Standardisation in Healthcare Systems

MSc Thesis

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Standardisation in Healthcare Systems

by

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Preface

About a year ago, I started to orient myself on what I wanted to do for my Master Thesis Project to conclude my Management of Technology studies. I had really enjoyed my classes on responsible innovation, and with an interest in the healthcare domain, I had decided that I wanted to perform my research in that area. Talking to multiple professors, I eventually crossed paths with this project proposal named 'Standardisation in Healthcare'. I was immediately hooked, and together with my committee, I formed that proposal to my own research plan and eventually this whole thesis.

It has been an incredible journey from that quest of finding a thesis topic to now. Many lessons were learned; how to handle such a big project, all different aspects of performing interviews, and how to continue working on a thesis when life happens, to name just a few. Throughout this whole journey, I was lucky to have the wonderful support of my friends, family, and supervisors, who made everything a lot easier. I am incredibly thankful for their listening ears, words of encouragement, and feedback. While there are too many to name, there are a few to whom I would like to express my appreciation especially.

First of all, I would like to thank my first supervisor, Irene Grossmann, for all her support. I really enjoyed our meetings together and I am incredibly grateful for her support when I had to deal with personal circumstances. I would also like to thank my second supervisor, Samantha Copeland, for her additional insights and the opportunity she gave me to talk about some of my research findings at the launch of the Institute for Health Systems Science, which was an amazing and valuable learning experience.

I would also like to thank my friends for their unwavering support. Thank you Roosa, Kristie, and Katha for always being there for me and being the best besties a girl could wish for. Thank you Jasmine for our fun study sessions at the most random locations. Thank you Flavio for keeping me sane with our daily coffee breaks. And thank you Robbin (and Yuki) for all the fun de-stress moments in our Artemis office.

Finally, although I had the support of my whole family, I want to especially express my gratitude to my grandfather, who was by far my number one fan. He was always looking forward to the day he would see me graduate, and it saddens me that he just missed it, but I know exactly how proud he would have been of my achievements and I am thankful for that. This whole journey has taught me so much and I would not have gotten here without the amazing support from my friends and family. Thank you to you all.

Aïcha van Veen
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Summary

The aim of this research is to gain an understanding of the balance between guideline standardisation and professional autonomy. This includes its impact on the safety and quality of healthcare. These are crucial aspects of providing good care as they can contribute to an overall healthcare system that is effective, reliable, and patient-centered. The reason for performing this research is the difficulty of finding a balance between guideline standardisation and professional autonomy. While guideline standardisation is crucial to ensure a structured approach to uniform care of high quality, professional autonomy is necessary to individualise this care for each patient. At times, the tension between these aspects arises as medical practitioners feel limited in their professional autonomy, but healthcare organisations require a structural set-up of healthcare systems to provide equal care.

Discussions regarding this tension are not new but have remained unresolved as both approaches have valuable arguments. This study aims to explore contributing factors to this tension, which could impact the fact that the discussions result in a standstill. For that purpose, three perspectives on the problem are considered: human, technical, and organisational. These three perspectives allow for a broader approach to possible contributing factors. The breast cancer guideline in the Netherlands is chosen as a case study to narrow down the scope and to apply the research on a real-life setting. The evidence-based knowledge on breast cancer is of high quality and its guidelines in the Netherlands are well-developed. This case study allows the research to focus on the standardisation of the guideline, professional autonomy, and their contributions to the safety and quality of care.

The research is set up as an exploratory qualitative empirical study using semi-structured interviews to collect empirical and observational data. Three groups of participants took part in the interviews to provide multiple points of view on the topics. The guideline group consisted of people who have worked on the revision of the breast cancer guideline; the doctor group consisted of medical practitioners who use this guideline in their day-to-day life; and the patient group provides a patient perspective. These three perspectives allow for the possible identification of contributing factors to the earlier stated tension and discussion, as the problem is now researched through the eyes of those who are directly impacted by tension. These empirical results are then tied together through a comparison with the literature findings and contents of the Dutch official guideline standardisation documents. These are validated through the content, context, and process framework, which allows for the identification of tension by evaluating each framework aspect of this healthcare system.

Regarding the findings of this research, the contribution of guideline standardisation to the quality and safety of care is seen as positive, but on the condition that next to adhering to the guideline, a doctor uses their professional autonomy to act with their expertise. Professional autonomy thus remains a part of the conversation when discussing the standardisation of guidelines. Additionally, the participants agreed that safety of care is a concept that should not be discussed in relation to guideline standardisation, as safety is ensured through protocols. This led to the finding that doctors do not view guidelines as a contributor to the safety of care even though they are indicated as such.

Crucial to professional autonomy is that it enables the individualisation of patient care, and this translates to its impact on the safety and quality of care. That also means it is dependent on the doctor, whose actions are more difficult to check than a standardised guideline. The question of how much space there should be for professional autonomy thus remains uncertain. What has been recognised however is how to start evaluating this, as multiple contributing factors have been identified. An important factor is the influence of the psychosocial elements, which plays a huge role in healthcare but is often left out of the conversation. There is much sensitivity around discussing professional autonomy with doctors. While the reasons for that sensitivity are only speculated, it does indicate a sore point interfering with the question of balancing guideline standardisation and professional autonomy.

Another possible contributing factor is the structural set-up of healthcare systems versus its domain. Many participants indicated that although the current guideline set-up follows an instruction-based model, they see much value in a constraint-based set-up instead. The execution of such a model remains to be researched, but a constraint-based set-up could allow for better structural integration of guideline standardisation and professional autonomy. In fact, multiple participants had indicated having ideas about changing the guideline set-up prior to this research, showing that there is some desire for change.

These findings resulted in six recommendations, including future research recommendations, structural changes, and mindful pointers. Three of these can be considered as recommendations to improve discussions regarding a balance between guideline standardisation and professional autonomy as well as the balance itself. These include the psychosocial elements in healthcare conversations, the sensitivity of discussing professional autonomy with doctors, and the implementation of structural changes regarding the system-based set-up. Two other recommendations are given on the guideline set-up and standardisation: the inclusion of doctors who do not work on guideline revision in its process and to co-operate better internationally for faster knowledge transfer and eventual guideline revision. Additionally, it is recommended to perform future research on the understanding of safety in healthcare among doctors.

The identification of a need for the inclusion of the psychosocial elements, research regarding sensitivity around professional autonomy, and structural changes is beneficial to get to a point where it is possible to identify a balance between guideline standardisation and professional autonomy and its impact on the safety and quality of care. While multiple points for further research are indicated in this study, these three factors contribute to improving the situation of both the tension itself and the discussions around it.

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Introduction

The healthcare domain is extremely important in society as it ensures human well-being. It is therefore crucial to ensure the safety and quality of healthcare, which can be achieved in one way through protocols, guidelines, and care pathways. The healthcare domain, however, is a complex socio-technical system, which includes many decision-making processes that differ per individual patient. A socio-technical environment implies that the effectiveness of health policies and healthcare delivery relies on various factors, situations, and the interplay between human actions and technological elements. This increases the complexity of creating a standardised approach to healthcare across the country that is able to ensure its quality and safety.

Medical guidelines are meant to both aid healthcare practitioners with these decision-making processes as well as ensure a standardised approach to uniform, high-quality healthcare as much as possible. It is impossible, however, to create guidelines for every individual scenario, which is where the professional autonomy of healthcare practitioners comes in. Professional autonomy refers to the ability of healthcare practitioners to exercise independent judgement and decision-making based on their knowledge and experience. It is highly valued in healthcare because it enables flexibility and adaptation to specific circumstances. Through the combination of the healthcare practitioner's professional autonomy and the standardised guidelines, the quality and safety of healthcare should theoretically be optimal for each individual patient.

However, the reality is that healthcare is complex, and the balance between the use of standardised guidelines and professional autonomy is not easily identifiable. This may raise questions such as 'when should a doctor trust one above the other?' or 'how much space should there be for professional autonomy?'. The organisational set-up of healthcare requires a standardised approach to healthcare countrywide, achievable through protocols and guidelines. On the other hand, medical practitioners need enough space for their professional autonomy to tackle the cases of individual patients. At times, these two aspects clash as some medical practitioners argue that the use of standardised guidelines can restrict their ability to exercise their professional judgement, while others criticise abuse of professional autonomy.

It is important to note that a standardised approach through guidelines and professional autonomy are crucial aspects of healthcare quality. However, it is equally important to continue to assess its balance and the consequences thereof critically. There is an ongoing tension within this balance that remains unresolved, as opinions differ on what is optimal. The standardisation of guidelines and professional autonomy should not be seen as two separate identities but rather intertwined concepts that go hand in hand. Simply put, healthcare organisations want a standardised approach to healthcare countrywide, achievable through guidelines, and give this a higher weight in the balance, while medical practitioners value professional autonomy more.

This tension is essential to research as it potentially impacts the quality and safety of care, but also because both aspects of the balance are crucial factors to high-quality healthcare. Although it is known

that this tension is present, resolutions remain absent. The goal of this study is thus to explore the balance between guideline standardisation and professional autonomy, and its impact on the quality and safety of care. This led to the following main research question:

What is the contribution of standardisation in the quality and safety of healthcare, and how does this relate to professional autonomy in the context of medical guidelines?

This report aims to answer this question after a clarification of the research scope in chapter 2, a theoretical background and concept definitions in chapter 3, a description of the method in chapter 4, and analysis in chapter 5. The findings from this analysis are stated in chapter 6, which is followed by a discussion, recommendations, and limitations in chapter 7 and conclusions in chapter 8.

2

Research Scope

This chapter describes the research scope of the study, which includes the reason for undertaking this research, the central and sub-research questions that guide the project, an explanation of the case study that is performed, the boundaries and limitations of the research scope, and the scientific and societal relevance of the study. These elements set the realm where this research takes place and provide an initial frame of reference for the study.

2.1. Research Gap

Discussions on the standardisation of guidelines and the use of professional autonomy are not new. Conversations on its balance between providing clear, uniform standards for medical practitioners to follow and allowing them the flexibility to exercise their judgement and expertise in their respective fields have been held throughout the years (Brands & van der J.M., 2015; Klazinga, 1994a; Traynor et al., 2010a). While the standardisation of guidelines makes way for a consistent approach to care, professional autonomy is necessary to provide individualised care.

Although guideline standardisation is widely acknowledged for its positive impact on evidence-based practice and enhanced patient outcomes, there remains a notable gap in research addressing the factors that influence the balance between guideline standardisation and professional autonomy, especially including an insufficient consideration of both healthcare providers, guideline, and patient perspectives in these discussions. Carlsen (2014) for example discusses the relation between standardisation and autonomy, but considers only the perspective of healthcare providers. A study including all three perspectives is not available. An exploratory study to identify important contributing factors to this relation is therefore valuable for the continuation of these discussions and for those that lead to improving changes.

A study concerning the identification of underlying factors contributing to a balance between guideline standardisation and professional autonomy has not been done including the viewpoints of both guideline developers, healthcare professionals, and healthcare users. These perspectives, and a comparison between them, are believed to provide valuable insights to the understanding of this balance, as they come from three point of views that directly impact the development or use of guidelines (Adviescommissie, 2021). Additionally, the impact of this balance on the quality and safety of care is currently still lacking, as discussions regarding this relation remain unsolved. The quality and safety of healthcare are core principles, however, so it is important to understand how this balance impacts these principles and how healthcare professionals view that relation.

The need for identifying the factors contributing to the balance between guideline standardisation and professional autonomy with the different perspectives and relation to quality and safety of care, provides the demand to perform this research study. To summarise, a research gap has been identified to explore the factors contributing to the understanding of a balance between guideline standardisation and professional autonomy in three perspectives from multiple crucial viewpoints, including its connection

to the healthcare core principles of quality and safety.

2.2. Research Questions

The purpose of this study is to research the contribution of medical guideline standardisation and professional autonomy to the quality and safety of healthcare, including the potential collision and preferred balance between standardisation of guidelines and professional autonomy. The ongoing tension between medical guidelines and the professional autonomy of medical practitioners, in combination with the research gaps described in the prior section, give rise to this study.

This research project aims to look into the causes of this tension and to identify how these two principles, standardisation and professional autonomy, can be merged to use the full potential of both. This is done while considering the impact of both the quality and safety of healthcare, as it is ultimately the goal to ensure and improve these core healthcare values. As stated earlier, contributing factors to this tension will be researched from a human, technical, and organisational perspective. In short, this thesis aims to research the contribution of standardisation to the quality and safety of healthcare and how that relates to professional autonomy in the context of medical guidelines. This is formulated as the primary research question:

What is the contribution of standardisation in quality and safety of healthcare and how does this relate to professional autonomy in the context of medical guidelines?

To guide the research towards answering the main research question, three sub-research questions have been formulated:

1. How does standardisation of medical guidelines contribute to the quality and safety of healthcare?
2. What role does professional autonomy have in the quality and safety of healthcare?
3. How do standardisation and professional autonomy relate and influence each other?

The sub-research questions have been formulated as such to guide the process of identifying contributing factors to the balance between guideline standardisation and professional autonomy within the context of its impact on the quality and safety of healthcare. This is done while considering the lack of consideration for a human and organisational perspective within these discussions as is identified in chapter 3 *Theory*. The purpose of the first two research questions is thus to understand the full context of the impact of guideline standardisation and professional autonomy on healthcare separately. The third sub-research question aims to understand the relation between the two concepts and identify the factors that come into play when these concepts come into contact with each other. Combined, these sub-research questions contribute to the main research question.

2.3. Research Boundaries and Limitations

This section describes the research boundaries and limitations. These are crucial to acknowledge and communicate as they help define the scope and context of the research. This study narrows its scope in multiple ways by focusing on a set number of perspectives, performing a case study, and interviewing a set group of people. Such boundaries and other aspects bring limitations to the study and shall be described here.

This research is an exploratory study, which can easily become very broad, so only three perspectives are explored: human, technical, and organisational. As healthcare is a complex socio-technical domain, the human and technical perspectives are crucial to include. In addition, however, the organisational perspective is included as the structure and set-up of medical guidelines, or healthcare systems in general, might play a role in the experience of healthcare professionals regarding a balance between standardisation and professional autonomy. A more elaborate reasoning for these perspectives can be found in chapter 5 *Analysis*. This brings the limitation that other perspectives, which can also bring valuable insights, are excluded.

This research further narrows its scope by focusing on the breast cancer guidelines in the Netherlands as part of its case study. Thus, not all findings from this research may be applicable on a broader geographical scale nor necessarily to other guidelines or protocols. Regarding the time period, this research is performed as a final master thesis project, which has a nominal duration of 21 weeks and a maximum of 25 weeks. This poses limits on the scale of the study, such as the number of perspectives and factors that can be considered, as well as the viewpoints that can be considered in the research. Therefore, it was chosen to interview three different point of views: guideline developers, doctors, and patients. While this includes the three main points of view within the scope of the research, it does exclude other healthcare stakeholders, medical students, and governmental institutions. These could have provided information on aspects contributing to the research, but they have been excluded to set boundaries for the study. That poses a limitation as well, as a stakeholder analysis has not been performed to determine the three groups of people to interview. It was decided to focus on these three groups as they are directly impacted by both guideline standardisation and professional autonomy. As stated by the Dutch guide for medical guidelines, the primary target audience for guidelines is both healthcare professionals and patients (van Zorg, 2012).

The boundaries and limitations regarding the data collection and methodology are regarding the selected interview techniques, sample bias, and interpretation subjectivity. Semi-structured interviews are used for the data collection, and while this allows for flexibility on top of a structured base, it is, naturally, up to the interviewer to guide the conversation in the right direction. A possible interviewer bias can limit the collected data. Eight experts are participating in the interview, two of whom are doctors who do not work on the guidelines. This is a small sample size compared to the guideline group, which may create a bias towards them. It is thus a crucial point to keep in mind when processing the data. Another point to keep in mind is the limitation of interpretation subjectivity. It is impossible to take out all of the interviewer's subjectivity, so it is a factor, although small, that should be kept in mind as a limitation.

2.4. Scientific & Societal Relevance

The healthcare domain is incredibly dynamic as it continuously undergoes changes as scientific knowledge advances. Scientific research allows for evaluating the efficacy of standardised guidelines in relation to their practical use with the professional autonomy of medical practitioners. Performing research on its balance provides information regarding possible excessive autonomy or insufficient standardisation. As this balance profoundly impacts the safety and quality of care, this research is scientifically relevant for further scientific developments regarding standardised guidelines and other healthcare systems.

Besides the scientific relevance of this research problem, it is also highly societally relevant as it is related to providing optimal healthcare. Striking the right balance or gaining an understanding of contributing factors ensures that patients receive care that is safe, effective, and of high quality. Research in this area ultimately leads to better healthcare for patients. Balancing the standardisation of guidelines and professional autonomy also aids in providing consistent care to all members of society despite their location or socioeconomic factors. The research problem tackled in this study is thus both scientifically and societally relevant.

2.5. Reading Guide

While this chapter indicates the initial backbone of the study, the remainder of this report fills in this structure chapter by chapter. At this point, the research gap and research questions to guide the study to fill in this gap are identified. With an explanation of the case study and the boundaries and limitations of this research, the main structure of the research is clear. The next step is to provide a theoretical understanding and to define the concepts. This theoretical foundation is described in chapter 3 *Theory*. Subsequently chapter 4, *Method*, shows how the research will be performed by explaining the research design, data collection, and method of data analysis. This is followed by chapter 5, describing the data analysis and integration of the data into the used framework in detail. The findings resulting from the analysis are stated in the results in chapter 6. These are discussed in chapter 7, which ultimately leads to the conclusions and recommendations described in chapter 8.

3

Theory

This chapter lays the foundation for the research performed in this study by explaining the relevant concepts and identifying the important factors through scientific literature research. This is achieved by answering the theoretical aspects of the first two sub-research questions, explaining the topic of the case study, and describing the framework that will be used to analyse the data. The following questions will be answered in this chapter:

1. How does standardisation of medical guidelines contribute to the quality and safety of healthcare?
2. What role does professional autonomy have in the quality and safety of healthcare?
3. How do guideline standardisation and professional autonomy relate to each other?

3.1. Defining the Concepts

In order to fully grasp the workings of standardisation of medical guidelines, it is essential to define both what is meant by 'standardisation' as well as 'medical guidelines'. Standardisation is defined by the International Organisation of Standardisation (ISO) as "an activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context" (ISO, 2004). In other words, standardisation is a process that guides the development or implementation of a standard, which is established through consensus decision-making. A standard is "a document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context" (ISO, 2004). In the context of this study, the terms standardisation or standardisation of guidelines indicate the standardised approach to provide care through medical guidelines, where the term standardised is defined as described above.

Within the health domain, there are multiple types of standards to guide medical healthcare. These can be divided into three main categories: care pathways, protocols, and medical guidelines (Ista et al., 2020). Care pathways, as defined by Vanhaecht et al. (2007), is "a complex intervention for the mutual decision-making and organisation of care processes for a well-defined group of patients during a well-defined period". It is the patient-specific organisation of care to ensure it is efficient and of high quality. While this standard is specifically for the care of patients, protocols and medical guidelines are incorporated in many healthcare systems (Kerstens, 2015). The difference between these two types of standards is a bit more nuanced. A protocol is a document that indicates a step-by-step process on how a medical practitioner has to act (Patiëntenfederatie, 2023). While a protocol is an instruction on how to act that needs to be adhered to, a medical guideline is a document that depicts collected knowledge and advice based on scientific evidence to improve care quality which use is highly recommended.

Medical guidelines are constructed through scientific knowledge and the advice of experts to guide medical practitioners nationally through a consistent decision-making process. These guidelines were set up to counter the variability of regional and inter-doctor care. This serves the purpose of providing

up-to-date knowledge regarding treatments (van Zorg, 2012). While these medical guidelines are built on evidence-based medicine, they are not fit-for-all guidelines. These recommendations are based on an average population and both the evidence and guidelines themselves change through the years as medical knowledge advances (Woolf et al., 1999). It is because of this, that it is up to the medical practitioner to decide when such a guideline, or parts of it, are relevant to their specific patient (Carlsen, 2014). That decision is part of the professional autonomy of medical practitioners. According to Hodgson (2016), professional autonomy is defined as the ability of healthcare practitioners to exercise independent judgment and decision-making based on their knowledge and experience. It gives medical practitioners the freedom to act as they see fit in accordance with their professional skills.

Another term that is used in this thesis is psychosocial elements. Psychosocial elements refer to the intricate interplay between psychological and social factors that collectively contribute to shaping an individual's mental and emotional state, as well as influencing their patterns of social interaction. Constituent psychological components involve cognitive processes, emotional responses, and adaptive coping mechanisms, while social elements encompass interpersonal relationships, cultural influences, and adherence to societal norms. The psychosocial paradigm acknowledges the dynamic interdependence between these two elements. To give a few examples, within the context of this thesis this may mean the subjective opinion of the doctor, patient wishes, both their emotional responses, and communication (Drench et al., 2007).

3.2. Standardisation of Medical Guidelines

Medical guideline standardisation aids medical practitioners in their decision-making processes through a highly recommended set of instructions to ensure the high quality and safety of patient care. The standardisation of care through guidelines aids in achieving that goal. To effectively set up this standardised approach to healthcare through a guideline however, guideline documentation and the healthcare environment have to be understood. The documentation of care processes through guidelines aids in improving the quality of healthcare as it provides a shared and founded understanding of patient care (McLachlan et al., 2020). This documentation is an ongoing process that requires collaboration and continuous evaluation to keep up with the latest medical developments. More in depth information regarding guideline documentation is given in section 5.1 *Theoretical Data Analysis*.

Continuing with the healthcare environment, it is known that scientific advances in the health domain are fast-paced. This has two implications: first, through protocols and guidelines, doctors are regularly and timely updated of new and improved insights. Second, there is a constant need for work on the guideline which is not always feasible due to limited man-power or time. This results in the fact that adaptations to the guidelines are frequently necessary. There are many guidelines however and to keep up with all adaptations systematically is a condition of a functional guideline, which is not always achievable (Shekelle et al., 2001). Deciding the optimal moment for guideline revision is difficult, despite the fact that there is guidance available through the 'Richtlijn voor Richtlijnen' (in English, 'Guideline for Guidelines') document (van Zorg, 2012), which is the official Dutch document for medical guideline developments. The difficulty of deciding when to make adaptations is due to the fast-paced nature of healthcare developments and the numeral involved parties such as health insurances, health organisations, the government, and the industry. As stated in the 'Richtlijn voor Richtlijnen' document, high tension points or problems in the field are identified through literature research, surveys or interviews by the assembled work group. Unclear however are the exact criteria these work groups use to prioritise and analyse these tension points as this is not explicitly mentioned in the document. This results in a decrease of trust in the information in guidelines, and with that limited adherence (Blume, 2019). This unclarity of how the work group decides on the most crucial tension points that have to be tackled could result in a risk of bias. Here, a risk of bias would indicate that the selection of tension point priority is influenced by the background, subjective opinions, and experiences of those in the work group. To some extent, the professional opinions are valuable indicators, but it is important to not let that take the upper hand. As it is uncertain how exactly the tension points are prioritised, some are concerned with the work group's potential biases (Woolf et al., 1999).

A different challenge to implementing standardisation in the health domain is the necessity to be flexible

regarding the patient's situation even though the objective of the standardisation model is to achieve a dependable and uniform process (Lehoux et al., 2019). While this is 'fixed' to some extent through the professional autonomy of medical practitioners, which is discussed later, it is a factor to the multi-faceted nature of guideline standardisation. In the words of van der Weijden et al. (2010), 'clinical practice guidelines are largely conceived as tools that will inform health professionals' decisions rather than foster patient involvement in decision making'. While shared-decision making between medical practitioners and patients has become more prevalent, the inclusion of varying preferences of individual patient care in guidelines is limited. How to adapt guidelines to be more flexible regarding the facilitation of individual patients is a question that still remains (van der Weijden et al., 2010, de Ridder, 2005).

Besides the setup, workings, and influences of standardised guidelines, it is equally important to consider the structure of the healthcare environment. One aspect in particular that was found to be lacking in healthcare research, is the differences between the structure of the healthcare domain and its practical use of medical guidelines. Considering guideline standardisation of healthcare systems as a specific task analysis in a complex socio-technical system, Vincente (1999) explains how there are two categories to describe the setup and workings of system processes: instruction-based and constraint-based. The difference in these approaches is the level of guidance. Instruction-based processes are heavily based on providing guidance, whereas constraint-based processes provides this only minimally. Instead, constraint-based processes specify boundaries with no indications on the path to get to a result. In the words of Vincente (1999), "Constraint-based processes specify what should not be done, while instruction-based processes specify what should". Many healthcare systems and processes are set up as constraint-based processes, while the guidelines are often setup with an instruction-based mindset (Hagglund et al., 2010; Shekelle et al., 1999). The healthcare workflow has been identified as a constraint-based environment, requiring flexibility and conditional work paths (Wainer and de Lima Bezerra, 2003). Hommersom et al. (2008) has done research regarding a constraint-based approach for medical protocols, based on the differences between guidelines and protocols. Research on adapting medical guidelines to a constraint-based model based on the perspective of medical practitioners and guideline developers has not been performed however.

3.3. Professional Autonomy

In the healthcare domain, medical practitioners use their professional autonomy in which they care for their patients in accordance to their professional knowledge and experience. Professional autonomy, as was stated earlier, is defined as the ability of healthcare practitioners to exercise independent judgment and decision-making based on their knowledge and experience. This principle is a crucial component of professional ethics and an important aspect is the practitioner's responsibility of applying their professional knowledge to the treatment of their patients (Hashimoto, 2006). The concept of professional autonomy is complicated as it is difficult to relate to standards and is subjective to the medical practitioner who applies it (Traynor et al., 2010b). The moral responsibility that professional autonomy lays on the practitioner is a big discussion point regarding the competence of the practitioner and the causation of their actions (Douglas, 2003). Nevertheless, the use of professional autonomy is positively correlated with better patient care, meaning that the care is more adapted to the needs of the patient. Still, there are certain aspects to the concept that are complex and could use improvement, including its ethical responsibility and boundaries, interrelation with guidelines, and feedback systems (Rafferty et al., 2001).

As posed by Hoogland and Jochemsen (2000), professional autonomy on its own can be viewed as a norm for medical practices. When regarding this normative view however, Hoogland and Jochemsen (2000) identifies one threat especially that is interesting to the purpose of this study. This threat is regarding the pressure put on the health domain to put limitations on professional autonomy practices, which originates from the desire to improve care through standardising its processes. Although standardisation is valuable to the consistency and efficiency of care, so is professional autonomy as it allows for individual patient specific care. Nevertheless, arguments are made both for and against the limitation of professional autonomy (Hoogland and Jochemsen, 2000).

There are some cases that show concerns regarding the rights of medical practitioners to practice pro-

fessional autonomy, especially regarding the amount of power this right gives them (Cheraghi-Sohi and Calnan, 2013). Timmermans and Kolker (2004) have indicated that professional autonomy, at times, allows medical practitioners to disregard new changes made to standards they should follow. Multiple studies have shown that there is an issue in adherence to some protocols, even though its intention is to have better patient care and less costs (Timmermans and Kolker, 2004, Bourgeault et al., 2001). Reasons given by health professionals for limited guideline adherence are patient individuality and preferences, clinical experience, and systemic issues such as time pressure and high workload demands (Nino de Guzman et al., 2020). While articles do identify these reasons, suggestions for systematic improvements in guideline standardisation on these grounds are often lacking.

Relating this back to standards in healthcare systems, this shows that cost and efficiency played a substantial part in decision-making in the content of standards, whilst healthcare professionals may not agree with this distribution of values or considerations. To further explore this set-up, the organisational characteristics of healthcare systems should be considered. Polder and Jochemsen (2000) describe the Dutch healthcare organisation as one that aims to achieve optimal healthcare in which a powerful medical profession is the foundation of a trustworthy relationship between patients and doctors. As a consequence however, the healthcare system places a significant demand on the self-discipline of medical professionals due to the high societal valuation of healthcare and the lack of societal control (Polder and Jochemsen, 2000). It is expected of the medical practitioners not to manipulate this power and it is their internal morality regarding medical decision-making processes that plays a role (Ten Have, 2000). In the Dutch healthcare system a focus is put on the development of guideline standardisation, while perhaps overlooking the importance of including professional autonomy in that development.

3.4. Quality and Safety of Healthcare

Quality and safety are core values in healthcare and healthcare systems. In this context, the quality of healthcare is defined as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes” in the words of the World Health Organisation (“Quality of care”, 2023). Hurtado et al. (2001) added “and are consistent with current professional knowledge” to this definition.

A universal measure to define the quality of healthcare systems is indicated as six dimensions, which is seen as a broader, more elaborate definition. These dimensions are effectiveness, efficiency, accessibility, patient-centered, equity, and safety (WHO, 2006). These dimensions are used as a quality measure in the Netherlands as well on the continuous quest to improve healthcare quality (IKNL, 2023). The definition of each dimension is given in Table 3.1.

Quality Dimension	Definition
Effectiveness	To provide evidence-based healthcare that results in needed improved care for both individuals and communities
Efficiency	To provide healthcare while minimising waste and utilising resources to the fullest extent
Accessibility	To efficiently use time, be geographically reasonable, and have the appropriate skills and resources available for medical care
Patient-centered	To consider the preferences and background of the individual patients
Equity	To remain equal healthcare regardless of race, gender, sexuality, ethnicity, or economical status
Safety	To provide healthcare that minimises risks and harm to patients

Table 3.1: Definition of the six healthcare quality domains (IKNL, 2023; WHO, 2006)

To speak of a high-quality healthcare domain includes both the process and outcome of its care, for both of which the above six dimensions are generally used. A high-quality healthcare system is then one that aims to achieve the most optimal status for each dimension. This has a snow-ball effect as well, meaning that for example effective healthcare is usually efficient as well. Similar relations can be made for the other dimensions as well, showing how it is the combination of all six that allows for an indicator for the quality of care. Although each dimension is an important factor, one could argue that

safety is among the most important ones. Especially with the increasing complexity of the healthcare domain, it becomes crucial to prevent and reduce risks or errors that could harm patients (Vincent and Amalberti, 2015). Safety of healthcare is characterised by the aim to reduce and mitigate unsafe actions with healthcare systems, while adopting best practices that result in the most optimal patient care results. That includes a continuous feedback cycle in which mistakes are learned from (Emanuel et al., 2008).

Waring et al. (2016) suggests that in addition to the mainstream approach to safety, as described above, a sociological approach offers important additional insights to quality and safety aspects. This approach considers the cultural, socio-technical, political, and institutional factors contributing to the quality and safety of care (Waring et al., 2016). He identifies three points of improvement. First, the general inclusion of a sociological viewpoint, which includes the subjective nature of risks and harm such as relationships, attitudes, and beliefs. Second is the social structure and interactions within the organisation (Waring, 2013). The final point of improvement is the influence of power and politics, or rather the acknowledgement thereof. Important is to take into account the political and ideological dynamics of healthcare organisations (Nugus et al., 2010).

Governing the quality and safety of healthcare comes with additional complex socio-cultural aspects such as knowledge and power plays within the organisation (A. Brown et al., 2018). Communication, relationship dynamics, and quality interpretations at the organisational level are key factors to the governance of quality and safety (Freeman et al., 2016, Millar et al., 2015). An important factor to consider is thus the difference in opinions between healthcare stakeholders within the organisational levels on what indicates high quality and safety. In the words of Ten Have (2000), “the quality of the organisational setting is a precondition of the quality of care”.

3.5. Relation Guideline Standardisation and Professional Autonomy

The relationship between guideline standardisation and professional autonomy in healthcare represents a complex balance. On one hand, guideline standardisation is crucial for maintaining consistent and evidence-based care, improving patient safety, and achieving cost-effectiveness. Standardised guidelines provide a framework that can help streamline processes and reduce variability in healthcare practices. On the other hand, healthcare professionals highly value their professional autonomy, which allows them to make individualised decisions based on their expertise and the unique needs of each patient. Balancing these two elements can be challenging, as excessive standardisation may stifle clinical creativity and hinder innovation, while too much professional autonomy can lead to variability in care and potential deviations from best practices (Carlsen, 2014). The challenge lies in finding the right equilibrium, where guidelines provide a strong foundation for care while allowing room for healthcare providers to exercise their judgment, adapt to specific patient situations, and contribute to ongoing improvements in healthcare practices.

As stated before, the relation between guideline standardisation and the professional autonomy of medical practitioners is complex. The main promoted objective of evidence-based guidelines is to guide medical practitioners and reduce harm and risks. With the increased involvement of external parties however, there are many additional influences and opinions on guideline standardisation. External parties such as governmental institutions, insurance companies, and healthcare authorities rely on guidelines as a concrete structure to limit costs and streamline healthcare across the country (Busse et al., 2019). While these parties have important reasons for their objectives, it raises the question of its impact on practical guideline quality and adherence.

The varying levels of guideline adherence are the result of multiple aspects, each with their own factors. These aspects are the medical practitioner, but also the structure of the guideline, system organisation, the patients themselves, and the external parties as mentioned above. Factors contributing to guideline adherence by the medical practitioners are the level of experience, knowledge of the guideline, work pressure, and social pressure (Bloemendal et al., 2011. A big portion of these factors are related to their professional autonomy, which is a crucial and important part of qualitative healthcare. Professional autonomy allows for patient-centered, qualitative care. However, there seems to exist a collision

between adhering to the standards and providing patient-centered care. In ideal circumstances such collisions should not exist, as both aim for the same values: quality and safe care. In real life however, that is unfortunately not the case.

Although it is expected from healthcare officials that medical practitioners follow guidelines consistently, their professional autonomy usually transcends (Timmermans and Mauck, 2005). While that is necessary to provide patient-centered care, limited guideline adherence indicates the existence of flaws within the current set-up of the guideline and professional autonomy system. However, if a limitation or restriction would be placed, the question of how much space there should be for professional autonomy would remain, as it could have negative impacts on individual healthcare with too harsh restrictions (Ten Have, 2000). The problem is that both the space necessary and how to reach such a consensus are unknown. Both the guidelines and professional autonomy are crucial aspects to good quality care, but each aspect is valued differently by different involved parties. Managerial parties highly value the structure and standardisation of the guidelines, while medical practitioners generally value their professional autonomy over these guidelines. The concrete information that managerial parties receive from structure and standardisation offer them ways to be cost efficient, have quality assurance, consistency, and accountability (Walshe and Smith, 2011). It's important to note however that while managerial parties value structure and standardization, it is crucial to strike a balance with the professional autonomy of medical practitioners. Healthcare is a complex field, and even though the managerial parties value guidelines, they cannot construct guidelines without the expertise of medical professionals.

3.6. Content Context Process Framework

This study considers the influence of different perspectives and factors on the balance between standardised guidelines and professional autonomy, as well as its impact on the quality and safety of healthcare. To tie together these perspectives and factors, the content context process (CCP) framework will be used (Stockdale and Standing, 2006). Through this framework it is possible to evaluate a complex system through multiple perspectives, which is convenient for a socio-technical system such as the healthcare domain. To analyse the factors that play a role in the balance between guidelines and professional autonomy, it is necessary to couple them together with the different perspectives. The setup of the framework is based on an evaluation of information systems, but it can be formed to an evaluative interpretation of any complex socio-technical system (Stockdale and Standing, 2006). Relating this to the healthcare matter that is explored in this study, the standardisation of guidelines can be compared to the information system.

The CCP framework guides the evaluation of a system through three key points: content, context, and process. Through these aspects all factors of a system evaluation can be identified using what, why, who, how, and when questions. This combination allows for an evaluation in which every possible aspect is covered. Even more appealing however, is that this framework allows for the integration of multiple perspectives on a socio-technical problem. It provides a holistic view of all included perspectives. A common combination of perspectives is social, technical, organisational, economic, and political. Although the use of such a wide variety of perspectives is recommended for a complete evaluation, it remains valuable when only a few perspectives are considered (Stockdale and Standing, 2006).

This framework is proposed by Pettigrew (1985) to identify factors necessary for organisational structure and culture changes. The interpretive approach of different perspectives on multiple aspects of a problem, allows for a relatively simple identification of points of improvement within a system. The influence of the internal and external environment are incorporated throughout the three key points of content, context, and process. The schematic shown in Figure 3.1 depicts how these aspects are tied together.

3.6.1. Content

The content part of the framework provides deeper understanding of *what* is evaluated. Besides the literal content of the system, this includes its benefits, limitations, and opportunities (Serafeimidis and Smithson, 2000). The selected perspectives play a role in the focus that is placed on the evaluation of these factors, but these four aspects should always be included for completeness sake. Additional

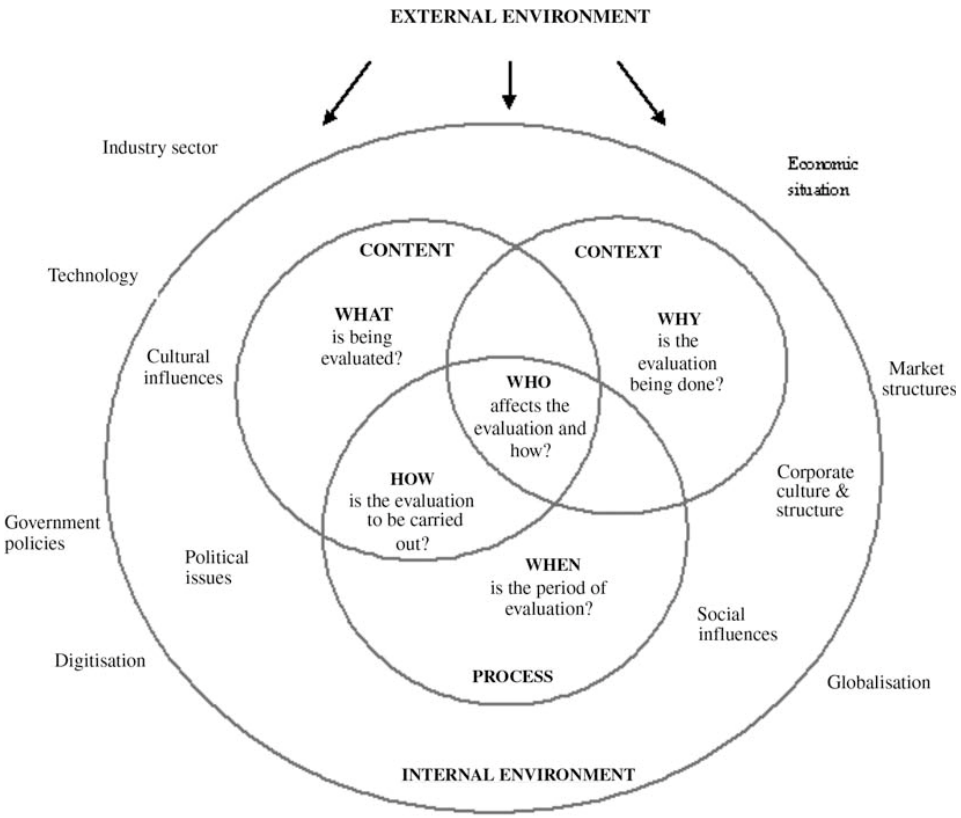

Figure 3.1: Schematic of Content, Context, Process Framework (Stockdale and Standing, 2006)

aspects, such as economic, organisational, or managerial aspects, can be included if relevant to the system being evaluated, however if these are part of the perspectives considered within the framework, they can be left out of this section (Stockdale and Standing, 2006).

As the content specific analysis would only consider the *what* factor of the evaluation, the interaction between content and context, and content and process, are equally or perhaps even more important. This allows for the evaluation of each aspect of a complicated socio-technical system in a thorough manner through the integration of the different aspects (Stockdale and Standing, 2006). These interactions between the CCP aspects are explained in more detail after the explanation on the context and process aspects.

3.6.2. Context

A socio-technical system needs to be analysed within the context of its environment. The context determines the *why* of the evaluation, or in other words, the reason an evaluation is necessary. Combined with the content aspect, it allows for an evaluative understanding of the *who* aspect of the evaluation. This describes those affected by the system, but also those who influence it. This includes relevant, or influential, stakeholders and system users. The organisational and environmental context includes both internal and external influences (Avgerou, 2008). The internal influences come from an organisational point of view, including the structure, strategies, and culture of the organisation. The managerial structure, social structure, and stakeholders are a part of the internal influences as well (Stockdale and Standing, 2006). The external context is given through the earlier mentioned social, political, economic, and technological factors. While this is dependent on the technical domain at hand, a few factors include the governmental policy, national economical status, technological developments, and cultural influences (Rogers et al., 2020).

3.6.3. Process

The process, or rather the evaluation of the process, requires knowledge on the *how* question. Although many methods that consider a process evaluation exist, few consider a holistic view like the CCP framework (Stockdale and Standing, 2006). Factors that are included in the CCP approach, but are not usually found in other methods are evaluation role recognition, high focus on strategic values, and social processes. Social processes that are usually excluded are informal evaluations and communications, even though these are important influences on the realistic use of a system (Andargoli et al., 2017). The involvement of stakeholders in the organisational nature of a system and their commitment are a part of the *how* factors as well.

The last part of the five questions is the *when* aspect. *How* answered the interaction between the content and the process, but *when* gives space for the consideration of when an evaluation of the system is necessary. Although arguments are given for the positive influences of continuous system evaluations, practice shows that this is neglected (Stockdale and Standing, 2006). Ideally, process evaluations should occur before, during, and after system changes are implemented.

3.6.4. CCP Integration

The CCP approach to an evaluation of a complex socio-technical system is so valuable because of its holistic view and interrelation between the five main aspects. The three key points, content, context, and process, should not be considered alone, as that would indicate missing links and factors. This increases the complexity of the framework however, so an interpretive approach that captures all links and factors is important (Stockdale and Standing, 2006). Although this is a more elaborate and inclusive evaluation framework than commonly used in system assessments, the fact that it incorporates a holistic approach is valuable.

As for the methodological approach of using this framework, it starts high level with the three main concepts of content, context, and process. To dive deeper into these, the five elements of what, why, who, how, and when, are established to allow for a more concrete understanding of each key point. The interrelationships between the concepts and elements are shown in Figure 3.1. In the figure, internal and external environment are drawn around the concepts and elements as they are incorporated in each section as relevant. Through these steps, the desired perspectives of a socio-technical system relation can be analysed by the interplay of all elements. Each concept and element can be framed to the required domain, so that an effective evaluation is possible. The conflicts and contradictions of a complex system can thus be analysed through multiple perspectives.

The flexibility of the framework to apply it to any complex socio-technical problem, while still providing a broad overview that incorporates many perspectives, is what makes this framework valuable to this research study. The factors contributing to the balance between guidelines and professional autonomy can be explored from different relevant perspectives to highlight the sore points that need attention and formulate organisational or structural changes to improve the situation.

4

Method

The methodology of this thesis is presented in this chapter, which is centralised around the research approach. The research design is explained first, which is followed by a description of the case study, data collection, processing, and analysis. This chapter is concluded by reviewing the validity and trustworthiness of the research approach.

4.1. Research Design

This research is designed around the main research question, '*What is the contribution of standardisation in quality and safety of healthcare and how does this relate to professional autonomy in the context of medical guidelines?*'. In order to answer that research question, it was decided to perform an exploratory qualitative empirical research. This was chosen as the focus of the research is on understanding and explaining the factors contributing to the balance between guideline standardisation and the professional autonomy of medical practitioners, as well as its impact on the quality and safety of healthcare.

The research is of exploratory nature for various reasons. Discussions regarding the balance between guideline standardisation and professional autonomy are not new, but have remained without a solution in healthcare. To understand the contributing factors to this stagnation, an exploratory study is done as it allows for an initial investigation, understanding of its complexity, and generation of hypothesis (Tesch, 2013). Additionally, the impact of each aspect on the quality and safety of care as a combined study has not been done before, so to perform the research as an exploratory study allows for a basic foundation. The qualitative empirical nature of the study is well-suited for studying complex, multifaceted phenomena such as a system within the complex socio-technical environment of healthcare. It allows for contextual understanding and an identification of the complex relations between multiple concepts or perspectives.

This research aims to reach a deeper understanding of standardised guidelines, professional autonomy, the balance between standardised guidelines and professional autonomy, and their impacts on the quality and safety of healthcare through interviews with medical practitioners and professionals who setup the guidelines. The professional opinions of medical practitioners, who use the guidelines, is valuable to understand the experiences and perspectives on the reality of the balance between standardised guidelines and professional autonomy. The perspectives of professionals who setup these guidelines shows an intended use and balance, which allows for a comparison between the theoretical and realistic balance. To narrow the scope of this research, a case study is done.

4.2. Case Study

The purpose of selecting a case study is to narrow the scope of the research, but also to allow for a focus on specific aspects. As there are variations between available evidence-based knowledge or known tension points for different guidelines, it was necessary to know what type of guideline to choose

for the case study. The purpose of this study is to explore the contributors to the discussion of how much space there should be for professional autonomy and how this relates to guideline standardisation. To put as much focus on that as possible, it was important to choose a guideline which has a lot of available evidence-based knowledge and whose care is already of high quality. This allows the focus of the research to be on the standardisation and professional autonomy itself.

Both of these points are valid for the breast cancer guideline. Breast cancer care in the Netherlands is known for its high quality and Dutch research on breast cancer is internationally acclaimed (NKI, 2023). That provides an optimal setting for this research, allowing a focus on all aspects surrounding the content such as the context and processes. The latest breast cancer guideline revision was authorised in 2020, which is recent enough that it was possible to contact a few of the guideline work group for the interviews, but also old enough to discuss its practice in the field (FMS, 2020). A new revision for the breast cancer guideline has started in 2021, but this has not been completed or updated on the database website. This research is performed with the knowledge of the latest version of the guideline that is publicly available. All guideline participants that have been interviewed were a part of this guideline version, not the revision that is currently ongoing.

4.3. Data Collection

The data collection of this research is done through theoretical and empirical data collection. The theoretical aspect, a literature study, is important both for gaining background information and defining the concepts as well as to perform a comparative analysis between the theoretical data and empirical data. The empirical data is collected through semi-structured interviews on the knowledge, experience, and perspectives of experts.

4.3.1. Theoretical Data Collection

The theoretical data collection is done twofold, resulting from two data sources. First, a literature study is performed, of which the outcome can be found in chapter 3 *Theory*. The purpose of the literature study is to define all concepts and gain understanding on guidelines, standardisation, professional autonomy, the balance between these concepts, system processes, and the framework that is used for the research validation. Additionally, the factors that could potentially influence the balance between standardised guidelines and professional autonomy as well as the quality and safety of healthcare are explored.

Keywords	**Synonyms and/or related keywords**
Guideline	Protocols, pathways
Standardisation	Development, implementation
Healthcare	Medical, care, healthcare systems
Balance	Relation, influence, impact
Professional autonomy	Judgement, expertise, shared-decision making
Organisation	Structure, constraint-based, instruction-based
Human perspective	Behaviour, emotion, identity
Quality & safety	-

Table 4.1: Literature study keywords

In order to perform the literature study, first the research questions and objective were determined. These are described in Section 2.2 *Research Questions*. Next, the inclusion and exclusion criteria for the types of sources have been determined, which are stated in Table (4.2). Once these criteria were determined, a comprehensive search was done using academic databases, libraries, and search engines to find relevant literature. In order to do that a set of keywords and combinations thereof were used to refine the search. All keywords, synonyms, and combinations that were used to find the articles for this literature study are stated in Table (4.1). Important to note is that some related keywords are not synonyms, for example 'guideline' and 'protocol'. Using the word 'protocol' in the search engines might still provide useful articles and have therefore been included in the related keywords section.

Criterion	Inclusion	Exclusion
Language	English, Dutch	Other
Research type	Scientific article, journal, book, case studies	Blogs, forum, patent
Publication tool	Google scholar, Web of Science, Scopus	Other
Year of publication	2000 and up, unless relevant for framework / old situations	Studies before 2000

Table 4.2: Literature study search criteria

The second theoretical data point are the two documents used in healthcare in the Netherlands to standardise guideline development. These are the *'Richtlijn voor Richtlijnen'* (Guideline for Guidelines) and *Medisch Specialistische Richtlijnen* (Medical Specialist Guidelines) documents. Using these as another data point allows for a deeper understanding of the status quo of guideline standardisation in the Netherlands, enriching the results of this research. The relevant aspects of these documents are described in chapter 5 *Analysis*, and are later used to draw relations and conclusions from in chapter 7 *Discussion*.

4.3.2. Empirical Data Collection

The empirical data is collected through semi-structured interviews and observations around the interviews. This allows for the exploration of complex topics, like the relation between guideline standardisation and professional autonomy, while keeping the flexibility of guiding the interview based on the respondent's answers. Deeper contextual understanding and the opportunity to achieve rich qualitative data are then provided (Adams, 2015).

The goal of these interviews is to understand the perspective of professionals on standardised guidelines, professional autonomy, the balance between these two concepts, and its impact on the quality and safety of healthcare. For that purpose, both guideline developers and users are interviewed for this research, which allows for a comparative analysis between both the intended use of standardized guidelines and its intended balance with the professional autonomy of medical professionals, and its realistic use and balance as experienced by medical practitioners. A third perspective is given by patient relevant participants, which is an important point of view to include as the shared-decision making between doctors and patients plays a factor in the relation between guideline standardisation and professional autonomy as well.

In preparation for these interviews an interview protocol is set up based on relevant results from the literature study. This interview protocol, presented in appendix A, provides the backbone of the semi-structured interviews. All topics that need to be covered are clearly pointed out, but it leaves space for the personal contributions of the respondent. This is equally important as it may provide useful input on what the professional deems most important and relevant to this research.

4.4. Data Processing & Analysis

The empirical data needs processing before it can be analysed. The interviews are recorded and transcribed using MS Teams. As sensitive data can be provided, the data and privacy of the respondent is protected through secure storage of the recordings and transcription as well as destruction of the recordings as soon as the transcripts have been made. The transcripts are destroyed after the completion of the study. Before the interview could take place, an informed consent form was signed by the participant. The template that was used can be found in Appendix B. The interview questions that were used to guide the conversation are given in Appendix A. Both appendices contain purely the templates used, as the answers from the participants cannot be publicly shared for anonymity purposes.

In order to process the transcripts to tangible data, they are coded using the ATLAS.ti program locally, a software specifically designed for coding interviews. The data is organised and analysed using this program, which allowed for drawing meaningful insights from the interviews. For personal processing of the results, an excel spreadsheet was used to lay out all identified categories and possible relations. Through the comparison between the different codes, the similarities, discrepancies, and other useful statements were more easily deduced. This document is stored on the same secured drive as the

transcripts. The results of this comparative analysis are described in chapter 6 *Results*.

4.5. Validation

In this study, a multi-faceted approach is employed to validate the findings derived from the interviews, utilising a combination of a comparative analysis and an evaluation framework. This validation process is integral to ensuring the trustworthiness and reliability of the research outcomes. The primary data source in this study consists of in-depth semi-structured interviews with experts who possessed valuable insights and experiences related to the research objectives. The process of validating the interviews includes rigorous data collection and transcription, followed by an analysis to identify relevant factors and views from the empirical data.

For the sake of credibility and confirmability of the interview findings, a comparative analysis approach is used. This involves comparing and contrasting the information and perspectives gathered from different interview participants, as well as a comparison with the literature and official guideline standardisation documents. Key aspects of the comparative analysis include cross-participant consistency and triangulation. The cross-participant consistency entails the comparison of responses across different interviews with the aim of identifying similarities and discrepancies between interview groups. Triangulation of the data is achieved by comparing the interview findings with the literature study and guideline standardisation documents.

In addition to the comparative analysis, an evaluation framework is used to assess the validity of the interview findings within the broader context of the research. The content, context, process (CCP) framework is used which allows for an evaluation of aspects within a complex system that need attention. This is done by exploring the tension points in each content, context, and process block, but also the interrelations between. Combined with the inclusion of a human, technical, and organisation perspective on the healthcare research problem of this study, the framework allows for a complete evaluation of potential attention points. Together with the comparative analysis and literature study, this allows for the validation of the interview data.

5 Analysis

There are two aspects to the analysis performed in this research. First, two Dutch guideline standardisation documents are analysed as a part of the theoretical data collection. This analysis is described in section 5.1 *Theoretical Data Analysis*. To get interpretive results from the interviews, the data is analysed through coding and a comparative analysis, after which the findings are validated using the CCP framework as described in chapter 4 *Method*. The analysis of this empirical data is described in section 5.2 *Empirical Data Analysis*.

5.1. Theoretical Data Analysis

As described in chapter 4 *Method*, the theoretical data encompasses both the literature study and the guideline standardisation documents used for clinical guideline development in healthcare. This section analyses the two regulatory documents that are used in the Netherlands, which are *'AQUA-Leidraad'* (also phrased as Guideline for Guidelines) and *'Medisch Specialistische Richtlijnen* (Medical Specialist Guidelines). The content of each document is analysed in this section.

5.1.1. Guideline for Guidelines

The *'AQUA-Leidraad'* document contains all criteria for the development and implementation of clinical guidelines in healthcare (Zorginstituut, 2021). This document is a revised version of the prior document named *' Guideline for Guidelines'* , which was developed in 2010 after the Dutch Minister of Health, Welfare, and Sports asked the *Regieraad Kwaliteit van Zorg* to develop a vision for nation-wide guideline development. To set up this document, AGREE-criteria were initially used. This is an internationally accredited instrument to check the quality of guidelines, but it is also used as a guide for developing high-quality guidelines. The *Guideline for Guidelines* document used the AGREE instrument as a foundation to set up a guide for guideline development specifically for the Dutch healthcare.

In this document, a national guideline is defined as ‘’a document with recommendations, focused on improving the quality of care, based on systematic summaries of scientific research and considerations of the advantages and disadvantages of different care options, supplemented with the expertise and experience of healthcare professionals and users’’. The primary target audience of guidelines are healthcare professionals and (potential) healthcare users, for whom guidelines aid in their decision-making processes. The purpose of a guideline is that it provides a tool to show which treatments should be performed in which order and circumstances to provide the correct care as well as possible.

A specific section of the document is dedicated to the use of guidelines. It is stated that guideline users have to realise that guidelines are not strict instructions. Rather, they contain explicit, evidence-based recommendations and insights to which healthcare professionals are highly recommended to comply in order to deliver optimal, qualitative care. Explicitly noted is the fact that these recommendations are mainly focused on the average patient and that in practice care is usually more complex than stated in a guideline, resulting in the fact that healthcare professionals can, and sometimes should, make use of their professional autonomy to diverge from these recommendations. Additionally, it is also stated

that the investment into guidelines does not stop after its publication, but continuous to the spread and implementation of guidelines. Its evaluation is used as well as data for the revision of the guideline. The guideline work group pleads for a continuous cycle of development, implementation, evaluation, revision, and maintenance of guidelines.

To set-up or revise a guideline, the document describes a certain road map for guideline developers to follow. This starts with a problem analysis, which is done before a decision is made to develop a guideline. No details are given in this document as to how the problem analysis is performed. Once the development of the guideline is kicked off, there are three phases to complete: preparation, development, and completion. Each phase has its own set of criteria which a guideline has to satisfy at that point, as listed in the bullet points below:

Preparation Phase

1. The subject, goal, and target audience of the guideline are defined
2. The guideline initiator identifies the primary involved industry and patient organisations
3. The primary involved organisations form the work group and set the work method
4. Healthcare professionals, healthcare users, and methodological experts, are included during all phases of guideline development
5. The influence of conflict of interest has to be prevented

As understood from the criteria that a guideline has to satisfy during the preparation phase, there are multiple work methods a work group can choose from. The research questions that are set up to create or revise a guideline can be worked out together, multi-disciplinary, or in multiple mono-disciplinary projects. The structure and work method of the work group thus depends on the primary organisations and their opinion. The method of guideline development does need to be stated in the final guideline. Similarly, one of the criteria requires the inclusion of the patient perspective, but the method may vary from participation in the work group, to a focus group, survey research, and literature study or a combination thereof.

Development Phase

6. The guideline development starts with a problem analysis
7. Research questions are developed based on the problem analysis
8. The literature is systematically summarised and presented in a transparent manner
9. The method used to set up the recommendations is is presented in a transparent manner
10. The recommendations are explicitly formulated
11. The guideline contains set and recognisable components and is modular of nature
12. The guideline pays attention to cost and other economical aspects
13. The guideline pays attention to knowledge gaps
14. The guideline contains a proposal to evaluate the implemented care
15. The result of the guideline creation / revision is beneficial to the quality of the guideline

When deciding on new or updated recommendations, the document states to prefer the new method over the old method if there is sufficient proof for its additional value. If there is an uncertainty regarding which method to go for, the advantages and disadvantages of each should be described to support the decision-making processes in practice. Regarding criteria 12, this is explained as making financially conscious and effective decisions in proposing treatments. That means that the preference goes to recommendation alternatives with the most optimal cost-effectiveness. The set sections of a guideline are the healthcare content and general information. The healthcare content includes the research questions, systemic summaries, conclusions, discussions, and recommendations. The general section should include the goal, target audience, method, and included parties.

Completion Phase

16. Before publication, experts and future guideline users are consulted

17. The guideline is approved by at least all primary involved organisations
18. The procedure for (future) guideline revision is presented
19. The primary involved organisations actively work towards improving the application of the guideline in practice

In the final phase before publishing the (revised) guideline, a quality check is done. The guideline has to be approved by all primary involved organisations and is sent to relevant organisations to provide their feedback.

5.1.2. Medical Specialist Guidelines

While the *'AQUA-Leidraad'* document states all criteria that a guideline has to satisfy, the *'Medical Specialist Guidelines'* document provides a more elaborate explanation of all components for clinical guidelines (Adviescommissie, 2021). The vision, development, and methodology of guideline development are further explained in this section, including the shift from theoretical guidelines to practical use.

Medical Specialist Vision on Guidelines

First, the goals of guidelines, as described in this document, are to provide recommendations for qualitative care and to support clinical decision-making. Secondary goals are reducing variation in practice and increasing treatment transparency. These recommendations give guiding advice, which together with shared-decision making allows for qualitative care. Over time, other goals have been connected to guidelines as well, especially from the political-societal perspective. This includes for example, cost-effectiveness, accessibility, and enforceability. These tertiary goals and perspectives go together with different interests, increasing the complexity and number of involved actors.

Guidelines describe care for the different parts of patient's care process: from their diagnosis to after-care and follow-up. The tension points experienced in practice during a patient's care process are the starting points for guideline creation or revision. For medical specialist guidelines, a multidisciplinary method is used for its development. Such guidelines are not focused on one specialty, but rather a condition or process.

The process of guideline development is complex, labour intensive, and the resources for implementation are limited. Prioritising and making responsible decisions regarding guideline revision are thus crucial, especially with the ambition to continuously keep guideline topical. Important considerations to decide on the relevance of a topic for guideline revision or development are thus; possibilities for quality improvement, availability of new scientific insights, seriousness of the condition, and the impact on care within its discipline.

Development and Maintenance of Guidelines

The *'Medical Specialist Guidelines'* document describes the phases in the development and maintenance process of guideline (modules) more elaborate than is done in the *'Guideline for Guidelines'* document. Instead of simply a preparation, development, and completion phase, it is split up into inventory and prioritisation, module development, feedback, authorisation, and implementation phase. This allows for more detailed explanation on specific, important aspects to developing a guideline.

The first step is researching which modules need to be revised or developed. This is done based on new scientific evidence, undesired practical variance, or current implementation problems. This is followed by prioritising the points of improvement, as there is limited available resources. Important factors to make that decision are the potential healthcare improvement for the patient, societal impact such as costs, and practical achievability.

In a module, the literature study is done according to a certain method. First, the relevant scientific augmentations are laid out, which is translated to a research question in accordance to the PICO-format. This format ensures all important aspects of a literature study are included, in which PICO stands for Population, Intervention, Control, and Outcome. Based on the formed research questions, a systematic literature study is performed. Interesting to note is the statement regarding the shift of meaning in use of Evidence-Based Medicine (EBM) in the development of guidelines. The document states that

recently EBM, in the context of guideline development, has been constricted to methodological discussions regarding the level of evidence, shifting its focus to those types of discussions and the statistical hardness of evidence. This is described as a logical progression, as judgements regarding guideline development are always scientific and statistical and could never include the 'individual clinical expertise of the doctor'.

The feedback, authorisation, and implementation phases in this document, describe the same as is written in the *'Guideline for Guidelines'* document under partly the development and completion phase. Two points that are discussed here however, are how to ensure continuous healthcare maintenance, and how to include internationally accredited knowledge. Regarding continuous care development, a permanent guideline organisation has been set up to act fast on including new knowledge in guidelines. However, as there are currently a lot of active guidelines an efficient design is necessary. The current aims of this organisation are the multidisciplinary cooperation during the actuality consideration, module prioritisation, and maintenance implementation. The *Richtlijnendatabase*, or database for guidelines, is designed to facilitate the process of modular guideline revision. Efficiency improvements are still developing, with important points of attention to reduce the administrative steps, install continuous work groups, and alter process components to become more efficient.

International collaborations in literature research and analysis are beneficial to efficient use of time and resources. To promote such collaborations, the introduction, evidence tables, and arguments of a guideline are aimed to be written in English as well. The recommendations and considerations have to be written in Dutch, but can be made available in English for international collaborations. Still, many countries are performing similar literature studies about the same topics. Increasing the number of international collaborations would be beneficial to the efficiency of guideline development. In addition to these collaborations, adapting internationally available guidelines can be beneficial to efficient guideline development as well. Important however, is to critically assess these guidelines before adaptation. This is done based on three criteria: the independence of the guideline, methodological quality, and whether an adaptation is more beneficial than the regular process of guideline development. Only if an international guideline satisfies these criteria, it is worthwhile to adapt these to a Dutch guideline according to the *'Medical Specialist Guidelines'* document.

Methodology of Guideline Development
For Medical Specialist Guidelines, the GRADE methodology is generally used to go from research question to recommendation. GRADE is a transparent framework standing for Grading of Recommendations, Assessment, Development, and Evaluations. This methodological framework rates the efficacy of treatment based on the certainty of the scientific evidence from high to very low (Siemieniuk and Guyatt, 2023). In certain situations, it is not useful to use the GRADE framework, for example when there is no similar research available.

In the case that there is no systematic overview of the available literature, a search strategy is performed to find relevant literature in scientific databases. For this, an information specialist or clinical librarian is required. The found literature is then checked on relevance and systematically summarised, including the search strategy, methodological quality, results, proof of evidence, and conclusions. Here, the GRADE methodology is used as well. Next to scientific evidence, the considerations from practice play a role as well. These considerations are regarding patient values and preferences, costs, acceptance, feasibility, and implementation.

Before the guideline development is kicked-off, the potential conflict of interest of all involved work group participants is recorded. Especially for the chair of the group, it is important that there is no conflict of interest. If these are found among any of the work group participants, restrictions or even exclusions are set in place. To research the potential conflict of interest, the Federation of Medical Specialists has set up a committee that judges this. Besides this, also the organisation of healthcare is considered in the development of guidelines according to the *'Medical Specialist Guidelines'* document. It is not mandatory to include the organisation of care as a module in a guideline, but it adds to the understanding of care in general. This includes aspects such as coordination, communication, (cost) resources, man power, and infrastructure. This is partly already included in the GRADE methodology used in the

development phase. Nevertheless, it is stated that at the moment there is a great variance in guideline modules regarding the organisation of care. The development of such modules is necessary for an improvement in the organisation of care.

From Guidelines to Practice
Then finally, attention is brought to the transition of a newly developed guideline from theory to practice. Important is the accessibility, implementation, and active spread of these guidelines. For this purpose, all medical specialist guidelines have to be published on the *Richtlijndatabase* (Guideline database) and are accessible to anyone. Besides that, it is a digital platform that facilitates the modular maintenance of guidelines. Guideline users can provide input on the content of guideline modules using this platform.

For the support of guideline implementation, tools can be added to help guideline users in understanding and visualising the guideline. Examples are flowcharts, presentations, webinars, or e-learning. Additionally, for each guideline (module), an implementation plan is made which includes a specified period for implementation, and limiting and promoting factors. The actions required by varying healthcare parties are included in this plan as well.

5.2. Empirical Data Analysis

To fully understand the findings from performed interviews, the analytical process of getting to the results is described in this chapter. This includes a description of participant notations, the emotional aspect of the interviews, the comparative analysis, the CCP framework applied to the healthcare domain, and how the interview codes relate to the framework.

5.2.1. Interview Participants

As explained in chapter 4 *Method*, participants with different backgrounds and/or types of involvement were selected. There are participants who have contributed to the development of the breast cancer guideline, participants who use this guideline in their day-to-day life, and participants who provide a patient perspective. This latter includes both people who have been a patient or who have gone through the breast cancer journey along the side, and patient advocates. These three parties have been included as they are mentioned in the *'Guideline for Guidelines'* document as main guideline users (van Zorg, 2012). In addition to that, the patient perspective is relevant regarding the shared-decision making principles, which is a factor to relation between guideline standardisation and professional autonomy. To ensure the anonymity of the participants, all participants related to the patient perspective are grouped together.

Group Indication	Group Description	Number of Participants
G	Contributors to the development of the breast cancer guideline	6
D	Doctors who use the breast cancer guideline in their daily life	4
P	Patients, patient advocates, and patient supporters	3

Table 5.1: Overview of the different types of participants

In order to discuss the results of the interviews while the participants remain anonymous, they are indicated through a letter and number combination. The letter is connected to the group that a participant is part of, as can be seen in Table 5.1. There are three groups in total, one which consists of guideline contributors (G), one with doctors (D), and one for the patient perspective (P). There is a total of eight participants, which means that six fall under group G, four of the eight fall under group D, and three under group P. Some participants may fall under multiple groups, but for anonymity purposes this information will not be stated. This means that a participant can have multiple participant codes, so the code most relevant to the subject at hand will be used. To give an example, Participant X may be an oncologist who is part of the work group for the breast cancer guideline revision. They can then be assigned D2 and G4 for example. A statement given by Participant X in relation to guideline development will then be quoted by G4, and a statement from the perspective of a doctor as D2. Additionally, in the interest of participant anonymity, the quotes are paraphrased in addition to the direct quotes being translated from Dutch to English.

5.2.2. Observational Data

Interviewing participants does not only provide the expert information that is sought after for the research. Through the face-to-face contact, this type of data collection includes observational data such as body language, non-verbal cues, pre- and post- interview conversations and the overall atmosphere of the interaction. While this was initially not considered as part of the data collection, throughout the set of interviews, it was deemed useful for the research as these elements allow for a more comprehensive understanding of some results (Irani, 2019).

The initial approach to the interviews did not include the non-verbal communication as part of the data collection since the goal was purely to get the information on guidelines, professional autonomy, and quality and safety of healthcare directly from experts in the field. It was not considered as potentially useful data for this study. This approach was quickly reconsidered - after the first interview already - when realising that there is significant importance in including the human aspect of these interviews within this research. The reason for this is that the topic of balance between professional autonomy and guideline standardisation was a highly sensitive and emotional one. This was the case for both the patient-centered group and the doctor group, although in different ways. For the patient (advocate) group, some of the emotions came from frustration regarding guideline involvement, closeness to the situation, and the feeling of having to walk on eggshells when discussing guideline related topics with doctors. The strong emotions that some participants from the doctor group expressed, came up when talking about topics related to professional autonomy. That includes the importance, advantages and possible limitations of their professional autonomy, but also the balance between exercising this and using the guidelines. Not all participants showed such strong emotional responses, but more than half of the participants did show some type of emotional response to one of these topics. In fact, a ninth participant was interviewed, but they were too emotionally evoked to continue the interview, which shows that a sensitive topic was touched upon. This indicated the importance of considering the emotional perspective throughout the analysis, as well as the fact that the link between doctor identity and discussions on professional autonomy needed to be explored further.

5.2.3. Comparative Analysis

To draw conclusions from the performed interviews, a comparative analysis on the answers from the three participant groups is done. These are then compared to the literature findings and guideline standardisation documents, for which the results can be found in chapter 6 *Results*. Its aim is to compare and contrast the information obtained from the various interviewees to gain a deeper understanding of the subject matter from three different perspectives. This allows the identification of commonalities, differences, and other significant notions within the data.

The empirical data obtained from the interviews has been coded into six main topics, out of which five have been included in the code tree as depicted in Figure 5.1. These five topics are standardisation, guideline, professional autonomy, balance, and system process. The standardisation block contains all data regarding the systematic approach of equal healthcare through guidelines. The content and development of the guideline itself is analysed separately in the guideline block. All data points related to professional autonomy, which includes its impact on the quality and safety of healthcare, are depicted in the professional autonomy block. The interplay between standardisation of guidelines and professional autonomy is described in the balance block. The final block, system process, includes all data regarding the type of process-based thinking that is used both for the guideline development as well as its use.

The sixth main topic derived from the empirical data is named *'psychosocial elements'* and includes communication between doctors internally and with patients, emotional aspects, and the behaviour of medical practitioners. It is not included as a block in the code tree, as it is a topic that is woven into the content of the other blocks. It is a crucial component of the research, however, which is why it is denoted as the sixth main topic derived from the empirical data. The observational data derived from arranging and performing the interviews is included in the *'psychosocial elements'* aspect as well, as it concerns equal data topics.

The data derived from the interviews is split up into three different views; the guideline, doctor, and patient view. Each block, except for the system process block, is covered per view. This allows for rel-

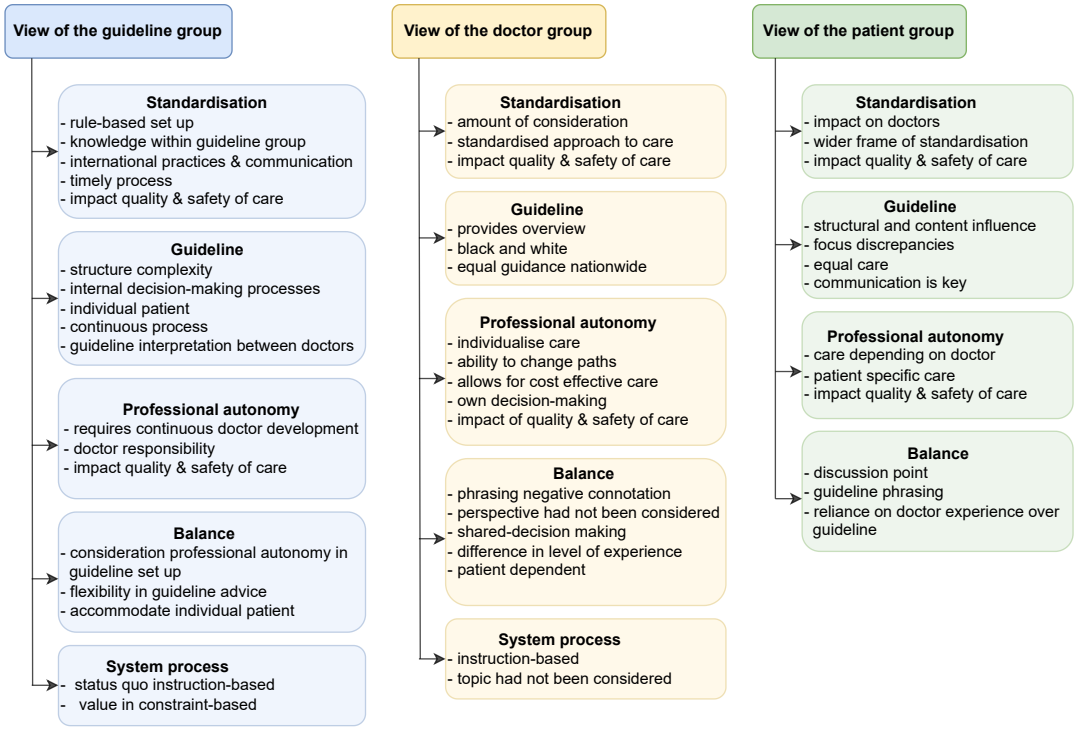

Figure 5.1: Interview Code Tree

atively straightforward comparisons of a block topic between different views. The patient view does not have a system process block as no relevant data on this topic was received from the patient group. The findings and discussion thereof are stated in chapter 6 *Results* and chapter 7 *Discussion* respectively.

5.2.4. CCP Framework Application

As described in chapter 3, the CCP framework works well to evaluate a system within the healthcare domain as it is designed for complex socio-technical systems. This framework is used to validate the findings of the comparative analysis. To generate useful results from this framework however, it is crucial to explain what each aspect means within the healthcare domain and more specifically the topic of this research. This includes an identification of all perspectives that are important to include and how this influences each aspect of the framework.

Content, Context, and Process

The content aspect of the framework evaluates the set information or knowledge within the system. Within the topic of this study, this means that the standardised approach to breast cancer healthcare through its guideline falls under the content aspect. That means that the set-up of the guideline, how this is standardised, and breast cancer care are considered as content. It should be noted that the focus of this research lies on the standardisation of the guideline and not on the actual content of the breast cancer guideline. Nevertheless, important content-specific comments on breast cancer that have been made by participants are included within the content aspect of the framework.

The evaluation of professional autonomy, its importance, advantages, and limitations, falls under both the content and context aspects. Professional autonomy, as described by Hoogland and Jochemsen (2000), is a standard for medical practices. As a given, it is used in combination with the guidelines to provide qualitative care and it is necessary to do so. For this reason, professional autonomy is a concept that falls under the content aspect. However, there are many contextual aspects to professional autonomy that make this a concept that is covered by both the content and context aspects. Professional autonomy is subject to the experience, knowledge, medical behaviour, and responsibility of the medical practitioner that exercises it. These are not concrete entities but rather contextual aspects that can be influenced from internal and external environments. It is for that reason that professional au-

tonomy is considered between the content and context aspect of the framework, depending on which aspect of professional autonomy is being analysed and discussed.

The evaluation of the context part of the framework is about the context in which guideline standardisation and professional autonomy play a role. That includes internal and external environmental influences within the healthcare domain, but also the *'psychosocial elements'* of doctors and the individual circumstances of patient care. This context plays a crucial role in understanding the potential collision and preferred balance between standardised guidelines and professional autonomy.

The process aspect of the framework is multi-faceted within this study, as there are three types of processes that can be identified. First, the standardisation of guidelines is a process on its own. The process that standardisation describes is the path to reach a standardised approach to care through guidelines. This comes with its own external influences, such as the increased involving interest of governmental institutions, insurance companies, and healthcare authorities, which impacts its process as well. The view of all three participant groups, G, D, and P, on the standardisation of guidelines is explored between the content and process aspect of the framework, as it goes hand in hand with the guideline as evaluated under the content aspect.

Second, a big part of the CCP process component is the system based process mindset of both the guideline developers and medical practitioners. In chapter 3 *Theory*, the instruction and constraint based processes are described, which are used to identify the differences in process based mindset between guideline developers and guideline users who are not involved in guideline development. This allows for an identification of discrepancies between the system based process that is used to set up systems within the healthcare domain and the mindset of those who use these systems in reality. Exploring these processes allows for a deeper understanding of potential collisions and preferred balances between standardised guidelines and professional autonomy. Additionally, Stockdale and Standing (2006) considers communication to be a part of the process component as well. In this case, communication relates to the communication between the doctor and patient. This process mainly considers the shared decision-making processes between doctor and patient, but includes the multidisciplinary consultation between doctors as well. Within the application of the framework, this aspect of communication falls under the description of *'psychosocial elements'* which is applied under both the context and process aspect of the framework.

Two of the sub-research questions concern the impact of guideline standardisation and professional autonomy on the quality and safety of healthcare. Within the framework, these are considered as factors that are impacted by standardisation and professional autonomy, and are therefore included in the sections that describe these.

Perspectives

The CCP framework allows for the incorporation of multiple perspectives, which can be selected based on relevance to the project. For a complete evaluation that includes a broad range of perspectives, the following four are recommended: social, technical, economic, and political. While many other perspectives can be valuable as well, these four allow for a basic foundation (Cherp et al., 2018). For the purpose of this study however, a different selection is made. From the four basic perspectives, only the social and technical perspective will be considered, rephrased as the human perspective. While an economic and political perspective are valuable, and would provide a more complete picture, it was decided not to include these. To keep the scope of this study realistic, it was necessary to make a selection of the most relevant perspectives in light of the topics considered. The study is regarding a complex socio-technical system in which the focus lies on the technical perspective of guideline standardisation and the human perspective that comes with professional autonomy. This is simply because both perspectives have a different take on guideline standardisation and professional autonomy as well. The political and economic perspectives are left for future studies due to the limited time and resources for this research.

The human perspective looks at interactions, relationships, and behaviours. It considers factors such as roles and responsibilities, power dynamics, communication patterns, and social hierarchies. This

perspective delves into the social implications of decisions, how individuals and groups influence each other, and how broader human aspects impact the functioning of a system. Within the healthcare domain, this is a very relevant perspective to include as the decision-making processes and communication between doctors internally and between doctors and patient are crucial (Land, 2000).

The technical perspective involves the examination of processes, systems, and tools within a certain context. In this case, that context would be standardised guidelines within the healthcare domain. This perspective addresses aspects like data management, system reliability, security, and efficiency. The goal of this perspective is to understand how a system is used to achieve specific goals, how it interfaces with users, and how it shapes the overall performance of a system.

In addition to the human and technical perspective, the organisational perspective is taken into account. From literature, personal communication with experts, and the interviews, it was found that the organisational structure of the healthcare domain, guideline set-up, and guideline use is a valuable point to consider. This perspective was formed through the different views of different groups on the organisational structure, as this could indicate discrepancies between intended set up and actual use of healthcare systems. For this purpose it was deemed important to include the organisational perspective in the framework too.

The third perspective included in the CCP framework, the organisational perspective, focuses on the structure, processes, and dynamics of the entities involved in a system. It examines how roles and responsibilities are distributed, how decision-making occurs, and how workflows are managed. This perspective also considers aspects like organisational hierarchy, communication, coordination, and adaptation to change. It aims to uncover how the structure of an organisation or system influences its interactions with other entities (Gal and Berente, 2008). The combination of these three perspectives allows for a holistic understanding of the system's dynamics, interactions, and impacts.

Data Integration into Framework

The application of the data in the CCP framework has multiple aspects. The three participant groups, five data blocks, and three perspectives integrated into a framework with three aspects requires a clear explanation of how each part is analysed, what the interrelations are, and how this leads to comprehensible findings. This section aims to provide a clear overview of these interlinkages.

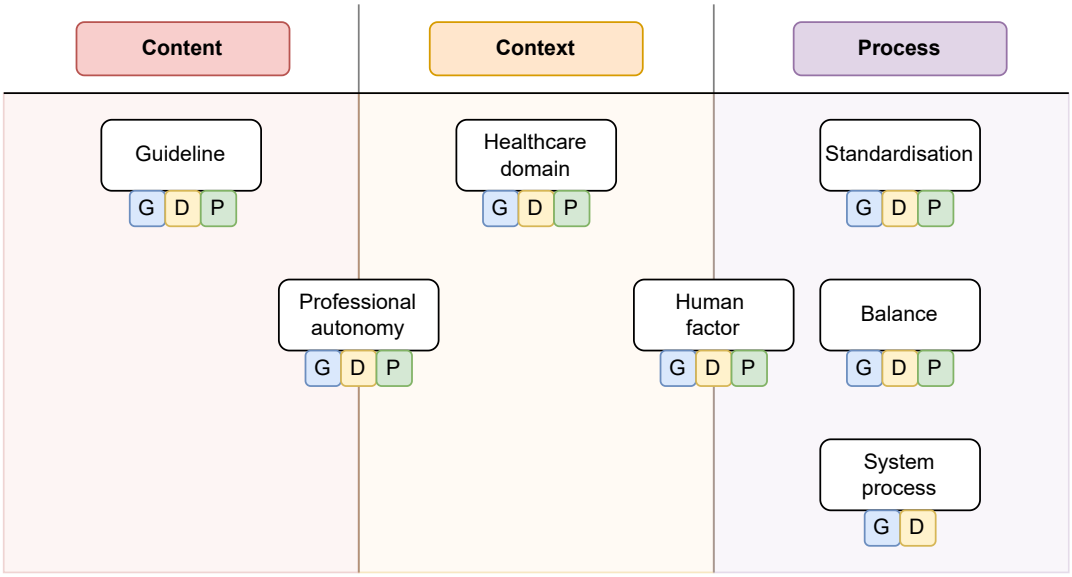

Figure 5.2: Data Integration into Framework

As explained in chapter 3, the CCP framework allows for an elaborate evaluation of a socio-tchnical system through the identification of the content, context, and process aspects. An overview of all

the data contributing to the analysis is depicted in Figure 5.2. It includes the five blocks as shown in the code tree in Figure 5.1, but also a block for the healthcare domain and psychosocial elements. Although these two blocks are not included in the code tree, they are important parts to the research and crucial to the completeness of the framework. Through both observational and empirical data, information has been provided by all participants on the influences of the psychosocial elements and healthcare domain on its systems and processes. In Figure 5.2, a clear diagram is shown of which blocks are evaluated under which aspect of the framework, including the different participant views that have provided insights on the topic. The human, technical, and organisational perspectives are not shown in this diagram as all three are applied to each block shown in the figure.

6 Results

This chapter states the findings resulting from the analysis performed in chapter 5 *Analysis*. The structure of the chapter follows the code tree depicted in Figure 5.1. First the findings of the guideline, standardisation, and professional autonomy aspects are stated, which is followed by the balance of these three aspects. The results of exploring the organisational structure of the guideline set-up and its use, the healthcare domain, and the psychosocial elements follow. To conclude and validate the findings, the CCP framework is used to evaluate the areas that will require the most attention in future studies.

6.1. Guideline

The findings regarding the definition, structure, set-up, use, advantages, and limitations of the breast cancer guideline are stated in this section. Figure 6.1 indicates the key statements given by the participants regarding these topics. The discrepancies and consistencies between participant views are explained using their examples. These statements are also compared with the theory and theoretical analysis of the guideline standardisation documents.

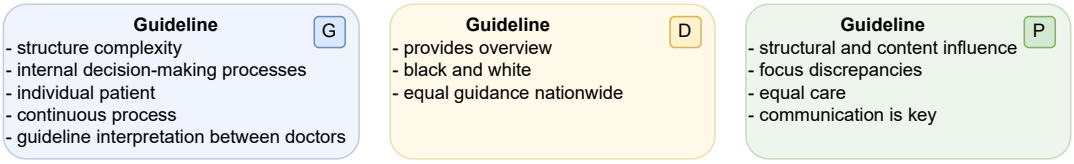

Figure 6.1: Guideline section of the code tree

6.1.1. Guideline Definition

As stated in chapter 3 *Theory*, a guideline is defined as a systematically developed and evidence-based set of recommendations intended to guide medical practitioners in providing consistent treatment nationally. While this definition resonates with the participants, and the core definition provided by the participants is similar, they each highlight different aspects of what defines a guideline. A consensus among the participants is that a guideline is a continuously developing entity that provides guidance to medical practitioners. The patient group highlights in their definition that the guideline is developed for the average patient, emphasising on the fact that most patients are not average. In the guideline standardisation documents, that aspect is considered as part of the shared-decision making practices during consultation, and is not a part of the definition of a guideline.

Participants from the guideline group had multiple additions to the definition of a guideline. Participant G4 states that a guideline is purely indicative, as they are well aware that the scientific evidence and the interpretation thereof can fluctuate. In their opinion, the most important thing about a guideline is that it explicitly says that it is not definitive. This statement can also be found in the *'Guideline for Guidelines'* document, stating that guidelines are not strict prescriptions, but rather contain explicit, evidence-based

recommendations. Another point made by Participant G4, is that the guideline should not be used as a "law to be interpreted literally". It is meant to guide the medical practitioners, but more importantly it is meant to provide different possibilities that could fit the patient best. This ties in with the point made by participant G2, who states that one of the aims of the guideline is to aid in the shared-decision making between both doctors internally and between doctors and patients. In practice however, this principle is not always adopted even though it is one of the goals of guidelines (van der Weijden et al., 2010). While the guideline itself purely contains advice on the most optimal diagnostics and treatments, it is how the guideline is handled that defines its use. This raises the question whether the current structure and preferred use are clear enough to guideline users. There is a consensus among the guideline group that communication and shared-decision making is what makes a guideline most effective, even though that is not a part of the guideline definition.

The most important aspect of a guideline, in the perspective of the doctor group, is the fact that a guideline provides support to medical practitioners and that each healthcare professional uses the same support system to provide consistent care country-wide. Their view on the guideline definition is less elaborate than that of the guideline group or as is intended from the guideline standardisation documents. Participant D2 actually posed that a "guideline is quite black and white"; you either follow its advice, or you do not. This is an interesting statement when combined with that of participant P2, who mentioned that some consider the guideline to be a safety net even though that is not its purpose (Adviescommissie, 2021). Combining the statements given by all participant groups, a more complete guideline definition would be 'a continuously developing set of recommendations based on scientific evidence and its interpretation to guide medical practitioners in providing consistent treatment nationally and patient specific care through shared-decision making'.

6.1.2. Guideline Structure and Set-up

As stated before, a healthcare guideline in the Netherlands has to be set up in accordance to the guideline for guidelines as described in AQUA-Leidraad or 'Medische Specialistische Richtlijnen'. These provide attention points and required considerations for the development and revision of guidelines for qualitative healthcare (Adviescommissie, 2021; Zorginstituut, 2021). Participant G6 summarised the use of these documents as the set up or revision of a guideline that starts with a bottleneck that is identified in practice. There could be a new law, medicine, diagnostics, or another issue that requires revision. A so-called work group is assembled who will analyse the bottleneck and start performing scientific research in the available literature to find the new information necessary to update the guideline (G6, personal communication).

When an initial revision is performed, this new version is peer reviewed by other medical practitioners through multiple rounds until the revised guideline has been checked often enough that all parties contributing agree with the renewed content, which is in accordance to criteria 16 of the *'AQUA-Leidraad'* (G4, personal communication; Zorginstituut, 2021). This process has both advantages and disadvantages for the content of the guideline. The advantage is that there is a high level of quality control and that eventually the guideline is widely accepted. Its limitation however is that the guideline is never as up to date as the scientific knowledge available. This gives the disadvantage that a patient looking for the best possible care for their situation is dependent on having a professional who can add to the guideline through their own expertise along with the patient wishes (G4 & G2, personal communication).

From the guideline group, a critique has been raised on this process of guideline revision. In their opinion, there are too many rules on how to set up a guideline in the Netherlands. A lot of revision and scientific work is done repetitively, or has been done in accordance to health standards internationally. Multiple guideline group participants are of the opinion that this many rules and checks are redundant. Considering the analysis of the guideline standardisation documents however, the use of internationally accredited resources is stated as a way to increase the efficiency of time and resources for guideline development (Adviescommissie, 2021). Included is also the use of English in Dutch guidelines to strengthen this cooperation. Relating this to the statements by the interview participants and the lack of English in the guidelines published in the Guideline Database (Richtlijnendatabase) however, results in the hypothesis that these international cooperations occur a lot less frequently than would be optimal.

There are multiple factors contributing to guideline revision. Rules regarding guideline set-up and dilemmas on the readiness of literature have been mentioned so far, but also the consideration of the individual patient, care outside of treatments, and decisions on section revisions are relevant topics. Another dilemma in guideline revision is the question of how to incorporate information if it is not yet fully certain whether this new information will be part of an essential treatment. Guideline revisions are not a fast and flexible process, resulting in these sorts of dilemmas. The scientific research is fast-paced, while the process of guideline revision is relatively slow. In addition to the question whether the literature is ready to be included in a guideline, another point of discussion is how elaborate the guideline should be and what topics it should cover. In the words of participant G4, “the guideline is already very elaborate and it is not possible to make it so elaborate that it incorporates all variables and pathways”. Discussions on what is important to include and what should be left to the professional expertise of doctors thus remain relevant. That raises questions like ’how do we decide what is important enough and what is not? Can we formulate criteria to determine this?’

In the words of participant G1, there is no structural method to decide which topic needs revision. It is dependent on the participants of the work group and their opinions on what should be updated. While this is a group of experts in the field, another participant raised the concern that that might create a bias towards what will be revised. This raises questions regarding the topics that were not chosen to be updated or added at the moment of guideline revision. What happens to those topics? Is it left to the doctor’s professional autonomy to be up to date on this information themselves? This adds to the complexity of guideline revision, but also the balance between guideline standardisation and professional autonomy. To compare this with the information in the guideline standardisation documents, there is indeed little information given regarding the problem analysis and prioritisation details. The concern for bias within the work group is addressed in the *Guideline for Guidelines* as its own criteria, criteria 5. With a dedicated committee to counter a potential conflict of interest, it is attempted to limit this influence but specific details are lacking (Zorginstituut, 2021; Adviescommissie, 2021).

The phrasing of its content is a precise process as well. Participant G6 mentions that two hour discussions about the inclusion of a word or two in a recommendation have occurred. Thus, even though a lot of thought is put into the wording and content of the guideline, there are still a few points of discussion. One point that has not been stated yet is regarding the consideration of the individual patient in the guideline. The consensus of the guideline group was actually that this topic has not been considered much, although it has gotten more attention in recent years. The guideline is written on what is best for a patient based on scientific evidence; other factors such as patient desires and situations are not or barely present, as this is ”to be discussed in the consultation room” (Adviescommissie, 2021). In the last revision however, explicit paragraphs have been included in the guideline on the fact that decisions should be made with the patient through shared-decision making, and that their individual desires should be incorporated. Participant G3 mentions that although this is an improvement regarding the inclusion of individual patient considerations in the guideline, there is still work to be done. A point that they mention is the fact that the full focus of the guideline is on its treatment and the survival of breast cancer. While those are of course important and rightfully so the main focus of the guideline, the quality of patient life is subordinate. There is little consideration for the impact of treatments on the quality of life, while that ultimately should be a big focus (G2 & P2, personal communication). This indicates that guidelines are not designed for having this shared-decision making support, even though some interviewees do say so. Relating this back to the guideline standardisation documents, it is mentioned that the primary goal of guidelines is to aid the shared-decision making processes that occur in the consultation room, but there is indeed limited information on how to design the guideline in a way that supports that (Adviescommissie, 2021). Briefly mentioned are the possibilities of creating a so-called selection aid (keuzehulp) or choice card (keuzekaart) for support, but that is about the extent to which it goes.

6.1.3. Advantages & Limitations

The advantages and limitations of the guideline with its current structure and development process are explored in this section. The arguments given by each participant group are stated in Table 6.1 under either the advantages or limitations column. A few statements can be derived from this table, both in consensus and contradiction.

Group	Guideline advantage	Guideline limitation
G	Guidelines allow for standardised diagnostics and treatment nationwide based on evidence and scientific deliberations New scientifically relevant information gets spread relatively fast Doctors do not need to follow all scientific literature themselves	A guideline can seem compulsory, even if that is not the case. With proper motivation, you can and sometimes have to take a step back Updating a guideline is a slow and bureaucratic process, which results in the guideline always being behind in practice as doctors already know the new information A patient can say they were not treated as stated in the guideline The guideline is a snapshot of the moment during which revision was done, which may be different from the current knowledge state by a few years Not all medical variables can be included in the guideline
D	A guideline provides equal support to all practicing doctors, resulting in an equal foundation in care It provides an overview of all best proven treatments	More complex treatment plans cannot be written into a guideline clearly You have to give proper motivation if you want to deviate from the guideline
P	It is a good resource to explain to patients why they receive certain treatments The guideline is developed by doctors themselves through scientific literature It enables equal care in hospitals all around the country	The guideline is a consensus of the work group that develops it

Table 6.1: Guideline advantages and limitations

The participants from the guideline group had a lot to say regarding both the advantages and limitations of the guideline. A few remarks can be made regarding their statements. First, it was mentioned by one participant that a guideline is a useful tool to spread new scientific information to doctors fast. This allows doctors to spend less time researching new scientific developments. However, two other participants noted that the process of updating a guideline is a slow and bureaucratic process, resulting in the guideline always being behind on available evidence-based medicine. In fact participant G4 said that “the guideline is a snapshot of the moment during which revision was done, which may be different from the current knowledge state by a few years”. These are two contradicting statements made by participants within the guideline group, indicating that this is indeed a point of discussion, as was identified in the literature study (Shekelle et al., 2001).

Another set of statements that will play into this point of discussion, is the discrepancy between the advantage statement “doctors do not need to follow all scientific literature themselves” and the argument given in the limitation that there is a difference between what is said in the guideline and what happens in practice as “doctors already know the new information”, as said by guideline participants. Actually, a third point of view comes into play as participant D3 mentioned that they ’‘use the guideline as their source of information so that they do not need to do their research to remind themselves what the details were”. This indicates that there are discrepancies between what the guideline group thinks doctors do and what they actually do, and there are discrepancies between the flow of information to doctors through guidelines and scientific literature.

Interesting to mention is the disadvantage mentioned by participant D2 that “proper motivation has to be given if one wants to deviate from the guideline”. In accordance to the ‘Medical Specialist Guidelines’, a motivation for deviating from the guideline has to be written in the patient file. The fact that this is seen as a disadvantage of the guideline rather than a form of necessary and useful quality control, indicates a difference in guideline view from guideline developers and users. It should be noted however that this sort of statement was given by only one participant. The patient group raises a relevant point as well, stating that it is beneficial to the guideline that it is developed by doctors themselves through scientific literature, but a limitation of guideline revision is that it is a consensus of the work group that develops it as they identify the tension points to be tackled.

6.2. Standardisation

Now that the findings of guideline definition, development, and use have been stated, the results of the standardisation of the guideline can be considered. The findings on the impact of guideline standardisation on the quality and safety of healthcare is stated as well. The key statements given by the patients

regarding the standardisation of guidelines, as indicated in the code tree, can be seen in Figure 6.2.

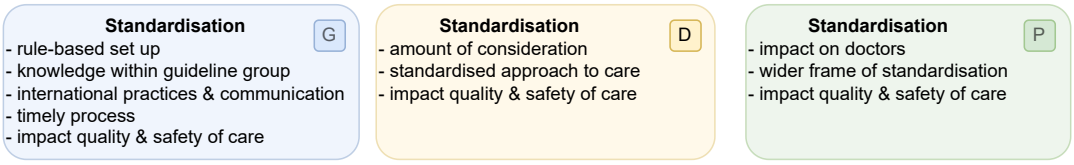

Figure 6.2: Standardisation section of the code tree

Some aspects that have been stated under the findings of the guideline block actually have to do with the standardisation of the guideline as well. The set up of the guideline through the set of rules and process of quality control is part of its standardisation. Through the guideline standardisation documents a standardised approach to developing guidelines is present. This section outlines the view of the interview participants on the current process of guideline standardisation and its relation to these documents.

To start with the guideline group, a consensus can be found regarding the set of rules used to revise or develop a guideline. In their opinion, too many rules have been formulated resulting in a slower process of guideline revision than necessary. Participant G6 states that the standardisation of guideline development as written in the 'guideline for guidelines' document is too strict. A lot of time is lost in working solely evidence-based and not taking advantage of the knowledge and experience of the medical experts present. They can identify the main tension points that require attention and indicate preliminary pointers. More freedom to write sections based on their autonomy would be beneficial to the timely process of revising guidelines in their opinion (G6, personal communication). The rewritten sections still undergo multiple round of quality control, so if incorrect information had been written, it should be filtered out.

Multiple participants have pointed out that the process of guideline development can also be reduced in time by making more use of international guideline findings. In the words of participant G2, "treatments have often already been fully researched and documented internationally and in the Netherlands we have a whole circus of going round and round with a research question. There is even a guideline for guidelines". They are of the opinion that a lot of work is done repeatedly, even though some of that work has been proofed and checked internationally. Participant G5 would like to see some form of standardised guideline approach on a European level at least. Both for the purpose of decreasing how long this process takes, but also to learn from the different views on certain diagnostics, treatments, and medicine from other countries. In that case, good quality control is of course crucial, but that could be incorporated in the current quality control system in the Netherlands. This impacts the question that was raised earlier regarding what should be included in a guideline, but also raises a new question. In the standardisation documents, the inclusion of internationally accredited research is described and indicated as an option. Then why do the guideline developers of today feel like this does not, or barely, happen?

Standardising the process of guideline revision does help to reduce the amount of time, as the work group would need to spend less time discussing in what way to tackle the guideline revision. The guidance of a non-medical specialist who understands the process and healthcare domain also aids in stream lining the discussions and guideline revision. At this point however, it has become so overly processed that the standardisation has actually become a delaying factor (G6, personal communication). An example of this is the authorisation process of rewritten guideline modules. If an involved medical association needs to authorise sections, but only gather to discuss these a few times per year, it is possible that the work group needs to wait a few months before an answer is given. At that point however, the literature might have been updated already resulting in a delay. Additionally, it delays the improvement of care a revised guideline can offer. These types of slow decision-making processes result in difficulty of delivering the most up-to-date care as possible. On the other hand, trustworthiness and quality of a recommendation is key. That results in a tension point between quality control and remaining at the leading edge of healthcare.

The doctor group had not given the process of guideline standardisation much thought before the interview took place. They value that there is a standardised approach to care and see its importance to provide equal care among hospitals in the country where applicable. No comments were given however on influence of guideline standardisation on the guideline specifically, as that was not a topic they had considered before (D2 & D4, personal communication). Similarly for the patient group, their views were also not regarding the guideline standardisation process, but rather on the impact of standardisation on doctors. This point of view is sensible however, as this group does not develop or use the guideline in their professional lives besides the shared-decision making processes. They view the guideline standardisation as a way to equalise care by guiding doctors onto the same path. The impact this would have in their opinion is to increase the performance of doctors whose experience is limited, but also to limit the performance of doctors who have a lot of experience (P1 & P2, personal communication).

6.2.1. Impact on Quality & Safety of Care

An important aim of standardisation is to increase the quality and safety of healthcare. This section explores the view of guideline developers, doctors, and patients on the reality of its impact on the quality and safety of healthcare.

The consensus of all participant groups is that standardisation increases the quality of care. Doctors have easy access to standardised medical information and can reach the right treatment path well (D2, personal communication). One point that is made by two participants (G4 and G5) however, is that it is still dependent on the doctor who is treating the patient. In their words, standardisation increases the quality of care on the condition that the doctor adheres to the guideline. That includes their experience and professional autonomy as well, which cannot be caught by a guideline. In the words of participant G4, “one should be careful moving the judgement of safety and quality of care to impersonal situations”. Psychosocial elements are a big part of all healthcare systems, which can often be forgotten. It is an aspect that is not included in the guideline standardisation documents for example. At the same time however, psychosocial elements are not quantifiable variables, making it more difficult to find a way to incorporate them into such documents.

Also regarding the safety of healthcare, the consensus of all participants is that generally speaking the impact is positive and similar statements are given as for the quality of healthcare. However, there is also ambiguity about trying to connect safety of healthcare to guideline standardisation. Participant G3 believes that they are two concepts that are not closely related to each other. Considering safety of healthcare relates more to protocols and medicine doses in their opinion, which signals a very limited understanding of safety in healthcare. Interesting to observe is also the fact that safety of care is not considered in the guideline standardisation documents, besides a short statement that effective and safe care is expected to be given (Adviescommissie, 2021). In combination with the statements of the guideline group, that raises the question of how much safety of care is considered in the development of guidelines.

Another opinion is that the guideline does not guarantee the safety of healthcare. In the words of participant G4, “the fact that we are living beings implies uncertainties”. If the guideline were created with the goal of implying a guarantee for the safety of healthcare, you would create a false sense of security. In fact, if any doctor promises full security for a treatment plan, then they are making false promises. Participant G4 is of the opinion that it is a societal problem that absolute safety is sought after, when that is a concept that does not exist. The idea that this could exist, is the foundation of unrealistic expectations (G4, personal communication).

6.3. Professional Autonomy

Professional autonomy is a crucial and key aspect of providing healthcare. But as a concept that is important yet subjective, discussions remain ongoing about how much space there should be for professional autonomy in healthcare. This section maps out the opinions of guideline developers, doctors, and patients on the importance, advantages, and limitations of professional autonomy. The impact of professional autonomy on the quality and safety of care is considered as well. The key findings per

participant group as stated in the code tree are indicated in Figure 6.3.

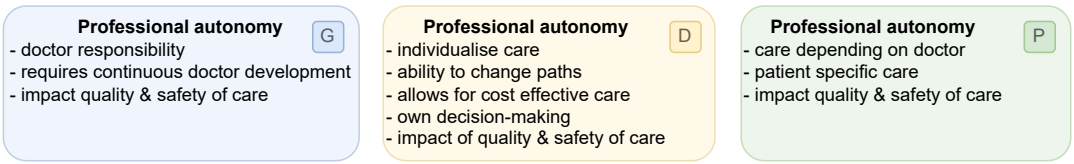

Figure 6.3: Professional autonomy section of the code tree

Participant G4 defines that professional autonomy exists as a concept to personalise a guideline in a professional manner, keeping in mind the advantages and disadvantages of multiple variables. It should not become an excuse to suggest just any unfounded suggestions to a patient, as that would be irresponsible. A big part of professional autonomy is the personal responsibility of a doctor to consider the best treatment plan for a patient with them. This responsibility consists of explaining the advantages and disadvantages of a treatment or situation well and discuss all alternatives in a professional and objective manner. Participant G2 indicates that a part of a doctor's professional autonomy is also the shared-decision making with patients as the doctor uses their knowledge to present all treatment options considering the patients wishes. For that to be possible, a doctor needs to be aware of the latest developments regarding scientific medicine and needs to be connected with the patient's background and desires. Participant P2 ties into this opinion stating that "if you have the luck of having a geek of a doctor, then I'll award them all the autonomy". But if a doctor is too convinced by their own experience and knowledge stating that "I always do it like this, I've never had a negative response to this", then that can give a patient a negative impression of the doctor's professional autonomy (P2, personal communication). This is in line with the research by Traynor et al. (2010a), who stated that the complexity of professional autonomy is the consequence of it relying on the subjectivity of the medical practitioner.

Professional autonomy does not only allow the doctor to make the best choices regarding a patient's treatment plan, but it also allows them to protect them from unnecessary expensive treatments. This, once again, goes hand-in-hand with doctor-patient communication. Participant G4 explains how they would rather spend half an hour explaining to a patient why a certain scan is not necessary than quickly getting a signature for an expensive treatment. It is all about the interpretation of a guideline and using professional autonomy to personalise that interpretation. This point of view however differs between the different interview groups. Participant D4 mentions that the most important aspect of professional autonomy is that "I can take my own policy decisions and can base those off of my considerations". They value professional autonomy above the guideline as treating a patient is a subjective interpretation of their situation. "Autonomy plays a big role in that decision of whether someone can get my treatment" (D4, personal communication). Professional autonomy, as a consensus from the doctor group, is important to have, as it is important to use the expert knowledge and experience of a doctor. It should be mentioned however, that in their professional opinion a guideline is useful and important too, but their professional autonomy might be even more important. Considering the reasons for limited guideline adherence, as given by Nino de Guzman et al. (2020) in chapter 3 *Theory*, the results from the empirical analysis propose that the judgement of healthcare professionals should be added to this list of reasons, which were patient individuality and preferences, clinical experience, and systemic issues.

6.3.1. Impact on Quality & Safety of Care

Sometimes, it is necessary to deviate from a guideline to provide the best care to a patient. In that case, professional autonomy is a quality increasing concept, which ultimately increases the safety of care as well. This is on the condition however that the word professional is defined correctly, including a doctor's responsibility, knowledge, and experience (G2, G4 & P2, personal communication). Through the phrasing of their statements, it can be deduced that they see that safety of care is improved once its quality has. Going back to the six dimensions necessary for qualitative care in the Netherlands, safety is considered to be one of these dimensions (IKNL, 2023). This indicates that the interviewees see

the relation between the quality and safety of care differently than defined by healthcare organisations. Another aspect regarding the quality of the professional use of autonomy is to appreciate the patient for who they are. If a patient would rather stop with the subscribed treatment plan and try homeopathy instead, then those wishes should be respected. That is a part of a doctor's professional autonomy and its quality as well (G4, personal communication). This aspect considers the patient-centered dimension of quality.

For the safety of professional autonomy, two specific aspects were identified. Participant G4 mentions that volume is an important factor to safety, in which volume is defined as how many people with breast cancer a doctor sees per year. There are a lot of options regarding treatment plans, so if a doctor only sees 50 people per year, then they are never able to compare all options and gain as much experience as possible. A factor to the safety, but also quality, of professional autonomy is thus experience through volume of patients (G4, personal communication). The second aspect contributing to the safety of professional autonomy is the mandatory continuity of education for doctors. It is crucial that doctors are aware of the latest developments, which requires them to remain educated. For that purpose, it is required for a doctor to obtain a certain amount of 'education refresher points' in the GAIA register. While its purpose is to increase the safety and quality of healthcare, participant G3 critiques that it is not a guarantee as the points are awarded for attending. Whether a doctor has actually refreshed their knowledge or not is not tested.

Participant D4 indicates that the question on the impact of professional autonomy on the quality and safety of healthcare is difficult to answer. They state that safety of care is the same as quality of care in principle, as negative qualitative healthcare would also indicate low safety. The doctor group does however indicate its impact as positive, as professional autonomy means individualised care, protecting patients from unnecessary side effects (D2 & D4, personal communication). Nevertheless, these statements indicate that the definition of safety in care is unclear to some medical practitioners, as safety and quality of care do not describe the same principle.

6.4. Balance Standardised Guidelines and Professional Autonomy

This section states the findings of the participants' opinions on the balance between standardisation through guidelines and professional autonomy. Their view on the current state, potential conflicts, optimal balance, and accommodation of the individual patient within this balance are stated here.

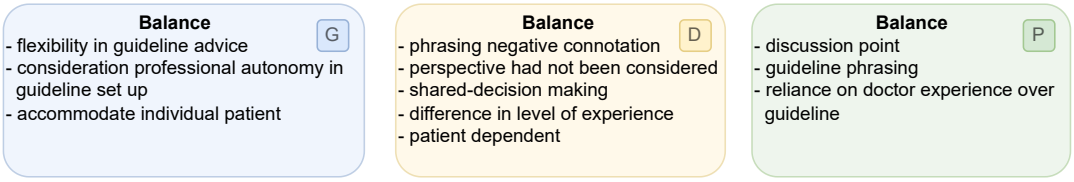

Figure 6.4: Balance section of the code tree

Before considering the findings on the topic of balance, the implications of using the word balance to describe this relation are explored. It was found during the interviews that the word balance in this context was initially perceived with a negative connotation. Participants either started by mentioning their opinions regarding conflicts between the two concepts or more directly said that "a balance suggests that one contradicts the other" (D2, personal communication). The word balance is scientifically speaking a neutral term, implying that there are social and contextual factors playing into their view on this word.

Regarding the findings on the balance itself, it seems to be a topic that many participants had not considered prior to their interview. This allowed for insights on the trail of thought of some participants to their opinion on this balance. Participant G2 went from "guideline standardisation and professional autonomy do not contradict each other, so I am not sure if there even is a balance. They are two concepts that go well together" to "guideline standardisation and professional autonomy can contradict

each other a little sometimes, but it works well together. It does complement each other". A first point that can be identified from this, is that this participant identified the word balance as a relation between two contraries. Second, they got to the result that although there can be contradictions at times, it does work well together. These contradictions come from uncertainty in space regarding how much a doctor should stick to a guideline or use their autonomy to profoundly deviate from it. A contributing factor to this uncertainty is identified as the years of experience of a doctor and their confidence to deviate (G2 & G4, personal communication).

From the doctor group, another intriguing observation was done regarding the phrasing of words. While they interpreted the conversation about a balance with a negative connotation as well, they put this on the guideline aspect. "Guidelines are not an obstacle for me, but rather a guidance," as said by participant D4. This differs from the view of the guideline group who simply interpreted the word balance with a negative connotation, but not necessary towards one of the two aspects. Nevertheless, the doctor group does not view the guideline as something that limits them in their professional autonomy. They view it as a useful guidance and two intertwined concepts. Participant D3 identifies no conflicts within this balance because of how they view it. A guideline is dynamic and not a law. It is not something you can hold a doctor responsible for or oblige a patient to follow. In their opinion, this is a topic that guideline developers should consider more.

Participant G4 describes the balance as "you use the autonomy to modulate the guideline. The guideline is an instrument that you can turn in many ways and through your autonomy you can adapt it to a preferred setting". This is also how the individual patient is considered within the balance, as the general consensus is that it is not a part of the guideline itself. This description aligns with the general consensus of the guideline group, which is also the point of view gathered from the guideline standardisation documents. How much space there should be for professional autonomy next to the guideline then, is a question that participants were unable to answer as they are intertwined concepts. Participant P2 agreed that discussions regarding this balance have been ongoing for quite some time, but always remain vague, as was found by Carlsen (2014).

6.5. System Process

The purpose of considering the system based process of guideline standardisation and guideline use is to explore a potential cause of balance discussions remaining vague and unsolvable. To do so, the instruction and constraint based processes, as explained in chapter 3, are used. Participants identify the type of process based on an explanation of these two processes.

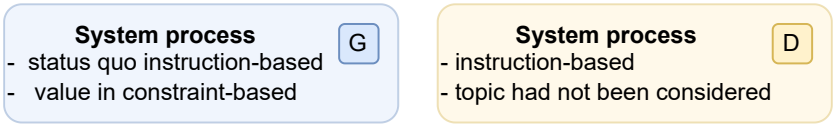

Figure 6.5: System process section of the code tree

The consensus of both the guideline and doctor group is that the current structure of the guideline is based on an instruction-based process. There is a directive path that indicates certain decisions or treatments to follow (G2 & D4, personal communication). The same goes for the set-up of the guideline, which follows the process of finding a tension point, performing a literature study, and writing down the new findings. However, participant G6 relates that it is not as simple as that. In their opinion, arguments can be made for both types of process based thinking regarding the set up of the guideline. At the start of a guideline revision, the tension point might be known, but the final solution is not. To reach that point of a final solution, the process of performing a literature study and finding the optimal path, would follow an instruction-based process. However, the process of performing a literature study to find the end solution can be described as more constraint-based as the path towards the final goal is unknown. Considering both arguments, the participant is of the opinion that the set-up is still more instruction-based, but would benefit of a constraint-based process instead.

This way of guideline set-up translates to the structure of the guideline. It is inherently instruction-based as it shows a clear path for doctors to follow. From their point of view however, the reality of the guideline set-up follows a systematic process that is somewhere in between the instruction- and constraint-based process. Participant D2 thinks that the guideline indicates clear paths to follow, but it is important to be able to take your own path. If it were a complete constraint-based system however, in which a doctor could choose the whole way, that would be unacceptable. A system that would include check-points, but is constraint-based otherwise would work quite well in their opinion. This need for flexibility in guidelines was identified in the literature as well, but is hard to find in the guideline standardisation documents (Lehoux et al., 2019). Instead the flexibility aspect is shifted towards the professional autonomy of healthcare professionals.

A few guideline participants actually looked into creating a different form of guideline lay-out to improve its readability for doctors with minimal time. One way is to visualise the data through a sort of flowchart that works with checks (G5 & G6, personal communication). Participant G4 was not too content with this system, as it is not possible to take a few steps back and change direction in the guideline flowchart. A system that would rely more on a constraint-based process could be beneficial. This ties in with an example given by participant D3, who is in favour of a constraint-based system as guideline information remains clear even if treatment paths change. If participant D3 has a patient who does not agree with the next step in the proposed plan, then participant D3 holds the opinion that one should have a different path ready. They prepare such plans for their patients every day and believe that a guideline set up in accordance to a constraint-based process would be beneficial. Participant D4 does mention that a constraint-based process would not work with the current set-up of research studies and the processing thereof. The possible options for a treatment path are decided by scientific studies and those result in an instruction-based set-up for the guideline (D4, personal communication). In addition to what can or cannot be done in the opinion of the participants, participant G6 mentions a high likelihood of doctors appreciating a constraint-based model. In their words, “doctors can be stubborn and do not like to hear what to do. On the other hand, they do want to know what to do. A constraint-based model would fit that ideology, as they do not need to be told what to do, but if they want to know they can find out in their own way”. This confirms that there is desire to work with a constraint-based model instead of an instruction-based model, as was suggested by the literature (Hagglund et al., 2010, Shekelle et al., 1999).

6.6. Healthcare Domain and Psychosocial Elements

To tackle the human perspective on the standardised guideline and professional autonomy balance, the context of the healthcare domain and social factor are explored. This includes the view of the interview participants on the human aspects of care, emotional influences, and communication. The observational data obtained from performing the interviews is included here as well as it contributes to the identification of certain psychosocial elements.

The healthcare domain is a complex socio-technical system, but the social aspects can sometimes be overlooked. There is a huge social and mental aspect to being a doctor and that should translate to the development of healthcare systems, but that is not always the case (G2, personal communication). In the words of participant D1, “the healthcare domain is not as definitive and evidence-based as we sometimes want to believe”. Participant D4 also shares this opinion, stating that many people think that oncology is a straight-forward cookbook. In practice however, human aspects such as the subjective opinions of the doctor, patient wishes, and communication play a huge role. A guideline cannot encompass all of these factors, although it does include statements that decisions should be made with the patient since its last revision in 2020 (G2 & G4, personal communication). These factors actually come into play through the professional autonomy of the doctor, but that does raise the question if and how this should be taken into consideration as a factor to healthcare quality and safety.

Some of these factors make conversations regarding structural changes difficult, especially if emotion starts to play a role. One of the participants identified that “conversations about knowledge are very sensitive topics for doctors”. This was corroborated through the observational data as well, having one participant who was too emotionally evoked to continue the interview, and other participants that were

surprised to be asked questions about their professional autonomy. Due to this sensitivity, discussing this topic with doctors is therefore a difficult endeavor. This raises two questions to be discussed, which are both recommended for future research. What causes this emotional response and how can conversations involving professional autonomy, including how much space it should have, be held with doctors?

The communication and decision-making processes between doctors internally and between doctors and patients are important aspects of the healthcare domain. In the words of participant G2, “The shared-decision making with patients has become a standard practice over the past twenty years”. From the literature however, shared-decision making between patients and doctors seems to be more of an ideal rather than standard practice in reality (S. Brown and Salmon, 2019; Coulter and Collins, 2011). Shared-decision making has to do with the communication of all relevant information towards the patient and deciding together how to move forward. According to participant P2 however, the status quo is that shared-decision making in practice consists of giving a patient all the information and letting them decide which path they want to follow, amplifying the suggestion that guideline developers see guideline use, or in this case shared-decision making, different than is the case in practice. Participant P2 mentions that both the information given lacks focus on quality of life and that making such a decision based on all those options is too overwhelming for a patient. So, more guidance from doctors throughout the shared-decision making process is desired and both the doctors and guidelines should have a higher focus on quality of life from a patient’s perspective.

The multidisciplinary consultation, during which doctors consult with each other on what an optimal treatment plan would be, is one of the decision-making processes between doctors. Participant G4 mentions however that this method of treatment consultation lacks the consideration of a patient’s wishes as they have not spoken to the patient themselves. Participant P1 gives an example of this stating they had an experience in which they arrived at the radiologist who stated what would be done without listening to their story first. The patient then put a pause on the conversation themselves to talk about concerns a different doctor had told them earlier. Such experiences are of course dependent on the doctor treating the patient. Another scenario which highlights the difference between different doctors is a comment by participant P2. They stated that it has happened that they went for a second opinion and the second doctor was confused by the advise given by the first one. The question then remains whether the second doctor informs the first doctor about their difference in opinions and the cause thereof. This shows how much the decision-making processes and communication relies on the doctor themselves and their personal responsibilities, norms, values, and beliefs.

6.7. Content, context, process

Integrating all the findings that have been stated so far into the CCP framework according to the diagram in Figure 5.2 allows for an evaluation of the content, context and process of the research topic. The content, consisting of breast cancer care, guideline set-up, and the definition of professional autonomy is quite well defined and has proven a consensus among all participants in most aspects. The aspects in which discrepancies or a lack of topic consideration have been found, are aspects that are influenced by either system processes or contextual aspects such as communication and psychosocial elements.

Both the context and process aspects of the framework indicate quite a few unanswered questions and differences in opinions between participants. Regarding context, it is mostly about the inclusion of the psychosocial elements in the development and use of the guideline, but also its influence on the professional autonomy of doctors is a conversation barely touched upon. Psychosocial elements include the social aspects of being a doctor, communication between doctors and between doctors and patients, and social responsibilities. The interviews have indicated through both in-depth conversations and observational data that this is an important aspect regarding conversations about a balance between guideline standardisation and professional autonomy. It has also indicated that this is a topic rarely included in these conversations.

The process, which includes the standardisation of guidelines and organisational system process, is

in need of structural changes as well. Discussions regarding the standardisation and professional autonomy balance so far have not included a conversation on potential organisational differences, but this series of interviews has indicated that the current structural set-up of guidelines is not optimal due to differences in use and set-up. While participants were not able to identify more optimal structural set-ups themselves, they were able to indicate points for improvement through the help of an explanation of instruction- and constraint-based processes. Overall, the evaluation of a balance between guideline standardisation and professional autonomy has resulted in the finding that the content is well set up and provides clear and qualitative information. Some points for improvement were indicated, but these are intertwined with the context and process aspects. Multiple points of improvement or questions for discussions have been identified within these aspects as mentioned throughout the chapter.

7

Discussion

A few of the findings stated in chapter 6 *Results*, led to questions or showed discrepancies between participant groups, which are both discussed in this chapter. Its purpose is to explain and elaborate on the implications of the findings in relation to the already existing knowledge as described in chapter 3 *Theory*. First, a general discussion of the interview findings is given. This is followed by a discussion of the research limitations, recommendations for future research, and how the discussed topics link to the study of Management of Technology.

7.1. Contribution of Guideline Standardisation

The first point to be discussed are the discrepancies between the views of doctors who work on guidelines and of those who do not. More specifically, their views on what some common practices or opinions are. As an example, participant G4 mentioned that a guideline is purely indicative, as they are well aware that the scientific evidence and the interpretation thereof can fluctuate. But considering the statements of the doctor group, they do not often think of how a guideline is set up, they simply use it (D2 & D4, personal communication). So, although they know that scientific evidence changes throughout the years, and that the guideline is updated every so often, the part where participant G4 mentions that “as they are well aware that the scientific evidence and the interpretation thereof can fluctuate” is inaccurate. It seems like doctors who work on the guideline do not consider that they are a step ahead in thinking through scientific evidence and guideline considerations. This leads to differences in how guideline developers intend for a guideline to be seen and used, and how this occurs in practice, as found in chapter 6 *Results*. From these results, a recommendation follows to close this gap by including doctors who are not at all involved in guideline development or control into this process, a concept also known as co-creation. It has been found throughout the interviews, which is discussed at a later point as well, that doctors find their professional image and expertise very important. That on its own could have an impact on a ‘random’ doctor’s involvement into a guideline reality check. For that purpose, it could be that an anonymous check on guideline use by non-guideline developer doctors would be more realistic.

Regarding the contribution of guideline standardisation to the quality and safety of care, most participants were unsure on what to respond. It was clear that it is not a topic often thought of. The influence was seen as positive, but besides that, no further details or remarks were given. Nevertheless, the importance of including psychosocial elements in the determination of qualitative and safe healthcare was stated. In fact, it is worth it to dive deeper into the point of participant G4. They mentioned that “one should be careful moving the judgement of safety and quality of care to impersonal situations”. The context of this comment was that social factors play a huge role in the safety and quality of care, and thus in their opinion, it is not possible to determine the quality and safety of care on just the technical aspects of healthcare systems. These systems have a huge human aspect to it through the doctor that uses it and its ultimate application to a patient. Determining the quality or safety level based on purely a guideline without considering the way it is used would be incomplete in the opinion of participant G4. This shows the importance of including psychosocial elements in the design and development of healthcare systems, but it also shows how intertwined all these topics - guideline standardisation,

professional autonomy, psychosocial elements - really are. They should not be considered as demarcated aspects, but instead the complexity of its intertwined nature should be embraced. Attempting to reduce its complexity by enforcing standards might actually lead to negative results (Hanseth et al., 2006). As of now, neither professional autonomy nor psychosocial elements are included in the guideline standardisation documents, besides the statement that the guideline should aid a doctor in their professional autonomy (Adviescommissie, 2021, Zorginstituut, 2021). That should change, if these aspects are wished to be included more in the development of guidelines.

This result alone also indicates that the meaning of safety in healthcare is misunderstood. Multiple participants stated that one should be careful about using guideline standardisation to put a value on the safety of care. One participant even gave the opinion that guideline standardisation and safety have nothing to do with each other, as the safety of care is ensured through protocols instead of guidelines. In the words of the participants, a guideline is not created as an entity to guarantee safety. In fact, one of the participants even mentioned that if one would place the valuation of safety on a guideline, that would create a false sense of security. Again, the safety of healthcare is considered to be in the hands of the doctors themselves, not the guideline structure healthcare is based on. This same conclusion is understood from the guideline standardisation documents, which barely mention the safety of healthcare at all. That is an interesting point of view however, especially since guideline standardisation and professional autonomy were earlier identified as intertwined concepts. If that is the case, then why can the safety of healthcare only be evaluated based on one of the two concepts? In fact, considering the supporting role of guidelines in decision-making, safety of healthcare should be considered in the development and use of guidelines as well. But then how come the participants expect the safety of healthcare to lie in the hands of the doctors, but not in its supporting systems? This indicates a misunderstanding of the placement of safety in healthcare, which should be incorporated in future research to understand what impact this point of view of doctors has on the balance between guideline standardisation and professional autonomy.

7.2. Role of Professional Autonomy

Similar points regarding discrepancies in expectations of doctors who do and do not work on guidelines are identified within professional autonomy definitions and use. Again, doctors who work on a guideline assume that other doctors have a similar mindset regarding their work as they do, whereas practice shows that this is not the case (G3, personal communication; observational data). As stated in chapter 6 *Results*, a discrepancy was found between the views of the guideline and doctor group. The guideline group views that part of a doctor's professional autonomy is to be aware of the latest scientific evidence development, while that of the doctor group is that they use the guideline to provide this knowledge. The guideline group is aware that there is a delay in 'the latest scientific evidence' and what is actually stated in the guideline. This is a delay of a few years, so if doctors use the guideline as their source, then that is not in line with the opinion of guideline doctors on awareness of the latest scientific developments as part of professional autonomy. One of the goals of these guidelines is indeed the spread of knowledge, as stated in the *'Medical Specialist Guidelines'* document. So, there seems to be a discrepancy between the opinion of the guideline developers and what is stated in the guideline standardisation documents regarding a doctor's source for the latest scientific evidence. Researching the effects of this discrepancy on the actual guideline development is recommended for future research.

Additionally, the definition given regarding professional autonomy had a different focus between the guideline group and the doctor group. While the guideline group focuses on using professional autonomy to individualise care, the doctor group focuses on the fact that they should be allowed to use their professional knowledge and experience. The latest guideline revision resulted in the inclusion of a section on shared decision-making in each chapter of the breast cancer guideline; should this, therefore, include a reminder that for individualised care the role of the medical professional assessing the situation is critical? On the other hand, such a reminder might spark elevated responses from doctors, as another finding was the sensitivity of discussions around professional autonomy. From the patient's perspective, shared decision-making is an important factor in the personalisation of care, but unfortunately, it still lacks actual implementation in reality (P2, personal communication; van der Weijden et

al., 2010). In the guideline standardisation documents however, shared-decision making is mentioned as a principle used in the consultation room, not as a definition included in a guideline. In the breast cancer guideline a section on shared decision-making has been included, as its work group deemed it important. Still, it was mentioned by participants, and indicated in the literature, that its incorporation in reality is lacking. That then adds to the question if a reminder is enough for the principle to be actually included in practice and what can be done to improve its implementation.

From both the observational data and direct interview data, it became apparent that professional autonomy is a sensitive topic to discuss with doctors. Responses were either highly emotional or defensive, even if the question asked was to understand its importance. That raised the question of why this is such a touchy and emotional topic and what its consequences are. Professional autonomy is how doctors express their expert knowledge and experiences. Questions to understand its importance, as well as advantages and limitations, could have felt like an attack on their expertise, even though it came from a place of developing an objective understanding of the healthcare domain. Does this mean that professional autonomy is perceived by doctors to be a characteristic or identity trait rather than a tool to be used to individualise patient care? Following the interview results, it very well may be that the emotional responses of the interviewees were a result of them feeling like their identity or characteristic traits were being questioned. That does increase the complexity of conversations regarding both professional autonomy itself and its balance with guideline standardisation. It could, however, partly explain why discussions on balancing professional autonomy and standardisation through guidelines remain vague and without a solution. Perhaps first, the relation between professional autonomy and a doctor's attachment to it should be explored. Such a change in the relation paradigm would aid the identification of relevant factors to conversations regarding how much space there should be for professional autonomy while using standardisation of guidelines for equal, qualitative, and safe care. This is therefore recommended for future research.

7.3. Balance Guideline Standardisation and Professional Autonomy

The topic of a balance, or relation, between medical guidelines and professional autonomy had not been considered much by the participants prior to their interviews. While that is an interesting finding on its own, as it has been a topic of discussion for years, it did lead to insights on how they view this balance in different ways and their uncertainty in forming an absolute answer. These contradictions come from uncertainty regarding how much a doctor should adhere to a guideline or use their autonomy to deviate from it profoundly, but also because they have not thought about its balance as its intertwined use is part of their daily practice. Such uncertainties make it difficult to define such a balance because guideline use and professional autonomy are not two separate entities. However, that raises the question: if these two aspects are so intertwined in their practical use, why are they not considered as such in conversations or guideline standardisation documents? Perhaps discussions regarding such a balance and how much space there should be for professional autonomy should start with identifying why doctors have not considered these topics and what that means for their view on and use of guidelines and professional autonomy.

The conversations about the current and optimal balance during the interviews appeared to evoke emotional and confused responses as well. The word balance was used with the expectation that it would be perceived as a neutral term; however, most participants with a medical background had a negative connotation with the word. To them, the word balance was perceived as something to describe conflicts and contradictions. An interesting distinction between the guideline and doctor group, nevertheless, is that while the guideline group puts this negative connotation on the balance, the doctor group puts it more on the guideline. This raises questions on the view of doctors on professional autonomy if their reaction to a question about a balance is 'guidelines are not an obstacle for me, but rather a guidance' (D4, personal communication). These views indicates that they might think that possible issues regarding a balance start with the guidelines and not their professional autonomy. Especially in combination with the previous point regarding emotional responses when asked about their professional autonomy, it is worth researching why these topics and phrases are perceived in such a negative and biased manner and what influence that has on healthcare practices.

Another perspective that has shown important influences is the organisational perspective. Multiple participants showed interest in a constraint-based set-up for the guidelines in contrast to the current instruction-based set-up. Unlike the human perspective, ideas for different system implementations have been considered (G4, G6) or thought of (G3). These have not been brought to fruition, but they show doctors' interest in changing the current system. The next step is to study what a guideline set up as a constraint-based process could look like and how such a systematic change would take place. Part of the considerations necessary for that is the discussion points raised in the guideline and standardisation section of chapter 6 *Results*. The guideline group mentioned that the guideline is a tool that also serves the goal of easily spreading relevant scientific knowledge to doctors, and participant D4 confirmed that they indeed use the guideline as their source of knowledge. However, in the words of participant G4, "the guideline is a snapshot of the moment during which revision was done," and multiple guideline participants mentioned that they assume that doctors do separate research as well. If a doctor uses the guidelines as their source of knowledge, however, then there is a small knowledge gap. Is it then up to the doctor's professional autonomy to be up to date on the scientific information that has not been included in the guideline yet? Theoretically, yes, but practice shows that this is not always done, even though the guideline group does assume so.

The tension between a slow and bureaucratic process of revising a guideline to ensure quality control and remaining at the leading edge of healthcare is a point that multiple guideline participants identified. They mentioned too many rules and a lack of using internationally proved knowledge as key factors contributing to this tension. That raised the question, why are there so many rules and why is international knowledge not used more? While protocols for guideline revision are crucial, if guideline developers experience the plethora of rules as an obstacle slowing down the revision process instead of ensuring quality of care, then this set of rules should perhaps be reconsidered. Co-creation is important for the inclusion of diverse insights, and guidelines should be designed keeping the user in mind. Methods using co-creation for guideline development are in development, but the question of how to implement those remains (Labib et al., 2022). At the same time, internationally accredited guidelines, or updated healthcare information, should be considered more to aid the guideline revision process, as the interview participants indicated. As resulted from the guideline standardisation document analysis, such international cooperations occur a lot less frequently than would be optimal. That is the case even though it is stated in the documents, although briefly, as potentially beneficial. Considering that multiple participants mentioned that it would be beneficial to make more use of international collaborations, perhaps some more research should be done on why this is done minimally at the moment and how this could be incorporated better in guideline development.

7.4. Recommendations

There are several recommendations that resulted from discussing the findings. These include future research recommendations, structural changes, and mindful pointers. All recommendations are listed and explained in this section.

1. **Inclusion of 'regular' doctors in guideline revision**
   The guideline revision is currently already performed by doctors, however these are doctors who decided themselves to put in the extra effort of being involved. Their mindset, and what they think of the mindset of other doctors, is different than that of doctors who do not work on guidelines. This leads to discrepancies in intended and actual guideline interpretations. As part of the quality control, perhaps 'regular' doctors could be picked at random and provide quality control feedback either anonymously or face-to-face.

2. **Psychosocial elements as a part of healthcare conversations**
   This research has shown that the inclusion of human perspectives in healthcare systems and its discussions are crucial. It is a factor that is often left out, even though it is known that healthcare is a socio-technical domain. There should be more attention for awareness and inclusion of the psychosocial elements. An example of future research that should be done is on why the phrasing of the word balance has such a negative connotation and what influences that has on

healthcare practices.

3. **The sensitivity of discussing professional autonomy**
   The relation between professional autonomy and a doctor's attachment to it should be explored, including the effects this has on the quality and safety of healthcare. Understanding this relation will aid in the improvement of the prior recommendation, as it is part of the psychosocial elements. Additionally, it might help to improve the vagueness of discussions regarding how much space there should be for professional autonomy and its balance between guideline standardisation and professional autonomy.

4. **Consideration of structural changes**
   The current set up and use of guidelines follows an instruction-based process, whereas multiple participants showed genuine interest in a constraint-based model instead. The fact that some already attempted to create a new model shows that there is demand for an improved system. The follow-up is then to research how a guideline could be set up following a constraint-based process and how such structural changes can be implemented without too much hassle. This would include considering the knowledge already available, such as the concept of constraint-based and instruction-based models, as was used in this study.

5. **International guideline co-operations**
   To improve the slow and bureaucratic process of guideline revisions, multiple participants suggested international co-operations for faster knowledge transfer. International co-operations within the healthcare domain already exist, and discussions on how to structurally co-operate between countries are currently underway and some are even included in the guideline standardisation documents already (Kroezen et al., 2016). Nevertheless, it is recommended to explore international co-operations for guideline development in more detail, with the purpose of finding ways in which these will be used in practice as well.

6. **Understanding of safety in healthcare**
   From this study it became clear that the participants were unsure of how to place safety in the context of guidelines and professional autonomy. Safety is a core value of healthcare however and it is important that guideline developers and users understand how healthcare systems such as medical guidelines support this value. The cause for this uncertainty and its impact on the balance between guideline standardisation and professional autonomy is recommended for future research.

7.5. Limitations

The method chosen for this research was an exploratory empirical research. While that was optimal for the topics, as contributing factors to the balance and possible improving changes were explored, it did result in multiple aspects being explored with less depth than if, for example, only structural changes were explored. However, it is because of the set-up of this research study that some important contributing factors were identified, which would not have been possible if only one or two aspects were considered. Additionally, no stakeholder analysis was performed to identify which were the most important parties to consider in the research. Instead, the three parties considered or included most in the guideline standardisation documents were used, as this was one of the three data sources. While a stakeholder analysis would have been more in depth and inclusive, the decision to go for these three parties can be considered valid as it is based off a reliable document.

Another limitation is regarding the anonymity of the research. Performing expert interviews had the advantage of exploring the topics through practical insights and expert experiences. However, considering the sensitivity of some topics discussed, it was necessary to ensure the anonymity of the participants. As a result, some findings could not be explicitly stated without violating their anonymity. These have thus been excluded in this thesis report. Similarly, some statements given in the report could have been written with more impact if it had been possible to include the participant's background, function, or otherwise valuable relation to the topic.

In total, eight participants were interviewed to completion. While a lot of valuable results came from these eight participants, the researcher believes that it would have been beneficial to the study if one or two additional doctors who have not worked on a guideline had been involved. Many of the participants were part of the guideline group. While that gave a lot of useful information, the comparison between the guideline and non-guideline groups would have been more elaborate if the non-guideline group would have had a bigger sample size. Additionally, the research was performed with a case study on the Dutch breast cancer guideline. This brings the limitation that the results may only be applicable in the Netherlands as all participants interviewed, and the official guideline documents used, are Dutch.

Then finally, the background of the researcher could be considered as a limitation as well as a strength. There was no prior knowledge on the healthcare domain, its systems, and its socio-technical nature. While this did allow for a structural and analytical engineering point of view on the matter, some aspects that come natural to people active in the healthcare domain may have been overlooked. However, all general medical information has been checked thoroughly, both through literature and conversations with medical professionals. In the end, it is thought to have been a strength to observe this research topic from an 'outsider' point of view.

7.6. Relevance to Management of Technology

This research was performed as part of the final master thesis project of the Management of Technology study program at Delft University of Technology. This is a program that combines technology and corporations that allows its student to understand management, entrepreneurship, and analysis of technological markets.

In accordance to the program, this research had to be a scientific study in a technological context, show the understanding of technology from a corporate perspective, and use scientific methods to analyse a problem. This research was done within the context of the healthcare domain, which has both a technological and social aspect. The corporate perspective on understanding guideline standardisation can be interpreted in two ways within this study. The perspective of the guideline developers was a big part of the research, which can be seen as a corporate perspective in the form of healthcare system developers. Additionally, an organisational perspective was considered for the set-up and use of guidelines, which provided a corporate perspective from a different angle. Regarding the use of scientific methods to analyse a problem, this research was performed using three different scientific methods; a literature study, exploratory expert interviews, standardisation document analysis, and framework validation to analyse the problem. This allowed for a triangulation of the data and verify the results.

In addition to the three main criteria of the Management of Technology programme, it is important to mention the ethical aspects that were incorporated in the study. This can be viewed in two ways; performing research ethically and considering ethical topics within the research. In this study, both of these were incorporated. The integrity of the research was ensured in an ethical sense by complying with the TU Delft Human Research Ethics Regulations. For the participants, this meant informed consent and ensuring their anonymity throughout the research. Regarding the incorporation of ethical topics in the research, this was included in the human perspective, psychosocial elements, and more generally the context aspects of the healthcare environment.

7.7. Contribution to Academia and the Industry

This study contributes to both the Management of Technology programme and healthcare industry in multiple ways. Regarding the academic contributions, this research has resulted in an increased understanding of the underlying factors contributing to the difficulty of finding a balance between guideline standardisation and professional autonomy. Through the identification of these aspects, it contributes to possible future development of healthcare system design through the recommendation of adapting its organisational set-up, or the development of theoretical frameworks to include psychosocial elements.

Regarding this research's contribution to the industry, through the performed analysis and recommen-

dations resulting from that, industry professionals can benefit from the study by gaining a deeper understanding of why discussions regarding a balance between guideline standardisation and professional autonomy thus far remain without solution. This allows for a more informed decision-making within the healthcare organisation regarding the development of healthcare systems, as the factors that were identified to contribute to the balance discussion apply to other healthcare systems as well. Ultimately, the incorporation of the results from this study could lead to better fitting systems within its environment and a more inclusive approach to the development of such systems through the consideration of psychosocial elements.

8

Conclusion

This chapter describes the conclusion of this research, providing the answers to the three sub-research questions and the main research question. For convenience, these questions are repeated in their respective sections. Throughout this research, it became clear that human and organisational aspects were important to consider. As they were initially not included in the research questions, the research scope was widened early to ensure its inclusion. These aspects are part of the research question concerning the balance between guideline standardisation and professional autonomy.

8.1. Contribution of Guideline Standardisation

How does standardisation of medical guidelines contribute to the quality and safety of healthcare?

The goal of this sub-research question was to understand the contribution of guideline standardisation on the quality and safety of healthcare through the perspectives of the guideline and doctor groups. While all participants showed a clear consensus that the contributions of guideline standardisation to the quality and safety of care are positive, only a few pointers were given regarding the reasoning. Participants view guideline standardisation as a principle that allows for equal care around the country, ensuring that the quality is the same in different hospitals. Regarding the quality itself, the guideline's content goes through extensive quality control, meaning that the most optimal treatments and options available are present. However, multiple participants stated that this is on the condition that a doctor uses their professional autonomy to act with their expertise next to adhering to the guideline. From this, it could be concluded that even considering the impact of standardisation on the quality and safety of care relates to professional autonomy in the eyes of medical practitioners.

So, to answer the research question, guideline standardisation has a positive impact on healthcare quality, allowing for easy access to standardised medical information, reaching the right treatment path well, and providing uniform care. The answer is more complex in terms of the safety of healthcare, as neither the participants nor the guideline standardisation documents had much to say about its contribution. Safety of care was not considered something that should be a part of a conversation about standardisation by either the participants or the guideline standardisation documents.

8.2. Role of Professional Autonomy

What role does professional autonomy play in the quality and safety of healthcare?

A key aspect of professional autonomy contributing to ensuring the quality and safety of care is that it enables the personalisation of patient care. That means that it is dependent on the doctor, as mentioned in the prior section. Professional autonomy is a concept that is more difficult to check than a standardised guideline. That contributes to the discussion regarding how much space there should be for professional autonomy if it is both the main contributor to ensuring the quality and safety of care in

the eyes of doctors and difficult to evaluate.

There are two essential aspects in ensuring that the contribution of professional autonomy on the safety of care remains at a high level: first, the volume of patients a doctor sees per year, and second, the mandatory continuity of medical education. Doctors must be aware of the latest developments, which requires them to remain educated. To keep healthcare professionals up to date an education refresher points program is used; however, attending was deemed not to guarantee safety as points are awarded solely for attending, meaning that the learning achievements are not checked. A notable observation is that the response to the contribution of professional autonomy to the safety of care did not result in the comment that the two concepts cannot be connected, as was the case for guideline standardisation, even though professional autonomy is a more abstract concept. It may be that this is due to the personal link of professional autonomy to doctor identity, meaning that ensuring the safety of care through professional autonomy is the doctor's responsibility.

8.3. Balance Guideline Standardisation and Professional Autonomy

How do standardisation and professional autonomy relate and influence each other?

The third sub-research question did not only provide insights on a balance between guideline standardisation and professional autonomy, but also the influence of psychosocial elements on healthcare systems. Prior to the interview, participants had not extensively considered the balance between guideline standardisation and professional autonomy, which allowed for a peek into their thought process. Considering the fact that participants jumped between different views while getting to their conclusion, this may indicate that there is uncertainty regarding their view on the balance. Generally speaking however, they see a balance in that a guideline provides information regarding procedures, which allows for a standardised approach to care nationally. However, to provide the actual care the main aspect is their professional autonomy. The guideline is viewed as a tool useful for scientific knowledge, but it is the professional autonomy that is leading from the perspective of medical practitioners.

Participants were unable to identify how much space there should be for professional autonomy, besides the fact that it is crucial they are allowed to exercise it. In their words, professional autonomy and guideline standardisation are not two separate concepts that should be balanced, but are rather seen as intertwined. From a professional autonomy point of view, a guideline is a useful tool providing information, and from a guideline standardisation perspective, professional autonomy is a useful tool to provide personalised care. Both principles have to make use of the other to ultimately provide qualitative and safe care. Discussions regarding this balance are not new, but always remain vague, perhaps because of its intertwined nature. One purpose of this research was to find out why this problem persists without a clear path forward. First, the influence of psychosocial elements and need for including the human perspective in the development of healthcare systems was identified as a contributing factor. Second, the difference between the organisational set-up and practical use of healthcare systems was recognised as another contributing factor to the vagueness of this balance and its discussions.

8.3.1. Influence of Psychosocial Elements

Social factors, such as the subjective opinion of the doctor, patient wishes, and communication, play a huge role in healthcare. A guideline cannot encompass all of these factors, but through the doctor's professional autonomy they are still incorporated in patient care. However, this is not the only situation during which social factors play a role. Discussions regarding healthcare systems, or how much space there should be for professional autonomy, often leave out this factor too. This research has shown however, that it is incredibly important to keep the psychosocial elements in mind during these discussions as well as the development of healthcare systems. Both professional autonomy and its relation with guideline standardisation were experienced as sensitive or emotional topics by some of the participants. Some participants behaved defensively when asked about these topics neutrally, indicating that this is an interesting point for future research. This showed that the aspect of psychosocial elements is important to consider during the development of healthcare systems as it is clearly a factor influencing its use. If factors contributing to a doctor's attachment to professional autonomy are researched more, it could help in conversations about how much space there should be for it and the development of healthcare systems in general.

8.3.2. Suggestions for Structural Changes

Next to the human perspective, the organisational perspective has also been explored, as in the words of Ten Have (2000), “quality of the organisational setting is a precondition of the quality of care”. The current set-up of the guidelines follows an instruction-based model, whereas the healthcare domain, in general, can be seen as more constraint-based. The participants indicated that although the current system is instruction-based, they see value in a constraint-based model. In fact, three of the guidelines’ participants had already thought of ways to change the current guideline model before the interviews, indicating that the desire to change the current system is already present. The next steps are to research what exactly a constraint-based guideline set-up would look like and how this could be implemented seamlessly into healthcare systems.

Another suggestion for structural changes is to utilise the evidence-based knowledge of other countries to decrease the time required to revise a guideline. The slow and bureaucratic process of revising a guideline was identified as a problem, as the guideline is always falling behind the latest scientific developments. An international cooperation to transfer knowledge regarding guidelines and their revision was suggested to help this process, even though this is technically already considered in the guideline standardisation documents. This research has shown, however, that its current set-up in the documents is insufficient compared to its practical use during guideline development. Additionally, it was mentioned by multiple participants that there are too many rules for guideline revision in the Netherlands, to the point where it acts as a slowing factor. Improving the international cooperation section in the guideline standardisation documents and realising its contributions would help decrease the time needed for guideline revision and the transfer of knowledge between countries.

8.4. Standardisation of Medical Guidelines

What is the contribution of standardisation in quality and safety of healthcare and how does this relate to professional autonomy in the context of medical guidelines?

The three sub-research questions each answer a part of the main research question. It was found that the participants are of the opinion that in general both guideline standardisation and professional autonomy have a positive impact on the quality and safety of care. However, healthcare professionals do not consider guideline standardisation to contribute to the safety of care. Regarding the balance between guideline standardisation and professional autonomy, two key contributing factors were identified: the influence of psychosocial elements and suggestions for structural changes. On the first factor, the exploration of a doctor’s attachment to professional autonomy could be extremely beneficial to the research regarding this topic. Regarding the second factor, the suggestion to move toward a constraint-based set-up for healthcare systems could improve a doctor’s experience of the balance. In the words of participant G6: *“Doctors can be stubborn and do not like to hear what to do. On the other hand, they do want to know what to do. A constraint-based model would fit that ideology, as they do not need to be told what to do, but if they want to know they can find out in their own way.”*

8.5. Thesis Project Reflection

Undertaking this thesis project has been both an enriching and challenging experience, prompting a reflection into the academic and personal journey it entailed. The content of the research was chosen such that it aligned with my academic interests and would contribute meaningful insights to the healthcare domain, which is believed to have been achieved. As data collection unfolded, unforeseen challenges and perspectives emerged, which required flexibility, but also resulted in interesting findings.

The process of conducting this thesis project was a dynamic and interactive journey that involved planning, execution, and adaptation. Performing the interviews themselves brought a lot of new insights into guideline standardisation and professional autonomy, but also taught me interviewing skills and how unexpected prompts may bring one of the most interesting results. Deriving meaningful results from the interview findings and comparing those to the literature and guideline documents required multiple revisions. This taught me how to refine my work, improve its quality, and remain critical. To conclude, this thesis project has been a rewarding journey, with many lessons learned, in which the content explored and process undertaken collectively contributed to my academic and personal growth.

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A

Interview Protocol

Target audience: those who use the breast cancer guideline and those who have worked on the guideline itself.

Introduction

The purpose of this project is to study the contribution of medical guideline standardisation to the quality and safety of healthcare, including the potential collision and preferred balance between standardisation and professional autonomy. Currently, there is an ongoing tension between the standardisation of these medical guidelines and the professional autonomy of medical practitioners. The aim of this project is to look at the causes for this friction and to identify how these two approaches, standardisation and professional autonomy, can be merged to use the full potential of both. To narrow the scope of the project, a case study on the breast cancer guideline is done.

1. Introduction interviewer
2. Discuss privacy regulations and have interviewee sign consent form
3. Discuss process of interview: aim, topics, open questions
    (a) Explain that the study is regarding the mamma carcinoma guideline and that all questions should be answered in relation to this guideline
4. Introduction interviewee
    (a) What is your job description?
    (b) For how long have you been active in the healthcare sector?

Contribution Guideline Standardisation to Healthcare Quality & Safety

1. What do you think of guideline standardisation in general?
    (a) What do you consider the importance of guideline standardisation?
    (b) What are the benefits of guideline standardisation?
    (c) What are the limitations or drawbacks of guideline standardisation?
2. What impact do you think guideline standardisation has on the quality of healthcare?
3. What impact do you think guideline standardisation has on the safety of healthcare?
    (a) If interviewee describes big difference, how do you define quality and safety in this context?

Contribution Professional Autonomy to Healthcare Quality & Safety

1. What do you think in general of the use of professional autonomy in healthcare? How do you define professional autonomy?
    (a) What do you consider the importance of professional autonomy?
    (b) What are its benefits?
    (c) What are its limitations or drawbacks?
2. What impact do you think the use of professional autonomy has on the quality of healthcare?
3. What impact do you think the use of professional autonomy has on the safety of healthcare?

For those using the guideline:

Relation Guideline Standardisation & Professional Autonomy

1. How do you experience the balance between adhering to the guideline and maintaining professional autonomy?
2. What causes you to decide to take a step back from the guideline and use your professional autonomy over the guideline? In what situations do you decide to do this?
    (a) What impact does this have on the quality and safety of healthcare?
    (b) If a specific situation is described, what effect did that have?
3. Have you ever experienced conflicts between the standardised guideline and professional autonomy before?
    (a) If so, could you give an example? How did you handle that situation? What were the consequences?
    (b) If not, have you observed or heard about such conflicts? Could you share any insights or stories you have come across that shed a light on this issue?
    (c) What have you learned from such conflicts?

For those creating the guideline:

Guideline Creation

1. How do you ensure that guidelines are flexible enough to accommodate individual patient variations while still providing a standardised approach to care?
2. When creating the guideline, how is the balance between guideline standardisation and professional autonomy a part of that process?
    (a) What is the thought process behind creating a guideline?
    (b) Explaining the principles of instruction-based versus constraint-based processes, what sort of process was used to create the guideline?

For all:

Preferred Balance

1. How would you describe an optimal balance to ensure effective guideline implementation while respecting professional autonomy?
2. Do you have any recommendations on how to achieve a balance between guideline standardisation and professional autonomy?
3. Getting back to the instruction-based versus constraint-based processes, what is your opinion on this regarding guideline standardisation and professional autonomy?

Closing

1. What is your opinion on achieving a balance between guideline standardisation and professional autonomy?
2. Thank you for your time and valuable input
3. Is there anything else you would like to ask or any additional comments you would like to share that are related to the topic we discussed today?

B

Informed Consent Form

Dear participant,

You are being invited to participate in a research study titled Standardisation in Healthcare. This study is being done as a master's thesis from TU Delft.

The purpose of this research study is to study the contribution of medical guideline standardisation to the quality and safety of healthcare, including the potential collision and preferred balance between standardisation and professional autonomy. It will take you approximately 30 minutes to complete, with a maximum of 45 minutes. The data will be used to gain understanding on standardisation practices in healthcare and will be included in the results section of the master thesis in aggregated form. The master thesis will be uploaded to the TU Delft repository after completion.

As with any online activity the risk of a breach is always possible. To the best of our ability your answers in this study will remain confidential. We will minimize any risks by storing all data on the secured TU Delft drive and deleting all personal data one month after the end of the project. The interview will be audio recorded. The recordings will be deleted immediately after transcription.

Your participation in this study is entirely voluntary and you can withdraw at any time. You are free to omit any questions.

For any questions, you can contact me through:

Aïcha van Veen
a.s.y.vanveen@student.tudelft.nl

PLEASE TICK THE APPROPRIATE BOXES	Yes	No
A: GENERAL AGREEMENT – RESEARCH GOALS, PARTICPANT TASKS AND VOLUNTARY PARTICIPATION		
1. I have read and understood the study information above, or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.		
2. I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.		
3. I understand that taking part in the study involves: • Answering interview questions • Giving a job description • An audio recording of the conversation that will be destroyed after transcription		
4. I understand that the study will end by the end of September.		
B: POTENTIAL RISKS OF PARTICIPATING (INCLUDING DATA PROTECTION)		
5. I understand that the following steps will be taken to minimise the threat of a data breach, and protect my identity in the event of such a breach: • All data (consent form, contact information, audio recordings, and transcriptions) will be stored on a secured TU Delft drive named OneDrive • This data will only be accessible to the research team • The consent form will be digitalised, after which the paper version will be destroyed • The audio recordings of the interview will be destroyed after transcription. The transcription will be done through a locally run program		
6. I understand that taking in the study involves the risk of data breach, which may lead to my identity being revealed. The data (audio recording, transcripts, contact information, and consent form) will be stored on a TUD institutional storage accessible only to the research and the supervisory team, as to limit such risks		

7. I understand that the personal data I provide will be destroyed one month after the end of the thesis.		
C: RESEARCH PUBLICATION, DISSEMINATION AND APPLICATION		
8. I understand that the information I give during the interview will be used in the results section of the master thesis in the form of aggregated data.		
9. I agree that my responses, views or other input can be quoted anonymously in research outputs.		
D: (LONGTERM) DATA STORAGE, ACCESS AND REUSE		
10. I understand that the master thesis will be published on the TU Delft education repository after completion of the project.		
11. I understand that all personal data will be deleted one month after completion of the thesis.		

Signature

_____ _____ _____

Name of participant Signature Date