 12; Laureys & Tonini 2009, p. 23.

patient and let him die.[23] Especially with this condition, it is important that a correct diagnosis is made to prevent a patient from being in this situation for years. The diagnosis of this stage is challenging because it is hard to distinguish VS from a minimally conscious state (see state four). If they think a patient is in a minimally conscious state, this can be a reason to preserve life-sustaining aids. However, you can question if it is in the best interest of the patient to continue a severely handicapped life.[24] In this question, you can see the moral component that plays a role in this kind of situations.

The last stage is the minimally conscious state (hereafter: MCS). In a MCS, the brains operate in a limited way. In this stage, the behavior is variable, and there is irregular intentional behavior. So the brain is damaged, but not entirely switched off.[25] They show signs of awareness, but not at the same level as a healthy person with a full level of awareness. There must be clear evidence of awareness of himself or his environment to label the stage as MCS.[26]

2.2. Current methods

So, now we can distinguish the different states of coma; we need to look at how we can determine in what condition the patient is. Signs of consciousness are often small and fluctuating in time. Therefore the MCS may be challenging to diagnose and to differentiate from the vegetative state or the PVS.[27] With PVS, the difficulty is also that only after a few months (3 to 12 months) you can determine if the condition of the patient can be denoted as permanent.[28] The question is how to make a proper diagnose of coma patients? You can distinguish three categories of techniques that physicians use to make a proper diagnose. These categories are clinical features, different imaging techniques and bedside exams. In the following section, I will describe the techniques used to make a diagnosis.

Clinical features

With clinical features physicians look at etiology (cause of the coma), depth of coma (level of consciousness), duration of coma and clinical signs.[29] The etiology is important, because the outcome of coma is related to the cause independent of physical signs, depth of coma or length of coma.[30] Not every cause is equally dramatic for the prognosis. The level of coma is important to estimate the duration of the coma. Concerning the duration of the coma, it counts that the longer the patient remains in a coma, the poorer the chance of recovery is. The possibility that the patient will enter a vegetative state is also higher.[31]

Imaging

The neuroimaging techniques that physicians use are the Computed Tomography (CT-scan), positron emission tomography (PET-scan), magnetic resonance imaging (MRI), Functional MRI (fMRI) and the electroencephalogram (EEG).

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[23] Van Daele 2012, p. 12.
[24] Demertzi 2018, p. 226.
[25] Van Daele 2012, p. 4 en 5; Laureys & Tonini 2009, p. 18-28.
[26] Van Daele 2012, p. 13; Racine 2010, p. 148.
[27] Demertzi 2018, p. 226.
[28] Ibit, p. 229.
[29] Bates 2001, p. 21.
[30] Ibit, p. 21.
[31] Ibit, p. 21.

The fMRI is used the most in analysing patients with a disorder of consciousness. The fMRI has a prognostic value and can also detect covert awareness in behaviorally unresponsive patients. The fMRI could be used to distinguish PVS from MCS. The downside of the use of fMRI is the same as the downside from the MRI, namely that a scanner is needed. This limits the use of fMRI in hospital settings and precludes the use of fMRI on patients with pace makers or metal implants or patients who are in a critical condition in the intensive care units.[32] The EEG is also often used, because it has as an advantage that a scanner is not needed. This technique also permits consciousness assessment at a single subject level, unlike the majority of fMRI and PET-scans.[33] A downside of the EEG is the technical problem of performing the technique in the circumstances of a busy intensive care unit where there are considerable potential sources of electrical interference.[34] Since a few years physicians use the PET-scan. A study in 2014 showed that a PET -scan was even better than the fMRI scan in predicting who had signs of consciousness and also who might recover function a year later.[35] According to Laureys, PET-scans can also detect processes in the brain which cannot be identified by bedside tests (like the Glasgow Outcome Scale). Laureys stated that the PET-scan could be used to complement bedside examinations.[36] The downside of a PET-scan is that it cannot (yet) disentangle between vegetative state and minimally consciousness state at the single subject level.[37]

Bedside exams

In the acute phase, physicians often use bedside exams to determine the level of consciousness of the patient. Bedside tests that are used by physicians are the Glasgow Outcome Scale (hereafter: GOS) and the Coma Recovery Scale-Revised.

The GOS is based upon eye opening, verbal and motor responses. Annex 1 contains a table with the series of reactions which indicate the score that relates to the reaction. When you combine these observations with clinical features such as patient's age and brain stem function you can predict an outcome.[38] The GOS defines five categories, namely: death, persistent vegetative state, severe disability, moderate disability, and good recovery. The higher the score in the end, the better the prognosis of the patient.

The use of the GOS is simple and highly reliable. Still, the score cannot provide detailed information about individual differences in consciousness levels for patients.[39] The downside of bedside eye movement exams is that they have a high rate of misdiagnoses of vegetative states or minimally conscious states. Still, these exams are often used to determine whether or not a patient will recover.[40] Another downside is that the scale does not look at brain stem reflexes and does not take the breathing of the patient into account. If you use the method for a patient who is on a ventilator, you cannot test the verbal components.[41]

[32] Di Perri et al. 2014, p.594.
[33] Di Perri et al. 2014, p.594.
[34] Bates 2001, p. 22.
[35] Novella 2016.
[36] Cafasso 2016.
[37] Di Perri et al. 2014, p.592.
[38] Teasdale and Jennet, 1976, p.45.
[39] Ming Song et al. 2018, p. 19.
[40] Cafasso 2016.
[41] Maassen 2009, p.275.

The CRS-R is often used for diagnosis to distinguish VS from MCS.[42] The CRS-R can assist with differential diagnosis, prognostic assessment and treatment planning in patients. Doctors give a specific sensory stimulus, and on that basis, a score is based on the presence or absence of operationally defined behavioral responses on these sensory stimuli.[43] The range of the score is from 0 (worst) to 23 (best).[44] See Annex 2 for a record sheet of the CRS-R.

The CRS-R is solely based on behavior and therefore challenging. Although the scale is of unquestionable value; there is a chance of misjudgments. The lack of knowledge regarding consciousness, inadequate training, and non-use of adequate behavioral assessments increase the chance of misjudgment. The downside of behavioral assessments is that they are inevitably subjective and vulnerable to a variety of personal influences.[45] Another disadvantage of bedside tests is that it can be the case that a physician does not detect any signals and therefore states that the patient is in a VS or a PVS. The fact that the patient does not show any responses does not mean that the patient is in a VS or PVS. When you perform a fMRI-scan for example, it is possible that the scan shows some brain activity.

2.3. Why we need better techniques

In short, it is not an easy task to determine the level of consciousness. Therefore, it is difficult to make a correct diagnosis.[46] As Laureys states, there is always a difference between the observation of a stage of consciousness like coma and the personal experience of the patient himself. If a physician makes a diagnosis, he cannot do this objectively and with 100 percent certainty. Techniques like fMRI can improve this, but if we look at a patient in a comatose stage or a vegetative state, we can barely see any differences.[47] The amount of misdiagnosis is very high. About 40 percent of the patients get the wrong diagnosis.[48] We try to solve this by using scales like the CRS-R. These scales are more detailed than the GOS.[49] But also with the use of the CRS-R a third of the diagnosis is wrong.[50] Because of the chance of misdiagnosis, we need assisting technologies. Technologies which use data-driven objective evaluations of consciousness levels are becoming more important for the physician to improve their clinical verdict.[51]

It is very important to make the right diagnosis. The physician will base her subsequent actions and decisions on this diagnosis. When a physician thinks a patient cannot feel any pain, he or she may decide not to provide pain medication during care or the dying process. It could also influence the vision of the physician on end of life decisions.[52] When a physician thinks the patient is in a PVS, he will probably decide sooner to stop the treatment than when someone is in a MCS. In intensive care, the majority of deaths are the result of a medical decision to withhold or withdraw treatment.[53] Therefore it is necessary to make the right diagnosis so that a patient in MCS will not be seen as a patient in a VS/PVS.

[42] Ming Song, Yuijn Zhang et al. 2018, p. 593.
[43] http://www.tbims.org/combi/crs/.
[44] https://www.physio-pedia.com/Coma_Recovery_Scale_(Revised).
[45] Ming Song, Yuijn Zhang et al. 2018, p. 593.
[46] Van Daele 2012, p. 7.
[47] Ibit, p. 11.
[48] Van Daele 2012, p. 11; Gosseries et al. 2011, p.4.
[49] Van Daele 2012, p. 11 en 12; Gosseries et al. 2011, p.4.
[50] Maassen 2009, p.275.
[51] Demertzi 2018, p. 226.
[52] Ibit, p. 228.
[53] Laureys 2005, p. 899-909; Demertzi 2018, p. 229.

Laureys states that it is also important to know the prognosis of the patient in an early stage. This is important for the family members for the considerations about medical and ethical questions. If a patient is for instance in a PVS, we do not want to know this after a year but after several weeks. Laureys prefers to make a diagnosis in the acute phase (when a patient is still in a coma).[54]

Despite all these techniques, there are still problems which are impossible to eliminate and cause difficulty in the evaluation. One is the self-fulfilling nature of poor prognoses. Self-fulfilling prophecy means a, in the beginning, false prognosis of the situation that evokes behavior which makes the original false conception come true.[55] Predictions of poor prognosis for patients that are in a critical condition may become self-fulfilling if life-sustaining treatment or resuscitation is subsequently withheld based on that prediction. This can also be the case with the use of the techniques. When using the techniques, there is still a chance of misdiagnosis. The physician acts based on this diagnosis, and then you have the problem of a self-fulfilling prophecy because the physician can stop the treatment for example. To minimize the effects of self-fulfilling prophecies, it is important to collect and appraise evidence about the prognosis.[56] Especially in the case of coma, where there is a lack of knowledge and a lot of uncertainty, this is very important. The ideal situation would be that studies about the use of certain techniques are only performed on patients who will receive maximal life support for as long as possible. Only then it can become clear if the prognosis of the patient is right. The question is whether this is possible. It may be inhuman if a person is kept alive for years through technologies such as ventilation, despite the fact that the chance of recovery is minimal.[57] The starting point in healthcare is doing well to a patient. If medical treatment no longer contributes to the recovery of the condition, then the aspect of beneficence will disappear. Continuing treatment against better judgment is not a benefit, but harm.[58] As we will see in chapter 3, this can be inhuman and an infringement of the principle of non-harm and physical integrity of a person (art. 8 ECHR).

2.4. The multidomain prognostic model

The new 'multidomain prognostic model' that is developed by Chinese neurologists at the Academy of Sciences and the PLA General Hospital in Beijing is a model that intends to overcome some of the disadvantages of the existing prognostic techniques. The researchers had two main objectives with the development of the MDPM. Their first aim was to develop a method to predict the prognosis of an individual patient by combining clinical characteristics and resting state fMRI. Their second aim was to further explore the different prognostic effects of these clinical and brain imaging features.[59]

The three clinical characteristics that are used are the cause of the person's injury (etiology), their age at the time of the injury, and how long they have had impaired consciousness. The etiology was categorized into three types, namely: traumatic brain injury, stroke, and anoxic brain injury. The fMRI is used to measure communication between different parts of the brain. The multidomain prognostic model took the fMRI image and the clinical characteristics as input and returned a predicted score as output.[60]

[54] Maassen 2009, p.275.
[55] Wilkinson 2009, p. 402.
[56] Ibit, p. 402.
[57] Bates 2001, p. 3.
[58] Commissie ethiek NVIC, p. 8.
[59] Ming Song et al. 2018, p. 3.
[60] Ming Song et al. 2018, p. 9.

Because of the use of the MDPM, prognostic predictions can be improved at an individual level and could lead to the early identification of patients who could recover consciousness. This early identification is important for the physicians and families to plan better and manage patients care. According to the researchers, the MDPM also has the potential to improve prediction accuracy. The MDPM was tested on 112 patients from two medical centers and could tell which patients would regain consciousness 88 percent of the time. There were also several patients to whom the initial prediction of the physician was that they would not recover. The MDPM identified several of these patients who got better despite this initial prediction.[61]

2.4.1. The use of Big data analysis and AI

The MDPM is a model that uses big data analysis, AI and Machine Learning (hereafter: ML) to make a diagnosis. Big data analyses and AI are closely related. Analyzing vast amounts of data is a complex task which is made possible by data mining and AI. Algorithms play a crucial connecting role between Big Data and AI. The purpose of the data-driven analysis is finding relevant patterns and relationships in datasets in an automated matter using an algorithm.[62] These algorithms test large quantities of relationships and try to distill the relevant information in this way. The knowledge that is gathered goes beyond the hypothesis made by human that is put in the algorithm. It primarily relies on what the data itself says.[63]

One important kind of algorithm is the ML algorithm. ML algorithms can learn from previous experiences. Because of this, ML algorithms can react differently in the same circumstances and adjust to new circumstances.[64] The most advanced application of ML is called Deep Learning. This technology uses neural networks. It performs a layered analysis, where results from one layer are the input for the analysis of the next layer. In this way, complex and hidden relationships can be discovered in large data sets.[65] The ML algorithms are capable of recognizing patterns, relationships, and characteristics in large amounts of data. Previously recognized patterns are then used in data analyses, and therefore the algorithm can adapt itself to previously found results.[66]

The ultimate goal of Big Data analyses is to facilitate evidence-based decision making. The analysis leads to actionable knowledge. Decisions can be made based on the insights that are obtained through the analysis. The analysis can be used before decision making and during decision making. When it is used prior to decision making, the outcome is taken into account when making decisions. This is how the outcome of the MPD is used. It is important to realize that decisions based on Big Data analyses can have a significant influence on people's lives. This means that decisions that are (semi) automated based on Big Data-analyses can also have significant consequences.[67]

So, the functioning of Big Data analysis, and AI will depend on the algorithm that is used. For example, if it uses ML or not. Bellow I will explain the functioning of the big data analysis and AI of the MDPM.

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[61] Ming Song et al. 2018, p. 2-3.
[62] Vetzo, Gerards & Nehmelman 2018, p. 20; Custers 2017, p. 28.
[63] Vetzo, Gerards & Nehmelman 2018, p. 18.
[64] Vetzo, Gerards & Nehmelman 2018, p. 43; Cerka, Grigiene & Sirbikytels 2017, p. 377.
[65] Vetzo, Gerards & Nehmelman 2018, p. 43.
[66] Ibit, p. 44.
[67] Ibit, p. 24 en 25.

2.4.2. How does the MDPM work

In order to collect data for the MDPMs data analysis, the resting state fMRI and clinical data from patients were collected at the time that the vital signs and the consciousness level had stabilized and a diagnosis had been made (*T0*). The outcomes were assessed after 12 months (*T1*). The collected data was used in a training data set. The MDPM also uses this data for classification and regression. With classification, the programmer creates different categories. The algorithm divides the data among the different categories. In the case of the MDPM, the researchers used the different categories of the consciousness recovery scale. In this way, the MDPM can divide the data among the different categories.[68] The classification technique was used to predict consciousness recovery or not for each patient. The classification accuracy was assessed by comparing the predicted label and the actual GOS score.[69] The regression technique formulates numerical predictions on identified relationships that are led down in datasets. The data that is already available in the datasets is therefore analysed.[70] The regression technique was used to fit patients CRS-R score after 12 months based on their clinical characteristics and resting state fMRI data.[71] In this way, the MDPM was set up as prognostic regression and classification model.

The MDPM also uses a predictive analysis. With a predictive analysis, the algorithm is trained by exposing it to series of classified examples. This 'practice data' may, for example, consist of data about persons who are classified as unhealthy.[72] In the case of the MDPM, it predicts consciousness recovery or not for each patient. After the test phase, the next step is to release the algorithm on a new set of data, so it can classify new cases based on correlations and comparability with the examples.[73] In figure 4 below, the described process is illustrated.

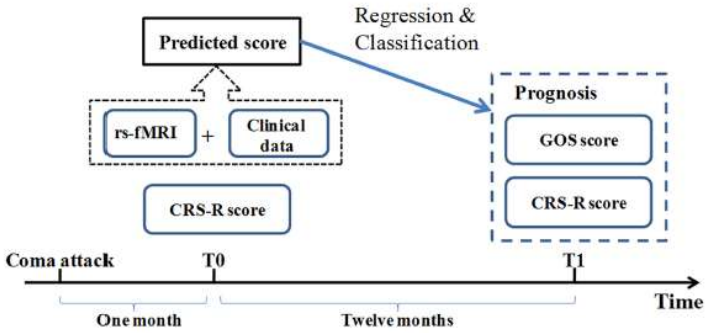

Figure 4: the conceptual paradigm of the study.[74]

In this study, three datasets are involved. These datasets are the 'Beijing 750', 'Beijing HCxt' (both collected in the PLA Army General Hospital in Beijing) and the 'Guangzhou HDxt' database (collected from the Guangzhou General Hospital).[75] The Beijing 750 dataset contained 46 VS patients and 17 MCS patients. The Beijing HDxt dataset included 20 VS patients and 5 MCS patients. Lastly, the Guangzhou HDxt dataset contained 16 VS patients

[68] Vetzo, Gerards & Nehmelman 2018, p. 21.
[69] Ming Song et al. 2018, p. 6.
[70] Vetzo, Gerards & Nehmelman 2018, p. 21.
[71] Ming Song et al. 2018, p. 3.
[72] Vetzo, Gerards & Nehmelman 2018, p. 23.
[73] Ming Song et al. 2018, p. 3.
[74] Ibit, p. 4.
[75] Ming Song et al. 2018, p. 3.

and 8 MCS patients. Also, 40 healthy people are included in the datasets. The Beijing 750 dataset was used as a training dataset.[76] The other two datasets were used as testing datasets.[77]

The diagnosis of each patient in the datasets were made by the physician according to the CRS-R scale. The assessment based on the CRS-R scale was carried out at various times. The highest CRS-R score (score between 0 and 23) was used as a diagnosis. All the participants in the datasets were scanned with resting state fMRI.[78] For an image of the data analysis pipeline, see annex 3.

According to the researchers, the multidomain prognostic model is the first model that is based on resting-state fMRI and clinical characteristics.[79] Therefore, they suggest that this MDPM is accurate, robust and interpretable. Because of combining resting-state fMRI with three clinical characteristics, the researchers built a computational model that can make predictions regarding the prognosis of patients at an individual level. The researchers compared the models that separately use only imaging features or only the clinical characteristics and found that the combination of these predictors achieved greater accuracy.

Also important is the statement of the researchers that there is a lower false-negative rate in comparison with the current methods, which would avoid predicting non-recovery in a patient who can recover. This can be deducted from the fact that the MDPM has a sensitivity of 83% and 100% obtained across the two testing datasets. The MDPM successfully identified 16 out of a total of 18 patients who later recovered consciousness.[80]

2.5. Advantages and disadvantages of the MDPM

Physicians use different techniques for the prognostication of coma patients. A physician is not 100 percent objective and cannot make a diagnosis that is 100 percent certain. Techniques like fMRI improve the prognostication, but we are not there yet. There is still a high amount of misdiagnosis, namely a third of the cases.[81] The MDPM cannot solve this completely. The MDPM has an accuracy of 88 percent, so also not 100 percent. But, it is more accurate then we have now based on the current techniques. With the use of the MDPM, the number of misdiagnoses will decrease to about a fifth of the cases.

If a physician wants to compare the different information from different tests, he first needs to do all of the tests and then needs to evaluate the results. Most coma patients are on the intensive care, and in the intensive care practice, there is no time to spend this much time in diagnosis. Because the MDPM uses algorithms, it can analyse the data much faster than the physician. The MDPM also compares all the data in the data sets. This means that it takes previous cases into account. A physician does not have the time to do this.

But the MDPM also has some downsides. First of all, AI systems are opaque and complicated. This means that researchers cannot understand the working and the outcome of the algorithm and cannot find out where the error is in the algorithm.[82] When the system makes a mistake, it is not always clear why the system makes this mistake. Because of this,

[76] Ibit, p. 4.
[77] Ibit, p. 6.
[78] Ibit, p. 6.
[79] Ibit, p. 18.
[80] Ibit, p. 19.
[81] Van Daele 2012, p. 11; Gosseries et al. 2011, p.4.
[82] Vetzo, Gerards & Nehmelman 2018, P. 42

algorithms are often seen as a 'black box'.[83] The input and output of an algorithm are known, but it is hard to understand how the intermediate process functions.[84] With this MDPM, this is even a bigger problem. I will explain with an example why this is a bigger problem. Imagine a self-driving car. If the system makes a mistake, you can see this, because the vehicle hits a tree for example. Even though it is still hard to track down the source of the error, at least you know that the system makes a mistake.[85] With the use of the MDPM, this is not always clear. When the MDPM predicts for example that the patient will wake up, it will take some time to see if this outcome is correct. A person in a PVS can be in this stage for years for example. But also the other way around. When the MDPM predicts that the patient will not recover, it is possible that the physician and the relatives decide to stop the treatment. They will then never know if the person would have recovered. The opacity of this MDPM is therefore only higher. The problem of the self-fulfilling prophecy is closely related to this. This problem will not be solved when using the MDPM, because we assume that the outcome of the MDPM is correct. The physicians and family members will behave according to the outcome, so that the outcome will automatically become true. The ideal situation would be that studies about the use of certain techniques are only performed on patients who will receive maximal life support for as long as possible. Only then it can become clear if the prognosis of the patient is right, but this is ethically not possible because this may be inhuman as already mentioned before.

Another point of attention is that we need to realize that algorithms are not as objective as we sometimes think. Algorithms are not neutral human constructs. Humans are responsible for the programming and training of the algorithms. Humans primarily create algorithms. People make certain choices when creating an algorithm. These choices can influence the analysis and the outcome of the analysis.[86] The prejudices and values of the programmer can be embedded in the algorithm.[87] The training data that is used can also obtain biases that influence the outcome of the algorithm. This also counts for the MDPM, especially because it uses classification. As the researchers already stated, more extensive studies are needed to confirm that the MDPM is reliable.[88]

When the MDPM is used, there is a chance that the outcome will largely contribute to the decisions that are made. First of all, the outcome can obtain errors and is not always certain. When you handle the outcome unthoughtfull or uncritical, it can lead to errors in decision making.[89] Second, when someone makes a decision based on the outcome of the algorithm, it is often an automatic approval because people lack the time, skills and understanding of how the algorithm works to form an independent opinion (also called automation bias). Especially in an intensive care unit, there is not so much time to evaluate the outcome. The MDPM is used to save some time. This leads to an unclear distinction between semi-automated and automated decision-making. This despite the notion of the researchers that the outcome of the MDPM should only influence your decision for 20 to 50 percent.[90]

[83] Vetzo, Gerards & Nehmelman 2018, p. 49; Pasquale 2015.
[84] Vetzo, Gerards & Nehmelman 2018, p. 49.
[85] Ibit, p. 42.
[86] Vetzo, Gerards & Nehmelman 2018, p. 49; Diakopoulos 2015, p. 402.
[87] Vetzo, Gerards & Nehmelman 2018, p. 48; Citron & Pasquale 2014, p. 4; Vedder & Naudts 2017, p. 208.
[88] Ming Song et al. 2018, p. 2.
[89] Vetzo, Gerards & Nehmelman 2018, p. 50.
[90] Tangemann 2018.

2.6. Conclusion

There are different levels of consciousness, namely brain death, coma, VS/PVS and MCS. VS and MCS are hard to distinguish. The techniques we use already improve the diagnosis. However, there is still a big chance of misjudgment. Because of the chance of misjudgment, we need assisting technologies. Technologies which use data-driven objective evaluations of consciousness levels are becoming more important for the physician to improve their clinical verdict.[91] Chinese researchers came up with a multidomain prognostic model to improve diagnosis. This MDPM uses clinical features and resting- state fMRI and combines these data by using predicting analysis based on regression and classification. The MDPM has an accuracy of 88 percent, so this is an improvement when you compare it with the accuracy of the techniques that are already used. However, the MDPM also have disadvantages. It is opaque because we do not know how the MDPM comes to a certain outcome and we do not know if it makes a mistake. The MDPM is also not so objective as we may think. To conclude, the MDPM can be used as a tool by a physician as a second opinion of his own diagnosis. But we must be careful that the outcome of the MDPM is not thoughtlessly copied, so that the decisions based on the outcome would be (semi) automated.

[91] Demertzi 2018, p. 226.

Chapter 3 The fundamental rights of the patient

The use of AI can be incompatible with several fundamental rights. In this chapter, I will explain the fundamental rights of the patient which are important when we want to use the MDPM. Fundamental rights are rooted in several principles. I will first explain these principles in paragraph 1 because these principles will help with the interpretation of the fundamental rights.[92] After this I will explain art. 8 of the European Convention on Human Rights (ECHR) which is important for the use of the MDPM (paragraph 2). Paragraph 3 contains a conclusion for this chapter.

3.1. Most important principles

Fundamental rights are based on certain principles that are not explicitly included in the European Convention on Human Rights (hereafter: ECHR) and the Dutch Constitution (Hereafter: DC).[93] These principles are dignity, fairness, equality, respect, and autonomy.[94] The principles that are important for this research are human dignity, and personal autonomy (or more specifically self-determination), because jurisprudence shows that they are closely related with art. 8 ECHR and the protection of physical integrity (see paragraph 3.2.). In this paragraph I will explain the meaning of human dignity and autonomy. This explanation is needed to understand the meaning of art. 8 ECHR which I will explain in paragraph 3.2.

The first principle is the principle of human dignity. All fundamental rights are rooted in this principle. Also in healthcare, this principle is one of the most fundamental principles, because it underlies all fundamental rights.[95] Human dignity means that you have a certain dignity that offers protection against intrusion from the government and third parties, because you are a human.[96] This principle has three functions:

- It helps with the interpretation of fundamental rights
- It serves as a limitation for the permitted restriction of fundamental rights. Restricting a fundamental right is not permitted if it diminishes human dignity.[97]
- You can see it as an autonomous fundamental right.

Especially the first two functions are used most often, because we see these functions most often reflected in case law.[98]

There are two ways to explain human dignity. On the one hand, it is an empowerment. Human Dignity makes you able to do things and to fill in your own life. On the other hand, it is a constraint. This means that you cannot act in a way that crosses the boundaries that are inherent for human dignity. In other words, there are restrictions to prevent the degradation of human dignity. An example that makes these two explanations clear is the Wackenheim case.[99] This case is about dwarf tossing. Dwarf tossing was a game in French, English, and

[92] Vetzo, Gerards & Nehmelman 2018, p. 56; EHRM 29 April 2002, nr. 2346/02, ECLI:CE:ECHR:2002:0429JUD000234602 (*Pretty t. het Verenigd Koninkrijk*), *EHRC* 2002/47 m.nt. J.H. Gerards&H.L. Janssen, *NJ* 2004/543 m.nt. E.A. Alkema, *NJCM-Bull.* 2002, p. 910 m.nt. B.E.P. Myjer, par. 64.
[93] Buyse 2016.
[94] https://www.equalityhumanrights.com/en/human-rights/what-are-human-rights
[95] Vetzo, Gerards & Nehmelman 2018, p. 53 en 54.
[96] Ibit, p. 53 en 54.
[97] Vetzo, Gerards & Nehmelman 2018, p. 54; Leijten 2015.
[98] EUCJ 18 October 2011, zaak C-34/10, ECLI:EU:C:2011:669 (*Brüstle*), *EHRC* 2012/54 m.nt. F.M. Fleurke, *NTM-NJCM-Bull.* 2012, p. 242 m.nt. B. van Beers; HvJ 5 April 2016, gev. zaken C-404/15 en C-659/15 PPU, ECLI:EU:C:2016:198 (*Aranyosi en Căldăraru*), *EHRC* 2016/157 m.nt. H. van der Wilt, par. 85.
[99] ECRM 15 July 2002, 854/1999 (*Wackenheim/Frankrijk*).

American pubs. Strong men pick up a dwarf person and throw them to see how far they come. Mr. Wackenheim was a dwarf person that was used for this voluntarily. The French state forbade Wackenheim to use himself for dwarf tossing. Wackenheim said that he has the right to do so. He has the right to shape his own life and use the fact that he is a dwarf to get a job. It is his job, and he gets paid for it. He said it was his own choice. Having a job and income contributes to his human dignity (empowerment). The court determined that he could not sell himself for dwarf tossing. The court uses human dignity as a constraint. If you sell yourself for these kinds of practices it is an infringement on human dignity. Another example of human dignity as a constraint is the selling of organs, which is not allowed. If you sell your organs, you use your body as a means to an end and not as an end in itself. This is an infringement on human dignity.[100]

The second principle is personal autonomy (or self-determination). The right of personal autonomy is recognized by the European Court of Human Rights (hereafter: ECtHR) in her verdict of 20th March 2007.[101] Autonomy is an extension of human dignity. This principle means that people can freely make their own choices and decide how to organize their own lives.[102] Personal autonomy is a more specific elaboration of human dignity.[103]

However, it is not the case that autonomy has absolute significance in health law and ethics. In health law, there is also the requirement of good or responsible care.[104] This principle gives the obligation to physicians to protect the patient. A good care provider should not only look at what the patient wants, but must also look at the health interests of the patient.[105] This view is also in line with the ethical principles of non-harm and beneficence. This principle means that you must not cause any damage or harm. The starting point in healthcare is doing well to a patient.[106] If medical treatment no longer contributes to the recovery of the condition, then the aspect of beneficence will disappear. To protect the human dignity of the patient it is better to stop the treatment if it is medically meaningless. It harms if you treat them anyway. Although you end someone's life, which seems to cause harm, it is still beneficial. Continuing treatment against better judgment is not a benefit, but a harm.[107]

3.2. Fundamental Rights

The most important rights for the use of the MDPM are the right to private life and the right to physical integrity. In the ECHR these two rights are both included in art. 8 ECHR. At European level, the right of physical integrity is part of the right to private life.[108] First, I will explain the right to private life. After that, I will elaborate on the right to physical integrity, because this is a more specific right rooted in the right to private life.

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[100] Hendriks et al. 2008, p.4.
[101] EHRM 20 March 2007, (*Tysiac/Polen*) nr. 5410/03, NJCM-Bulletin 2007, p. 497 (m.nt. A.C. Hendriks).
[102] Vetzo, Gerards & Nehmelman 2018, p. 53 en 54.
[103] Vetzo, Gerards & Nehmelman 2018, p. 56 en 57; EHRM March 2006, nr. 6339/05, ECLI:CE:ECHR:2007:0410JUD000633905 (*evans t. het Verenigd Koninkrijk*), *NJ* 2007/459 m.nt. J. de Boer, *ECHR* 2006/47 m.nt. E. Brems, par. 57. ; EHRM 29 April 2002, ECLI:NL:XX:2002:AP0678 (*pretty/VK*); EHRM 11 July 2002, nr. 28957/95,*NJCM-Bulletin* 2003, p. 330 (*Goodwin/VK)*; Hendriks et al. 2008, p.1.
[104] Hendriks et al. 2008, p.3.
[105] Ibit, p. 3
[106] Commissie ethiek NVIC, p. 8.
[107] Ibit, p. 8.
[108] Van Beers 2013; EHRM 26 March 1985, ECLI:NL:XX:1985:AC8813, NJ 1985, 525, m.nt. E.A. Alkema (X en Y t. Nederland)

Right to private life

The right to private life implies that people can be themselves without prejudice. This right has a close relationship with the principles of autonomy and human dignity.[109] This right also applies to coma patients. When someone is in a coma, the patient cannot express his/her will. Therefore, the patient cannot decide about his/her own life. Others need to make decisions for the patient based on the outcome of the MDPM. This may be a limitation of the right to the private life of the patient. After all, someone else decides how his life will be filled in.

The right to private life is not an absolute right, which means that it can be limited. In the ECHR, the article itself includes when the right may be limited. In this case, paragraph 2 of art. 8 determines when the right to privacy can be limited. In short, the limitation must have a legal basis, needs to be for the purposes mentioned in paragraph 2 of art. 8, and needs to be necessary in a democratic society. The legal basis must be foreseeable and accessible and needs to protect people against arbitrariness. This means that you must be able to become acquainted with the law and that you know what legal consequences certain behavior has.[110] The law that provides the limitation also needs to be transparent.[111] The necessity test means that the infringement needs to be proportional and subsidiary.

Right to physical integrity

Another important fundamental right in the context of this investigation is the right to protection of the physical integrity. The right to protection of physical integrity is closely related with the right to private life. The right to protection of physical integrity is a core element of the right to private life. The right to protection of physical integrity is about the right to repel external influences of the body.[112] In other words, it provides protection against unwanted interference by third parties. Based on the outcome of the MDPM, treatment can be continued or stopped. In any case, there is medical treatment as a result of the outcome. Medical treatment can infringe physical integrity. Therefore, the MDPM can even infringe human integrity indirectly.

The ECHR includes both the right to private life as the right to protection of physical integrity in art. 8 ECHR. Under the ECHR, the right of protection of the physical integrity is not only protected under art. 8 ECHR but under several rights. Certain aspects of integrity do not fall under the protection of art. 8 ECHR, but under the protection of art. 3 ECHR (prohibition of inhuman and degrading treatment or art. 2 ECHR (right to life). When it concerns a far-reaching infringement such as forced treatment and forced feeding in the event of a hunger strike, the infringement falls under art. 2 or 3 ECHR. In less severe cases, art. 8 ECHR applies.[113]

In health law and ethics, as mentioned above, autonomy is a guiding principle. It is often associated with the protection of physical integrity. The right to make decisions about your own body not only protects the body against external influences, but autonomy also means that one can claim the right to perform certain actions with one's own body. In fact, based on the right to self-determination, the right to the inviolability of the body ultimately implies also the right to affect one's own body. An example of this approach is, for example, the selling of your organs. You could state that because of the autonomy, you can determine what you want

[109] Vetzo, Gerards & Nehmelman 2018, p. 60.
[110] Altena 2016, par. 5.5.1.
[111] Vetzo, Gerards & Nehmelman 2018, p. 78.
[112] Van Beers 2013; *kamerstukken II*, 1978/79, 15463, 2, p.5.
[113] Vetzo, Gerards & Nehmelman 2018, p. 71.

to do with your body. If you want to sell parts of your body, this should be allowed because it is your own choice. However, just like explained with human dignity, another interpretation is that respect for physical integrity is a value that also the person himself must take into account.[114] Physical integrity prevents you from doing certain things with your own body. We see this approach reflected in case law and legislation. Think, for example, of the Wackenheim case that I discussed earlier and the fact that selling organs is prohibited by law.[115]

In the Netherlands, the rights of art. 8 ECHR are included in art. 10 and 11 DC. Art. 10 is about the right to private life, and art. 11 DC is about the protection of physical integrity. Art. 11 DC reads as follows: '*everyone has the right, except for restrictions imposed by or pursuant the law, to inviolability of his body'*. In the Netherlands, art. 8 ECHR is divided in two separate articles. Art. 11 is a lex specialis of art. 10 DC.[116] The protection of physical integrity is further elaborated in the Dutch Law on medical treatment agreement (WGBO). The WGBO contains requirements of informed consent that contribute to the protection of physical integrity. In chapter 4, I will elaborate on the elaboration of art. 8 ECHR in Dutch legislation and the requirements of informed consent.

Art. 8 ECHR not only offers protection against state interference. It also has meaning in the relationship between citizens. Based on the principle of effective enjoyment of rights, the state has the positive obligation to create an effective system to make sure that other (also private) actors do not violate art. 8 ECHR.[117] This is called an indirect horizontal relationship, whereby the importance of respecting these rights is taken into account when implementing (civil) legal provisions.[118] In the I. v. Finland judgement is determined that states may be found liable when they fail to ensure that private parties take positive steps to prevent violations of art. 8 ECHR.[119] This horizontal effect can be seen in the relationship between doctor and patient.

3.3. Conclusion

The use of the MDPM may infringe the fundamental rights and principles of patients because medical decisions will be made based on the outcome of the MDPM. Therefore, the use of the MDPM can cause an infringement of the rights mentioned in this chapter. The fundamental rights that are important in the case of the use of the MDPM in practice are the right to private life and the right to protection of physical integrity (art. 8 ECHR). The right to private life implies that people can be themselves without prejudice. This right has a close relationship with the protection of physical integrity, which means that you have the right to repel external influences on the body. When you combine these two rights with the principle of autonomy, you could say that a patient has the right to decide what happens with his/her body. A patient should, therefore, determine if he or she wants a medical treatment or not. With coma patients, this is problematic because the patient is unconscious. A coma patient cannot express his will. In the case of coma patients, it is the physician (possibly in consultation with the relatives), who decides what kind of treatment he applies to the patient. It is primarily a decision on medical grounds and arguments, and therefore, made by a physician. Because of

[114] Van Beers 2013, p. 9.
[115] The law on organ donation prohibits this in art. 7.
[116] Van Beers 2013.
[117] Purtova 2010, p. 187 en 191; ECHR 13 August 1981, 7601/76;7806/77 (*Young James and Webster v. UK).*
[118] Vetzo, Gerards & Nehmelman 2018, p. 62.
[119] ECHR 17 July 2008, 20511/03 (*I. v. Finland*).

this, family members of the patient do not have to give permission to stop the treatment for example.[120] When the physician makes the decision and the patient is not able to express his will, this means that the patient does not decide over his own life without the interference of others. Therefore, there may be an infringement on the right to the private life of the patient and the right to protection of physical integrity. In the next chapter, I will discuss how art. 8 is elaborated in the Dutch legislation. This is necessary to examine if the use of the model in the Netherlands is compatible with art. 8 ECHR. However, these rights are not absolute and can be limited. A limitation is allowed when it is provided by law, in accordance with a purpose that is mentioned in paragraph 2 of art. 8 ECHR, and when it is necessary in a democratic society. For the necessity test the limitation needs to be proportional and subsidiary. In chapter 5 I will examine if the use of the model is proportional and subsidiary, but as already discussed we first need to know how art. 8 is elaborated in the Dutch legislation.

[120] Commissie ethiek NVIC, p. 6.

Chapter 4 The right to physical integrity under Dutch Law

The right to private life and the protection of physical integrity (art. 8 ECHR) gives the state a positive obligation to protect people against interference. Concerning medical treatments, the state has a positive obligation to introduce a good system of regulations to prevent breaches of physical integrity and autonomy by private individuals. In the Netherlands, art. 8 ECHR is laid down in art. 10 and 11 DC. The right to physical integrity is further elaborated in the Dutch Medical Treatment Act (WGBO). The WGBO is the most important national law about the rights of patients. The WGBO aims to strengthen and clarify the legal status of the patient. It regulates, for example, the requirements of informed consent. Informed consent is an elaboration of the protection of physical integrity. In short, this right means that the physician needs to inform the patient about the benefits and risks of treatment. The question, however, is if we can meet the requirement of informed consent if we use the MDPM because of the 'black box' problem, which I already discussed in chapter 2. To determine this, I first need to explain what the right of information means. I will do this in paragraph 1. The law is not the only important element for the relationship between the physician and the patient. The way the physician and the patient interact is also important. In paragraph 2, I will explain how the relationship between physician and patient is changing towards a more patient-centered approach. Paragraph 3 contains a conclusion.

4.1. Physicians and patient's rights under Dutch law.

The WGBO has several rights that are important for this research. This is the right to information (art. 7:448 Dutch Civil Code), the right not to know (art. 7:449 Dutch Civil Code) and the consent requirements of art. 7:450 and further of the Dutch Civil Code. The right to information and the consent requirement together constitute the requirement of informed consent. Next to those rights that apply directly to the patient, there are also rights for the representative of someone who is unable to express himself. Because a coma patient is unconscious, the rights of the representative are also crucial for this research. First, I will discuss the rights that apply directly to the patient, and after that, I will discuss the rights of the representative.

4.1.1. Right to information and informed consent

According to art. 7:448 paragraph 1 and 2 of the Dutch Civil Code, the physician must provide the patient with information in a clear manner about the intended investigation, proposed treatment, the developments regarding the research and the health condition of the patient. The physician must be guided by what the patient should reasonably know. If a patient is unconsciousness, the physician needs to try to inform the parents, partner or other involved relatives. So, in the case of coma patients, the physician cannot inform the patient himself, but he can and needs to inform the relatives.

Why is the right to information so valuable? This is because the patient can get a good impression of his health condition and can make a responsible decision based on this information. Next to this, the right to information is also essential in a legal sense because consent without prior information has no legal value.[121] The scope of the right to information depends on the reasonableness and fairness and the care of a good care provider. Therefore, it depends on the circumstances.[122] On the one hand, this causes uncertainty because you cannot determine in advance whether the law will be followed. On the other side, it is necessary due

[121] Doppegieter 2004, p. 4.
[122] Legemaate 2001, p.5.

to the complex practice and gives the physician the opportunity to involve generally accepted views of the profession in the information obligation.[123]

Case law has given further substance to the right to information. In the judgment of the Dutch Supreme Court in the paraplegic case, the court has determined that the doctor is obliged to inform his patient clearly about the possible risks of medical treatment so that the patient can make an informed decision whether or not he gives his consent for this (also called informed consent).[124] The court decided for instance that more value is attached to the right of information when it comes to radical or unusual treatments.[125] With coma patients it is about radical treatments because the decisions are most of the time about life or death. Therefore, the right of informed consent has more value. However, the question is whether we can meet the requirements of informed consent when we use the MDPM because of the 'black box' problem of algorithms. I will discuss this problem in chapter 5. For now, it is enough to realize that the right to information is an important right when we want to use the MDPM in the Netherlands.

The information needs to be given in an early stage so that the patient can think about the information and process it or discuss it with others (in this case not to the patient but the relatives). The WGBO does not require that the physician must check whether the patient has understood the information, but it is evident that he will keep an eye on this. It is essential for the informed consent that the patient understands the information. If the patient does not understand the information, there is no well-considered decision.

Because in the case of coma patients the decisions are far-reaching decisions, it is advisable to repeat the information. The information that the people involved get, have a major impact on them. Because of this, they may not process and remember everything.[126] It can also help to have the information provided by different people.[127] Also, with radical decisions such as these, it is advisable to have a third person present at the discussions. This person can quietly go through the information with the person concerned to improve understanding and information may be better absorbed and processed. This person can also provide emotional support to the persons involved.[128]

Art. 7:449 Dutch Civil Code gives the patient the right not to receive information. The patient must state this explicitly.[129] If the patient's right not to know does not outweigh the disadvantages that can result for himself or others, the physician still needs to provide the information. An example is that the disease influences the driving ability or a significant risk of transmitting a serious infection.[130]

Art. 7:450 Dutch Civil Code determines that a physician needs the consent of a patient before he can treat the patient. It has to be a consent that is given voluntarily without the pressure of family members or the physician. The consent based on the information provided is called

[123] Legemaate 2001, p.5.
[124] *Kamerstukken II* 2010/11, 32711, 3, p. 6-8 (Explanatory statement); HR 25 juni 1996, ECLI:NL:HR:1996:ZD049 (*Niet-behandelde longinfectie*).
[125] Legemaate 2001, p.6-7.
[126] Ibit, p. 13.
[127] Ibit, p. 13.
[128] Ibit, p. 13.
[129] Ibit, p. 6.
[130] Doppegieter 2004, p. 5-6.

informed consent. So, the information and the consent together is informed consent.[131] Informed consent does not need to be in writing. Treatment may not be denied if a patient refuses to give written permission. The most important question is if the patient understands where he gives his consent for.[132]

Informed consent has a legal value. A poor implementation of this can be addressed through complaint, disciplinary or civil law. It does not only have legal value; it also contributes to communication and interaction.[133]

Liability and informed consent

In case law there are more and more cases that concern the right to information and informed consent. For example, the Amsterdam Court of Appeal ruled that the withholding of information affects the patient in his right of self-determination (autonomy) and thereby in his person.[134] Also, due to providing insufficient information, the patient is wrongly denied choices.[135] Due to the development in case law, the risk for the physician of a complaint or even of liability has increased.[136]

When a physician is held liable, it may be that he is sentenced to pay compensation for damages. The mere fact of providing insufficient information is not enough to hold the physician liable. This is only possible if there is a direct relationship between not informing or insufficiently informing and the damage suffered by the patient. This is called the causality question.[137] Another requirement is that the patient if he was well informed, would have made a different decision (also called causal relationship). It is challenging for both patient and physician to prove this situation. In this case, the question is what a reasonable patient would have done in comparable circumstances.[138]

To illustrate that the causal relationship is hard to prove, I will use a case from the court of 2014.[139] In this case, a complication occurred after an operation that made the patient infertile. The patient took the position that he had not received sufficient information to make an informed decision. He believes that the physician did not inform him about the chance of the complication while the physician knew that the patient feared this complication. The patient states that if he was aware of the risk of this complication, he might not have given permission for the operation and had first investigated other treatment methods. Therefore, the requirement of informed consent is not met, which is an infringement of his autonomy. The disciplinary court has confirmed the patient's point of view.

However, the physician takes the view that the complication that has occurred is a common complication so that he does not have to inform the patient about it. He was also unaware of the patient's fear of this complication. Also, the possibility of a complication is not a reason for most patients to opt out of treatment. Given the symptoms and their severity, the physician should not have expected the patient to consider the chance of the complication in his

[131] Ibit, p. 7.
[132] Ibit, p. 7.
[133] Legemaate 2001, p.3.
[134] Legemaate 2001, p. 15; HR 23 November 2001, ECLI:NL:HR:2001:AB:2737.
[135] Legemaate 2001, p.15.
[136] Ibit, p. 15.
[137] Ibit, p. 15.
[138] Ibit, p. 15.
[139] Rb Zeeland-West-Brabant, 9 February 2017, ECLI:NL:RBZWB:2017:851.

decision. Especially considering the age of the patient and the fact that he has already conceived several children.

The court indicates that if the physician has not adequately informed the patient, the patient must prove that he would not have opted for treatment if he had received the information. This involves looking at both the objective measure of reasonably treated patient and the subjective measure of personal reasons. When assessing if the patient would not have opted for treatment, it needs to be taken into account how significant the risk was, how the situation would have developed without treatment and whether there were reasonable fewer risky treatments and what the chance of success of these treatments was. The judge believed that the patient had insufficiently substantiated that he would not have opted for treatment as a reasonably acting patient if he had been sufficiently informed. After all, it is not in dispute that he had long-term complaints that he experienced as very unpleasant and that could not be remedied with medication. In addition, evidence shows that other treatments do not offer a serious alternative and that all treatments are at risk of this complication.

This judgment illustrates that even though the doctor does not seem to have fulfilled his obligation to provide information and the disciplinary court has also confirmed this, this does not mean that there is a causal relationship. Only if there is a causal relationship, the patient can get compensation for the damage. This judgment also shows that the burden of proof of the causal relationship is rather heavy.

4.1.2. Rights of the representative of the patient

Art. 7:450 paragraph 3 and art. 7:465 Dutch Civil Code are about the representation of a patient.[140] An incapacitated patient cannot independently enter into a treatment agreement with a physician and exercise the resulting rights and duties. These patients can also not determine and express their will. A coma patient is also an incapacitated patient. The idea is that these vulnerable group of patients need extra legal protection. For this reason, a representative of the patient has a role to play. This representative must receive the information he needs to be able to perform his duties properly. The WGBO has a ranking for representatives for these patients. In the first place, the person who is appointed by a judge has the authority to represent the patient. If the judge did not appoint someone, then you need to look if there is a written declaration of intent in which the patient points out a authorized representative. If there is no written authorisation, the patient will be presented by the partner, parent, child, sister or brother.[141]

In urgent cases, to prevent serious harm to the patient, the physician may proceed with the treatment himself if the time is lacking to ask the representative for permission.
Also, the physician who believes that the patient's representative makes irresponsible or even harmful decisions, he can ignore these decisions. The physician can then rely on the criterion of good care that we discussed in paragraph one of this chapter. However, the relationship between physician and patient is shifting towards a more patient-centred relationship (see paragraph 2). This would mean that the meaning of the representative would be more respected. They should then make a decision together. However, it is still about the patient. If the doctor believes that the patient's interests are harmed by the opinion of the family, he will have to look more closely at the interests of the patient.

[140] Commissie ethiek NVIC, p. 5.
[141] Doppegieter 2004, p. 20.

4.2. Towards a more patient-centred relationship

Recently, people are increasingly concerned with the question of whether the wishes of the patient can play a more significant role in decision-making about care.[142] Traditionally, care is according to the medical model, in which the advice of the physician is leading rather than the patient's wishes.[143] According to the Council for Public Health and Care (hereafter: RVZ), it is necessary for the patient to participate, so that the care fits in well with the preferences of the patient.[144] This is also called shared decision-making. The RVZ has established that we need a mental change for all parties involved to achieve shared decision-making. This would result in shared decisions about the provision of care and the implementation of a treatment plan.[145] In the advice, the RVZ makes a large number of recommendations that should promote the participation of the patient in care. One of these recommendations is to adjust the law.[146]

As a result of this recommendation, there is a legislative proposal to amend the WGBO. The first chamber has not yet adopted this bill, but it is proposed to modernize art. 7:448 of the Dutch Civil Code by supplementing the current information obligation.[147] As a result, the patient is seen more like a conversation partner of the care provider. The intention is that the physician does not only provide unilateral information about the treatment he recommends, but conducts a dialogue with the patient. The bill adds some elements to the existing obligation of art. 7:448 Dutch Civil Code. First of all, the doctor needs to discuss the option of not treating the patient. In addition, alternative treatments must be discussed, including treatments performed by other care providers. They also need to discuss the period during which the treatment can take place. And, not unimportantly, the patient has the opportunity to ask questions.[148] This would allow the patient to make better decisions. Joint decision making also demands something from the patient. The patient must tell the physician what he/she wants because this creates the best possible picture of the patient's wishes. For this, the patient must also think carefully about the questions he/she wants to ask during the interview. Information that the patient has found on the internet can also be discussed during the conversation.[149]

With the approach of shared-decision making, it is no longer the case that the advice of the physician is leading, as is the case in the current provisions of the WGBO in which the physician can ignore the wishes of the patient. Under the current provision of the WGBO, it is primarily a decision on medical grounds and arguments, and therefore made by a doctor. Because of this, family members of the patient do not have to give permission to stop the treatment, for example.[150] Instead, we are moving towards an approach in which the patient increasingly arranges and determines his care.

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[142] *Kamerstukken II* 2013/14, 29689, 506 (advice RVZ).
[143] *Kamerstukken II* 2017/18, 34994, 3 (Explanatory statement).
[144] *Kammerstukken II* 2013/14, 29689, 483, p. 1 (Letter from Minister and Secretary of State public health, welfare and sport to the President of the Second Chamber of the States General at November 13th 2013).
[145] Ibit, p. 2.
[146] *Kamerstukken II* 2013/14, 29689, 506 (advice RVZ).
[147] *Kamerstukken II* 2017/18, 34994, 3, p. 4 (explanatory statement).
[148] Ibit, p. 4.
[149] Ibit, p.5.
[150] Commissie ethiek NVIC, p. 6.

4.3. Conclusion

I discussed in chapter 3 that art. 8 ECHR and art. 10 and 11 DC are important rights of the patient. Also, the principle of autonomy and human dignity are very important for the interpretation of these rights. The state must protect citizens from infringement of these rights by individuals. The Dutch WGBO (which is included in the DCC) gives meaning to these rights in a medical treatment relation. The most important provisions of the WGBO are art. 7:448 and 7:450 Dutch Civil Code, which together form the requirement of informed consent. Under the current WGBO, this requirement means that the physician needs to inform his patient about the intended treatment. Currently, this is more an advice of the physician. He is the one that predicts if the clinical status or the prognosis is hopeless and treatment will be disproportionate. The physician can ignore the wish of family members and doesn't need permission from them if he has reasonable grounds for this. It is primarily a decision made on medical grounds and arguments, and, therefore, the physician needs to take this decision. However, in the last few years, there is a shift towards a more patient-centered approach. This also means that we are moving more towards shared decision-making. To achieve shared decision-making in practice, we need to amend the requirements of informed consent. There is a legislative proposal to do this, but this proposal is not yet adopted. Based on this bill, the physician must provide information about the risks and benefits of the treatment, alternative treatments, or the option not to treat. The physician needs to take into account the wishes of the patient and must allow the patient to ask questions. This means that the physician can no longer ignore the wishes of the patient or the relatives, which is now the case. This results in a joint decision about the treatment that fits the wishes of the patient instead of only looking at the doctor's advice. In the next chapter, I will discuss if we can meet the requirements of informed consent when we use the MDPM. I will also explain why it is better if we use shared decision-making when we want to use the MDPM.

Chapter 5 The compatibility of the MDPM with the fundamental right to physical integrity

In general, algorithm-driven technologies have an impact on the private life of people.[151] In previous chapters, I already explained that the right to physical integrity is important in assessing whether physicians can use the MDPM in the Netherlands to make decisions regarding coma patient. In paragraph 1, I will discuss the compatibility of the MDPM with fundamental rights and principles. Paragraph 2 is about the use of the MDPM and the requirement of informed consent. In paragraph 3, I will explain why we strive for shared decision-making if we use the MDPM. Paragraph 4 contains a conclusion.

5.1. The compatibility of the MDPM with fundamental rights and principles

The MDPM can conflict with the fundamental rights in various ways. It may infringe personal autonomy and thus infringe the right to physical integrity. Below I will discuss several risks of the MDPM.

Chilling effect

One of the risks is the chilling effect and the threat to people to act autonomously. Chilling effect means that people adjust their behavior because they know that large amounts of data are stored and analysed about them. Because people adjust their behavior, they are limited in their freedom.[152] The chilling effect is closely related to the right to freedom of expression, but in the case law of the ECtHR, it also comes to light in cases based on art. 8 ECHR. The potential constitutional consequences of chilling effects also occur with personal autonomy. Behavioral changes resulting from the chilling effect of big data creates a bottleneck in the exercise of the right to personal autonomy. The use of Big Data and data analysing technologies may negatively influence the ability to think and act autonomously.[153]

The use of the MDPM can influence the behavior of people as well. This is because the outcome of the MDPM pushes you in a particular direction. Based on the outcome, you make decisions. These decisions could be different if you did not know the outcome of the MDPM. With the current techniques to determine recovery chances of coma patients, there is a high chance of misdiagnosis. When the physician tells you that the patient will not wake up again, you know that this diagnosis can be wrong. However, the MDPM should lead to less misdiagnosis. The accuracy of the MDPM will be higher. At least this is what the researchers state. Therefore, you know that the chance that the MDPM gives a wrong diagnosis is smaller. This can influence the decision that is made based on the outcome of the MDPM. You will be less likely to ignore the outcome if you know that the chance that the outcome is incorrect is minimal. This is a limitation of personal autonomy, because the MDPM influences someones own choice. Even though the researchers claim that people only need to take the outcome into account for a certain percentage, the outcome will influence the decision in any case. After all, the question is to what extent someone can partially ignore the outcome. Also, how the decision is influenced also depends on how the physician handles the outcome of the MDPM. However, we can protect autonomy by letting the relatives decide whether to use the

[151] Vetzo, Gerards & Nehmelman 2018, p. 123.
[152] Ibit, p. 127.
[153] Vetzo, Gerards & Nehmelman 2018, p. 128 en 129; EHRM 29 April 2002, nr. 2346/02, ECLI:CE:ECHR:2002:0429JUD000234602 (*Pretty t. het VerenigdKoninkrijk)*, *NJ* 2004/543, m.nt. E.E.A. Alkema, *EHRC* 2002/47, m.nt. J.H. Gerards & H.L. Janssen, par. 62.

MDPM or not. When they choose to use the MDPM, they need to realize that the outcome of the MDPM will influence their decision.

De-individualization

Despite Big Data's pursuit of complete data collections, it is impossible to collect all data about a person. Decisions made out of data analyses are therefore based on the available information about the person (in the case of the MDPM, the fMRI-scans, for example). This information is not complete. When Big Data forms the basis for decision-making, the importance of one's digital personality increases. It is not the individual, but his or her digital representation that is central to decision making.[154] This also clarifies why the outcome of the MDPM should only count for a certain percentage of the decision. The outcome is only based on medical information. However, in the decision of the treatment of coma patients, it is also important to look at the person who is in a coma. For example, how does this person relate to life? Or, could he or she accept the fact that there are permanent physical and mental limitations? After all, there is a chance that someone will no longer be the same after suffering from a coma. Take, for example, a professional football player. When he is in a coma, the MDPM only uses medical information. The MDPM does not know that the person in coma plays football at a high level, and football means everything in his life. However, we also need to take this information into account. It is, for example, possible that this person does not want to live with a severe handicap. Therefore, it is important not to look only at the information that the MDPM uses, but also to look at how the patient lives his life to prevent de-individualization.

Differentiation and discrimination

AI can also differentiate or discriminate. Automatic decision-making may contain prejudices. Human prepossession and biases mainly cause discrimination. You should think that automated decision-making uses objective and neutral algorithms to prevent this. However, algorithms aren't neutral.[155] These algorithms can also be based on stereotypes or prejudices so that this can still lead to a distinction between individuals and groups.

Data mining aims to differentiate between individuals. Classification techniques, like the MDPM, place individuals in different groups and then make group-oriented decisions based on this classification. Regression algorithms result in numerical predictions about individual users (for example, about life expectancy) and make decisions based on these predictions. Because of this, there is a danger that individuals will be disadvantaged based on suspicious grounds, without this being easily traceable.[156] This is also the case when we use the MDPM because the MDPM also uses classification and regression techniques. An example of differentiation is if the MDPM gives people with overweight a lower score than people with a normal weight. The MDPM then uses the weight as a relevant factor for recovery, while this does not have to be the case. As a result, overweighed people are disadvantaged. If private (horizontal relationship) or government actors take decisions based on suspicious grounds, relationships, and profiles, that are embedded in the algorithm, this may cause discrimination.[157]

[154] Vetzo, Gerards & Nehmelman 2018, p. 134.
[155] Penel 2019.
[156] Ibit, p. 139.
[157] Ibit, p. 139 en 140.

Biases

An algorithm is linked to a database that may contain biases. Datasets may, therefore, contain data that may not be included in the algorithmic model. If a database contains biases, the output of the algorithmic analysis may then result in unequal treatment.[158] The situation can become even more problematic when training data is used in predictive analyses. The MDPM also uses training data. If the training data contains a bias, the algorithm will reproduce this in the data analysis and the algorithm learns a discriminatory approach. This often happens unknowingly and unnoticed. The data of a specific group can be over- or under-represented in the data set. In that case, the result of the data analysis may be to the disadvantage of this group.[159] Finally, the data from the MDPM with which the MDPM is trained is already classified. This classification can also contain prejudices.[160] For example, that a patient is in a PVS, while this is a misdiagnosis and the person is actually in a MCS.

The final effects of biases in data analysis depend on the extent to which decisions are based (automatically or otherwise) on the outcomes of this data analysis. If the results of the analysis determine the decision, a bias in the data analysis penetrates directly into the lives of people. But even if people officially make an algorithmically prepared decision, there is a danger that biases will influence the decision to be made. After all, people lack the knowledge and insight to recognize discrimination through algorithms.[161] This is also the case when we use the MDPM. There is not yet enough knowledge in the field of coma to find out whether the outcome of the MDPM is correct or not. If one does not know whether the MDPM contains a bias, one does not know whether the outcome of the MDPM can be trusted. Therefore, people have to be very careful in assuming that the outcome of the MDPM is correct. Especially considering the impact of decisions made based on the outcome of the MDPM.

The question is also if the accuracy of the MDPM is reliable. As we saw in chapter 2, the MDPM uses classification, which means that the data is divided into groups by the programmer. He determines what is considered as, for example, a coma or vegetative state so that the MDPM can subsequently recognize this. The training set consists of diagnoses made by experienced physicians, using the GOS score and the CRS-scale.[162] The patients underwent the evaluation twice a week, two weeks before the MRI scan took place. All patients were followed for at least 12 months after the MRI scan took place. The classification accuracy was assessed by comparing the predicted label and the actual GOS score. We saw that 40 percent of the diagnosis is wrong. Therefore, there is a high probability that the dataset of the MDPM contains errors. Then, the MDPM is tested and used, and an outcome rolls out. How do the researchers determine if this outcome is correct? Is this when the MDPM gives the same result as the diagnosis already made? Because this diagnosis can be wrong, the result of the MDPM can also be wrong. And if the MDPM gives another outcome then the initial diagnosis, is it then the MDPM that is incorrect or the initial diagnosis? Or has it been checked whether the MDPM's prediction is right? In my opinion, only if this outcome can actually be checked, the accuracy of the MDPM can be determined correctly. This means that the researchers have to wait and see whether the patient recovers or not. The methodology of the researchers is very technical and complex to understand. Consequently, it is difficult to understand how the researchers tested the accuracy of the MDPM. However, it does not

[158] Vetzo, Gerards & Nehmelman 2018, p. 142.
[159] Ibit, p. 143.
[160] Ibit, p. 143.
[161] Ibit, p. 145 en 146.
[162] Ming Song et al. 2018, p. 6.

become clear that they waited several years to check whether the patient recovered or not. I cannot imagine that they tested the accuracy by given the patients maximum life support for as long as it takes to establish if a patient recovers or not, because this would be inhuman, as already explained in chapter 2. However, the MDPM predicts a one-year outcome. Therefore, the researcher only have to wait one year. It seems that they have done this because they performed tests on the patients for 12 months. I still wonder if this is reliable because it can take longer than a year before you can find out if the diagnosis has been correct.

5.2. Impact of the MDPM on the requirements of informed consent

With the use of the multidomain prognostic model, it can be problematic to provide the relatives of a patient with information. As we saw in chapter two, the MDPM uses algorithms. These algorithms are hard to understand. As a result, the physician does not know how the MDPM comes to a particular outcome (black-box problem). Certainly not because the MDPM can make connections that the physician cannot. Therefore, the question is how to communicate possible biases, risks, and errors of the MDPM during the informed consent process. The physician can only say: 'this is so, because the computer says so.' This is especially problematic when the MDPM comes to a different prognosis than the physician based on his findings. If the physician comes to the same prognosis as the MDPM, he can use his findings to give the information or he can use the outcome as substantiation for his own findings. In addition, uncertainties, fears, or even overconfidence about the use of AI can make the consent process very difficult.[163] So, we need to determine if and how the physician could meet the requirements of informed consent when using the MDPM. If he cannot meet the requirements, this would be an infringement on the on the right to personal integrity of the patient, and therefore art. 8 ECHR. An infringement is only allowed when it is proportional and subsidiary. For the infringement to be subsidiary, we need to provide sufficient information.

So, how could we possibly solve the black-box problem so that we can still provide sufficient information? First of all, physicians should seek to explain the nature of the algorithm. The physician can, for example, explain that the MDPM is more accurate than other techniques but that the MDPM can contain biases. He can also compare the use of the MDPM with the use of other techniques. The physician can also distinguish between the role of the MDPM and himself. He can tell the relatives, for example, that he uses the MDPM only as a tool in making a diagnosis. He can, and in my opinion, should explain to the relatives how he deals with the outcome. He also needs to warn the relatives that if they want to use the MDPM for the diagnosis, that the outcome of the MDPM can influence their decisions because it is hard to ignore the outcome of the MDPM. Lastly, he needs to discuss the potential harms that might result from the inaccurate data and biases that may underlie the outcome of the MDPM, and thus that there are chances of misdiagnosis.[164]

Justifying the use of the MDPM also requires training of physicians on how the MDPM works. Physicians who use the MDPM should have knowledge about how the MDPM is constructed, which data sets it uses and what the limitation of the MDPM are.[165] The process of the AI system about how it comes to a decision, and the data sets it uses should be documented as good as possible. This is important in the view of the transparency and explicability of the MDPM. Another way to provide information about the MDPM is to

[163] Schiff & Borenstein 2019, p. 139.
[164] Ibit, p. 139-140.
[165] Martinez-Martin et al. 2018, p. 806-807.

involve a person with technical knowledge about the MDPM in decision making. This person could then answer to questions of the relatives about the MDPM.

A physician can also be liable for infringing the right to informed consent. When a physician is held liable, it may be that he is sentenced to pay compensation. This is only possible if there is a direct relationship between not informing or insufficiently informing and the damage suffered by the patient. I already explained this requirement of causal relationship in the previous chapter, and illustrated that this causal relationship is hard to prove. With the use of the MDPM, the causal relationship is even more difficult to prove, in my opinion. There may be a lack of information because the physician cannot explain the MDPM. However, I discussed above that there is a lot of information that the physician can give. It will depend on the circumstances of the case if the provided information was sufficient or not. In addition, it is unclear whether an incorrect decision has been made due to the lack of information, resulting in damage. The choice is not only made based on the outcome of the MDPM. The physician and the relatives also take other interests into account. We also saw that it is not clear whether the MDPM makes a mistake. If you then make a choice based on the outcome, you do not know whether this was the right choice or not. You, therefore, do not know whether the lack of information has caused damage.

5.3. Why we need shared decision-making if we use the MDPM

When we want to use the MDPM, shared decision-making is an important aspect, with regard to the subsidiarity. The decisions made based on the outcome of the MDPM can have far-reaching consequences. In such situations, it is all the more important that proper consultation takes place between physician and patient or in this case, the relatives of the patient. The starting point for decisions regarding coma patients would be, among other things, the quality of life of the patient. Besides, the decision not only has an impact on the patient but also on the relatives. When, for example, the patient is kept alive, this also requires a lot from the relatives. This makes it all the more important to involve them properly in decision-making. Involving the family can also provide a better picture of the patient. How does the person live? Can the person live with permanent limitation? Is the family able to provide good care to the patient? All this should play a part in making a decision. This is only possible when a joint decision is made.

Because the use of the MDPM can influence the autonomy of the persons involved in a way that it may influence their decision, it is all the more important to include the relatives in the decision to use the MDPM or not. If the physician provides the information based on the current provisions of the WGBO, the physician may have a significant share in the decision making. After all, he provides information about the treatment he proposes. By applying shared decision-making, the physician takes the wishes of the patient into account, and the relatives also can determine whether or not to use the MDPM. This decision can be made based on the information discussed in the previous paragraph. This way, the autonomy of the patients or their relatives is infringed as little as possible. This better meets the subsidiarity requirement of the necessity test of art. 8 ECHR. Therefore, I think it would be a good development if the new law were adopted.

In addition, I think that only using shared decision-making can lead society to can gain confidence in the use of the MDPM. Also, concerning the liability of the physician, it is better to apply shared decision-making. If the physician ignores the wishes of the patient or the relatives, he has a higher chance that they cannot accept this decision and will bring a complaint against it.

5.4. Conclusion

The use of the MDPM can cause an infringement of art. 8 ECHR (respectively art. 10 and 11 DC). Especially the personal autonomy can be limited, and therefore there can be an infringement on the protection of physical integrity because personal autonomy is a fundamental principle of the right to physical integrity. When we use the MDPM, there is also a change of a chilling-effect, de-individualization, differentiation, and most important biases. Another point of attention is informed consent. It can be challenging to meet the requirements of informed consent because of the 'black box' problem of algorithms. The physician will not be able to explain the MDPM in detail. He cannot explain, for example, how it comes to a certain prediction or how errors might occur. With regard to the proportionality and the subsidiarity, it is important that the physicians can provide sufficient information. The physicians can achieve this by explaining the nature of the algorithm and the benefits and the risks of the MDPM. To do this, the physician needs to be trained on how the MDPM is constructed and which data sets it uses. It is important to provide proper information, coming from both the physician and the (relatives of) patient to achieve a shared decision-making. With shared decision-making, the relatives are involved in the decision making rather than it will be only an advice of the physician about the proposed treatment. As a result, the relatives confidence to use the MDPM will sooner be gained. Because the use of the MDPM may influence the autonomy of the patient or his relatives, the use of shared decision-making is even more important. In this way, the autonomy of the patient or the relatives is infringed as little as possible. This is because at least they have the choice to use the MDPM or not. They can also provide the physician with information about the patient, like how he lives his life. In this way, not only the outcome of the MDPM will count for the decision, but also the wishes of the patient and the relatives.

Chapter 6 Conclusion and recommendation

In this chapter I will briefly summarize the problem in paragraph 1. In paragraph 2, I will answer the research question. In paragraph 3, I give recommendations for further research and I conclude this research with a final word.

6.1. Recap of the problem

There are different levels of consciousness. These range from coma to full consciousness. It sometimes is difficult to distinguish between these levels because signs of consciousness are often small and fluctuating in time. Another difficulty is that some of the levels like PVS only become clear after a few months. It is essential to make a correct diagnosis to prevent patients from being in the same situation for years. An accurate diagnosis is also important because radical decisions are made based on the diagnosis. However, the question is how to make a proper diagnose of coma patients? The techniques that physician use at this time are clinical features, imaging techniques, and bedside exams. The problem is that when a physician makes a diagnosis, he cannot do this objectively and with 100 percent certainty. The techniques that physicians currently use already improved the making of diagnosis, but there is still a very high amount of misdiagnosis. About 40 percent of the patients get the wrong diagnosis.[166] The CRS-R improves this, but also with the use of the CRS-R, a third of the diagnosis is still wrong.[167] Because of the chance of misjudgment, we need assisting technologies. Technologies which use data-driven objective evaluations of consciousness levels are becoming more important for the physician to improve their clinical verdict.[168] The MDPM may be a technology that can improve the clinical judgment of the physicians. In this research, I investigated what the advantages and disadvantages of the MDPM are, and whether the use of the MDPM is compatible with art. 8 ECHR.

6.2. The answer to the research question

From a legal point of view, we need to investigate if the use of the MDPM is compatible with art. 8 ECHR. The main research-question is, therefore:

'Under which conditions is the use of the MDPM compatible with the right to physical integrity as laid down in art. 8 ECHR and further explained in Dutch legislation regarding medical situations?'

In this paragraph I will give an answer to this question. I will do this by answering the sub-questions. First I will explain how the model works and what the benefits and drawbacks of the MDPM are. Second I will explain the meaning of art. 8 ECHR and the principles that help to interpret art. 8 ECHR. After that I will shortly explain how art. 8 ECHR is elaborated in Dutch legislation. Third I will discuss whether the use of the model causes an infringement of art. 8 ECHR and under what conditions this infringement is allowed.

The MDPM and its benefits and drawbacks

The MDPM uses big data analysis and AI and ML to make a diagnosis. The purpose of the data-driven analysis is to find relevant patterns and relationships in the dataset in an automated

[166] Van Daele 2012, p. 11; Gosseries et al. 2011, p.4.
[167] Maassen 2009, p.275.
[168] Demertzi 2018, p. 226.

matter using an algorithm.[169] The ultimate goal of big data analyses is to facilitate evidence-based decision making. This is what is needed to improve the making of a diagnosis. The MDPM uses a classification algorithm to divide the data among the different categories. It also uses a regression technique to formulate a numerical prediction on identified relationships that are laid down in datasets, by analyzing data that is already available.[170] By using these techniques that combine fMRI and clinical features, the MDPM would be more accurate and sensitive than the current methods. In a third of the cases, there was a chance of misdiagnosis. With the use of the MDPM, the number of misdiagnoses will decrease to a fifth of the cases. The MDPM also could save a lot of time because it is way faster in its evaluation then the physician. It also takes previous cases into account, which can help make a better diagnosis.

However, the way the MDPM works also has some downsides. First of all, the MDPM is opaque. This means that researchers cannot find out if there is an error in the system or what causes the error.[171] This is mainly a problem because drastic decisions are made based on the MDPM. For example, when treatment is stopped based on the MDPM, the patient dies, and no one will ever know if the outcome of the MDPM was correct. The problem with the self-fulfilling prophecy is closely related to this. This problem will not be solved when using the MDPM, because we assume that the outcome of the MDPM is correct. Physicians and family members will behave according to the outcome so that the outcome will automatically become true. Unless the prognosis was that the patient would recover and the patient dies. The ideal situation would be that studies about the use of certain techniques are only performed on patients who will receive maximal life support for as long as possible, this is however not possible because this would be inhuman.

Another point of attention is that the algorithm is not as objective as we think. This is especially the case with the MDPM because it uses classification techniques. This means that the researcher makes the classifications and determines what falls under coma or what falls under PVS, for example. Therefore, the researcher needs to make choices when creating the algorithm. These choices can influence the analysis and the outcome of the MDPM.[172] Another downside is that the MDPM can contain biases because of this.

The MDPM also causes differentiation because it differentiates the patients into different categories. Because the MDPM is not objective and made by humans, this differentiation can obtain prejudices and biases. If the result of the analysis determines the decision that is made, a bias in the data analysis penetrates directly into the lives of people. But even though the choice is officially made by the physician and therefore by people, there is a danger that biases will influence the decisions to be made. After all, people lack the knowledge and insight to recognize discrimination through algorithms.[173]

A fourth problem is the change of automation bias so that the outcome of the MDPM is used as automated decision-making, because people lack time to evaluate the outcome of the MDPM properly. This goes against the statement of the researchers that the outcome of the MDPM should only influence your decision for 20 to 50 percent.[174]

[169] Vetzo, Gerards & Nehmelman 2018, p. 20; Custers 2017, p. 28.
[170] Ming Song et al. 2018, p. 6; Vetzo, Gerards & Nehmelman 2018, p. 21.
[171] Vetzo, Gerards & Nehmelman 2018, P. 42.
[172] Vetzo, Gerards & Nehmelman 2018, p. 49; Diakopoulos 2015, p. 402.
[173] Vetzo, Gerards & Nehmelman 2018, P. 145/146.
[174] Tangemann 2018.

Lastly, the use of the MDPM could also cause de-individualization because the MDPM only looks at the clinical data and not to the person itself. It does not take into account, for example, if the person would accept a severely handicapped life.

The meaning of art. 8 ECHR

The question is whether the use of the MDPM is compatible with art. 8 ECHR? In art. 8 ECHR, the private life and physical integrity of a person are protected. The right to private life implies that people can be themselves without prejudice.[175] The right to protection of physical integrity is closely related to the right to private life. The right to protection of physical integrity is a core element of the right to private life. It implies the right to repel external influences of the body.[176] The principles which underly art. 8 ECHR are human dignity and personal autonomy. These principles help in interpreting art. 8 ECHR. Human dignity means that you have a certain dignity that offers protection against intrusion from the government and third parties because you are human.[177] Human dignity can be explained as empowerment or a constraint. Autonomy is an extension of human dignity. This principle means that people can freely make their own choices and decide how to organize their own lives.[178]

The elaboration of art. 8 ECHR in Dutch legislation

In the Netherlands, physical integrity is included in art. 11 DC and further elaborated in the WGBO. The requirements of informed consent, which are laid down in the WGBO, are particularly important concerning the protection of physical integrity. In short, the requirement of informed consent means that the doctor must provide the patient with information about the intended investigation, proposed treatment and the developments regarding the research and the health condition of the patient. Based on this information the patient must give his consent before the physician can treat the patient. In the case of coma, the patient is unconsciousness. This means that the information must be given to the representatives of the patient.

The use of the model in line with art. 8 ECHR

So, when we want to use the MDPM, we need to determine if the MDPM causes infringement on the physical integrity of the patient. First of all, based on the outcome of the MDPM, treatment can be continued or stopped. In any case, there is medical treatment as a result of the outcome. Medical treatment can infringe physical integrity. Therefore, the MDPM can even violate human integrity indirectly. Second, the model can cause a chilling effect, and therefore, people will change their behaviors. In the case of the MDPM, the outcome of the MDPM influences the decision based on this outcome. When your decision is influenced, this is a limitation of personal autonomy, which underlies the right to protection of physical integrity. Considering the above, the MDPM may cause a limitation of art. 8 ECHR. A limitation is allowed when it is provided by law, based on one of the grounds mentioned in art. 8 paragraph 2 ECHR, and is necessary in a democratic society. For the necessity test it must be proportional and subsidiary.

The use of the MDPM could be subsidiary if sufficient information is provided (informed consent), and the medical decision is based on shared decision-making. However, providing adequate information is a problem because of the black-box problem of algorithms. This problem causes challenges to meet the requirement of informed consent. When the physician

[175] Vetzo, Gerards & Nehmelman 2018, p. 60.
[176] Van Beers 2013, p. 5.
[177] Vetzo, Gerards & Nehmelman 2018, p. 53 en 54.
[178] Vetzo, Gerards & Nehmelman 2018, p. 53 en 54.

does not meet the requirements of informed consent, this creates an infringement on the personal autonomy and the protection of physical integrity of the patients. The question is how physicians can meet the requirements of informed consent when they want to use the MDPM. First of all, the physician needs to be trained about how the MDPM is constructed and which data sets it uses. When he has this information, he can provide the relatives with information about the nature, benefits, and risks of the MDPM. He can do this by comparing the current techniques with the MDPM. He also needs to explain how he deals with the outcome of the MDPM.

I think the best way to provide the information is by using shared decision-making. I believe that when we use the MDPM, physicians must be open and honest about the pros and cons of the MDPM. The physician and the relatives should make a joint decision on whether or not to use the MDPM rather than it only being an advice of the physician about the proposed treatment. In this way, the available information is given, and the persons concerned have the option to refuse the use of the MDPM. As a result, the requirements of informed consent are met, and the infringement on personal autonomy is as little as possible. This will also contribute to the fact that the outcome of the MDPM can only assist for 20 to 50 percent in the decision. Using shared decision-making, other interests of the patient are also taken into account like the way he lives his life. However, we need to keep in mind that it is still unclear to what extent the outcome of the MDPM will influence the decisions of physicians and relatives. As long as the concerned people are involved in making decisions about the use of the MDPM or the decisions based on the outcome of the MDPM using shared decision-making, I believe that the interests of the parties involved concerning informed consent are sufficiently safeguarded. I also think that it is then more important to strive for higher accuracy, even when this is at the expense of the clarity of the MDPM.

However, I do not know how we can assure that the MDPM has a high accuracy or sensitivity. It is not clear to me how the accuracy and sensitivity of the MDPM are tested. The MDPM compares the outcome of the MDPM with the actual GOS-score. However, the actual GOS-score is a diagnosis, and we saw that a third of the diagnosis is incorrect. When the outcome of the MDPM is different from the actual GOS-score, is it then the MDPM that is incorrect or is it the GOS-score that is incorrect? This question can only be answered by waiting to see if the MDPM's prediction comes true. This would mean that the patients need to receive maximal life support for as long as possible, but this may be inhuman.

6.3. The implication of the findings

The subject of this thesis is very broad, so my answer to the research question does not cover all the problems. This means that there is still a lot unclear and we need further research if we want to use the MDPM in the Netherlands. First off all, we need further clinical research about the accuracy of the MDPM because the MDPM is only tested on a small amount of patients. We also need to research liability. If the physician does not meet the requirements of informed consent, he can be liable for this. However, we already saw that the causal relationship between the lack of information and the damage is hard to prove. First of all, because it is hard to prove that a wrong decision causes the damage and second, it is also hard to prove that the wrong decision is made because of the lack of information about the outcome of the MDPM.

Final word

This thesis has provided a picture of the pros and cons of the MDPM. It also shows that the use of AI raises many questions. AI can improve the world, but we also need to be very careful with the use of AI given the impact it can have on people's lives. Now that you have finished reading this research, I have one question for you. When you or a family member falls into a coma, would you like to use the MDPM?

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Annex 1 Glasgow Coma Scale

TABLE 38-2

Glasgow Coma Scale

BEHAVIOR	RESPONSE	SCORE
Eye opening response	Spontaneously	4
	To speech	3
	To pain	2
	No response	1
Best verbal response	Oriented to time, place, and person	5
	Confused	4
	Inappropriate words	3
	Incomprehensible sounds	2
	No response	1
Best motor response	Obeys commands	6
	Moves to localized pain	5
	Flexion withdrawal from pain	4
	Abnormal flexion (decorticate)	3
	Abnormal extension (decerebrate)	2
	No response	1
Total score:	*Best response*	15
	Comatose client	8 or less
	Totally unresponsive	3

Annex 2 CRS-R

Coma Recovery Scale – Revised ©2004

Record Sheet

This form should only be used in conjunction with the CRS-R Administration and Scoring Manual which defines guidelines for standardized application of the scale

Patient:	**Diagnosis:**	**Etiology:**
Date of onset:	**Date of Examination:**	

Date																
Week	**Admission**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
AUDITORY FUNCTIONS																
4 Consistent Movement to Command *																
3 Reproducible Movement to Command *																
2 Localization to Sound																
1 Auditory Startle																
0 None																
VISUAL FUNCTIONS																
5 Object Recognition*																
4 Object Localization: Reaching*																
3 Visual Pursuit *																
2 Fixation*																
1 Visual Startle																
0 None																
MOTOR FUNCTIONS																
6 Functional Object Use**																
5 Automatic Motor Response*																
4 Object Manipulation*																
3 Localization to Noxious Stimulation*																
2 Flexion Withdrawal																
1 Abnormal Posturing																
0 None/Flaccid																
OROMOTOR/ VERBAL FUNCTIONS																
3 Intelligible Verbalization*																
2 Vocalization / Oral Movement																
1 Oral Reflexive Movement																
0 None																
COMMUNICATION SCALE																
2 Functional: Accurate**																
1 Non-functional: Intentional*																
0 None																
AROUSAL SCALE																
3 Attention																
2 Eye opening without stimulation																
1 Eye opening with stimulation																
0 no arousal response																
TOTAL SCORE																

Denotes emergence from MCS**
Denotes MCS*

Annex 3 Pipeline data analysis